06.3 HHS PIA Summary for Posting (Form) / NIH CC 4D Mac Platform [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/25/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): Not Applicable

5. OMB Information Collection Approval Number: N/A

- 7. System Name (Align with system Item name): NIH CC 4D Mac Platform
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sue Martin, 301-496-4240
- **10. Provide an overview of the system:** CC 4D Mac Platform is comprised of multiple separate applications using a software suite called 4D. 4D is an integrated development platform a single product comprised of the components needed to create and distribute professional applications. The CC has 3 systems developed on the 4D Mac Platform that are included in the boundary of this GSS. The CC systems are NIH CC Protocol Tracking (PROTRAK), NIH CC Medicolegal Request Tracking System (MRT) and NIH CC Medical Staff Credentialing Processes (SACRED.) The systems support administrative functions of the Clinical Center. Details about the individual systems listed are available in the system's Privacy Impact Assessment.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\rm N\!/\!A$

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: This is a GSS for the 4D Mac Platform and does not collect, maintain or disseminate PII.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Not Applicable - No PII is collected, stored or processed.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No PII is collected, stored or processed. Details on the administrative, technical, and physical controls are not required for the CC 4D Mac Platform GSS. The controls for applications that do collect, store or process PII within the boundaries of the 4D Mac Platform are covered by separate system Privacy Impact Assessments (PIA).

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin: CC Privacy Officer, 301-496-4240, smartin@cc.nih.gov

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC Admissions and Travel Voucher Application [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/28/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: Not Applicable

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0099

5. OMB Information Collection Approval Number: Not Applicable

- **7. System Name (Align with system Item name):** Admissions and Travel Voucher Application (ATV)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sue Martin
- **10. Provide an overview of the system:** This is an ancillary application which works with the CRIS system allowing research teams to register new patients, submit admission requests, update patient demographics and submit travel requisitions and payments.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Shares reports containing patient names, demographics and travel dates with Omega travel agents so that travel arrangements can be made. Additionally shares reports containing patient names, demographics and travel requests with Chief of Ambulatory Care Services to approve reimbursement of travel expenses. Information sharing is in accordance with SORN 09-25-0200.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Legislation authority is the Public Health Service Act. (42 U.S.C. 241, 242, 248, 281, 282, 284, 285a, 285b, 285c, 285d, 285e, 285f, 285g, 285h, 285i, 285j, 285l, 285m, 285n, 285o, 285p, 285q, 287, 287b, 287c, 289a, 289c, and 44 U.S.C. 3101.) The information collected is name, date of birth, social security number, mailing address, phone number and medical record number. This information is used to register individuals as participitants in clinical trials and to assist in providing travel arrangements for those individuals and provide reimbursement. Information is disclosed to travel agents to assist in making the necessary travel arangements. Information submission is voluntary.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The CC Information Practices Notice is provided to each patient when initially registered and admitted to the Clinical Center. Each patient would be advised at the time of admission about major system changes and the CC Information Practices Notice would be revised and provided to each patient.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The system and all contained data are protected using administrative, technical and physical security controls. The system is physically located behind locked doors, monitored by CC TV and Systems Monitoring staff in attendance around the clock. Additionally, the system is behind the NIH, CC and CRIS firewalls. Access to PII and privileges are based on user's assigned roles. Authentication with NIH PIVcard will occur at the time of login to the CC network via CC CASPER for remote users.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin, CC Privacy Officer, (301) 496-4240, smartin@cc.nih.gov

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC Automated Medication Dispensing (Omnicell)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-3097-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0099

5. OMB Information Collection Approval Number: Not Applicable

- **7. System Name (Align with system Item name):** CC Automated Medication Dispensing (Omnicell)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sue Martin
- **10. Provide an overview of the system:** The system automates the Pharmacy Dept's ability to manage and dispense medications at the point of use, increasing patient safety with the use of medication profiles, improving workflow efficiency and enhancing medication security.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Not Applicable
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system captures and maintains information on registered CC patients including patient name, Date of Birth, MRN,

gender, allergies, medication order number, visit number and administration instructions. The system captures and maintains information on CC caregivers including staff name, user role and fingerprint biometric identifier. The information is shared with Omnicell administrators in Pharmacy, CC Nurse Managers responsible for the investigation of dispensing cabinet diversion reports. The collection of PII is voluntary since admission to the CC and specific research protocol(s) is completely voluntary.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Admission to the Clinical Center (CC) is completely voluntary and requires consent of each patient. Additionally, each patient is provided a full written accounting of established information practices at the CC, including the capture and use of PII, and has the opportunity to ask questions. Each patient must acknowledge receipt of same through manual signature on the CC Information Practices Notice Form.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: PII will reside on a server in the CC DataCenter protected by restricted access and video closed circuit TV. The server will be behind the NIH and CC clinical firewall. The Omnicell SecureVault PC and stand alone PC in the Pharmacy Dept are protected by restricted access and video monitoring. The Omnicell automated medication dispensing cabinets are on the medical VLAN and located in the Nursing Units behind locked doors with access restricted by Staff ID badge or key. Access to the dispensing cabinets is granted by user type and is set by the Pharmacy Dept Omnicell Administrator in accordance with Pharmacy policies. Access to the dispensing cabinets will require password or fingerprint identification and inclusion in specific user types based on the user role.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin: CC Privacy Officer, 301-496-4240

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC Automated Nurse Staff Office Schedule [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/1/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-26-02-3008-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-90-0018

5. OMB Information Collection Approval Number: None

- 7. System Name (Align with system Item name): CC ANSOS: Automated Nurse Staff Office Schedule
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Barbara Quinn
- **10. Provide an overview of the system:** The ANSOS System is used to arrange schedules and project staffing needs for nurses caring for patients at the Clinical Center and is authorized by Section 301 of the Public Health Service Act.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\rm N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Includes basic identification data including name, date of birth, address, phone numbers and related information (CC training

attendance records) necessary to develop schedules for nurses. Submission is mandatory if the individual wishes to be employed as a nurse at the Clinical Center. In addition, inpatient census data by patient care unit and outpatient census data by outpatient clinic and day hospital is collected to project utilization and staffing needs across the Clinical Center.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Each individual is informed of information practices at the time of job application and subsequently when individual schedules are developed. In addition, the CC Nursing Department is responsible for notifying each nurse of major system changes related to PII, which may be done electronically or in written form.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Only authorized person may have access to the ANSOS System and the system is protected through door locks and other physical controls, as well as technical controls including user identification and password protection. Authentication with NIH PIVcard will occur at time of login to CC Network via CC CASPER for remote application users.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin: CC Privacy Officer, (301) 496-4240, smartin@cc.nih.gov

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/30/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC Barcode Enabled Automated Point of Care Technology (BEAPOCT)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/21/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0099

5. OMB Information Collection Approval Number: N/A

- **7. System Name (Align with system Item name):** NIH CC Barcode Enabled Automated Point of Care Technology (BEAPOCT)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sue Martin
- **10. Provide an overview of the system:** BEAPOCT consists of 2 applications with interfaces to existing hospital and lab systems. SMARTworks Patient Linkup Enterprise (PLUE) system provides printed barcoded patient wristbands, picture wallet ID cards and labels. CareFusion utilizes the barcode technology and wireless scanning to identify patients, staff, lab tests, specimens and blood products while capturing data that is pertinent for safe, accurate and timely documentation.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): NA
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Information collected includes individual patient demographics, medical notes, vital signs at time of transfusion, Donor ID, photographic images, staff name, role and NED ID. Patient name, DOB, MRN and photographs enhance positive patient identification processes, thus safety, throughout the NIH Clinical Center. Donor ID, medical notes and vital signs are collected to document care and satisfy reporting requirements for blood administration. Staff name, role and NED ID associate resources with critical clinical tasks performed such as labeling of laboratory specimens and verification of blood transfusion products. Patient and staff information does contain PII. The information is submitted voluntarily based on an individual's consent to become a registered patient at NIH or be employed in the clinical care of CC patients.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Information is obtained from interfaces to existing CC clinical systems, including the admission, discharge and transfer (ADT) system, Clinical Research Information System (CRIS) and laboratory information system (LIS), including SoftBank. Admission and protocol consent forms are signed by each patient and an information practices notification form is provided to each patient at the time of initial admission. Each patient would be advised at the time of admission about major system changes and the CC Information Practices Notice would be revised and provided to each patient.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The system and all contained data are protected using administrative, technical, physical security and privacy controls. The system is located on servers in the CC Data Center protected by restricted access and video monitoring. Access to the application is granted by scanning an authorized user's NED ID. Authorized user's access and privileges are restricted by assigned user roles. Authentication with NIH PIVcards will occur at the time of login to the CC network via CC CASPER for remote application users.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin, CC Privacy Officer, (301) 496-4240, smartin@cc.nih.gov

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC Biomedical Translational Research Information System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/27/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-3009-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: N/A

- **7. System Name (Align with system Item name):** NIH Biomedical Translational Research Information System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Elaine Ayres
- **10. Provide an overview of the system:** BTRIS will provide longitudinal data, text and images from NIH intramural clinical care and research systems to facilitate data analysis, hypothesis generation and patient recruitment in support of the NIH intramural research mission. Principal investigators and designees (e.g. associate investigators), IC Data Extractors and Administrative Users will be allowed to access identified data only as permitted by their active protocol(s). Other users with appropriate IRB or OHSR clearances will be able to access and query only data in a de-identified manner.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): PII data in BTRIS will only be shared with authorized principal investigators for patients enrolled in their active protocols or others authorized by the appropriate IRB or OHSR e.g. associate investigators, IC Data Extractors and Administrative Users. All others will only be

granted access to de-identified data. Data will be used for statistical analysis, hypothesis development & testing, quality assurance, clinical comparison and subject recruitment.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Clinical and research data including diagnostic, therapeutic, imaging, and research testing results will be stored in BTRIS. PII will be collected and will include names, medical record numbers and diagnosis. PII data in BTRIS will only be shared with authorized principal investigators for patients enrolled in their active protocols or others authorized by the appropriate IRB or OHSR e.g. associate investigators, IC Data Extractors, Administrative Users. All others will only be granted access to de-identified data. Data will be used for statistical analysis, hypothesis development & testing, clinical comparison, quality assurance purposes, and subject recruitment. The collection of all data is voluntary. Every patient must voluntarily execute a protocol consent and admission consent prior to entry onto an intramural research protocol and treatment at the Clinical Center. In addition, each patient is provided a formal notification of Information Practices at the Clinical Center and must certify that they have been so advised.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Every patient must voluntarily execute a protocol consent and admission consent prior to entry onto an intramural research protocol and treatment at the Clinical Center. In addition, each patient is provided a formal notification of Information Practices at the Clinical Center and must certify that they have been so advised. BTRIS will contain longitudinal data, text and images from NIH intramural clinical care and research systems to facilitate data analysis, hypothesis generation and patient recruitment in support of the NIH intramural research mission. Principal investigators and designees (e.g. associate investigators) will be allowed to access identified data only as permitted by their active protocol(s). Other users with appropriate IRB or OHSR clearances will be able to access and query only data in a de-identified manner. If a major change occurs, a revised Information Practices Form will be developed and presented to each patient.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The BTRIS system and all data contained therein are protected using administrative, technical and physical security and privacy controls. The system is behind locked doors and monitored by closed circuit TV. Access to the physical

system is limited to authorized staff with common access cards. In addition, only principal investigators or others authorized by an appropriate IRB or OHSR have access to PII in the application, while all others only have access to de-identified data. Application access is also restricted based on user roles and password authentication. Authentication with NIH PIVcards using SiteMinder will occur for remote application users.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin, CC Privacy Officer, (301) 496-4240, smartin@cc.nih.gov

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC Blood Bank Control System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-26-02-3007-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0011

5. OMB Information Collection Approval Number: None

- 7. System Name (Align with system Item name): Blood Bank Control System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Boyd Conley
- **10. Provide an overview of the system:** The systems contains data regarding donors at the Department of Transfusion Medicine used to conduct clinical care and research at the Clinical Center as authorized by Section 301 of the Public Health Service Act.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Not Applicable
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Information, including past donations, blood types, phenotypes, lab results, serologic reactions and related information, is collected from donors of blood and blood components to be used for clinical care and research at

the Clinical Center. Submission is mandatory since donations must be directly attributable to each individual donor.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Each individual donor is informed of required information collection and uses before donation. Major systems changes would be sent directly to each donor and new consents obtained upon new donations.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Only authorized persons may have access and the system is protected through door locks and other physical controls, as well as technical controls including user identification and password protection. Fingerprint recognition access controls are in place at the alternate location site in Bldg 12.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin: CC Privacy Officer, (301) 496-4240, smartin@cc.nih.gov

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Pla

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC CC 3M Medical Record Processing System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/22/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: Not Applicable

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0099

5. OMB Information Collection Approval Number: None

- **7. System Name (Align with system Item name):** Automated Medical Record Processing and Tracking Applications
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sue Martin
- **10. Provide an overview of the system:** Automated medical record processing and tracking applications containing demographic and tracking information is maintained on registered Clinical Center patients in order to route documents for creation, recording, retention, signature and location.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): None
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Information is collected to

identify and route clinical documentation electronically for user review and confirmation. Patient and clinician demographic information, along with clinical documentation identifiers and location information. The information is voluntarily provided at the time of dictation or authorship and each patient is informed of CC information practices before admission as a patient at the Clinical Center.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The automated medical record processing and tracking applications are a part of the medical record system which is an approved Privacy Act System. As such, each individual is informed of all information practices and any major system changes are published under a revised SORN.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: All information is protected by applying user ID, hierarchical passwords and administrative controls including supervisor limiting employee access on a need-to-know and minimum amount basis. Authentication with NIH PIV cards will occur at time of login to CC Network via CC CASPER for remote application users.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin: CC Privacy Officer, (301) 496-4240, smartin@cc.nih.gov

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC CC Clinical Research Volunteer Program [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/3/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-3099-00-110-031

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0012

5. OMB Information Collection Approval Number: None

- 7. System Name (Align with system Item name): CC Clinical Research Volunteer Program
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sue Martin
- **10. Provide an overview of the system:** System is used to contain information about potential candidates for participation as volunteers or research subjects participating in clinical research protocols at the Clinical Center.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): This information is addressed in the NIH Privacy Act Systems of Record Notice 09-25-0012, published in the Federal Register, Volume 67, No. 187, September 26, 2002. Clinical research volunteers data is made available to approved or collaborating intramural researchers.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Demographics and health

information are collected from program applications, health questionnaires and records of prior participation to provide appropriate persons as volunteers or research subjects in approved research protocols conducted at the Clinical Center. Submission is voluntary if applicant wants to be referred as a potential research subject. Information is also used to process requests for compensation and authorization of payments to research volunteers. Checks are issued by the Treasury Department.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Each person is verbally informed of information uses and verbal consent is obtained from each person who wishes to be evaluated as a potential research subject. Each individual is informed of information collection and uses prior to referral as a volunteer or patient. Each applicant would be notified directly by phone of any major system changes and new consent would be obtained.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: As per standard CIT procedures for the collection, maintenance and destruction of computer files, as well as specified in the PA Systems Notice. Authentication will occur at time of login to CC Network via CC CASPER for remote application users.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin: CC Privacy Officer, (301) 496-4240 - smartin@cc.nih.gov

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC CC Executive Information System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/1/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-09-02-3099-00-403-131

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0099

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): CC Executive Information System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sue Martin
- **10. Provide an overview of the system:** The Executive Information System (EIS) is an application designed to provide real time reporting of key hospital performance indicators. The EIS provides query and reporting capabilities for executive decision makers, and allows staff to view daily, monthly, annual patient census information and key hospital performance metrics. Census data can be reported by hospital unit and protocol, IC, branch, and Principal Investigator name associated with protocol activity.

EIS reports (does not collect) census statistics and resource utilization. Metrics include admissions, inpatient days, outpatient visits, average length of stay, discharges, patient counts and volume and cost of services provided. The information is used by nursing staff, clinical departments and institutes to manage operations and by executive leadership to track trends in hospital census activity and resource utilization.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes

- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Not Applicable
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: EIS reports (does not collect) census statistics. Metrics include admissions, inpatient days, outpatient visits, average length of stay, discharges, and patient counts. The information is used by nursing and clinical departments to manage operations and is used by executive leadership to track trends in hospital census activity. Principle investigator name (federal employee PII) associated with protocol activity is reported. CC social workers name collected from scheduling system is also reported in EIS system.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Principle investigators provide name at the time they apply for protocol approval from their IRB, which is required for protocol review and administrative approval. If any information other than principle investigator names are collected, then notification will be sent out from OMAR to each individual. CC social workers provide name when they confirm the outpatient appointment in the scheduling.com application. If any information other than CC social workers name are collected, then notification will be sent out from OMAR to each individual.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: PII is secured using user names/passwords, least privilege, separation of duties, an intrusion detection system, firewalls, locks, badge access to NIH campus and background investigations.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin, CC Privacy Officer, 301-496-4240

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC CC IT Infrastructure [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/21/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): Not Applicable

5. OMB Information Collection Approval Number: Not Applicable

6. Other Identifying Number(s): Not Applicable

- 7. System Name (Align with system Item name): CC IT Infrastructure
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sue Martin
- 10. Provide an overview of the system: The CC IT Infrastructure (CC ITI) is a GSS that supports approximately 4,500 users within the NIH Clinical Center, and is located in Bldg 10-CRC on the NIH campus in Bethesda, Maryland. The CC ITI hosts a myriad of servers, components, workstations, network and infrastructure devices uses to manage the NIH information. The Department of Clinical Research Informatics (DCRI) is responsible for the management of the CC ITI. The CC ITI comprises a variety of servers including network servers, application servers, Web and Internet Servers. While many applications with PII reside on servers in the CC ITI, the CC ITI provides the infrastructure to support those applications. The collection, storage and processing of PII for those applications will be covered by separate system Privacy Impact Assessments (PIA), not by the CC ITI PIA
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): PII collected, stored or processed by applications in the CC ITI are covered by separate Privacy Impact Assessments; not by the CC ITI PIA.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: This is a GSS for the IT infrastructure and does not collect, maintain or disseminate PII. No PII is collected, stored or processed. Private shares on the CC ITI file servers are used by CC personnel for storage of working documents to facilitate performance of their assigned duties. The information in working documents does not contain PII per NIH and CC policies.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Not Applicable - No PII is collected, stored or processed.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No PII is collected, stored or processed. Details on the administrative, technical, and physical controls are not required for the CC ITI GSS but have been provided where relevant for server and network access. The controls for applications that do collect, store or process PII residing in the CC ITI will be covered by separate system Privacy Impact Assessments (PIA), not the CC ITI PIA.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin: CC Privacy Officer, 301-496-4240, smartin@cc.nih.gov

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC CC Protocol Tracking [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/4/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-26-02-3099-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: None

- **7. System Name (Align with system Item name):** CC Patient & Research Services: Protocol Tracking
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sue Martin
- **10. Provide an overview of the system:** The Protocol Tracking System is used to collect, maintain and report administrative data about intramural research protocols under authority of Section 301 of the Public Health Service Act.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): NIH Employees for protocol approval, control and reporting.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The only PII contained in the Protocol Tracking System are the names of the investigators related to each protocol,

including NIH employees, contractors and other collaborators. The submission of all names are mandatory when the protocol is submitted to the IRB for approval.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Employees provide names at the time as a part of the protocol approval process and the names of Government employees are a matter of public record. There are no plans to add additional PII information at the current time, but the Office of Protocol Services would provide notification to each investigator if additions were made in the future.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Only authorized person may have access to the Protocol Tracking System and the system is protected through door locks and other physical controls, as well as technical controls including user identification and password protection.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin: CC Privacy Officer, (301) 496-4240, smartin@cc.nih.gov

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC CC Prototype [System] PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/14/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: Not Applicable

6. Other Identifying Number(s): Not Applicable

- 7. System Name (Align with system Item name): CC Prototype
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sue Martin
- **10. Provide an overview of the system:** Custom application providing a Web-based protocol authoring tool that utilizes a systematic framework to develop and maintain research protocols throughout their lifecycle. The application utilizes templates and language specified by the IC Institutional Review Board (IRB). Users include Primary Investigators (PI), Associate Investigators (AI) and IC reveiwers.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Not Applicable
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Information collected includes protocol documents, protocol workflows, status of protocol review, user's name, user's contact information and user's IC. The information is utilized to support authoring, reviewing

and management of a protocol from cradle to grave. The system includes PII about the Primary Investigator and Associate Investigator. The submission of federal contact information is voluntary for IC staff who choose to use the protocol authorizing system.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Release Notes describing system changes are electronically distributed to the registered users accessing the CC Prototype system with each version upgrade. The Release Notes provides notice of changes made during upgrades to add/modify data fields and add/modify data flow and add new features and functionality. The PII collected about users is limited, i.e., name, federal contact address, federal contact phone number, personal email and organization. The PII is collected from the user at the time a new account is created. The user may update the address, phone number and email at any time. The information is used to identify the authors and reviewers associated with protocols during the protocol development and approval phase. The information is not shared with other systems.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The system and all contained data are protected using administrative, technical, physical security and privacy controls. The system is located behind locked doors, monitored on CC TV and requires key card access for admission to the CC Data Center. In addition only authorized user may access the system based on user roles and passwords.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin, CC Privacy Officer, (301) 496-4240

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC CC Visual Supply Catalog [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/14/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0099

5. OMB Information Collection Approval Number: none

- 7. System Name (Align with system Item name): NIH:CC:Visual Supply Catalog
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sue Martin, CC Privacy Officer
- **10. Provide an overview of the system:** The Visual Supply Catalog is a web-based application that displays photographs of individual medical-surgical items, along with pertinent ordering information. The VSC was formulated using the electronic "shopping cart" concept typically used for on-line ordering and supports ordering by medical staff members supplies for use by Clinical Center patients.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Not Applicable
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The PII collected will

include patient name, medical record number, address and phone number. These data are necessary to assure that medical-surgical supplies ordered are accurately filled and mailed to the proper patient. Admission to the Clinical Center is entirely voluntary and each patient is advised of the Clinical Center information management practices in writing at the time of admission.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Admission to the Clinical Center is entirely voluntary and each patient is advised of the Clinical Center information management practices in writing at the time of admission.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Access to the system is controlled through the use of user IDs, passwords and access levels. Authentication with NIH PIVcards will occur at the time of login to the CC network via CC CASPER for remote application users. The servers are located in a controlled environment of the DCRI Data Center and physical controls include locked doors, key card access, cameras, etc.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin, CC Privacy Officer, 301-496-4240, smartin@cc.nih.gov

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC Citrix Netscaler PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 8/4/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): Not Applicable

5. OMB Information Collection Approval Number: Not Applicable

6. Other Identifying Number(s): Not Applicable

- 7. System Name (Align with system Item name): NIH CC CITRIX Netscaler
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sue Martin
- **10. Provide an overview of the system:** The Clinical Center (CC) CITRIX Netscaler system is used as a FIPS compliant secure authentication portal for the CC CITRIX published applications. It is a hardened appliance that requires LDAP or Smartcard authentication in order to access applications published in the CC CITRIX farm. It is a high availability network load balancer and is used to limit outages due to server maintenance and problem resolution.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Not Applicable
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: No PII is collected, stored or processed.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Not Applicable - No PII is collected, stored or processed.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** No PII is collected, stored or processed by the CC CITRIX Netscaler system. The CITRIX farm servers are protected using administrative, technical and physical security controls. The system is located behind locked doors, monitored by closed circuit TV and requires key card access for admission to the CC Data Center. Biometric authentication is required for admission to the high availability location in Bldg. 12 Customer Service Area. The system will enforce two factor authentication at the time of login to the CC network via CC CASPER for remote users accessing applications published in the CC CITRIX farm.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin: CC Privacy Officer, 301-496-4240, smartin@cc.nih.gov

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/29/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC Clinical Research Information System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-01-3006-00-110-219

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0099

5. OMB Information Collection Approval Number: NO

6. Other Identifying Number(s): CC-1

- 7. System Name (Align with system Item name): Clinical Research Information System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Dr. Jon McKeeby
- **10. Provide an overview of the system:** Core system and component applications to document clinical care and research for registered patients at the Clinical Research Center: NIH. This activity is authorized by Section 301 of the Public Health and Safety Act.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The Mayo Clinic for contracted lab tests not performed by the Department Of Laboratory Medicine at the CC.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Information collected includes individual patient demographics, confirmed appointments, clinical research data and

those related to diagnosis and treatment at the Clinical Center. These may include results of laboratory tests, imaging studies, blood product utilization, social work encounters, medical & ethical consults, surgery and other related clinical interactions while a patient at the Clinical Center. Patient information collected by the NIH as described in the NIH System of Records 09-25-0099 is utilized as the official clinical research record for each research participant. The information contains PII and the submission is voluntary based on an individual's consent to become a registered patient at NIH.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Information is obtained from patient interviews, referring physicians, a datafeed from the hospital scheduling system, a multi-disciplinary care team, and diagnostic, therapeutic, and research results. Admission and protocol consent forms are signed by each patient and an information practices notification form is provided to each patient a the time of initial admission. Each patient would be advised at the time of admission about major system changes and the CC Information Practices Notice would be revised and provided to each patient.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The system and all contained data are protected using administrative, technical, and physical security controls. System components are located behind locked doors, monitored by CC TV and Systems Monitoring staff in attendance around the clock. Additionally, the system is behind the NIH, CC and CRIS firewalls. Access to PII and privileges are based on user's assigned roles. Authentication with NIH PIVcards will occur at time of login to the CC Network via CC CASPER for remote application users.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin, CC Privacy Officer, (301) 496-4240

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Pla

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC Clinical Research Student Records System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/22/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0014

5. OMB Information Collection Approval Number: N/A

- 7. System Name (Align with system Item name): NIH CC Clinical Research Student Records System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Bob Lembo (301)-496-2636
- **10. Provide an overview of the system:** This system tracks applications from healthcare researchers, providers and administrators in training to the NIH Clinical Center Office of Clinical Research Training and Medical Education's undergraduate and graduate medical education programs, including the Clinical Electives Program (CEP), the Resident Electives Program (REP), Clinical Research Training Program (CRTP), Sabbatical Program and to selected Graduate Medical Education (GME) programs sponsored by various Institutes and Centers within the NIH.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Not Applicable

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The PII information collected includes name, personal mailing address, personal phone number, personal email address and educational records. The information is not disseminated and is used to process applicants for training programs sponsored by various Institutes and Centers within the NIH. The information is submitted voluntarily by medical/dental students or physicians and is collected to determine the suitability of applicants for NIH clinical research training programs.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) There is no current process to notify individuals when a major change occurs. Individuals are notified by email communications and electronic notice that submission of information is voluntary and how it will be used.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The electronic versions are password protected. Access to hard copies have physical controls in place and require administrative requests and access. The system resides in the CC Data Center where it is protected by locks, video monitoring and controlled access.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin, NIH/CC/DCRI, 301-496-4240

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC DTM SQL System Applications

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0011

5. OMB Information Collection Approval Number: N/A

- 7. System Name (Align with system Item name): CC DTM Applications Non-COTS (DANC)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Boyd Conley
- **10. Provide an overview of the system:** The DTM Applications Non-Cots (DANC) provides the Department of Transfusion Medicine (DTM) with administrative reporting functionality for donors and research management. The system provides DTM staff with tools to make decisions about the collection, use and distribution of donated blood.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Not Applicable
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The DANC system will collect demographic information, medical notes, travel history and laboratory results on donors

and NIH research participants. The information is used by DTM staff to perform routine tasks required by the American Association of Blood Banks and the FDA and support CC research protocols. The system will collect PII on donors and NIH research participants. The submission is mandatory since donations must be directly attributable to each individual donor.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Each individual donor is informed of required information collection and uses before donation. Major systems changes would be sent directly to each donor and new consents obtained upon new donations.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Only authorized persons with assigned roles may have access to the system. The DANC system is protected in the CC Data Center through door locks and other physical controls. Access to DANC is secured by technical controls; including user identification and password protection.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin: CC Privacy Officer, 301-496-4240

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC EKG System PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0099

5. OMB Information Collection Approval Number: N/A

- 7. System Name (Align with system Item name): NIH CC EKG System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Dennis Brown
- **10. Provide an overview of the system:** The TraceMasterVue ECG management system automates ECG data acquired from EKG machines and provides viewing, editing, resulting and report management functionality to the EKG technician and cardiologist users working in the EKG Dept. ORDERLINK is a bi-directional interface for ADT/orders that come the hospital clinical information system known as Clinical Research Information System (CRIS Sunrise). After verification by the cardiologists, test results and reports from TraceMasterVue are sent to CRIS Sunrise.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system collects,

maintains and disseminates electrocardiogram (ECG) tracings and reports on CC patients for the purpose of diagnosis and treatment of underlying heart conditions while enrolled in NIH intramural protocols. The ECG reports contain PII, which includes patient name, date of birth, medical record number, medical notes, Order ID and name of cardiologist reviewing transmitted ECG tracings. The submission is voluntary based on an individual's consent to become a registered patient at NIH.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Information is obtained from patient interviews, medical orders, and EKG machines when the diagnostic ECG test is performed at the CC. Admission and protocol consent forms are signed by each patient. CC Information Practices Notification is provided to each patient at the time of initial admission to the CC. If there is a major system change, each patient would be advised at the time of subsequent admissions and a revised CC Information Practices Notification would be provided to each patient.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The EKG system hardware and software employ administrative, technical and physical controls to protect patient's PII and sensitive data. The TraceMasterVue and ORDERLINK servers are located in locked areas of the CC. System administrators must have physical keys and/or cardkeys to work on servers in these secure locations. Data is backed up nightly and stored offsite. Application access requires a user ID and password. All PII is logically located behind multiple firewalls for increased protection. Authentication with NIH PIVcard will occur at time of login to CC Network via CC CASPER for remote application users.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin, CC Privacy Officer, (301)-496-4240

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC eSphere System PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/27/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0099

5. OMB Information Collection Approval Number: N/A

- 7. System Name (Align with system Item name): NIH CC eSphere System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sue Martin
- **10. Provide an overview of the system:** The CC eSphere System is used by the CC Pain and Palliative Care department clinical staff to document and report the results of pain consults performed on CC patients. The eSphere application receives Admissions, Discharge and Transfer (ADT), consult orders, medication orders and allergy information from CRIS Sunrise via interface. Additionally, the eSphere application sends the completed consult report to CRIS Sunrise via interface so it becomes part of the patient's electronic medical record.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Not Applicable
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The information collected, maintained and disseminated to CRIS Sunrise by the eSphere application does include PII. The

information includes name, date of birth, medical record and medical notes such as medications and allergies on CC patients. Information is collected for the purpose of diagnosis and treatment by the CC Pain and Palliative Care department clinical staff. The information is submitted voluntarily based on the individual's consent to become a registered patient at NIH.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Information is obtained from patient interviews, referring physicians and CRIS Sunrise, the electronic medical record for CC patients. Admission and protocol consents forms are signed by each patient and the CC Information Practices Notifice form is signed by each patient at the time of their initial admission. Each patient would be advised at the time of admission about major system changes and the CC Information Practices Notice would be revised and provided to each patient.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The system and all contained data are protected using administrative, technical and physical controls. The servers and application are physically located in the CC Data Center with access limited to authorized CC IT staff. The information is logically located behind multiple firewalls. User access and privileges in the application are based on their assigned roles in the application. Access to the application is controlled by Citrix technology and encryption is employed. Authentication with NIH PIVcards will occur at the time of login to the CC network via CC CASPER for remote application users.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin, CC Privacy Officer, (301) 496-4240

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC Histotrac PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 8/11/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0099

5. OMB Information Collection Approval Number: N/A

- 7. System Name (Align with system Item name): NIH CC Histotrac
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sue Martin
- **10. Provide an overview of the system:** CC Histotrac is a laboratory software application that tracks the results of human leukocyte antigen (HLA) performed on blood samples from CC patients and potential donors. The Histotrac system provides a single database to track the status of samples received and tested at the CC, query results for CC patients and donors, and provides a reporting functionality for the Department of Transfusion Medicine (DTM) clinicians and leadership team. The system is utilized by DTM staff to support the intramural transplant programs operated by NHLBI and NCI.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Limited PII is shared with the NIH intramural research transplant program staff from NHLBI and NCI for the purposes of clinical care and research.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: (1) The system collects, maintains and disseminates blood types, HLA testing results, and related medical information collected from donors and potential transplant recipients. (2) The information is required by the DTM staff and intramural research team to make clinical decisions regarding potential transplantation. (3) The information contains PII, including name, date of birth, medical record number and medical notes. (4) Submission is mandatory since donations must be directly attributable to each donor.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Each individual donor is informed of required information collection and uses before donation. Major system changes would be sent directly to each donor and new consents obtained upon new donations. The information will be used to make clinical decisions regarding potential transplantation of CC patients.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Only authorized persons with assigned roles may have access to the system. The Histotrac system is protected in the CC Data Center through door locks and other physical controls. Access to Histotrac is secured by technical controls; including user identification and password protection.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin, Clinical Center, Privacy Officer

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/29/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC Hospital Materials Management System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/28/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-3099-00-110-031

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

- 7. System Name (Align with system Item name): CC Hospital Materials Management System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sue Martin
- **10. Provide an overview of the system:** CC Hospital Materials Management System also know as Lawson is an Inventory Management System. Everything that is bought, received, stored, transferred, issued, or disposed of is recorded and controlled. The program is a live inventory instantaneously recording any supply activity that is entered in the system. It makes daily recommendations for both replenishing the Central Hospital Supply shelves from the Storage & Distribution Warehouse; as well as provides reorder for supplies that have fallen below their "par levels". It is the database that is linked to the Visual Supply Catalogue to provide the users the best "picture" and information on medical supplies. Finally, it is a tracking system for receiving supply orders that is used by Materials Management Dept staff.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\rm N\!/\!A$

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: CC Hospital Materials Management System also known as Lawson is a supply/inventory software that stores CC customer (patient care unit names, Clinic names, ancillary dept. names, not PII) and product information. The information stored is a history of purchases, receipts, issues, transfers etc. of supplies purchased and equipment purchased by the Materials Management Department and consumed by the CC customer locations.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) This is an inventory management system - No PII is collected or maintained

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: This is an inventory management system no PII is collected or maintained. Authentication with NIH PIVcards will occur at the time of login to the CC network via CC CASPER fore remot application users.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: smartin@cc.nih.gov Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC Investigational Drug Management System

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0099

5. OMB Information Collection Approval Number: N/A

- **7. System Name (Align with system Item name):** CC Investigational Drug Management System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sue Martin
- **10. Provide an overview of the system:** The CC Investigational Drug Management System (IDMS) is used by the Pharmacy Dept. to create, manage and store data related to investigational drugs used in the Clinical Center. The Pharmaceutical Development Section (PDS) provides investigational drug services for IRB approved intramural research protocols. IDMS provides PDS with the ability to track the inventory of the investigational drugs and the raw materials used to make the drugs. The system also provides the ability to fill prescriptions from the inventory of investigational drugs tracked by IDMS. Additionally, it provides Protocol/Study tracking capability.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The IDMS system receives patient and prescription order data from CRIS Sunrise, the CC

hospital information system. There are no external systems that share or disclose data with IDMS.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system collects, maintains and disseminates IDMS data about CC patients for the purpose of filling prescriptions and tracking the use of investigational drug administration on IRB approved protocols. The IDMS reports contain PII, which includes patient name, medical record number, patient study number, prescribing physician name, protocol name, and protocol number. The submission is voluntary based on an individual's consent to become a registered patient at NIH and enroll in an intramural research protocol.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) PII information is collected in CRIS Sunrise. Admission and protocol consent forms are signed by each patient. CC Information Practices Notification is provided to each patient at the time of initial admission to the CC. If there is a major system change, each patient would be advised at the time of subsequent admissions and a revised CC Information Practices Notification would be provided to each patient.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The IDMS system employs administrative, technical and physical controls to protect PII and sensitive data. The servers are located in the CC Data Center, behind locked doors and monitored 24/7 by DCRI Systems Operations team. Data is backed up nightly and stored offsite. User authentication is based on NIH Active Directory. Access and privileges in IDMS are determined by the user's assigned role. All PII is logically located behind multiple firewalls for increased protection. Authentication with NIH PIVcard will occur at time of login to CC Network via CC CASPER for remote application users.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin, CC Privacy Officer, (301) 496-4240

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC Laboratory Information System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/9/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0099

5. OMB Information Collection Approval Number: None

- 7. System Name (Align with system Item name): Laboratory Information System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sue Martin
- **10. Provide an overview of the system:** The LIS is an automated system designed to track, report and maintain results for laboratory tests performed on Clinical Center patients. Results comprise part of the official patient medical record.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The LIS captures laboratory results for specific Clinical Center patients and shares those results along with identifying PII with caregivers and scientists at the Clinical Center.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The LIS contains information regarding the entry of specific orders to complete various lab tests ordered on

Clinical Center patients, along with the results of those tests and the PII required to identify the specific patients to which those orders, tests and results apply. PII collected includes names, identifying numbers, and other demographics. Information is shared with caregivers and scientists with authorized access in order to provide clinical care or conduct approved medical research. Admission to the Clinical Center is completely voluntary and each patient is advised of Clinical Center information practices at the time of admission.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Admission to the Clinical Center is completely voluntary and each patient is advised of Clinical Center information practices at the time of admission. In addition, each patient signs an informed consent at the time of each admission. All notifications and consents are done in hard copy.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** All data is maintained in digital form and can only be accessed by NIH employees who have been authorized to do so by virtue of their need to know, need to deliver clinical care or conduct biomedical research. Access is controlled by role and password. The system servers etc are maintained in a controlled-access data center. Authentication with the NIH PIVcard will occur at the time of login to CC Network via CC CASPER for remote application users.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin, Clinical Center, Privacy Officer

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC Medical Staff Credentialing System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-26-02-3099-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0169

5. OMB Information Collection Approval Number: Not Applicable

- 7. System Name (Align with system Item name): Medical Staff Credentialing Processes
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sue Martin
- **10. Provide an overview of the system:** Information is collected from individual members of the Clinical Center Medical Staff and is used to document their credentialing and privileging under authority of Section 301 of the Public Health Service Act.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Private medical facilities, state medical boards and accrediting bodies as part of the credentialing process. Read only view of Credentialing Process application is available on defined workstations in Special Procedures Dept, Surgical Services Dept and Admissions Dept allowing the call team to view the medical privileges of medical consultants at night, weekends and holidays when Credentialing Offices are closed. Names and email address of medical staff applying for privileges to practice at the CC is sent by nightly feed to Prescriber Training database to support remote on-line CRIS training.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Names, addresses, phone numbers, medical licenses, college information and related data as part of the individual's application for membership on the Clinical Center Medical Staff. Information does contain PII. Submission is voluntary since application for membership is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Information is obtained directly from each applicant and each is informed about information collection procedures and rules when each applicant signs the consent authorizing the collection. Major systems changes would be sent electronically to each member of the medical staff and new consents obtained at the time of reappointment to the staff.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The system and all contained data are protected using administrative, technical and physical security controls. System is located behind locked doors, monitored by CC TV and Systems Monitoring staff in attendance around the clock. Additionally, the system is behind the NIH, CC and CRIS firewalls. Access to PII and privileges are based on user's assigned role.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin: CC Privacy Officer, (301) 496-4240, smartin@cc.nih.gov

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Pla

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC Medicolegal Request Tracking [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/22/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-3099-00-110-031

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0099

5. OMB Information Collection Approval Number: None

- 7. System Name (Align with system Item name): Medicolegal Request Tracking System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sue Martin
- **10. Provide an overview of the system:** The Medicolegal Request Tracking System is used to receive requests for and track copies of medical record documentation sent out by the Medical Record Department to Clinical Center patients and the third parties they authorize to receive such information.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): This information is addressed in the NIH Privacy Act Systems of Record Notice 09-25-0099, published in the Federal Register, Volume 67, No 187, September 26, 2002.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system collects patient

names, addresses, type of documentation requested for release, as well as the name and addresses of the person/organization to which the documentation is to be sent and the dates of receipt and release. Information is voluntary since release requests are also voluntary.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Each individual patient is informed of CC information practices before they are accepted as patients. In addition, each patient must provide a written release before information if sent out for any other purpose. The Medical Record Department would be responsible for revising release request authorization and information practices forms if any major system changes take place.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The system is maintained under controlled physical access and user identification as well as passwords are in effect for all users.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin: CC Privacy Officer, (301) 496-4240, smartin@cc.nih.gov

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC Metabolic Kitchen Nutrition System

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/21/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0099

5. OMB Information Collection Approval Number: N/A

- **7. System Name (Align with system Item name):** NIH CC Metabolic Kitchen Nutrition System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sue Martin
- **10. Provide an overview of the system:** The NIH CC Metabolic Kitchen Nutrition System (also known as ProNutra application) is used within the CC Nutrition Department to maintain a database of nutrient information on foods used in research diets, to calculate research diets for patients on specific protocols, and to produce food labels and menus for these research diets. Records are stored linking patient name to research protocol and date that meals were served to the patient. These records contain information on what foods were eaten, and quantities consumed.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The system does not automatically disclose PII, but manual queries containing patient name, DOB and protocol number are provided to the research team.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Patient name and date of birth are the only PII collected. This information is used to identify patients in the system and for delivery of meals for research purposes. This information is retrieved from CRIS, the clinical research information system, by CC Nutrition Dept registered dieticians and manually entered into the CC Metabolic Kitchen Nutrition System. The submission of personal information is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Patients are advised about the information collection practices and uses of their data for purposes of clinical research at the time of admission to the CC. Patients agree to the collection of PII in clinical research systems and acknowledge their consent by signing the CC Information Practices Notice. Patients would be advised about major system changes affecting PII by a revision to the CC Information Practices Notice that would be presented for review and acknowledgement at the time of their next admission to the hospital.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The CC Nutrition Dept staff with access to the CC Metabolic Kitchen Nutrition System are required to complete NIH Computer Security and Privacy Awareness Training. Access to the system is controlled by user ID and password. The system is located in the CC Data Center behind locked doors. Individual workstations from which the CC Metabolic Kitchen Nutrition System may be accessed are located in the CC Nutrition Dept. Access to the CC Nutrition Dept is protected by card key readers. Authentication with NIH PIVcards will occur at the time of login to the CC network via CC CASPER for remote application users.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin, CC Privacy Office, 301-496-4240

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC NMD Server Room PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/18/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): Not Applicable

5. OMB Information Collection Approval Number: N/A

- 7. System Name (Align with system Item name): NIH CC NMD Server Room
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Charles Fraser
- **10. Provide an overview of the system:** The Positron Emission Tomography (PET) IT Infrastructure (formerly NIH CC Nuclear Medicine Server Room) is a GSS located in Bldg 10 in the CC PET Department. The PET IT Infrastructure hosts a myriad of servers, components, imaging workstations, network and infrastructure devices used to support the PET imaging studies at the Clinical Center. The PET IT staff is responsible for the management of the PET IT Infrastructure. Whie some applications with PII reside on servers and workstations in the PET IT Infrastructure, details regarding the collection, storage and processing of PII for those applications will be covered by separate system Privacy Impact Assessments (PIA).
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): PII collected, stored or processed by applications in the CC NMD Server Room are covered by separate Privacy Impact Assessments; not by the PET IT Infrastructure PIA
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: This is a GSS for the IT infrastructure and does not collect, maintain or disseminate PII.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Not Applicable - No PII is collected, stored or processed.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No PII is collected, stored or processed. Details on the administrative, technical, and physical controls are not required for the PET IT Infrastructure GSS. The controls for application that do collect, store or process PII residing in the PET IT Infrastructure will be covered by separate system Privacy Impact Assessments (PIA), not the PET IT Infrastructure.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin: CC Privacy Officer, (301)-496-4240, smartin@cc.nih.gov

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC Nutrition Department Research System (NDRS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/21/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0099

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH CC Nutrition Department Research System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sue Martin
- **10. Provide an overview of the system:** The CC Nutrition Department Research System (also known as Nutrition Department System for Research (NDSR)) is a dietary analysis program designed for the collection and analyses of 24-hour dietary recalls and the analysis of food records, menus, and recipes. Calculation of nutrients occur immediately providing data by ingredient, food, meal and day in both report and analysis file formats. The application includes a dietary supplement assessment module so that nutrient intake from both food and supplement sources may be captured and quantified for patients enrolled in intramural clinical research protocols.

NDSR is used to analyze 3-day and 7-day food records from patients enrolled in 8 protocols (NIDDK, NICHD, NIAID, NHGRI and NCI) coding approximately 150-200 days of food records each month. The food records are coded by CC Dept of Nutrition Health Technicians and reviewed by CC Dept of Nutrition registered dieticians.

- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Not Applicable
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The information collected includes PII specifically; name, date of birth, and medical record number. The information is used to track dietary intake of patients enrolled in intramural clinical research protocols from several Institutes within the NIH. The submission of information is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Patients are advised about information collection practices and uses of their data for purposes of clinical research at the time of admission to the CC. Patients agree to the collection of PII in clinical research and acknowledge their consent by signing the CC Information Practices Notice. Patients would be advised about major system changes affecting PII by a revision to the CC Information Practices Notice that would be presented for review and acknowledgment at the time of their next admission to the hospital.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** All staff are required to take NIH Information Security and NIH Privacy Awareness training. All application hardware is located in the CC Data Center behind locked doors. Individual workstations where data input occurs are located behind key card controlled locked doors in the CC Dept of Nutrition. Authentication with NIH PIVcards will occur at the time of login to the CC network via CC CASPER for remote application users.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin, NIH/CC/DCRI, 301-496-4240

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC Nutrition System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/21/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: None

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0099

5. OMB Information Collection Approval Number: Not Applicable

- 7. System Name (Align with system Item name): CC Nutrition System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sue Martin
- **10. Provide an overview of the system:** The CC Nutrition System consists of two major components; the Food Service Suite (FSS) and the Nutrition Service Suite (NSS). FSS is used to track information regarding recipes, nutritional values, stock inventory, and vendor information. NSS uses the recipe and nutrition information to determine which foods are appropriate for patients based upon their diets as entered into the CRIS. This determination is then used by employees in the room service call center to assist patients in selecting appropriate food items.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The Nutrition System receives PII from CRIS through a unidirectional interface. The Nutrition System doesn't share or disclose PII.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Demographic and clinical information is provided through an interface with CRIS to identify the patient, caregivers, clinical information, etc. No additional PII is collected other than that provided by CRIS. The information is used to screen out menu items not appropriate for patients based on physician orders and to identify appropriate items. Patients sign consents when admitted to the CC and admission is entirely voluntary. In addition, each patient is advised of the specific uses of information at the CC and signs an acknowlegement thereof.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) PII is collected from CRIS. Each patient would be advised at the time of admission about major system changes and the CC Information Practices Notice would be revised and provided to each patient upon the next admission.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The system and all contained data are protected using administrative, technical, physical and privacy controls. All staff with access are required to take Computer Security and Privacy Awareness Training. Access and privileges utilize role-based security and NIH credentials. All hardware is located in the CC Data Center behind locked doors and individual workstations are also kept behind locked doors. Authentication with NIH PIVcards will occur at the time of login to the CC network via CC CASPER for remote application users.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin: CC Privacy Office, 301-496-4240

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC OPUS Respiratory Information System (OPUS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/3/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0099

5. OMB Information Collection Approval Number: None

- **7. System Name (Align with system Item name):** CC OPUS Respiratory Information System (OPUS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Dennis Brown
- **10. Provide an overview of the system:** The OPUS Respiratory Information System is used by Critical Care Medicine Dept (CCMD) Respiratory Therapists to document clinical care activities performed on CC patients. The system provides functionality for clinical documentation, patient charges, workload productivity reporting and evaluation of the patient's respiratory status. The system receives patient demographics and medical orders from CRIS Sunrise.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Not Applicable
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: PII collected in OPUS from CRIS Sunrise includes patient name, date of birth, medical record number, medical orders, and protocol number. The information is required to support workflow and documentation by respiratory therapist on CC patients. The submission is voluntary based on an individuals consent to become a registered patient at the CC. Additional PII entered in OPUS by the CCMD Respiratory Therapists include employment status data such as dates of hire, personnel data and training records. The information is collected to support quality assurance programs and tracking of staff activities. The submission is mandatory based on a respiratory therapists acceptance of employment at the CC.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) CC Information Practices Notification is provided to each patient at the time of initial admission to the CC. If there is a major system change, each patient would be advised at the time of subsequent admissions and a revised CC Information Practices Notification would be provided to each patient. Respiratory Therapists are notified of the requirement to collect employment information during department orientation. If there is a major system change, staff would be advised of the changes through department communications.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The OPUS system application hardware and software employ administrative, technical and physical controls to protect patient and staff PII. The servers are located in locked areas of the CC. The PC Tablets used by Respiratory Therapists at the bedside utilize VPN technology to secure data on the CC wireless network. Data is backed up nightly and stored offsite. Application access requires user ID and password. All PII is logically located behind multiple firewalls for increased protection. Authentication with NIH PIVcard will occur at time of login to CC Network via CC CASPER for remote application users.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin, CC Privacy Officer, (301) 496-4240

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC Outpatient Pharmacy PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0099

5. OMB Information Collection Approval Number: Not Applicable

- 7. System Name (Align with system Item name): CC Outpatient Pharmacy
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sue Martin
- 10. Provide an overview of the system: The Outpatient Pharmacy system is a closed loop system that supports the Clinical Center (CC) Pharmacy Department core functions of filling medication orders and dispensing medications to NIH intramural patients. The system enhances the safety and efficiency of take-home medication dispensing functions performed by CC Pharmacy staff by incorporating bar-code scanning and visual identification of the dispensed medications. The system further improves efficiency by using a high-throughput dispensing robot and collating software to identify the location of each prescription in the dispensing process. The system's report functionality provides accurate inventory control, provides accurate cost data to facilitate management reports to Pharmacy and CC leadership and will allow more accurate budget projections.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Not Applicable

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The CC Outpatient Pharmacy system will collect and maintain PII on patients that includes full name, date of birth, personal mailing and email addresses, personal phone number, medical record number, medical notes and signatures. The CC Outpatient Pharmacy system will store the signature of the patient/family member picking up prescriptions for controlled substances. The CC Outpatient Pharmacy system will collect and maintain the full name of Pharmacy Dept staff who verify, fill and dispense medications to patients. The information will be used for patient care, specifically to track the medications provided to patients for administration at home. The information will also be used by CC Pharmacy to respond to FDA inquiries about recalled medications dispensed to patients and satisfy DEA reporting requirements about controlled substances dispensed to patients. The submission of personal information is entirely voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Admission to the Clinical Center (CC) is completely voluntary and requires consent of each patient. Additionally, each patient is provided a full written accounting of established information practices at the CC, including the capture and use of PII, and has the opportunity to ask questions. Each patient must acknowledge receipt of same through manual signature on the CC Information Practices Notice Form.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** PII will reside on a server in the CC DataCenter protected by restricted access and video monitoring. The server will be behind the NIH and CC firewall and dedicated Outpatient Pharmacy VLANs. The ScriptPro workstations in the Pharmacy Dept are protected by restricted access and locked doors. Access to the PII in the ScriptPro application is protected by security screen locks. Access is granted by user type and is set by the Pharmacy Dept ScriptPro Administrator in accordance with Pharmacy policies. Access to the PII in the ScriptPro application requires use of the NIH PIV smartcard.

PIA Approval

PIA Reviewer Approval: Demote

PIA Reviewer Name: Sue Martin: CC Privacy Officer, 301-496-4240

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 6/6/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC PeriOperative Information System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/13/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0099

5. OMB Information Collection Approval Number: Not Applicable

- **7. System Name (Align with system Item name):** NIH CC Perioperative Information System (POIS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sue Martin
- **10. Provide an overview of the system:** COTS application providing OR and Anesthesia specific functions to the Department of Perioperative Medicine (DPM). The functions include: Scheduling the OR, Anesthesia, IC human resources and material resources for surgical and anesthesia procedures at the Clinical Center, documentation of clinical and research care provided to registered patients, inventory management, tracking patients across the perioperative continuum, integration with CC Clinical Research Information Systems (CRIS) for receipt of patient demographics, allergies and laboratory test results, integration with patient care monitors for automated collection of specific vital signs, and reporting to DPM and CC Leadership.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Clinical documentation of perioperative care provided to CC patients which is created in POIS is shared with CRIS system for storage in the specific patient's official medical record.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Information collected includes individual patient demographics, scheduling of procedures and associated resources, clinical research data related to surgical and anesthetic care provided at the Clinical Center. Patient and staff information becomes part of the official medical record. Information about medical supplies, devices and medications collected during procedures supports inventory management for the the Department of Perioperative Medicine. The patient information contains PII and the submission is voluntary based on an individual's consent to become a registered patient at the NIH. The staff information contains PII and the submission is mandatory based on their credentialed status as care providers at the Clinical Center.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Information is obtained from patient interviews, a multi-disciplinary care team in the Department of Perioperative Medicine and patient observations. Admission and protocol consent forms are signed by each patient and a CC information practices notification form is provided to each patient at the time of initial admission. Consent to Invasive Procedure forms are signed by the patient before each procedure. Each patient would be advised at the time of admission about major system changes and the CC Information Practices Notice would be revised and provided to each patient.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The system and all contained data are protected using administrative, technical, physical security and privacy controls. The system is located behind locked doors, monitored by CC TV and requires key card access for admission to both the CC Data Center and the Department of Perioperative Medicine. In addition, only authorized users may access the system based on user roles and hierarchial passwords. User authentication with NIH PIVcards will occur at the time of login to the NIH network from CC desktops for local application users. Authentication with NIH PIVcards will occur at the time of login to the CC network via CC CASPER for remote application users.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin, CC Privacy Officer, (301) 496-4240

Sr. Official for Privacy Approval: Promote **Sr. Official for Privacy Name:** Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC Picker: Clinical Center Survey Results

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/25/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: Not Required

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0156

5. OMB Information Collection Approval Number: None

- 7. System Name (Align with system Item name): NIH-CC Picker: Clinical Center Survey Results
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sue Martin
- **10. Provide an overview of the system:** Information resulting from various surveys and questionnaires conducted by the Clinical Center from patients and staff regarding quality of care and hospital operations. The categories of evaluative information varies according to the service being surveyed and may include data related to the research experience, the clinical services received, the respondent's level of satisfaction, time of delivery and future plans.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): No identified data is shared. Only de-identified aggregate data is shared with CC Administration. Once individual responses are aggregated, individuals are no longer able to be retrieved by name.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Data is abstracted from various survey responses and questionnaires, including demographics and is primarily related to the quality and performance of various selected hospital services. The CC provides NRC with visit status, unit location, MRN, name, address, DOB, visit and discharge date, protocol number, Institute and Branch to identify a pool of CC patients who may receive the survey questionnaire in the mail. The information collected in the questionnaires returned to NRC is used to target areas for improvement to satisfy patient and staff expectations. Participation is entirely voluntary and CC Administration is provided with de-identified aggregate data only. Submission is completely voluntary.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Consent is not obtained because participation is entirely voluntary and because the data derived from the surveys and questionnaire is only provided in a de-identified aggregate manner to the CC reviewers. Any individual can opt not to participate by not responding to the survey mailed to them. Each participant is provided a written introduction and explanation of the survey in a cover letter. There has never been any major changes to the system and none are anticipated at this time. If such changes do occur, each participant will be notified directly. There are no other notification procedures in place.

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The information is kept in a physically secure location utilizing access controls that include security badges and key cards. Data is protected by technical controls that include User ID, passwords, firewalls, VPNs, and card key readers.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin, CC Privacy Officer, (301) 496-4240, smartin@cc.nih.gov

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC Picture Archive Communications System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/18/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: None

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0099

5. OMB Information Collection Approval Number: Not Applicable

- 7. System Name (Align with system Item name): CC Picture Archive Communications System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sue Martin
- **10. Provide an overview of the system:** The PACS collects, disseminates and stores radiological images pertaining to Clinical Center patients and provides those images to authorized caregivers involved in the delivery of clinical care or to scientists conducting approved biomedical research. The information collected includes PII to identify specific patients by name, medical record number and other identifiers. Admission to the Clinical Center is entirely voluntary and each individual is informed of Clinical Center information practices and gives informed consent before providing PII.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The PACS provides radiological images and PII identifying those images with specific Clinical Center patients with authorized caregivers and scientists.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The PACS collects, disseminates and stores radiological images pertaining to Clinical Center patients and provides those images to authorized caregivers involved in the delivery of clinical care or to scientists conducting approved biomedical research. The information collected includes PII to identify specific patients by name, medical record number and other identifiers. Admission to the Clinical Center is entirely voluntary and each individual is informed of Clinical Center information practices and gives informed consent before providing PII.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Admission to the Clinical Center is entirely voluntary and each individual is informed of Clinical Center information practices and gives informed consent before providing PII. The process may be completed again if major changes occur. All notifications are done in hard copy or using secure email.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Access is restricted only to authorized users with a need to know and is secured using passwords and role based security. Servers are located in the CC data center—behind locked doors, monitored by CCTV and supported by redundant power and cooling. Authentication with NIH PIVcard will occur at time of login to the CC Network using CC CASPER for remote application users.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin, Clinical Center, Privacy Officer

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC ProVation PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/14/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: No

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0099

5. OMB Information Collection Approval Number: Not Applicable

- 7. System Name (Align with system Item name): CC Provation
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sue Martin
- **10. Provide an overview of the system:** CC Provation is a Major Application whose mission is to digitally report findings from gastroenterological endoscopic exams of the upper and lower gastrointestinal tract, including the ability to record digital pictures. It is part of modern clinical practice in gastroenterology and considered a part of routine clinical care. Procedures are recorded as they are done and the information for each procedure is collected from a particular patient for a particular procedure.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Hard copy reports of endoscopic procedures are printed from the system and stored in the patient's medical record.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: CC Provation is a Major

Application whose mission is to digitally report findings from gastroenterologi-cal endoscopic exams of the upper and lower gastrointestinal- tract, including the ability to record digital pictures. It is part of modern clinical practice in gastroenterology- and considered a part of routine clinical care. Procedures are recorded as they are done and the information for each procedure is collected from a particular patient for a particular procedure.

The submission of the personal information is voluntary. The CC Provation system collects and stores PII; specifically, medical record number and name.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Protocol consent forms are signed by each patient and an information practices notification form is provided to each patient at the time of initial admission. Data is retained on servers maintained by DCRI in the CC Data Center and a hard copy is printed which is inserted into the patient's medical chart. This is kept in medical records.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Technical, Physical and administrative controls are in place to ensure the security of the information. These include a Contingency Plan, regular offsite backup of the data, and yearly security awareness training for all personnel.

The information is secured through multiple levels of security and access controls which have been established to identify permitted users and to determine if the user has the authorization to perform actions requested. The access controls are supplemented with a secure network at both NIH and the CC.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin, CC Privacy Officer, (301) 496-4240, smartin@cc.nih.gov

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC Pyxis Supply Station System

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/14/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0099

5. OMB Information Collection Approval Number: None

- 7. System Name (Align with system Item name): NIH CC Pyxis Supply Station System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sue Martin, CC Privacy Officer
- **10. Provide an overview of the system:** The Pyxis Supply Station System is an advanced point-of-use system that automates the distribution, management and control of medical supplies ordered by medical staff for Clinical Center patients.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Pyxis Supply System collects inventory data and PII data that includes unique identifiers such as patient name and medical record number to assure that the right patient gets the right medical supplies. The

submission is voluntary based on an individual's consent to become a registered patient at the CC.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Patient demographics, including patient name, medical record number and current hospital location are collected in CRIS Sunrise and shared with the Pyxis Supply Station System. CC Information Practices Notification is provided to each patient at the time of initial admission to the CC. If there is a major system change, each patient would be advised at the time of subsequent admissions and a revised CC Information Practices Notification would be provided to each patient.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The Pyxis Supply Station System and all contained data are protected using administrative, technical and physical security controls. Pyxis Supply Station dispensing units are located in controlled access areas of the CC nursing units. Access to PII and privileges are based on user's assigned roles. The Pyxis Supply Station application/database servers are located in the CC Data Center behind locked doors, monitored by CC TV and Systems Monitoring staff in attendance around the clock. Additionally, the system is logically located behind the NIH, CC and CRIS firewalls. Remote access to the Pyxis Supply Station require use of the NIH VPN.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin, Privacy Officer, Clinical Center

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC Quadramed Nursing Acuity System

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/5/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-90-0018

5. OMB Information Collection Approval Number: N/A

- 7. System Name (Align with system Item name): NIH CC Quadramed Nursing Acuity System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sue Martin
- **10. Provide an overview of the system:** Quadramed Nursing Acuity System provides the Nursing and Patient Care Services (NPCS) department with the functional ability to document patient acuity on CC inpatients and outpatients. The Quadramed system utilizes the QuadraMed Acuity-Plus application to collect staffing, acuity and visit data by way of input from CC Nurses and the Automated Nurse Staff Office Schedule (ANSOS) system. The application then provides recommended staffing levels to NPCS leadership.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\rm N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: The Quadramed system collects patient name, medical record number, acuity assessments, admission, discharge and transfer data derived from CRIS Sunrise. Additionally, the Quadramed system collects NPCS staff names and roles. The information is analyzed to project staffing requirements for the CC patient care locations. Patient information includes PII, i.e., name, medical record number and medical notes; submission is voluntary. Staff information includes PII, i.e., name and role which is publically available in NED. Staff information submission is a mandatory condition of employment.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Patients would be advised at the time of admission if major system changes occur, data uses or disclosures change. The CC Information Practices Notice would be revised and provided to each patient at the subsequent admission to the CC. NPCS staff would be advised of major system changes related to PII by the CC Nursing Department. Notification may be done electronically or in written form.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** PII is secured using administrative controls that include backup files, user manuals, and user training. Access and privileges in the Quadramed Nursing Acuity System are based on the user's assigned roles. PII is additionally protected by technical controls that require entry of a User ID and Password to open the application. The application is logically located behind the CRIS firewall and requires the NIH VPN for remote access. Only authorized DCRI IT staff have access to the Quadramed Nursing Acuity System servers in the CC Data Center. The system hardware is protected by door locks, CCTV, NIH security guards and Identification Badges. Authentication with NIH PIVcards will occur at time of login to the CC Network via CC CASPER for remote application users.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin: CC Privacy Officer, (301) 496-4240, smartin@cc.nih.gov

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC Rehabilitation-Social Security Administration Data Sharing System

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: None

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: Not Applicable

- **7. System Name (Align with system Item name):** CC: Rehabilitation Medicine Dept Social Security Administration Data Sharing System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sue Martin
- **10. Provide an overview of the system:** The Clinical Center Rehabilitation Medicine Department (CC-RMD) at the National Institutes of Health (NIH) has agreed to assist the Social Security Administration (SSA) to explore innovative methods for augmenting and improving the current disability evaluation process. The first major line of work requires analysis of data from longitudinal research files maintained by the Social Security Administration and assessing the feasibility of developing Computer Adaptive Testing (CAT) instruments that can be integrated into the SSA data collection and determination processes.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The research data set is only shared between the SSA and the specific RMD staff authorized to perform statistical and other related analyses of the information.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Analysis of data from longitudinal research files maintained by the Social Security Administration Office of Disability Program Information and Studies (ODPIS). These files house extensive administrative data, including application data and decisional data. Each record represents one disability claim. Past efforts to improve the quality and utility of the files were challenged by resource constraints. Users of the data files will need to creatively problem-solve and formulate solutions to data-related issues as they arise. The data includes limited personal identifiers including a pseudo social security number, medical notes, and birth month and year. Data is submitted as part of an application for a disability determination. The submission of data by applicants is required as part of the process when applying for benefits. Sharing of the data with the RMD is entirely voluntary on the part of the SSA.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) All individuals are notified of use at the time of disability filing and consent is written and maintained by SSA. Major changes will be communicated by the CC CIO to the SSA Project Director. A limited data set, aka, research data is shared between the SSA and the specific RMD staff authorized to perform statistical and other related analyses of the information. In the event a change to the CC system would include a new use or disclosure, the SSA Project Director would make a determination to notify individuals whose data is contained in the CC system.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** A limited data set, aka, research data is shared between the SSA and the specific RMD staff authorized to perform statistical and other related analyses of the information. Access is password protected and role based security is also used. All data resides on a server and SAN solely dedicated to that purpose and is located within the secure CC Data Center which uses state of the art backup and physical security measures. Individual files include a scrambled social security number (aka pseudo SSN). The key to unscramble the pseudo SSN is stored at the SSA to ensure protection of sensitive PII.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin, CC Privacy Officer

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC Scheduling System PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/27/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: None

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0099

5. OMB Information Collection Approval Number: None

- 7. System Name (Align with system Item name): NIH CC Scheduling System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sue Martin
- **10. Provide an overview of the system:** An ASP web-based application used for scheduling patient appointments in the Clinical Center. Schedules for physicians, nurses, ancillary care givers, resources and locations are built so that specific schedules can be created and viewed. A third-party contractor sends individualized appointment reminder letters to patients.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): PII is required for patient identification at the point of scheduling, as well as for contacting patients and mailing them reminder letters regarding their scheduled appointments.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Information is provided from CRIS to support the scheduling functionality including patient and clinician demographics which is used to create the specific appointments for each patient within the application.

Admission to the Clinical Center is entirely voluntary and each patient is advised of the specfic information practices at the Clinical Center at the time of admission.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Each patient signs a consent to be admitted to the Clinical Center and is advised as to each of the specific information practices at the Clinical Center including how information about them will be stored and shared and for what purposes. Major changes will be updated in the current information practices and patients will be informed at the time of admission.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: CC users and contractors have completed information security and privacy training. Access to data is based on user role. SCI Solutions security policy includes review of all incidents and action plans to mitigate, repair and prevent damage. Access is restricted by firewalls, use of virtual IP and physical separation of database servers from systems serving HTTP pages. Production systems access is limited to specific need-to-know employees. Physical access is limited by locked doors, pass-coded ID, cameras, etc. Authentication with NIH PIVcard will occur at time of login to the CC Network via CC CASPER for remote users.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin, Privacy Officer, Clinical Center, Department of Clinical

Research Informatics

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC StemLab PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0011

5. OMB Information Collection Approval Number: N/A

- 7. System Name (Align with system Item name): NIH CC StemLab
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Boyd Conley
- **10. Provide an overview of the system:** StemLab is a clinical and administrative management system. It manages and streamlines the unique work flow followed in the CC Dept of Transfusion Medicine's stem cell blood laboratory. StemLab also supports stem cell processing operations for bone marrow and apheresis products. The system also provides functionality to meet quality assurance practices and regulatory compliance for cell therapy transplant services at NIH.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Information related to donation and receipt of blood products for patients on IRB approved protocols is shared with intramural clinical research team.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The StemLab system will

collect demographic information, medical notes and laboratory results on donors and NIH research participants. The information is used by DTM staff to perorm routine tasks required by the American Association of Blood Banks and the FDA and support CC research protocols. The system will collect PII on donors and NIH research participants. The submission is mandatory since donations must be directly attributable to each individual donor.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Each individual donor is informed of required information collection and uses before donation. Major systems changes would be sent directly to each donor and new consents obtained upon new donations.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Only authorized persons with assigned roles may have access to the system. The StemLab system is protected in the CC Data Center through door locks and other physical controls. Access to StemLab is secured by technical controls; including user identification and password protection. Authentication with NIH PIVcard will occur at the time of login to CC Network via CC CASPER for remote users.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin: CC Privacy Officer, 301-496-4240, smartin@cc.nih.gov

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC Teramedica IS PACS PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 8/12/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: Not Applicable

6. Other Identifying Number(s): Not Applicable

- 7. System Name (Align with system Item name): NIH CC Teramedica IS PACS
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Ron Levin
- **10. Provide an overview of the system:** Teramedica IS PACS stores Digital Imaging and Communications in Medicine (DICOM) formatted image data acquired from imaging devices on the NIH network and images acquired from external research partners. The DICOM image data from external research partners includes limited data in the MRI image headers per the approved HIPAA release. The DICOM data from intramural research partners includes PII in the image headers. The system is operated by CC Diagnostic Radiology Department (DRD) and CC (Radiology and Imaging Sciences) RAD IS staff. Users include CC Radiology and Imaging Sciences staff and NIH intramural research staff whose DICOM images are stored in the system.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The Teramedica IS PAC system shares and/or discloses PII with Johns Hopkins Medical Institutes. The PII data is incorporated in reports by Dr. Bluemke's research team following their analysis of JHMI MRI images. The disclosure is pursuant to a JHMI IRB approved protocol and an NIH IRB approved protocol.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) The Teramedica system collects DICOM images, names, dates of birth, medical record numbers, medical notes, gender on NIH intramural research subjects for clinical research and analysis. (2) This information is collected for the purposes of analysis of MRI images by members of the IRB approved research study between Johns Hopkins Medical Institutes and the CC. (3) The information contains PII. (4) Submission of PII is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) NIH intramural research subjects are advised of data uses at the time of admission to the Clinical Center in the CC Information Practices Notice. Major changes in the use of their DICOM images in the Teramedica system would be incorporated in an amended CC Information Practices Notice and provided to the CC patients at the time of next admission.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** PII in the application is protected by technical controls that include user ID and password, firewalls and NIH VPN with authentication using NIH PIVcard for remote application users. The system hardware is located in Bldg 10 Data Center and Bldg 12 Data Center. The infrastructure is protected by guards, the use of identification badges, key cards and retinal scan for access to Bldg 12.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin, CC Privacy Officer, 301-496-4240, smartin@cc.nih.gov

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/29/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CC TheraDoc Epidemiology System

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/28/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: None

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0099

5. OMB Information Collection Approval Number: None

- 7. System Name (Align with system Item name): CC TheraDoc Epidemiology System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sue Martin
- **10. Provide an overview of the system:** The system provides the Hospital Epidemiology Service with continuous infection surveillance, alerts, and analysis to help promote better and more timely infection control practices.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Hard copy reports with PII are faxed as needed to Maryland, Virginia and District of Columbia Public Health Depts in compliance with public health reporting requirements for infectious diseases.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system captures and

maintains PII on registered Clinical Center patients, including demographics, lab results, radiology results, admission/discharge/transfer information, vital signs, medications and selected surgical information. PII is shared with staff epidemiologists and other care givers involved with the treatment of patients at the Clinical Center. The collection of PII is voluntary since admission to the Clinical Center and specific research protocol(s) is completely voluntary. Additionally, the Clinical Center is required to collect infectious disease surveillance information for JCAHO and the Public Health Service.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Admission to the Clinical Center is completely voluntary and requires consent of each patient. In addition, each patient is provided a full written accounting of established information practices at the Clinical Center, including the capture and use of PII, and has the opportunity to ask questions and must acknowlege receipt of same through their signature on the CC Information Practices Notices form.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** PII resides on a server in the CC Datacenter protected by restricted access and video monitoring. The server is behind the NIH & CC firewalls. Access is granted by the application administrator to each individual on a need-to-know basis. Access will require password and specific security group inclusion. Passwords at the NIH and application level require updates as required by NIH policy and users are automatically logged off the system after inactivity.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sue Martin, CC Privacy Officer, 301-496-4240

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CIT Billing System PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

- 7. System Name (Align with system Item name): CIT Billing System (CBS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: John Burke
- **10. Provide an overview of the system:** The CIT Billing System (CBS) provides comprehensive job accounting and chargeback reporting. CBS is integrated with CIMS to identify the billable services that each organization uses and creates invoices that are presented to Customer Accounts for payment.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The information collected are account usage and costs associated with use. This data is used to create invoices and summary reporting files for the central accounting system. The CIT Billing System is integrated

with CIMS to support fee for service and flat fee standard rates. the CIT Billings System collects no sensitive information.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michele Mulholland France, NIH/CIT/PECO

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CIT CIT Democracy II Server Room [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-02-00-01-3109-00

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): There is no PII this is for a server room
- **5. OMB Information Collection Approval Number:** There is no OMB ICA Number this is for a server room
- **6. Other Identifying Number(s):** There are no unique identifying numbers
- 7. System Name (Align with system Item name): Democracy II Server Room
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Chris Santos
- **10. Provide an overview of the system:** This is a development and test environment used by CIT's Division of Enterprise and Custom Applications.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Not applicable
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: There is no PII this is for a server room

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) There is no PII - this is for a server room

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: There is no PII this is for a server room

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michele France, NIH/CIT/PECO

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CIT CIT Division of Computational Bioscience Systems [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-26-02-3103-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** Division of Computational Bioscience Systems
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Anthony Fletcher NIH/CIT/DCB
- **10. Provide an overview of the system:** This system ("DCB Systems") is used to provide CIT support for the Institutes and Centers (IC) at NIH. DCB collaborates with the NIH intramural research program to provide expertise and develop software on computational research problems of significance to the ICs. DCB Systems host this software which includes development and preproduction versions. The application areas include molecular modeling, protein structure prediction, biomedical imaging, mathematical modeling, and biomedical informatics.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): SOR 09-25-0200 This information is addressed in the NIH Privacy Act Systems of Record Notice 09-25-0200, published in the Federal Register, Volume 67, No. 187, September 26, 2002.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: CIT/DCB does not collect any of the data it uses in its research and collaborations with the Institutes. DCB develops tools for principal investigators to use in collecting data. DCB merely keeps a copy of the data, which depends on the protocol but may include IIF such as name, date of birth, phone number, medical records, medical notes, and gender. The principal investigators with whom DCB collaborates determine which data will be collected. All data are provided voluntarily.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Any IIF data in the system are obtained from the ICs with which DCB collaborates, particularly NINDS. The processes by which the IIF data are collected are determined by the principal investigators in charge of the protocols. The clinical staff at NINDS handle all consent forms and notifications. DCB has no processes in place in addition to those processes provided by NINDS.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Restricted physical and logical access; no project personnel will be allowed to see project data.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michele Mulholland France NIH/CIT/PECO

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CIT CIT Status of Funds Internet Edition [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-02-00-01-3109-00

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): There is no PII.
- **5. OMB Information Collection Approval Number:** There is no PII.
- **6. Other Identifying Number(s):** There are no additional identifying numbers.
- 7. System Name (Align with system Item name): Status of Funds Internet Explorer (SOFie)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Robin Lyons
- **10. Provide an overview of the system:** SOFie is a Web based application employing Microsoft's IIS and SQL server software. The SOFie application supports the efforts of several offices and branches within CIY, allowing budget offices to track expenditures of direct, reimbursable, and non-appropriated funds in a fiscal year. Additionally, SOFie is used to reflect budget allocations and projected expenditures at the operating level. The program also contains a tracking mechanism to track prior year funds. The application downloads this information from the NIH Data Warehouse weekly. SOFie is not a source database for other information systems.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): There is no PII.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: SOFie is a commercial-off-the-shelf web-based application tool for providing advanced financial reporting and analysis. The application supports an Excel interface that allows for the development of spreadsheets using custom functions that extract real-time expenditure, budget, and planning data from the SOFiE database.

The CIT/FMO uses SOFie to track expenditures of direct, reimbursable, and non-appropriated funds in the fiscal year. Additionally, SOFie is used to reflect budget allocations and projected expenditures at the operating level. The program also contains a tracking mechanism to track prior year funds. The data used by SOFie is downloaded from the NIH Data Warehouse weekly. SOFie is not a source database for other information systems. SOFie does not contain PII.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) There is no PII.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: There is no PII.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michele France, NIH/CIT/PECO

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CIT Consolidated Colocation Site [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-02-00-01-3109-00-109-026

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): This is not applicable; there is no PII.
- 5. OMB Information Collection Approval Number: 009-25-02-00-01-3109-00
- **6. Other Identifying Number(s):** There are no additional identifying numbers.
- 7. System Name (Align with system Item name): NIH Consolidated Co-Location Site
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Adriane Burton
- **10. Provide an overview of the system:** The NIH Consolidated Co-Location Site (NCSS) is an off-campus site used to house IC servers, including CIT servers. The NCCS is a secure, environmentally controlled facility located approximately 30 miles from the NIH campus in Northern Virginia. Multiple telecommunications links between NIH and the NCCS provide extremely high bandwidth. These links are part of NIHnet which is managed and operated by the CIT Division of Network Systems and Telecommunications (DNST).
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): This system does not share or disclose PII.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: This C&A is for a facility only; this does not include any data.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) This C&A is for a facility only; this does not include any data.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: This C&A is for a facility only; this does not include any data.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michele Mulholland France, NIH/CIT

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CIT Data Center Collaborative Technology

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

- 3. Unique Project Identifier (UPI) Number:
- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A
- **5. OMB Information Collection Approval Number:** 009-25-02-00-01-3109-00-109-026
- **6. Other Identifying Number(s):** There are no other identifying numbers.
- **7. System Name (Align with system Item name):** NIH CIT Data Center Collaborative Technology
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Adrienne Yang
- **10. Provide an overview of the system:** The NIH Data Center provides video casting and web collaboration services to the NIH and HHS communities. Video casting allows customers to broadcast lectures, seminars, conferences, or meetings live to a broad audience over the internet as a real-time streaming video. Web collaboration provides web conferencing and online collaboration for real-time information sharing and document collaboration.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\rm N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: The only information collected from individuals is their name and work-related information solely for the purpose of establishing user accounts for using the web collaboration service. This information is only collected from NIH/federal staff.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michele Mulholland France, CIT/OD/EO/PECO

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CIT Data Center Scientific Computing

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A
- **5. OMB Information Collection Approval Number:** N/A
- **6. Other Identifying Number(s):** 009-25-02-00-01-3109-00-109-026
- 7. System Name (Align with system Item name): NIH CIT Data Center Scientific Computing
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Adrienne Yang
- **10. Provide an overview of the system:** The NIH Data Center scientific computing services provides high-performance scientific processing services to the NIH intramural research community. A wide range of scientific applications and web-based tools are provided to ease and enhance scientific research. Two processing platforms support the scientific applications: Helix is a multiprocessor shared-memory system for interactive use and Biowulf is a 6300+ processor cluster for large computational processing. Users are responsible for the protection of their data; Helix and Biowulf provide the tools for doing so.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The only information collected from individuals is their names and work-related information such as office locations, phone numbers, etc., solely for the purpose of establishing user accounts on the scientific computing services hosts. No personally-identifying information is collected, maintained, or disseminated as part of the scientific services. This information is collected from NIH employees and contractors only.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michele Mulholland France

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CIT Data Center Unix Hosting

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/4/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A
- **5. OMB Information Collection Approval Number:** N/A
- **6. Other Identifying Number(s):** 009-25-02-00-01-3109-00-109-026
- 7. System Name (Align with system Item name): NIH CIT Data Center Unix Hosting
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Adrienne Yang
- **10. Provide an overview of the system:** The NIH Data Center provides Unix application hosting services to NIH Institutes and Centers (ICs), the U.S. Department of Health and Human Services (HHS), and other federal agencies. The NIH Center for Information Technology (CIT) is responsible for the management and administration of the Unix general support system the operating system and Oracle relational database management system. Data and applications are the sole responsibility of the application owners. CIT provides the environment and utilities that enable customers to effectively manage the security of their applications and data.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The only information collected from individuals is their names and work-related information such as office locations, phone numbers, etc., solely for the purpose of establishing user accounts on the Unix hosts. No personally-identifying information is collected, maintained, or disseminated as part of customer support for Unix services. This information is collected from government employees and contractors only.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michele Mulholland France, CIT/NIH

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CIT Data Center Windows Hosting

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/4/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): 009-25-02-00-01-3109-00-109-026

- 7. System Name (Align with system Item name): NIH CIT Data Center Windows Hosting
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Adrienne Yang
- **10. Provide an overview of the system:** The NIH Data Center provides Windows application hosting services to NIH Institutes and Centers (ICs), the U.S. Department of Health and Human Services (HHS), and other federal agencies. The NIH Center for Information Technology (CIT) is responsible for the management and administration of the Windows general support system the operating system and Microsoft SQL relational database management system. Data and applications are the sole responsibility of the application owners. CIT provides the environment and utilities that enable customers to effectively manage the security of their applications and data.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system does not collect, maintain, or disseminate any information. Only authorized government employees and contractors have access to the servers using their nih.gov domain accounts. The information used to create the accounts is collected and stored by the NIH Employee Directory (NED) application and the information related to the domain accounts is stored in the nih.gov domain Active Directory database.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michele Mulholland France, CIT/NIH

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CIT Data Center Windows Infrastructure

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/4/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): 009-25-02-00-01-3109-00-109-026

- 7. System Name (Align with system Item name): NIH Windows Infrastructure
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Adrienne Yang
- 10. Provide an overview of the system: The NIH Data Center provides a Windows Infrastructure service that enables NIH users to access various services and systems in the nih.gov domain. Active Directory (AD) forms the core of this service. AD is an implementation of an LDAP (Lightweight Directory Access Protocol) directory service. AD is built around the Domain Name System (DNS) and LDAP. AD contains information about users and resources that allows it to manage nih.gov resources and broker the relationships among them.

The NIH Data Center provides two utilities for users to make updates to Active Directory: Active Directory Manager (ADM) and Password Self Service (PSS). ADM provides a Web interface for NIH IC administrators to manage their IC AD resources; i.e., it is used to access AD data. PSS provides a Web interface that allows users to reset their forgotten passwords (maintained by AD).

PSS uses a question/response verification for the password reset. The questions and answers are stored in the AD database in encrypted format. Users self-register for PSS and choose three questions from the following list for their challenge/response:

What is the last name of your favorite school teacher?

What is the name of your favorite sports team?

What is the name of your favorite singer or band?

What is the name of your favorite television series?

What is the name of your favorite restaurant?

What is the name of your favorite movie?

What is the name of your favorite song?

What is the furtherest place to which you have traveled?

What is the name of your favorite actor or actress?

Who is your personal hero?

What is your favorite hobby?

Your mother's first name?

The city name or town name of your birth?

A four digit PIN (personal identification number)?

What is your least favorite sports team?

What is your mother's occupation?

What was your SAT score?

What is your favorite brand of candy?

What is your least favorite food?

What is your least favorite beverage?

What was your first pet's name?

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\rm N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: AD information on individuals is solely used for establishing nih.gov domain accounts. The information is imported form the NIH Enterprise Directory (NED) and contains names and work-related contact information such as office locations, phone numbers, etc. No personally-identifying information is collected, maintained, or disseminated as part of customer support for infrastructure services.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original

collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michele Mulholland France, CIT/NIH

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CIT Enterprise Messaging PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/4/2011

2. OPDIV Name: NIH

- 3. Unique Project Identifier (UPI) Number:
- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A
- **5. OMB Information Collection Approval Number:** N/A
- **6. Other Identifying Number(s):** 009-25-02-00-01-3109-00-109-026
- 7. System Name (Align with system Item name): NIH CIT Enterprise Messaging
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Adrienne Yang
- **10. Provide an overview of the system:** The NIH Data Center Windows service provides the NIH-wide corporate messaging capability. This includes electronic mail, Microsoft Exchange electronic mail (email), and all necessary supporting services: Outlook Web Access (OWA) for users to access their mail using a Web browser; Electronic FAX for users to send and receive faxes in their mailboxes; support for users to access their mailboxes from portable devices (PDAs) (e.g., BlackBerry); instant messaging (IM); secure file transfer (SEFT) for sending large documents; NIH Listserv to support mail distribution to a large community; and SPAM filtering.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Other than serving as a

messaging distributer, the system in and of itself does not collect, maintain, or disseminate any information. Only authorized government employees and contractors have access to the messaging servers using their nih.gov domain accounts. The information used to create the accounts is collected and stored by the NIH Employee Directory (NED) application and the information related to the domain accounts is stored in the nih.gov domain Active Directory database.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michele Mulholland France, CIT/NIH

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CIT ePolicy Orchestrator [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-02-00-01-3109-00

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): There is no SOR for this application.
- **5. OMB Information Collection Approval Number:** There is no PII in this application.
- **6. Other Identifying Number(s):** There are no other identifying numbers.
- 7. System Name (Align with system Item name): ePolicy Orchestrator
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Connie Latzko
- **10. Provide an overview of the system:** This is a COTS product used for antivirus protection, tracking, removal and reporting for CIT systems.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The system does not contain any IIF.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system does not contain any IIF.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g.,

disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The system does not contain any IIF.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The system does not contain any IIF.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michele Mulholland France NIH/CIT/PECO

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CIT Infrastructure Graphical Database [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-02-00-01-3109-00

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): There is no SOR needed no IIF exists in this system
- **5. OMB Information Collection Approval Number:** This does not apply there is no IIF in this system
- **6. Other Identifying Number(s):** There are no other identifying numbers
- **7. System Name (Align with system Item name):** Infrastructure Graphical Database (CIT Archibus)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Tony Trang, NIH/CIT/DNST
- **10. Provide an overview of the system:** This is the National Institutes of Health (NIH) infrastructure assets management system used to track cabling and telecommunications infrastructure information.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): There is no IIF.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: There is no IIF. This system collects infrastructure, telecommunications and cabling pair information.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) There is no IIF.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: There is no IIF.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michele Mulholland France, NIH/CIT/PECO

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CIT KNOVA [System] PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-02-00-01-3109-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): Not applicable.

- 5. OMB Information Collection Approval Number: Not applicable.
- **6. Other Identifying Number(s):** Not applicable.
- 7. System Name (Align with system Item name): KNOVA
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Phil Day
- 10. Provide an overview of the system: This is a Commercial-Off-The-Shelf (COTS) product that provides help desk knowledge base services. It allows agents to type in the customer issue and then be presented with a variety of options depending on their search, including tailored search results, Q&A dialogs, and fields to fill in. It can exchange problem and incident management data with the Customer Relationship Management (CRM) system however no IIF data from the CRM system will be available to Knova. All customer information and IIF is collected in the CRM system, only technical problem related information is entered into Knova. Any integration between the two will strictly pass non-uniquely-identifiable problem information from the CRM to Knova, and then pass resolution information back from Knova to the CRM. No IIF will enter Knova.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): There is no IIF contained within this system

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system is a help desk knowledge management tool and as such, non-uniquely-identifiable information about technical problems and how to solve them will be housed in the system. These solutions are technical in nature (how-to's etc) and do not contain IIF. These solutions will be available to the NIH IT Service Desk and, in the future, support staff and the NIH user community. The information will be used to assist the NIH community with technical issues. There is no IIF in the system.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) There is no IIF contained within this system

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: There is no IIF contained within this system

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michele Mulholland France NIH/CIT/PECO

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CIT National Database for Autism Research [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-3110-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200; 09-25-0156

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): National Database for Autism Research
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Matthew McAuliffe, Ph.D.
- **10. Provide an overview of the system:** NDAR, the National Database for Autism Research, is a collaborative biomedical informatics system being created by the National Institutes of Health to provide a national resource to support and accelerate research in autism. *

NDAR will make it easier and faster for researchers to gather, evaluate, and share autism research data from a variety of sources. By giving researchers access to more data than they can collect on their own and making their own data collection more efficient, the time to discovery can be reduced.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): IIF information is not shared on research participants. However the PI's granted access to data will give permission to post their name on the NDAR Web site with the research aims. The

purpose of this is facilitate transparency in how NDAR data is being used. PIs who submit information to NDAR will not have their information posted on the Web site.

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system will collect a wide variety of clinical information including images of the brain, genetics information, and data from diagnostic criteria specific to clinicians in the autism field. Recent changes to NDAR make sure that all IIF on research subjects (used to generate encrypted hashes that allow cross checking studies for the same individuals) is kept at the researcher's institution.

NIH will collect IIF on PIs who submit information about research participants to NDAR. This information will be used by NIH to document, track, monitor and evaluate NIH clinical, basic, and population-based research activities.

NIH will also collect IIF on PIs who wish to gain access to the information. This information will be used to document, track, monitor, and evaluate the use of NDAR datasets and to notify recipients of updates, corrections or other changes to NDAR.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) As part of the research protocol, all subjects will be required to fill out consents that describe how their information will be used even though NDAR will contain no IIF on research participants. If these change or expire, all participants will be contacted.

PIs submitting information to NDAR and accessing information from NDAR will sign relevant agreements for submission and access, both of which include a Privacy Act notification.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: 1) Management policies require that all new users be part of an approved site, with the request coming through a system administrator.

- 2) Technical Controls require that each user log in to the NDAR application with a unique user name and password. Additionally, the password is set to expire after 75 days, must be at least 8 characters long, with at least 2 of the following character types: Control Character, Number, Capital Letter.
- 3) Physical Controls require badged access to all server rooms, with badge lockdown policies in line with existing NIH procedures.

Physical rack will be key-locked.

Physical rack will be located in data center behind both biometric and keycard access with 100% identification badge check by 24/7 security guard. The Data Center is behind 3 independent 24/7 security guards that will perform identification badge checks.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michele France, NIH/CIT/PECO

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CIT NIH Application Manager [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-02-00-01-3109-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH Application Manager (NAppMan)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Tanita Durant
- **10. Provide an overview of the system:** The intention of NAppMan is to alert a responsible individual when an application on NIHnet is not available or is suffering a problem of some sort. It summarizes information received from underlying monitors that more directly monitor the application and maintains statistics.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The NAppMan system does not collect IIF and therefore cannot disclose or share IIF.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: NAppMan stores application up-time information including the date and time of occurrence, the name of the application

component, and the status of the component, its relationship to other components, and business rules to represent the status properly at higher levels. No personal information, or IIF is gathered.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No IIF is being collected.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No IIF is available in the NAppMan system.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michele France, NIH/CIT/PECO

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CIT NIH Business Intelligence System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-09-01-3105-00-404-142

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-90-0018 and 09-90-0024

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): NIH CIT Business Intelligence System (NBIS) (nVision)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Michael Foecking
- **10. Provide an overview of the system:** The NIH Business Intelligence System (NBIS) is an enhanced data warehouse that is a consolidation of the legacy data warehouse, and the next generation data warehouse, nVision. It is designed to improve reporting capabilities of the NIH business source systems. This consolidation integrates the query and reporting capabilities of NIH business systems into one system. The legal authority is referenced in HHS Privacy Act Systems of Record 09-90-0018 and 09-90-0024.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Only authorized personnel have access to this data. PII is shared with the NIH FOIA officers who vet requests for information that is received from the public.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The agency collects both administrative and financial data. This data is collected from NIH source systems and includes name, DOB, SSN, education records, employee status, business mailing address, e-mail address and phone numbers, and is used for business reporting purposes. NIH BIS only collects the following PII when users are registered for NIH BIS: Username, Full Name, Phone Number, Office, Email, and Institute. This data is used for support, reporting, auditing purposes. This data is mandatory for any users of the NIH BIS system.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Agreements have been obtained from the NIH source systems in collaboration with the business community requirement groups to provide the data needed to support the mission of NIH. The warehouse and source systems teams are in constant communication with regards to the data and changes in that data or access permissions granted to users. Users sign the NIH BIS registration form, consenting to the use of PII for NIH BIS registration purposes. When a major change occurs to the NIH BIS system, users are notified by email. A privacy statement is posted on the NIH BIS website.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: NBIS administrative controls include C&A, a System Security Plan, a Contingency Plan, system backups, and documented procedures. Technical controls include a User ID and strong password to access the system and access is only granted when there is a documented request by an authorized official. Other technical controls include Firewalls and VPN. Physical controls to the server room include guards, ID Badges, Key Cards and locks.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michele Mulholland France NIH/CIT/PECO

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/30/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CIT NIH Data Center - Building 12 [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-02-00-01-3109-00-109-026

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH Data Center (Bldg 12)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Adrienne Yang
- **10. Provide an overview of the system:** NIH Data Center is a controlled access facility for housing (1) CIT-provided general support systems that host NIH, HHS, and other federal agency applications, (2) scientific computing services for NIH researchers, and (3) NIH infrastructure servers (Active Directory, email, and networking (NIHnet)). The facility also provides monthly rental space for housing customer-owned and operated equipment. An off-campus site, the NIH Consolidated Co-Location Site (NCSS) provides space for housing IC servers in a secure, environmentally controlled vendor-provided facility located approximately 30 miles from the NIH campus.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: N/A
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michele Mulholland France NIH/CIT/PECO

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CIT NIH Enterprise Directory [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-02-00-01-3109-00-109-026 (under NIH IT infrastructure)

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0216
- **5. OMB Information Collection Approval Number:** No
- **6. Other Identifying Number(s):** 009-25-02-00-01-3109-00-109-026 (under NIH IT Infrastructure)
- 7. System Name (Align with system Item name): NIH Enterprise Directory (NED), HHS/NIH
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Bobbye Underwood
- **10. Provide an overview of the system:** The purpose of the NIH Enterprise Directory (NED) is to maintain accurate, current locator and organization information for individuals utilizing NIH services or facilities, and to provide the basis for physical and information security systems. NED is used to authorize and provision NIH services such as ID badges, NIH Library access, Listing in the NIH Telephone and Services Directory, red parking permits, Active Directory accounts, Exchange mailboxes, and VPN remote access privileges. NED provides data to dozens of NIH applications and systems in support of numerous business processes.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The NED system shares or discloses PII with a number of NIH and HHS systems including LMS (HHS Learning Management System), IDMS (HHS Identity Management System), HRDB (NIH

Human Resources Database), BITS (NIH Background Tracking System), EDiE (NIH Employee Database Internet Edition), EMIS (NIH Ethics Management Information System), NIH Radiation Safety Database, and AlertNIH (SendWordNow). Contact the system owner for a complete list of systems. NED shares PII for a variety of reasons including personal identity verification, provisioning of NIH services, record matching, and in support of various NIH business processes.

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: NED contains individual identifying information, such as a person's name, HHS ID number, date of birth, place of birth, Social Security Number (SSN), and ID photo as well as information for locating or contacting a person at work or home, such as their email address, postal and delivery addresses, telephone numbers, organizational affiliation and classification (e.g., Employee, Contractor).

NED was developed to provide a convenient, single, logical source of identity and locator information at NIH. NED obtains, from the HHS Identity Management System (IDMS), and maintains a public identifier (HHS ID number) that follows a person throughout his or her NIH career. HHS ID numbers have been incorporated into numerous NIH systems and business processes and are tied to a common set of normalized data for all members of the NIH workforce. NED eliminates the need for application-specific repositories of people data, thus reducing the cost of application development and maintenance. This also reduces the amount of redundant data entry, since NED provides a single place to update people data used by a number of major applications.

NED makes deregistration of individuals occur more reliably when they leave NIH. Applications connected to NED can take advantage of this to deactivate accounts and revoke authorizations, thereby improving security. For example, when an individual is deregistered in NED, this deactivates their record in the ID badge system, which revokes their card key door lock access.

Submission of personal information is mandatory if the individual is to be employed with the National Institutes of Health (NIH), U.S. Department of Health and Human Services (HHS).

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) NIH administrative staff has the option of requesting that an individual enter their PII directly into NED and the individual must agree to the following prior to submission: "I hereby authorize the release of information in this application to appropriate Federal agencies for the purposes of processing this application and verifying my identity. I also acknowledge that if I provide or assist in the provision of false information or non-verifiable information, and/or I purposely omit information, it could result in loss of access

to HHS facilities and IT systems and in disciplinary action including removal from Federal service or a Federal contract, and I may be subject to prosecution under applicable Federal criminal and civil statutes. I declare under penalty of perjury that the foregoing is true and correct." When NIH administrative staff enters an individual's PII themselves, they must certify that the information is being entered using information from section A of a completed HHS-745 ID Badge Request form that was signed by the individual.

There are no other processes currently in place to obtain additional consent from the individual whose PII is stored in NED regarding what PII is being collected for them or how the information will be used or shared. There are also no processes in place at this time to obtain consent from the individuals whose PII is in the system when major changes occur to the system.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** Carson Associates completed a NED system recertification and the NIH DAA signed an ATO on 7/14/2010. As part of the C&A, security controls were reviewed, validated and tested to ensure that NED adheres to the standards required for operating as a MODERATE system. As part of the C&A process, a Plan of Action and Milestones was developed, addressing all areas requiring attention in order to achieve full compliance.

NED production and development servers reside in the NIH Computer Center machine room located in building 12A on the NIH main campus in Bethesda, MD. The NIH Center for Information Technology/Division of Computer System Services (CIT/DCSS) hosts and operates all servers. Physical and environmental controls are described in the NIH Computer Center C&A documentation, and is sufficient for the sensitivity level of the NED system. NED utilizes the NIH computer network (NIHnet) operated by CIT's Division of Network Systems and Telecommunications (CIT/DNST). NED physical, network and operating system security controls are maintained by CIT/DCSS and CIT/DNST as part of a service level agreement (SLA). The NED C&A defers to the DCSS and DNST C&A information on controls. In addition, the NIH Computer Center undergoes a SAS 70 audit and is currently in compliance.

All staff on the NED development and management team have appropriate position sensitivity levels. Background investigations are either complete or underway. Users of the NED web applications are responsible for the professional use of their accounts and user passwords as outlined in the NIH Rules of Behavior and are required to take NIH Security Awareness Training with annual refresher modules. Core users of the main NED web application (https://ned.nih.gov/ned) include users with the AO (Administrative Officer) or AT

(Administrative Technician) role. NED IC Coordinators or existing AO users grant, modify, and remove AO and AT access using a NED web interface. NED system administrators authorize people for other system roles upon request by an authorized NIH business owner. AO and AT maximum scope of authority is limited to records affiliated with their own Institute or Center (IC) and may be further restricted to records affiliated with specific organizations in the IC. NED automatically removes the AO and AT access when their NED record is deactivated or transferred to a different IC. Authentication to NED is via NIH Login, which uses NIH Active Directory accounts.

CIT/DCSS is responsible for the operation, maintenance, and support of NIH Active Directory. Following authentication using NIH Login, NED record owners are able to view private information contained in their own record via a secure website from a computer attached to NIHnet. Internet users can assess a limited amount of NED public data without authenticating.

NIH/CIT/DCSS staff performs most NED Oracle database administration activities (e.g., backups, logging and operating system support). NED staff manages the Oracle accounts used by downstream applications for accessing NED data stored in Oracle. NIH/CIT/DCSS staff manages the NIH Titan mainframe accounts used by downstream applications for accessing NED data stored in the DB2 database that resides on the mainframe computer. The NIH Privacy Office must authorize access by downstream applications to private data covered under the NED SORN. Following NIH Privacy Office approval, NED staff provides written confirmation to NIH/CIT/DCSS when requesting that access to private data be granted to a Titan account.

The NIH Incident Response Team (IRT) has established the NIH Incident Handling Procedures, which outline how to handle, report,

and track incidents and/or problems. The procedures describe the roles of the IRT and ISSOs. The IRT has a 24 x 7 contact number available to ISSOs (301-881-9726) and can be reached at IRT@nih.gov.

NED has a configuration management process where all system code is maintained under change control.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michele Mulholland France (NIH/CIT) francem@mail.nih.gov

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 3/18/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CIT NIH Integrated Service Center [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-02-00-01-3109-00-109-026

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A
- **5. OMB Information Collection Approval Number:** N/A
- **6. Other Identifying Number(s):** There are no additional numbers.
- 7. System Name (Align with system Item name): NIH Integrated Services Center (incldues NIH Login)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Debbie Bucci
- **10. Provide an overview of the system:** The Integrated Services Center includes NIH Login and TIBCO. NIH Login provides a single authentication mechanism for NIH enterprise systems and IC specific applications.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No IIF is shared or disclosed.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: There is no data collected.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) There is no data collected.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: There is no IIF.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michele Mulholland France, NIH/CIT/PECO

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CIT NIH Portal [System] PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/4/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-02-00-01-3109-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH Portal
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Renee Edwards
- **10. Provide an overview of the system:** The NIH Portal is a web-based application that gives NIH staff a single point of access to the data, documents, applications and services available at the National Institutes of Health.

The NIH portal enables employees to bring together in one site the links to NIH data and documents used to support the mission of the NIH.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The NIH Portal maintains links to NIH data and documents that NIH staff use to support the mission of the NIH.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A There is no IIF.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michele Mulholland France, NIH/CIT/PECO

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CIT NIHnet [System] PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-02-00-01-3109-00-109-026

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

7. System Name (Align with system Item name): NIHnet

- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Renita Anderson
- **10. Provide an overview of the system:** NIHnet is the network backbone infrastructure for the U.S. Department of Health and Human Services (HHS), National Institutes of Health (NIH). NIHnet provides data transport services, network security services and commodity Internet services to the NIH's 27 Institutes and Centers (ICs). NIHnet also provides connectivity from NIH to the HHS Operating Divisions (OPDIVS) and Staff Divisions (STAFFDIVS) via HHSnet.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{No}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: NIHnet provides data transport services for NIH Institutes and Centers. Per NIST SP 800-60 NIHnet maintains

Information and Technology Management information (e.g., IT infrastructure maintenance, IT security, system development, etc.). NIHnet does not collect, maintain or disseminate IIF.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michele Mulholland France, NIH/CIT/PECO

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CIT Remedy Problem Tracking System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-02-00-01-3109-00-109-026

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0216

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** Help Desk Ticket Tracking System (CIT Remedy)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Chris Ohlandt
- **10. Provide an overview of the system:** The system is used by the IT Support Community at NIH to track customer technical issues from the time of first contact to the point of problem resolution. Authorized users from NIH and certain sister agencies can log in, enter tickets, track their own tickets, and view tickets for other users within their own area.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Information is disclosed only to other support organizations within NIH or with DHHS organizations outside of NIH with whom we share an SLA. SOR 09-25-0216
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: Name, business contact information, business computer information, and IT support issue information is collected. Submission is voluntary. Information is shared in order to provide technical support, training, and other support services to the customer.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Consent is voluntary and is provided by users of NIH services in order to obtain IT support. Any changes to data collected will be addressed at the next contact with the customer. No disclosure is made outside the scope of this statement therefore no additional consent is needed.

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Physical hardware is located in a secured machine room environment and accessible only via cardkey and/or biometric retinal scanning.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michele Mulholland France, NIH/CIT/PECO

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CIT Scientific Coding System OnDemand [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-04-00-02-3106-00-110-219

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): Scientific Coding System (SCS) OnDemand
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Aileen Kelly
- **10. Provide an overview of the system:** SCS OnDemand is a scientific coding and reporting IMPAC II extension system application. The data included in the system is required for NIH to fulfill its scientific reporting obligation to the Public, Congress, and the White House, for national health policy and goals.

SCS uses the IMPAC II Reporting Database (IRDB) as the primary data source. SCS users also have the ability to add projects (e.g. contracts) to the system that are not included in the IRDB.

- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The system does not disclose IIF. SOR is 09-25-0036 09-25-0038

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: 1) PI Name (mandatory and extracted from IMPAC II) used as a business point of contact on grants and contracts
- 2) PI Birth Year (mandatory and extracted from bio-sketch info from the abstract/summary statement, or other internet data sources, and then entered into SCS by the Scientific Coder) used for analysis of the NIH scientific program
- 3) PI Gender (mandatory and extracted from bio-sketch info from the abstract/summary statement, or other internet data sources, and then entered into SCS by the Scientific Coder) used for analysis of the NIH scientific program.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Will use Privacy Act Notification Statement as defined by IMPAC II. Wil use the same format as that of IMPAC II to notify users.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The SCS is hosted by the NIH Data Center which provides the administrative, technical and physical controls. Technical controls will include the use of user ids, passwords, and a firewall. Physical access controls will include the use of identification badges and key cards. Administrative controls will include a security and contingency plan. Additionally, files will be backed up using the schedule defined by the NIH Data Center. User manuals will also be provided.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michele Mulholland France, NIH/CIT/PECO

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CIT Symantec Management Console [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 11/1/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-02-00-01-3109-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): Symantec Management Console
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Connie Latzko NIH/CIT/DCS
- **10. Provide an overview of the system:** Symentec Management Console is an agent based systems management solution used to provide hardware and software inventory, patch management, and software delivery for CIT commodity desktops.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The information collected includes Machine Hardware, Software, IP address, User ID, User Location (Imported from the GAL) and status of Tasks run or to be run on the machine. This data is collected to improve the

efficiency of managing and the security of CIT desktops and clients supported by CIT desktop support. The purpose is to manage the client system. i.e.: Provide missing patches, deliver software packages, to provide assistance for determining hardware/software upgrades required (such as minimum hardware requirements to run a new OS or Application). No IIF is collected.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No IIF is collected.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No IIF is collected

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michele Mulholland France NIH/CIT/PECO

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CIT Titan [System] PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/4/2011

2. OPDIV Name: NIH

- 3. Unique Project Identifier (UPI) Number:
- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A
- **5. OMB Information Collection Approval Number:** N/A
- **6. Other Identifying Number(s):** 009-25-02-00-01-3109-00-109-026
- 7. System Name (Align with system Item name): NIH Titan
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: John Dussault
- **10. Provide an overview of the system:** Titan is a general support system that hosts a wide range of applications. Provided services include:
- •Batch processing with the capability to process hundreds of concurrent jobs
- •Interactive systems
- Scientific Statistical systems
- •Language compilers
- Databases
- •Web hosting
- Central printing
- Disaster Recovery
- Automatic data backup
- •Gateways for client/server applications
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The only information collected from individuals is their names and work-related information such as office locations, phone numbers, etc., solely for the purpose of establishing user accounts on Titan. No personally-identifying information is collected, maintained, or disseminated as part of customer support for Titan services. This information is collected from government employees and contractors only.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) $\rm\ N/A$

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michele Mulholland France, CIT/NIH

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CSR Blanket Purchase Agreement - Hotel Application Tool (BPA HAT)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 7/25/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH CSR Blanket Purchase Agreement Hotel Application Tool (BPA HAT)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Dipak Bhattacharyya
- **10. Provide an overview of the system:** This database shall replace the current paper based process for accepting, reviewing and approving NIH Blanket Purchase Agreement (BPA) hotel applications. In addition, this system shall automate workflow through auto-generated alerts, emails and access to a centralized repository. The overall objective of this project is to minimize these manual touch points and increase the efficiency of the business processes for a new or renewed BPA application through a workflow engine / SQL database.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The system discloses PII to CSR system administrators for the purpose of maintaining and enhancing the system. The Hotel representative (non federal employee) enters their PII information (name) into the system for the purpose of streamlining workflow for their BPA. The NIH BPA Office (federal employees) also access the system for view only access. Only the NIH

BPA office and the CSR SREA office (federal employees) will be reviewing the information in the system.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) Hotel User Name, Duns Number (a nine-digit number issued by Dunn & Bradstreet (D&B) and assigned to each business location in the D&B database having a unique, separate, and distinct operation to businesses for the purpose of identifying them), EIN Number (Federal Tax Identification number), legal business name, Business email address, Hotel address (city, state, zip). The NIH BPA Office may upload NIH form SF 30 or 347 in relation to a particular Hotel that receives a BPA award.

 ** The DUNS # is not PII.
- (2) To review Hotel information and award Blanket Purchase Agreements.
- (3) Yes information contains PII.
- (4) Submission of personal information is mandatory which includes hotel representative name (non federal) and hotel representative email address (corporate/personal)
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.
- (Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) (1). The Hotel user will be notified via email when there are changes to the system.
- (2). The individual is voluntarily placing their information into the system. There is a privacy disclaimer and a link to the CSR statement is provided in the footer.
- (3). The information stored in the system is not accessible to anyone outside of HHS/NIH in a manner that identifies the individual except for the Hotel user themselves and except as permitted by the Privacy Act. The information will be used and shared for federal procurement and communication with Hotel representatives.
- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls: The PII is secured through Technical controls: User ID and passwords have to be used for network authentication.

Administrative controls: Documented training materials as well as face to face training will be provided.

Physical controls: Security guards, ID badges, and Key Cards are used to gain access to Sterling where the system will be housed.

The required password strength for CSR and NIH users is implemented by NIH through logical access controls that provide protection from unauthorized access, alteration, loss, disclosure, and availability of information in accordance with HHS information Security Program.

The SREA office will go on a Road Show to go through the steps of the application process. Estimated road show is 10/10, 11/10, and 12/10.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michael Floissac, CSR Privacy Coordinator

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Pla

Sign-off Date: 9/30/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CSR College of CSR Reviewers

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 7/25/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH-CSR College of CSR Reviewers
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Dipak Bhattacharyya
- **10. Provide an overview of the system:** The College of Distinguished Reviewers database maintains the profiles of grant reviewers, email address and their review performance history to enable effective time management in the assembly of a pre-screened and pre-committed pool of highly qualified reviewers. College of CSR revieweres agree to review up to 12 applications a year during a two-year period.

College reviewers primarily will provide written or "mail-in" critiques and be involved in two-stage reviews, which have successfully assessed thousands of special sets of applications, such as the Transformative RO1 and Challenge grant applications and small business applications.

In these reviews, the College reviewers will serve as firt-stage experts to assess each application and submit their critiques online. A second panel of reviewers with broad expertise will then examine the critiques and applications, focusing on the impact of the proposed research adn assigning in a more consistent fashion final overall impact/priority scores.

- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): System shares the reviewers email address and name, however email address is either home or business email address. The system shares it's data only in CSR with senior administrators. The purpose is for CSR senior administrators to determine the best reviewers based on expertise.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1). Lastname, FirstName, Title, Department, Institution, Email, Phone, Expertise keywords from RCDC and from reviewer, eRA commonsID, SRORating, Funding Hisotry, Review History, PubmedID, Publications, Commitment, SubscriptionEndDate, VerificationCode, IsExpertiseURLExpired, Lastmodifieddate.
- (2). CSR shall collect this information for the purpose of establishing the best set of reviewers based on background and expertise.
- (3). The phone number and email address provided by the reviewer can be either a personal or buisness contact information.
- (4). The submission of this data is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) (1). The consent is obtained electronically through an email verifying participation in the College of CSR Reviewers provided by the Reviewer.

- (2). The individual is notified via an email request if they would like to participate in the College of CSR Reviewers and provided the requested information. The information is voluntarily submitted by the potential reviewer.
- (3). Individuals will give notice of their consent via email notification. The individuals will self-consent by providing the requested information to take part in the College of CSR Reviewers. The information stored in the system is not accessible to anyone outside of HHS/NIH in a manner that identifies the individual except for the applicant themselves and except as permitted by the privacy act.
- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes

- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls: The PII is secured through Technical controls: User ID and passwords have to be used for network authentication.

Administrative controls: Training provided as needed. The system is backed up on a regular basis.

Physical controls: Security guards, ID badges, and Key Cards are used to gain access to Sterling where the system will be housed.

The required password strength for CSR and NIH users is implemented by NIH through logical access controls that provide protection from unauthorized access, alteration, loss, disclosure, and availability of information in accordance with HHS information Security Program.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michael Floissac, CSR Privacy Coordinator

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CSR Committee Management Application

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/25/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): Committee Management Application
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Dipak Bhattacharyya
- **10. Provide an overview of the system:** The Committee Management Application is a subapplication of the existing employee database (NIH Enterprise Directory via the CSR Intranet) which stores employee committee involvement data. The system also has a reporting capability for management and committee members.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The Committee Management Application allows senior management access to query and report functions. Other access will be granted on a need-to-know basis as determined by senior management. Application administrators will have access to add, edit, and delete all committees and memberships. Employees will have read-only access to their current list of committee memberships through a link in the employee information update screen located on the CSR Intranet. This application is only accessible to NIH employees and NIH/CIT employees as needed since the application resides on a CIT server.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) Application includes information on NIH/CSR Committee name, membership of committee, and member contact information (NIH email and phone number). (2) NIH/CSR uses this application to remove the manual touchpoints, i.e. paper, and streamline the flow of data to users and management. (3) Yes, PII data in the form of the employee name, NIH email address, and NIH phone number. (4) Per CSR policy, amm committee membership rosters are included.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) (1) N/A - no major changes anticipated. (2) On the CSR Intranet (the parent system to this application) a message is displayed to the employees explaining the purpose and protections in place to safeguard information. (3) Users have readonly access to view committee memberships; administrators have add, edit, and delete capability for all committee memberships; developers/contractors have access to maintain and operate the application.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls: Administrative Controls: role-based access; appropriate system security plan, contingency plan, file back-up, training of users, and retention and destruction policies are in place.

Technical: User ID, passwords, firewall, VPN, encryption and IDS are in place on all CSR systems.

Physical: guards, ID badges and key cards are utilized at the server location and the CSR offices.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michael Floissac, CSR Privacy Coordinator

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2010

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CSR CSR Sterling GSS [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/25/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-27-02-3204-00-305-109

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0216

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): CSR-2

- 7. System Name (Align with system Item name): CSR Intranet
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Dipak Bhattacharyya
- **10. Provide an overview of the system:** Provides information on all aspects of CSR work to CSR and NIH staff. Authorized by Section 301 of the PHS Act.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Provides information on all aspects of CSR work to CSR and NIH staff. The system provides contact information to CSR supervisors for crisis notification. SORN #09-25-0106 CSR staff directory contains working addresses for all CSR employees.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Provides information on CSR work (forms, publications, policies) to CSR and NIH staff. The system shares contact

information (home phone #, email address, cell phone #) with CSR supervisors for use for crisis notificiation. The mandatory information will be cell phone, home address, home phone, and personal email address. Voluntary information will be out of area contact information, i.e.: contact name, address, phone, and email address.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) A message is displayed to the employees explaining the purpose and protections in place to safeguard information. There is no consent process since this information is mandatory and critical to continue the CSR mission in case of emergency.

Also, CSR users make changes to their personal information by themselves thus eliminating errors and misrepresentation of their personal information such as phone and email address in CSR staff directory.

NIH maintains NED directory with CSR users PII information.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Photos of staff are limited to the NIHnet users. IIF in the form of home phone numbers will be restricted to a SSL enabled website and require user authentication with NIH login and password.

Administrative

To log on the Intranet requires an active directory account, which is created and maintained by the central NIH account authority. The initial employee record is entered by the supervisor as part of a desktop support request. Once the employee is settled, he/she enters additional emergency contact information, i.e. home address, cell phone or home phone number. This information is mandatory in case of emergency, so that CSR can contact employees. Prior to the employee departure/separation date, the employee is required to complete form on CSR Intranet and return NIH badge and CSR property items. The automated record is removed from the system in 30 calendar days after the departure date. All database backups no longer have the information about former employee after 60 calendar days.

Technical

The employee entry form is located on the CSR Intranet. The server where CSR database resides is hosted and maintained by the CIT hosting branch. It is physically located in Building 12. The building has the technical infrastructure to ensure protection of the server from physical and online attacks via ADP room access controls and WAN and LAN intrusion protection. The software program allows the following access to employee records:

Role: Director, CSR, Emergency Coordinator, Division Directors (6) - Records Access: All

Role: Branch and IRG Chiefs - Records Access: Employees Supervisor

Role: All Employees - Records Access: Supervisor

This access is maintained through NIH active directory. The system administrator's password is changed every year. Due to operational necessities, an exception to policy was granted for a year long password. The CIT hosting branch provides the operating and database systems patch in accordance with policy set by CERT and the manufacturer.

Physical

Building 12 has access controls procedures in place to prevent unauthorized access to CSR Severs. In addition, CSR employees are not authorized without escort to enter the ADP room or access servers. All supervisors have the ability to save and/or print a hardcopy of the employee directory. The supervisor is required to keep this information in a locked file cabinet at all times. In addition, the list is stored on the local drive of the supervisor. All hard drives are encrypted.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michael Floissac, CSR Privacy Coordinator

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CSR Directors Dashboard (DD)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision: Not Applicable

1. Date of this Submission: 8/4/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH CSR Directors Dashboard
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Doug Sur
- **10. Provide an overview of the system:** The Directors Dashboard is a web based application located on Sharepoint 2010 that contains canned reports & data elements for review by senior management of CSR. The function of the Directors Dashboard is to provide a way to quickly identify and monitor organizational factors to insure that SRO's (Scientific Review Officers) are performing at a level that will allow CSR to achieve its desired business objectives.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The system does not share or disclose PII.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) The information

disseminated in the Directors Dashboard includes; Division, IRG (Integrated Review Group), SRO, Meeting name, number of applications, number of Reviewers, percent of applications assigned, Deadline date, percent of scores submitted, percent of critiques submitted, percent of Summary Statements for new investigators and percent of Summary Statements for others.

- (2) The Directors Dashboard is to provide a way to quickly identify and monitor organizational factors to insure that SRO's are performing at a level that will allow CSR to achieve its desired business objectives.
- (3) The information contained in the Directors Dashboard does not contain PII.
- (4) Not applicable.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) (1) The system does not contain PII and therefore does not notify and obtain consent from individuals

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Not Applicable, as the system does not store PII.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michael Floissac, CSR Privacy Coordinator

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 8/5/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CSR Early Career Reviewer database (ECR)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision: Not Applicable

1. Date of this Submission: 9/9/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH CSR Early Career Reviewers Database
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Doug Sur
- **10. Provide an overview of the system:** This database provides a pool of potential reviewers for study sections. The data is pulled from IMPAC II (Information for Management, Planning, Analysis and Coordination). IMPAC II is the grants management database used by NIH (National Institutes of Health). The data is entered manually and the database has querry and reporting functionality. When a potential reviewer is identified the system allows for an email to be sent to the reviewer requesting their paticipation in a meeting. When a reviewer responds to a web form the database can be automatically updated with the response.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1). The data collected are: Name, Email, Institution, Professional Title, expertise keywords. The system also maintains data collected from IMPAC II: commons Identification number and profile Identification number.

- (2). The system shares PII, with internal staff for the purpose of generating participants for review meetings.
- (3). Yes
- (4). The personal information is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) (1). Individuals voluntarily provide consent of use of PII (even during major system changes) when they provide data on a web form. Individuals provide notice of consent electronically (web form).

- (2). All individuals are notified orally via a phone call as to the purpose and intent of the database, as well as, obtaining consent. In addition, all individuals are provided a letter notifying them of why the data is being collected and the purpose of the data collection.
- (3). The information is shared internal for purpose of obtaining participants for study section meetings via queries from the system database.
- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Technical Control: User ID and passwords have to be used for network authentication.

Administrative Control: Role-based access. Training materials are being developed.

Physical Controls: Security guards, ID badges, Cipher locks and close circuit TV at the data center.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michael Floissac, CSR Privacy Coordinator

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/9/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CSR Federal Travel Tracking Database

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/25/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH CSR Federal Travel Tracking Database
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Dipak Bhattacharyya
- **10. Provide an overview of the system:** The Federal Travel Tracking Database (FTTD) is an internal system to help the travel planner identity the individual that is reviewing or approving the travel, and manage and track documents returned to the travel planner for changes or to correct errors. The system does not disseminate any information. The system does contain infromation from the travel orders and vouchers, such as, names of federal employees.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The system does not share or disclose PII.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The Federal Travel Tracking

System is a CSR internal system used to track federal employees travel information. The only fields included are: traveler name, traveler work email, travel request number, (federal employee), travel date, travel mode, travel booking mechanism, arrival location, city, state, and country, type of travel. The system does not include date of birth of the federal employee.

The system pulls information from an internal CSR employee database but does not disseminate information to any systems. Only the name and email address are pulled from the internal CSR database.

Submission of the information are voluntary and for internal tracking of federal employees travel information only.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) 1. The system does not gather any information from the public. It is not publicly accessible and the information stored in the system is not disclosed to anyone outside of CSR. Only the federal employee's name and email addresss are pulled from the internal CSR employee database.

- 2. The system does not contain PII, only federal employees work information are stored in the database for the purpose of tracking and setting up their travel.
- 3. The system does not contain PII.
- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: There is only Federal employee work information in the database for the purpose of tracking and setting up their travel.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michael Floissac, CSR Privacy Coordinator

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Pla

Sign-off Date: 9/30/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CSR Financial Operating System (FOS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 7/25/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

- **4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** 09-25-0036 Extramural Awards and Chartered Advisory Committees (IMPAC 2), Contract Information (DCIS) and Cooperative Agreement Information, HHS/NIH
- **5. OMB Information Collection Approval Number:** N/A
- 6. Other Identifying Number(s): N/A
- **7. System Name (Align with system Item name):** NIH CSR Financial Operating System (FOS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Dipak Bhattacharyya
- 10. Provide an overview of the system: Due to the large volume of CSR peer review meetings, CSR decided to automate the process of transferring meeting rosters to WTS for the purpose of travel reservations. In the past CSR staff use to fax the meeting rosters to World Travel Services (WTS). As reviewers called WTS to make there travel reservations WTS uses the roster to confirm that the individuals making their reservations using the CSR meeting codes are included on each meeting roster. Financial Operating System (FOS) is a government-to-government contractor application which enhances the timeliness, accuracy and completeness of labor and travel expense data by automating the transmission of data to-from IMPAC II and WTS (World Travel Services) system. FOS is a conduit to transfer information between systems and is not accessed by users and information is not retrieved by PII.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): FOS is a conduit between IMPAC II and WTS (World Travel Services) purpose of FOS is not to display data, it is only to transmit data.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: 1. FOS transmits the following data; Study Section Meeting Name, Meeting Date, Reviewer Name, Title and work address, Scientific Review Officer name, government phone, and government email, Meeting location. This information is publicly available on the study section roster as available on the CSR website.
- 2. FOS transmits to WTS to confirm that individuals making reservations using the CSR meeting codes are included on each meeting roster.
- 3. The only PII is reviewer's name. This is not a Federal employee.
- 4. Yes, when the reviewer agrees to be on a study section panel they provide their information voluntarily.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.
- (Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Information is voluntarily provided by reviewers for input into the IMPAC II system. IMPAC II is the system that FOS derives all information from. Notification and consent is not applicable to FOS since FOS is a conduit with no user interface.
- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls:** The PII is secured through Technical Controls: user IDs and passwords are used for network authentication. SSL is used to secure downloaded data. Physical controls: security guards, identification badges, and key cards are used to gain access to Building 12, where the system is located. The required password strength for CSR and NIH users is implemented by NIH through logical access controls that provide protection from unauthorized access, alteration, loss, disclosure, and availability of information in accordance with HHS' Information Security Program. Administrative Controls: limited direct access to FOS to IMB team.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michael Floissac (301-435-0657)

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CSR Grant Redundant Application Search Program (GRASP)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/25/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** Grant Redundant Application Search Program (GRASP)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Dipak Bhattacharyya
- **10. Provide an overview of the system:** The system has the following operational functionality:
- Compare new grant application submissions to a database of previous application submissions (and potentially other sources).
 - (1) use of original material from others
 - (2) submission of multiple applications
 - (3) renamed applications
 - (4) already completed work
- Displays output summarizing findings
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes

- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The system discloses PII only internally and not with other systems or externally for the purpose of receipt and referral of applications.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) Data provided will be text parseable documents, specifically grant applications in one or more 'pdf' files and other files that communicate other grant application information as extracted from the IMPAC II system (eCommons name, PI name, etc).
- .) Only text will be uploaded to GRASP system; that text will be readily parseable, and not image format requiring optical character recognition.
- (2) CSR shall use the information provided in order to minimize the resources and time used in identifying inequality amongst grant applicants. These inequalities include the duplicative and overlapping use of original material from others, the submission of multiple applications, renamed applications, and requesting funding for already completed work.
- (3) Yes, this system does contain PII.
- (4) Voluntary. The PII information is collected from the existing IMPACII system where applicants submit grant applications for review.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) As GRASP will utilize historical data from IMPACII, no processes are in place to obtain consent from individuals whom submitted applications. IMPAC II Systems of Record Notice is in place.

The GRASP system shall collect historical application data to be part of the comparison effort and transferred to the data warehouse (dbGRASP) in the GRASP system. This data will be parsed, formatted and indexed for use by the GRASP system. The source for all comparison work will be historical information from IMPAC II. Periodically, a data extract representing new entries to IMPAC will be created and transferred to the GRASP data warehouse.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:

- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls: Administrative Controls: role-based access; appropriate system security plan, contingency plan, file back-up, training of users, and retention and destruction policies are in place.

Technical: User ID, passwords, firewall, VPN, encryption and IDS are in place on all CSR systems.

Physical: guards, ID badges and key cards are utilized at the server location and the CSR offices.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michael Floissac, CSR Privacy Coordinator

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CSR Internet Assisted Meeting (IAM)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/25/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-3222-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): Internet Assisted Meeting (IAM)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Dipak Bhattacharyya
- **10. Provide an overview of the system:** A strategic objective of the Center for Scientific Review is to enrich methods for review of grant applications. This new method, based upon the use of a threaded message board with features tailored to NIH review, permits the asynchronous discussion and private scoring of grant applications without the need for concurrent assembly or teleconference. As an alternative review format, it complements and extends the ways that CSR conducts peer-review at NIH.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The system shares or discloses email address, name and IMPAC II identifiers (Commons ID name, and NIH login name) with reviewers, NIH program officers, and CSR SRO's for the purposes of peer review.

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Information type: Grant related information is used during the discussion of grant applications in an online collaborative space in lieu of a physical meeting. The reviewers score applications on a scientific merit basis.

The submission is mandatory and does contain IIF (Information Identifiable Form which is name and email using SSL.).

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The system does not gather any information from the public and it is not a publicly accessible system. The system only uses downloaded data in read format from IMPAC II.

The information stored in the system is not disclosed to anyone outside of HHS/NIH in a manner that identifies the individual except for the applicants themselves and except as permitted by the Privacy Act.

IAM does not change any information and does not have any consent procedures for this. There might be minor changes in IMPACII of some information such as grant application identifiers. Applicants can also access their personal information through NIH Commons with their personal passwords and logon names. Significant changes to grant application information that IAM downloads from IMPACII are achieved by voluntary resubmission of grant application by applicants and there are no consent procedures in place for CSR staff. Applicants are informed of major changes in internal use of their data via publication in the NIH Guidelines published on the CSR Internet.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls: The PII is secured through Technical controls: User ID and passwords have to be used for network authentication. SSL is used to

secure downloaded data. Administrative controls: IAM training is available for CSR users and reviewers. Training materials are updated and IAM system is backed up on a regular basis.

Physical controls: 1 System located in 2 locations: Building 12: Security guards, identification badges, and key cards are used to gain access. CSR Data Center Sterling: security guards, identification badges, key cards, eipher locks biometrics (fingerprint scan) and close circuit tv.

The required password strength for CSR and NIH users is implemented by NIH through logical access controls that provide protection from unauthorized access, alteration, loss, disclosure, and availability of information in accordance with HHS' Information Security Program. The required password strength for external users is enforced through account lockout controls with limiting number of consecutive failed log-on attempts; sign-on warning banner at IAM access point; automatically timed out session; deletion of external user information with automatic deletion of whole IAM web site 2 hrs after the meeting is completed.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michael Floissac, CSR Privacy Coordinator

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CSR Internet Website PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/25/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-27-02-3204-00-305-109

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-90-0018

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): CSR-3

- 7. System Name (Align with system Item name): CSR Internet
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Bhattacharyya, Dipak
- **10. Provide an overview of the system:** Provide resources for applicants, news and reports, information about CSR and peer review meetings to the general public. Authorized by Section 301 of the PHS Act.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): General public, applicants and reviewers can get access to CSR staff directory and study sections rosters. CSR Internet application has been created for the purpose of providing information to NIH and scientific community on the world wide web.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: 1. CSR internet maintains and disseminates name and photographic identifiers.

- 2. To clearly identify the person within the organizational structure.
- 3. The only PII maintained within the system is the persons name and photgraphic identifiers.
- 4. The user does not submit information to CSR.

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31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Data in staff directory and rosters do not change without users' consent, and approval. Users submit their information for posting to CSR web developers mostly in electronic form.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Covered by CSR Security Plan

Authorized by Section 301 of the PHS Act.

CSR Web site is designed as a public service to provide information to general audience. Every page on CSR web site is accessible to general public including people with disabilities.

Technical controls are provided by NIH. The application data are backed up daily.

CSR Web site is updated regularly.

hysical controls: Security guards, identification badges, and key cards are used to gain access to building 12, where the system is located.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michael Floissac, CSR Privacy Coordinator

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 1/11/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CSR LAN [System] PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/25/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A GSS PIA included for C&A purposes only
- **5. OMB Information Collection Approval Number:** N/A -GSS PIA included for C&A purposes only
- **6. Other Identifying Number(s):** N/A -GSS PIA included for C&A purposes only
- 7. System Name (Align with system Item name): NIH CSR Local Area Network (CSR LAN)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Prema Nair
- **10. Provide an overview of the system:** CSR LAN GSS is the front end parent reportable system that passes NIH common controls to CSR internet, CSR telework program, GRASP, eCD, NIH College of CSR Reviewers, and Real Time Meeting Status Tool. In addition, it will also pass NIH common controls to CSR intranet parent reportable systems.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A GSS PIA included for C&A purposes only
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: N/A GSS PIA included for C&A purposes only

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A - GSS PIA included for C&A purposes only

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A GSS PIA included for C&A purposes only

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michael Floissac, CSR Privacy Coordinator

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CSR Member Application Notification (MAN)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/25/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): Member Application Notification (MAN)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Dipak Bhattacharyya
- **10. Provide an overview of the system:** The MAN system provides daily notifications of initial application assignment to a given Integrated Review Group (IRG) Chief (or their designee) if at least one application has received its initial review assignment to their IRG (or directly to a SRG or SEP within their IRG) or their SRC99 (in the case of ICs) and meets the specified business rules.
- Identify only applications with mechanism types limited to R01, R21, and R34 submitted by only appointed chartered study section members (not temporary or ad hoc) to as recorded in IMPAC II.
- Exclude applications for which appointed members have a role other than PD/PI, including appointed members serving as sponsors for fellowship applications or mentros for career award applications.
- Applications with multiple PI/PDs should be identified if one or more are eligible based on their status as a study section member (It's not necessary for all of the PI/PD's of a given application to be members)
- Identify and include eligible funding opportunity announcements such as PA, PAR, and PAS per CSR R&R guidance
- Send notifications to individual Outlook group addresses for each of the IRGs (Chiefs and their designees) and each of the ICs (Review Chief and their designees)
- The application accession number, applied, application title, application assignment information, and the list of PI/PDs should be included in the notification to the IRGs or ICs.
- Application title in the IRG Chief's report
- Allow IRG Chiefs to indicate whether or not applications are continuous submissions and capture designation in the database

- Allow IRG Chiefs to look at applications from all other IRGs received within the last two months and indicate which they can review by entering status into database.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The MAN system provides daily notifications of initial application assignment to a given Integrated Review Group (IRG) Chief (or their designee) if at least one application has received its initial review assignment to their IRG (or directly to a SRG or SEP within their IRG) or their SRC99 (in the case of ICs) and meets the specified business rules.
- Identify only applications with mechanism types limited to R01, R21, and R34 submitted by only appointed chartered study section members (not temporary or ad hoc) to as recorded in IMPAC II.
- Exclude applications for which appointed members have a role other than PD/PI, including appointed members serving as sponsors for fellowship applications or mentros for career award applications.
- Applications with multiple PI/PDs should be identified if one or more are eligible based on their status as a study section member (It's not necessary for all of the PI/PD's of a given application to be members)
- Identify and include eligible funding opportunity announcements such as PA, PAR, and PAS per CSR R&R guidance
- Send notifications to individual Outlook group addresses for each of the IRGs (Chiefs and their designees) and each of the ICs (Review Chief and their designees)
- The application accession number, applied, application title, application assignment information, and the list of PI/PDs should be included in the notification to the IRGs or ICs.
- Application title in the IRG Chief's report
- Allow IRG Chiefs to indicate whether or not applications are continuous submissions and capture designation in the database
- Allow IRG Chiefs to look at applications from all other IRGs received within the last two months and indicate which they can review by entering status into database.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: (1) The combined monthly report and the email generated have the fields specified:

- a. IC
- b. MEMBER IRG
- c. CMTE
- d. MEM PI NAME
- e. MEMBER START DATE
- f. MEMBER END DATE
- g. GRANT NUM
- h. ACCESSION NUM
- i. APPL CLUSTER IRG
- i. STUDY SECTION FULL
- k. RFA PA NUMBER
- 1. COUNCIL DATE
- m. APPLICATION RECEIVED DATE

IMPAC II is the source of all application data.

- (2) The MAN System ensures that Integrated Review Groups (IRGs) Chiefs and IC Review Chiefs/contacts are aware of the assignment of applications submitted by chartered members of the standing study sections to Integrated Review Groups (IRGs) and Study Sections.
- (3) Yes
- (4) Voluntary. All information is provided via the IMPAC II system.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) All data contained within this system is pulled from IMPAC II. The system does not gather any information directly from the public. It is not publically accessible and the information is not disclosed to anyone outside of CSR. Individuals have the opportunity to view the Privacy Statement from the IMPAC II website.

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:

- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls: Administrative Controls: role-based access; appropriate system security plan, contingency plan, file back-up, training of users, and retention and destruction policies are in place.

Technical: User ID, passwords, firewall, VPN, encryption and IDS are in place on all CSR systems.

Physical: guards, ID badges and key cards are utilized at the server location and the CSR offices.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michael Floissac, CSR Privacy Coordinator

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CSR National Registry of Volunteer Reviewers

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/25/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: NA

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): NIH CSR National Registry of Volunteer Reviewers
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Nair Prema, Diane Stassi, Weijia Ni
- **10. Provide an overview of the system:** The CSR National Registry of Volunteer Reviewers is an Access-based database that contains information provided by volunteer scientists who are interested in serving on CSR grant review panels. Information provided includes: Name, Degree, Title, Institution, Department, Email, Web Address(es), Area of Expertise/Keywords, Study Section or IRG, Recent funding sources, Referring Society, QVR Person ID, NIH review and grant history, Geographical Region, Date Registered, SRO Contact Records (check boxes for "Contacted" and "Served" as well as date and SRO name), and an SRO Reviewer Evaluation field (check boxes 1-5 for scientific expertise and review performance). The database is available to everyone in CSR who has access to the CSR share drive. The database is searchable by Keyword, IRG, and Region.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes

- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Information is disclosed to anyone in CSR with access to the Share Drive, including, Scientific Review Officers, IRG Chiefs, Division Directors, personnel in the Director's Office. The information will be used to 1) identify highly qualified reviewers who are willing to serve on study sections and 2) report back to the referring societies on how many of their recommended reviewers have served on panels.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The information collected for the CSR National Registry of Volunteer Reviewers contains IIF. The following information is voluntarily provided by scientists who are interested in serving on CSR grant review panels: Name, Degree, Title, Institution, Department, Email, Web Address(es), Area of Expertise/Keywords, Study Section or IRG, Recent funding sources, and Referring Society. In addition to this information, the developers of the database add the volunteer's QVR Person ID and NIH Review history (if they are in the system), Geographical Region, Date Registered, and Reviewer Evaluation (check boxes 1-5 for scientific expertise and review performance). Individuals using the database (primarily Scientific Review Officers) may add Contact Records (check boxes for "Contacted" and "Served", date and SRO name) as well as reviewer evaluation. The information will be used to identify highly qualified reviewers to serve on study section panels and to provide feedback to societies on whether their members are serving on panels.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.
- (Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No major changes are expected to occur to the database. If any changes are made, we will notify all individuals via email. We will be collecting the following IIF: Name, Mailing Address, Phone Numbers, Device Identifiers, Web Uniform Resource Locator(s) (URL), Email Address, and QVR Identifier. Individuals will be notified via email describing the IIF obtained and that we will use this information to identify highly qualified reviewers who are willing to serve on study sections. This information is stored in a database that is available to CSR employees, and specifically created for Scientific Review Officer use. The email notification will also give the individual the option of rescinding their information, at which point the system developers will destroy (permanently delete) the IIF provided.
- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Administrative controls. To run the database, SROs download it to their C-Drives from Share drive. Access to the CSR Share drive is limited. Personnel with access to the database have been trained and are aware of their responsibilities for protecting IIF.

Physical controls. Rockledge 2 is secured by guards, employee identification badges and keycards.

Technical controls: All CSR laptop computers are encrypted. User identification, passwords, firewall, VPN are currently in place. Security patches for servers and laptops are always kept current.

The NIH incident response team will notify the CSR ISSO of any security incidents detected. Users will notify the CSR ISSO and NIH Helpdesk of any security incidents.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michael Floissac, CSR Privacy Coordinator

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CSR Out of Town Calendar

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 7/25/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A - no PII

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH CSR Out of Town Calendar
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Dr. Dipak Bhattacharyya
- **10. Provide an overview of the system:** Out of town meeting calendar provides calendaring functionality allowing Scientific Review Officers and associated CSR staff, to verify peer review meeting dates and locations that take place across the United States. The calendar enables filtering and data input abilities that minimize extraneous processess currently being used; Scientific Review Officers will be able to select the location and time where they would like to schedule a meeting.

This calendar has the following features:

- 1) Coordinate out-of-town and local meetings across all institutional review groups
- 2) help DEAS provide coverage for out-of-town and local meetings
- 3) Create meeting reports for Chiefs and the Office of the Director
- 4) Provide a repository for meeting information such as hotel name, date & time of meeting.
- 5) Provide centralized access to Google Maps and hotel survey data

13. Indicate if the system is new or an existing one being modified: New

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass

through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) Meeting date, location, Scientific Reviewer Officer name, Council round, meeting staff name (CSR staff).
- (2) To coordinate scheduling activities for CSR staff.
- (3) The information does not contain PII.
- (4) CSR staff enters data, such as (see number 1 above). The only personal information is the names of the CSR staff involved in the meeting which is mandatory.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The system does not gather any information from the public and it is not a publicly accessible system. The system uses downloaded data in read format from IMPAC II as well as data entered by the user (Federal employee).

The information stored in the system is not disclosed to anyone outside of HHS/NIH in a manner that identifies the individual except for the applicants themselves and except as permitted by the privacy act.

We do not notify any individuals regarding PII, because there is no PII contained in the system.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The system does not contain any PII. However the systems has the following controls.

Administrative controls: Training as needed. The system is backed up on a regular basis.

Technical controls: User ID and password have to be used for network authentication.

Physical controls: Security guards, ID badges, and Key cards are used to gain access to bldg. 12 where it is housed.

The required password strength for CSR and NIH users is implemented by NIH through local access controls that provide protection from unathorized access, alteration, loss, disclosure, and availability of information in accordance with HHS information security program.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michael Floissac, CSR Privacy Coordinator

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CSR Performance Management Appraisal Program (PMAP)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/25/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN

number is required for Q.4): 09-90-0018

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** Performance Management Appraisal Program (PMAP)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Dipak Bhattacharyya
- **10. Provide an overview of the system:** The PMAP review system provides an automated process for specific members of Office of the Director (OD) and Managers to review the written performance summaries of two categories of CSR staff. This process streamlines the previously manual process and provides for more effective time management and evaluation techniques. The scope of the PMAP review system automates the previous process for performance reviews for ease of use. The following product features:
- PMAPs grouped by Division, IRG and/or Branch in a table-like structure
- Display the names of all CSR staff within selected group/IRG/branch
- Ability to individually select performance summary, out of staff listing
- Allow display of performance summary and assigned score, for the PMAP being reviewed
- Ability to change the assigned score, if desired
- Ability to update changes to the PMAP and create a permanent record
- Store the performance summaries
- Display the current number out of total for specified group (3 out of 10)
- Ability to move to next performance summary within same group
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether

provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Not Applicable
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) The PMAP system maintains information including employee name, work phone, work email, performance rating, and salary. (2) PMAP is a required HHS annual process to rate the performance of employees. This system streamlines the process electronically. (3) Yes. (4) Mandatory.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) (1) No major changes anticipated. (2) The PMAP process is a required HHS process of which employees are notified when they are hired. (3) Information will be used by supervisors and the administrators to rate the performance of employees.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Administrative

To log on the Intranet requires an active directory account, which is created and maintained by the central NIH account authority. This system is hosted by the CSR intranet and will have role-based access for supervisors, administrators and the technical team.

Technical

The employee entry form is located on the CSR Intranet. The server where CSR database resides is hosted and maintained by the CSR Sterling, VA data center. It is physically located in Sterling VA. The building has the technical infrastructure to ensure protection of the server from physical and online attacks via ADP room access controls and WAN and LAN intrusion protection.

This access is maintained through NIH active directory. The system administrator's password is changed 60 days. CSR provides the operating and database systems patch in accordance with policy set by CERT.

Physical

Building 12 has access controls procedures in place to prevent unauthorized access to CSR Severs. In addition, CSR employees are not authorized without escort to enter the ADP room or access servers. All hard drives are encrypted.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michael Floissac, CSR Privacy Coordinator

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CSR Qualifying Therapeutic Discovery Program

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 7/25/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH CSR Qualifying Therapeutic Discovery Program (QTDP)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Dipak Bhattacharyya; George Chacko
- **10. Provide an overview of the system:** The Qualifying Therapeutic Discovery Project (QTDP) program is provided under new section 48D of the Internal Revenue Code (IRC), enacted as part of the Patient Protection and Affordable Care Act of 2010 (P.L. 111-148).

Under the program, eligible taxpayers may apply for certification from the Internal Revenue Service (IRS) of a qualified investment with respect to a qualifying therapeutic discovery project as eligible for a credit, or for certain taxpayers, a grant from the Department of the Treasury.

The IRS will certify an eligible taxpayer's qualified investment only if:

(1) HHS determines that the taxpayer's project is a qualifying therapeutic discovery project (as defined in section 4.02 of IRS Notice 2010-45). Specifically, HHS will determine whether an applicant's project meets the definition of a "qualifying therapeutic discovery project", which means projects designed to:

treat or prevent diseases or conditions by conducting pre-clinical activities, clinical trials and clinical studies or carrying out research protocols, for the purpose of securing Food and Drug Administration approval of a product,

diagnose diseases or conditions or to determine molecular factors related to diseases or conditions by developing molecular diagnostics to guide therapeutic decisions, or develop a product, process or technology to further the delivery or administration of therapeutics.

(2) HHS determines that the taxpayer's project shows reasonable potential (a) to

result in new therapies (i) to treat areas of unmet medical need, or (ii) to prevent, detect, or treat chronic or acute diseases and conditions, (b) to reduce long-term health care costs in the United States, or (c) to significantly advance the goal of curing cancer within the 30-year period beginning on May 21, 2010; and

(3) The IRS determines that the taxpayer's project is among those projects that have the greatest potential (a) to create and sustain (directly or indirectly) high quality, high-paying jobs in the United States, and (b) to advance United States competitiveness in the fields of life, biological, and medical sciences.

To apply, companies must use:

- · Form 8942, Application for Certification of Qualified Investments Eligible for Credits and Grants Under the Qualifying Therapeutic Discovery Project Program (Catalog Number 37748D).
- · Applicants must also include a Project Information Memorandum (PIM), as instructed in IRS Notice 2010-45.

Applications may be submitted beginning June 21 and must be submitted no later than July 21, 2010. IRS will send to NIH the PIM. The IRS will issue certifications by October 29, 2010.

HHS/NIH's role: The statute requires the Secretary of the Department of the Treasury to consult with the Secretary of the Department of Health and Human Services (HHS) in conducting this program as described above in (1) and (2).

NIH's Role in Review of the PIM:

Applications will initially be reviewed by HHS/NIH to determine whether or not they meet the definition of "qualifying therapeutic discovery project" (see questions 1-4 in the Project Information Memorandum), and whether they show a reasonable potential to meet the statutory goals (see questions 5-8 and 9-11 in the Project Information Memorandum). The reviews will be accomplished by reviewers coordinated by the National Institutes of Health. All applications that are considered, based on that review, to cover qualifying therapeutic discovery projects that show a reasonable potential under § 48D(d)(3)(A) will be considered by the IRS as it makes its determination whether the requirements under § 48D(d)(3)(B) are satisfied.

Review Procedure:

- ·IRS sends by courier only the PIM sections of the application for NIH review.
- ·Each application is initially assigned for evaluation to one reviewer.
- ·The reviewer evaluates the contents of the application (PIM) and recommends scores. [Predecisional]
- ·In cases of s

- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) IRS sends by courier only the PIM sections of the application for NIH review. The PIM section includes Corporate Tax ID, Corporate Address, Principal Investigator Name, Location, Contact Information (federal employee information)
- ·Each application is initially assigned for evaluation to one reviewer.
- •The reviewer evaluates the contents of the application (PIM) and recommends scores. [Predecisional]
- ·In cases of scores below the cutoff value that would be recommended for funding, a second reviewer is assigned to ensure that applications that meet the definition of a qualifying therapeutic discovery project and show reasonable potential based on the statutory goals of the program (as defined in IRS Notice 2010-45) are not being eliminated.
- ·All results are reviewed and approved by a second level panel, which examines these suggestions and approves, rejects, or modifies them. [Decisional]
- ·In the interest of protecting reviewer confidentiality, predecisional details (specifically, the identity of the reviewer assigned to individual applications) are destroyed 15 days after the review. An aggregate list of all reviewers involved in the project is published. A similar procedure is followed in NIH grant review.
- (2) These results are reviewed by HHS and transmitted to IRS in the form of a list of applications for IRS to consider for certification.
- (3) Taxpayer ID # of submitting organization, name of organization, name of contact person for the organization are included/maintained as part of the application.
- (4) Voluntary submitting grant applications to IRS of their own accord.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original

collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) (1). The system contains information provided by the internal revenue service. We do not obtain any information from the public.

- (2). We are not collecting any PII from individuals the information that will be provided to us will be obtained from the internal revenue service. The IRS will provide the name of contact person for each Applicant organization, taxpayer identification number, and a unique identifier.
- (3). The information in each record will be evaluated for it's scientific potential. The data within the system will be looked at by scientific reviewers, project implementation team and returned to the IRS in about three months from now.
- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls: The PII is secured through Technical controls: User ID and passwords have to be used for network authentication.

Physical controls: Security guards, ID badges, and Key Cards are used to gain access to Sterling where the system will be housed.

The required password strength for CSR and NIH users is implemented by NIH through logical access controls that provide protection from unauthorized access, alteration, loss, disclosure, and availability of information in accordance with HHS information Security Program.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michael Floissac, CSR privacy coordinator

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/30/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CSR Real Time Meeting Status Tool

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 7/25/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: n/a

6. Other Identifying Number(s): n/a

- 7. System Name (Align with system Item name): NIH-CSR Real Time Meeting Status Tool
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Dipak Bhattacharyya
- **10. Provide an overview of the system:** The RTMS is an electronic tool which program officers will have real time access to the progress of the discussions of the applications in different review meetings. Updated information on review meeting progress allows program officers to plan their attendance to different meetings accordingly. This process allows for better time management to program officers and increase the transparency of our review meetings.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The system displays the Principal investigator's (PI) name for the purpose of viewing the associated PI's name for each grant under review. This PI name is static data for display purposes only and understanding the disscussion order of grant applications during the review meeting.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) RTMS pulls the following information from Internet Assisted Review (IAR); a subsystem of IMPACII: Grant application number, Application number, NIH Program Officers (NIH employees), Meeting agenda number, Application discussion order number, Application review order number, Meeting start date, Meeting end date, Meeting name.
- (2) To allow program officers to better regulate their time during the review of their IC respective applications.
- (3) The system contains the name of the Principal Investigator. This person can be a non Federal employee.
- (4) Data is not entered by the user. The system displays data from IAR.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.
- (Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) (1). The RTMS does not notify individuals whose PII is in the system of any changes occurring to the system.
- (2) The RTMS does not obtain consent from individuals regarding PII. The information is displayed in a static fashion from a feed to IAR, a subsystem of IMPAC II.
- (3). The system does not gather any information from the public and it is not a publicly accessible system. The system only uses downloaded data in read format from IAR. The information stored in the system is not disclose to anyone outside of HHS/NIH in a manner that identifies the individual except for the applicants and except as permitted by the privacy act. The sole purpose of this data display is to assist the program officer (PO) in viewing the status of the respective applications during meeting discussions. For example, they will see if it is: in progress or complete.
- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls: Technical controls: user id and passwords has to be used for network authentication. SSL is used to secure downloaded data. Administrative Controls: Role-based access

Physical controls: security guards, ID badges and Key Cards are used to gain access to Bldg 12 where the system in located.

Training materials are updated and system is backed up on a regualar basis.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michael Floissac, CSR Privacy Coordinator

Sr. Official for Privacy Approval: Promote **Sr. Official for Privacy Name:** Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CSR SOFie (Status of Funds)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/25/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): Status of Funds Internet Edition (SOFie)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Nair Prema, Debbie Elliott
- **10. Provide an overview of the system:** The SOFie application supports the efforts of several offices and branches within the IC, allowing budget offices to track expenditures in appropriate funds in a fiscal year. The program contains a tracking mechanism to track prior year funds as well. The application downloads this information from the NIH Data Warehouse weekly. Information entered into the SOFie database is not uploaded into the NIH Data Warehouse database. SOFie is not a source database for other information systems.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: Accounting data and related document information is downloaded from CAS/Central Accounting System mainframe and is specific to CSR for its fiscal year operations. The information is general accounting info by category (ex. wages), with totals by category, and nothing specific to individual employees. The system contains no IIF.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Authorized user access to information is limited to authorized personnel for performance of their duties. Authorized personnel include NIH employees, system managers and computer personnel. Physical safeguards are in place at CSR. and the contractor facilities. Access codes are deleted when employees leave CSR. New employees have obligatory training and NIH/CSR security department is notified of all staff members and contractors authorized to be in secured areas during working and nonworking hours. The list is revised at NIH and requires the completion of a computer-based training (CBT) course entitled 'Computer Security and Awareness' for NIH staff and contractors. This CBT provides an overview of basic IT security practices and the awareness that knowing or willful disclosure of the sensitive information processed in the system can result in criminal penalties associated with the Privacy Act, Computer Security Act, and other federal laws that apply.

All data transmitted between the server (currently at contractor location) and workstations at CSR are encrypted.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michael Floissac, CSR Privacy Coordinator

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CSR SREA Financial Tracking System

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/25/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-90-0024

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): CSR SREA Financial Tracking System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Renee Harris, Dipak Bhattacharyya, Thao Tran, and Prema Nair
- **10. Provide an overview of the system:** The SREA Office's main functions is to support the CSR Peer Review by the 1) procurement of hotel meeting rooms, sleeping rooms, reviewer airfare, AV and 2) Payment to Non-Federal Reviewers who provide expertise in reviewing grants applications.

We expect that by having a SREA Financial Tracking system we will be better equipped to serve NIH/CSR as a whole. Specifically, it is proposed a web-based system will enable SREA to better monitor and track Peer Review expenditures in an electronic format which can be queried to do historical data analyses on a regular basis. We will also be able to allow secured access to SREA Data at multiple levels: administrative, user, and read-only. In addition, we will be in compliance with the NIH COOP and NIH Vital Records initiatives by electronically housing procurement documents attached to a corresponding ticket.

SREA is implementing a pilot for other NIH Instiitute/Center personnel to access an IC specific report on the SREA Financial Tracking System via a web link.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Not Applicable
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The SREA Financial Tracking Database utitlizes PII in the form of the Scientific Review Officer (SRO) name from IMPAC-II. This information is used to create a dropdown menu with the SRO names listed in the SREA database. SRO names are used to identify review meetings. In the event a reviewer declines payment of honorarium, their name is manually entered into the SREA database by users to document payment refusals. SRO name is mandatory. Reviewer name is voluntary. Vendor information (hotels): contact name, phone number, email, DUNS, and Tax ID Number.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) We do not anticipate any major changes to the system. In the event of a major change involving PII, a process will be put in place. Individuals are notified via email regarding the PII in the system and how it is used.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Access controls are in place for servers along with FDCC guidelines.

NIST and FISMA rules and regulations are applied to servers.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michael Floissac, CSR Privacy Coordinator

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH CSR zApps PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 7/25/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A
- **5. OMB Information Collection Approval Number:** N/A
- **6. Other Identifying Number(s):** There are no additional identifying numbers.
- 7. System Name (Align with system Item name): NIH CSR Secure Email File Transfer
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Dipak Bhattacharyya
- 10. Provide an overview of the system: CSR will be using SEFT (Secure Electronic File Transfer) to allow CSR employees to share information securely with other federal agencies and external individuals. There are two roles in the exchange: sender and recipient. Senders initiate the file transfer and recipients can only receive the file transferred. The basic process is: (1) the sender creates a package of files and sends it to any email address; the email message contains a URL link to the package of files; (2) the recipient is notified about the delivery; (3) the recipient clicks on the link to retrieve the package; the recipient is prompted for an ID and password. Only NIH/CSR employees can send files. Both senders and recipients must be registered to use SEFT. Users self-register for the service. NIH/CSR employees register for the service through the CSR SEFT system. Recipients register for the service when they receive an email notification for the first time.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No PII is disclosed.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: CSR collects names, email addresses, and answers to password reset questions for users of the systems. Email addresses are required to identify users. The email addresses are personal and/or professional addresses of CSR reviewers and are provided voluntarily by those reviewers.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) users self-register for the SEFT service. The information collected is put into the system with their knowledge.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** Administrative controls include SOPs for administering the system and a change management process to ensure only authorized changes are implemented. Technical controls include user identification and authentication, assignment of roles within the SEFT service and access controls to protect the datea. Physical controls include guard(s) at the entrance to the data center where SEFT server is housed and card readers.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michael Floissac, CSR Privacy Coordinator

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH FIC CareerTrac [System] PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/3/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-1903-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0156

5. OMB Information Collection Approval Number: 0925-0568

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): CareerTrac

- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Linda Kupfer
- **10. Provide an overview of the system:** CareerTrac is a global trainee tracking and evaluation system for the Fogarty International Center (FIC), National Institutes of Health. The goal of this system is to create a complete trainee roster for all FIC research training programs and to monitor outputs, outcomes and impacts of FIC international trainees.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): FIC takes every reasonable precaution to protect information. CareerTrac system is securely hosted under NIH firewall and the password is encrypted. FIC maintains appropriate physical, electronic and procedural safeguards to ensure the security, integrity and privacy of trainee's personal information. Unless legally mandated, FIC will not disclose any of the following information: employment history, phone, fax, year of birth, biographical data, gender (except in aggregate), minority status (except in aggregate), current training status, return home (except in aggregate), and career accomplishments (only in aggregate except where in the public domain).

FIC understands the delicate balance between protecting the data and permitting access to those who need to use the data for authorized purposes. Access to CareerTrac data will be granted only to those organizations/individuals, which must, in the course of exercising their responsibilities, use the specific information. The requests for access to CareerTrac data will be carefully reviewed and the following information may be disclosed for routine uses: trainee's name, area of training, country of origin, work email, degrees earned through FIC funded programs, accomplishments that are public products, and career highlights of the trainee information. The audience for this information may include, but not restricted to:

The FIC, NIH, HHS and Congress for reporting and evaluation purposes;

The Principal Investigator (PI) and Collaborators for the purpose of monitoring the program, submitting progress reports and grant applications and writing journal articles describing the programs;

FIC co-funding partners and Co-sponsors of FIC programs for the purpose of reporting progress and conducting evaluations of the programs

Interested public, for example, for the purpose of convening a scientific meeting in a particular country to which former trainees will be invited

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system will collect, track, and report on information about international trainees - such as trainee name, contact information, biographical information, and training information. The system also supports tracking of trainee accomplishments - such as fellowships, awards, employment, other education, product or policy developments, publications, funding received, presentations, posters at scientific conferences, and students taught.

The purpose of the system is to enable effectiveness evaluations of health research training programs, funded by NIH/FIC, for international trainees.

The information may be used by or disclosure may be made to (1) the FIC, NIH, HHS and Congress for reporting and evaluation purposes; (2) the academic community (including PIs and Collaborators) for the purpose of monitoring the program submitting progress reports and grant applications and writing journal articles describing the programs; (3) FIC co-funding partners and co-sponsors of FIC programs for the purpose of reporting progress and conducting evaluations of the programs; (4) interested public, for example for the purpose of convening a scientific meeting in a particular country to which former trainees will be invited.

The personal information is submitted on a voluntary basis.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) We will provide the trainees with a written document that will notify the trainees about the purpose of data and how it will be used and shared. The

trainees will have to read Privacy Act Disclosure and sign 'Certificate and Acceptance' form (which is part of the document) before PIs can enter their personal information into the system.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** A variety of safeguards are implemented in order to protect the information collected through CareerTrac system. Regular access to information in CareerTrac is limited to PHS or to contractor employees who are conducting, reviewing or contributing to the system. Other access is granted only on a case-by-case basis, consistent with the restrictions, as authorized by the system manager or designated responsible official.

Administrative Control: CareerTrac has a system security plan and backup plan. The files are backedup regularly and they are stored in secure offsite locations.

Technical Control: CareerTrac system is securely hosted under NIH firewall and the password is encrypted and changed routinely. PIs can only view the trainees from their grant. FIC maintains appropriate physical, electronic and procedural safeguards to ensure the security, integrity and privacy of trainee's information.

Physical access controls are in place for CareerTrac. Records are stored in closed or locked containers, in areas which are not accessible to unauthorized users, and in facilities which are locked when not in use. Sensitive records are not left exposed to unauthorized persons at any time. The following are some of the physical controls in place to safeguard system and data collected: closed circuit TV, identification badges and guards.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Marcia Smith

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH FIC Status of Funds Internet Edition (SOFie)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH FIC Status of Funds Internet Edition (SOFie)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Danielle Bielenstein
- **10. Provide an overview of the system:** SOFie is a financial tracking tool that allows users to access financial data and download the data from nVision (the NIH Central Accounting System) into spreadsheets in order to perform budget analysis.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\rm N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: FIC accounting transactions and data are downloaded from nVision (the NIH Central Accounting System). The data is used

to plan, track, and report on expenditures, enabling the FIC budget office to comply with appropriation laws and regulations. The data contains no PII.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A - no PII in system.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A no PII in system.

PIA Approval

PIA Reviewer Approval: Promote PIA Reviewer Name: Marcia Smith

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCCAM Employee Database, Internet Edition (EDie)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: Significant System Management Changes

1. Date of this Submission: 12/15/2011

2. OPDIV Name: NIH

- 3. Unique Project Identifier (UPI) Number: No
- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-90-0018
- **5. OMB Information Collection Approval Number:** No
- 6. Other Identifying Number(s): NCCAM-014
- **7. System Name (Align with system Item name):** NIH NCCAM Employee Database, Internet Edition (EDie)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Robin Klevins
- **10. Provide an overview of the system:** EDie is a web-based application that allows institutes to accurately maintain individual employee, contractor, and volunteer information, as well as plan for, monitor, and report on workforce staffing levels.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Information is intended for internal senior administrative use only and will not be shared by other entities. Refer to SORN 09-90-0018.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: EDie tracks all information pertinent to a personnel file for the purpose of personnel management activities. Information is collected from employees via the Human Resources Database (HRDB) system, Fellowship Payment System (FPS), nVision Data Warehouse and NIH Enterprise Directory (NED). Uses consist of the following: a) tracking a time-limited appointment to ensure renewals are done in a timely manner, thereby avoiding any break in service; b) ensuring that allocated FTE ceilings are maintained; c) ensuring salary equity for various hiring mechanisms; d) providing reports requested by the NIH Director, the IC Director, and other management staff, as requested; and e) maintaining lists of non-FTEs, special volunteers, contractors, and other hiring appointments. The type of information collected constitutes PII and includes the following: name, address, phone number, social security number and date of birth, and is mandatory for all employees.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) PII in the system is downloaded from the HRDB, FPS, nVision Data Warehouse and NED. Changes to HRDB or changes in the way information is used is relayed to employees via official notices from the NIH Office of Human Resources (OHR). Individuals are notified of the collection and use of the data as part of the hiring process. This is a mandatory requirement of potential job applicants seeking employment at NIH.

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** PII stored in EDie is accessed by a very limited number of administrative staff with a "need-to-know" status. EDie is password protected and sensitive data is encrypted. The system is located in Building 31, Rm 2B11 behind the NIH firewall.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Erica St. Michel (301) 594-5769

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 2/2/2012

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCCAM Internet Website PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 3/12/2012

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: Not applicable

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NCCAM-001

- 7. System Name (Align with system Item name): NCCAM Internet Web Site
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Irene Liu
- **10. Provide an overview of the system:** The NCCAM Web site (www.nccam.nih.gov) is used to disseminate scientifically accurate information about complementary and alternative medicine to the public and to health officials via the World Wide Web.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\rm N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The NCCAM Web site (www.nccam.nih.gov) is used to disseminate scientifically accurate information about complementary and alternative medicine to the public and to health officials via the World Wide Web. NCCAM is not collecting personal information through the NCCAM Web site. Note:

NCCAM has submitted a separate PIA for the NCCAM Online Continuing Education Series (please reference that PIA for more information).

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Not Applicable

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Erica St. Michel (301) 594-5769

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCCAM Intranet Website PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 3/12/2012

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: Not applicable

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NCCAM-002

- 7. System Name (Align with system Item name): NCCAM Intranet Web Site
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Irene Liu
- **10. Provide an overview of the system:** The NCCAM Intranet Web site (intranet.nccam.nih.gov) is used to disseminate relevant information and useful dynamic applications to employees of the National Center for Complementary and Alternative Medicine (NCCAM). The key legislation authorizing this Web site is 42 USC 287c-21.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The NCCAM Intranet Web site (intranet.nccam.nih.gov) is used to disseminate relevant information and useful dynamic applications to employees of the National Center for Complementary and Alternative Medicine (NCCAM). We are not collecting personal information through the NCCAM intranet Web site.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Not Applicable

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Erica St. Michel (301) 594-5769

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCCAM Online Continuing Education Series

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/11/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: Not Applicable

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0106

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NCCAM-010

7. System Name (Align with system Item name): NCCAM Online Continuing Education Series

- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Irene Liu
- **10. Provide an overview of the system:** This program provides lectures on complementary and alternative medicine for health care professionals and the public. Continuing education credits are offered to physicians and nurses upon completion of the tests within the modules.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No SOR#09-25-0106
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: Users may

VOLUNTARILY provide the following information:

Name, Mailing address, Email, Degree or Credentials, Phone number, Fax number, Specialty, Hospital affiliation.

The purpose is to provide continuing education credits. The information is only to be used by Cine-med Inc, an accrediting entity.

Collection of this data is authorized under authority 42 USC 287c-21

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) NCCAM does not expect to have major changes to the system.

A privacy policy is posted to inform users of the purpose of data collection and explain that data will only be used to confirm registrant participation in the continuing education program (in case they request a copy of their certificate).

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Personnel using the system have been trained and made aware of their responsibilities- for protecting the information being collected. Technical controls are in place to minimize the possibility of unauthorized access, use, or dissemination of the data.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Erica St. Michel (301) 594-5769

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCCAM Records Management Database

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/8/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: Not applicable

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NCCAM-008

- 7. System Name (Align with system Item name): NCCAM Records Management Database
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Erica St. Michel
- **10. Provide an overview of the system:** The Records Management Database is a Microsoft Access 2007 database that tracks the status of NCCAM inactive paper records transferred to the Washington National Records Center and/or the National Archives. The database contains information about file types; file names; creation, disposition, transfer, and destruction dates; and records retentions schedule authorities, which are required to manage, track, and retrieve these files. No IIF is collected or stored at any point by the database. Authorizing legislation: 42 USC 287c-21.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{No}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The information collected includes file names and disposition dates in an effort to effectively manage records. Only necessary information is collected. No IIF is collected.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Erica St. Michel (301) 594-5769

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCCAM SharePoint PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/8/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: No

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NCCAM-013

- 7. System Name (Align with system Item name): NCCAM SharePoint
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Linda Rich
- **10. Provide an overview of the system:** The system holds grant application information that is retrieved from the IMPAC II database with additional tracking information added for the purpose of application grant approval. The system tracks grant applications under authority 42 USC 287c-21.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): For internal purposes only; IIF will not be shared OR disclosed. SOR #09-25-0036
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: A grant application is submitted voluntary by the Investigator through the electronic application submission process in Grants.gov. That information subsequently is stored in the centralized NIH eRA/IMPAC II database all notifications and consent procedures with subjects are handled at that level. For the

purpose of preparation and tracking of selected grants for funding at the IC/NCCAM level, selected data are downloaded from the eRA database into SharePoint. The selected IIF data are restricted to: Investigator Name and Degrees, Institution, Project Title, e-mail address. In SharePoint that data is used only by NCCAM staff members who have been selected and approved by senior level staff for the purpose of grant preparation and tracking. The data is not shared with nor disclosed to any party, and is deleted on a routine basis (each fiscal year) when it is no longer needed.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) All IIF information is obtained from the NIH IMPAC II system. Any major changes to the system should be handled at the NIH level. Notifications and consent procedures with subjects are also handled at the NIH level. NCCAM does not have a notification process in place as the applications database does not collect the initial IIF. It is only a recipient of IIF collected by another database that is maintained at the NIH level thus we do not have our own notification process to obtain IIF from individuals. This system does not have any notification procedures in place in addition to those in place for the IMPAC II system.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The SharePoint system is electronically behind the NIH firewall and can only be accessed from behind the firewall. The information is physically secured by a required key card and employee badge, and electronically secured by a password login procedure to the NIH computer system, and a requirement of a password when accessing the database. A comprehensive IRT is also maintained. Information is also secured by least privilege, separation of duties, an intrusion detection system, locks and background investigations.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Erica St. Michel (301) 594-5769

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCCAM Status of Funds Internet Edition (SOFie)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 2/22/2012

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-3199-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NCCAM-011

- **7. System Name (Align with system Item name):** NIH NCCAM Status of Funds Internet Edition (SOFie)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Valery Gheen
- **10. Provide an overview of the system:** SOFie is a financial tracking tool that allows users to access financial data and download data into spreadsheets in order to perform analysis.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Status of Funds internet edition (SOFie) is required by the Administrative and Budget offices of NCCAM for tracking and monitoring the Center's budget. Utilizing client-server technology, SOFie gives users

flexible views and summaries of their accounting structure. The Accounting data and related document information is downloaded from CAS and is relevant to/specific to NCCAM for its fiscal year operations. It is necessary to have access to this data in order to comply with appropriation laws and regulations. The system contains no IIF.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A - No IIF

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Information is secured using user name and password, least privilege, separation of duties and intrusion detection system, firewalls, locks, badge access, background investigations.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Erica St. Michel (301) 594-5769

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 2/29/2012

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI AARP Phase I Pilot Study (APS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: TBD

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: 0925-0594

6. Other Identifying Number(s): Z01 CP010196

- 7. System Name (Align with system Item name): NIH NCI AARP Phase I Pilot Study (APS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Yikyung Park
- 10. Provide an overview of the system: The APS is a web-based system that manages the data collection activities related to the completion of four web-based instruments that capture dietary, physical activity and health information. The APS allows for a respondent to consent and complete a self-enrollment process. Enrollment includes the collection of contact information. Upon successful enrollment, respondents are assigned instruments to complete and a schedule by which to complete. Access to the instruments is granted to respondent based on assigned schedule. Email, text messaging, and automated phone calls are generated to remind respondents of upcoming and overdue events.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): PII will not be shared nor disclosed. This collection is covered under System of Records Notice 09-25-0200.

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Respondents will be asked for their name, email address and phone numbers as part of the study conduct to send reminders of upcoming events via outgoing automated outgoing phone calls, cell phone text messaging and email. Respondents can opt-out of cell phone text message and automated phone call reminders.

Phone numbers are also collected for use of providing support to study respondents.

Date of birth is collected to verify enrollment criteria (>50 yrs of age) as well to characterize respondent when determining aggregate response rates.

Race, ethnicity, and state are also collected to characterize respondent.

Social security number is collected for a subset of the respondents in order to determine the response rates and the likelihood in any main study of being able to link to cancer and other health registries for endpoint analyses.

The following fields are required:

Gender, OMB race category(ies), ethnicity, first and last names, mailing address, email, and social security number for a subset of respondents.

Participation is voluntary.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The scope of the feasibility study is limited and there are no plans to make any major changes to the system. In the event of any changes that impact PII, respondents will be notified via email of a change and be directed to log into their APS account for details or contact the APS helpdesk.

The consent text included in the system specifies what PII is being collected and how it will be used or shared. Additionally, the systems includes frequently asked questions (FAQS) that further explain how IIQ information is stored and will be used.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The following classes of controls are in place to protect the APS and respondent PII: access such as user account management, access enforcement, password strength, least privilege concept, session termination; security awareness

and training; audit and accountability; configuration management; contingency planning; identification and authentication for users, devices; incident response including training, testing, monitoring; timely and controlled maintenance; media protection; physical and environment controls such as id badges, physical access authorization using access cards, key locks and cipher locks for building and room entry, monitoring, visitor control, emergency power, and shutoff, disaster protection and recovery; system security plan; personnel security; rules of behavior; risk assessment planning, monitoring, update; technical and communication protection including denial of service protection; boundary protection, programmable firewalls, transmission integrity; security certificates, encryption, regular virus detection and monitoring; policies and procedures are in place for each family control class

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI ABCC Laboratory Information Management System

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH NCI Advanced Bioinformatics Computer Center Laboratory Information Management System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Jin Chen, Building 430 FCRDC, 226,1050 Boyles Street, Frederick, MD, Phone: 301-846-5549
- **10. Provide an overview of the system:** The ABCC LIMS is a bio-informatics analysis tool in the ABCC (Advanced Biomedical Computing Center). It is a web based single server application hosted by the ABCC-IT Infrastructure and residing in that data center.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: LIMS collects sample,

inventory, parameters and data file used or generated in work flow. LIMS also uses project and client information from CSAS system for enterprise cross system integration purposes, where client information includes federal contact data. LIMS also holds lab user email address for identification purposes. Submission of federal contact information is voluntary. Information does not contain PII.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No PII in the system.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No PII in the system.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/30/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI AdEERS Filing System (AdEERS FS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: To be obtained

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: To be obtained

6. Other Identifying Number(s): NA

- 7. System Name (Align with system Item name): NIH NCI AdEERS Filing System (AdEERS FS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Jan Casadei
- **10. Provide an overview of the system:** The purpose of the CTEP AdEERS Filing System is to collect, store, manage and report expedited adverse events related data. The data collected is stored in hardcopy format in secure filing systems as well as secure Electronic Filing Systems operated by NCI CTEP contractors managing this process. Expedited adverse event information is reported to FDA as required in accordance with FDA regulations and guidelines.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): AdEERS FS shares and discloses adverse events related information on NCI sponsored clinical trials with FDA, NCI Investigators and Pharmaceutical sponsors in accordance with federal regulations and guidelines. Most of the information that AdEERS FS collects and shares in publicly available elsewhere.

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Legislation authority is the Public Health Service Act (42 U.S.C. 241, 242, 248, 282, 284, 285a-j, 285l-q, 287, 287b, 287c, 289a, 289c, and 44 U.S.C. 3101.).

The types of data collected are scientific and health data about cancer clinical trials, including clinical and pre-clinical data with associated regulatory and administrative supporting information.

AdEERS FS collects clinical trials data including study information, submitter/reporter information, principal investigator information, treatment assignment, relationship of events to treatments, time of resolution of events, narrative description, events that occurred and their grading and attribution, primary source documents that provide clinical information on the patient's evaluations and course of treatments and hospitalization, etc. Additionally, name, mailing address, phone number and email are also collected and maintained.

The information is used to assure patient safety, for scientific decision making, drug distribution, regulatory oversight (i.e., investigator registration, trial audits, etc.), and to facilitate administrative operations.

NCI Investigators who participate in NCI sponsored clinical trials submit their information to CTEP in a signed Investigator Registration (IR) packet. This investigator registration packet, along with additional cover letter, explains to the investigators intended purpose and usage of their information.

Patient participation in CTEP clinical trials is voluntary and participants in CTEP clinical trials sign an informed consent.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) All patients sign informed consent forms prior to enrollment on study. Informed consent forms are obtained in compliance with OHRP/IRB and ORI regulations.

AdEERS FS shares and discloses adverse events related information on NCI sponsored clinical trials with FDA, NCI Investigators and Pharmaceutical sponsors in accordance with federal regulations and guidelines. Most of the information that AdEERS FS collects and shares in publicly available elsewhere.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** Data in AdEERS Filing System is protected via Administrative, Technical and Physical controls. Hard copy documents are filed in the secure filing cabinets behind locked door in a secure environment with restricted access to the facilities. Only select authorized staffs are allowed to access the hard copies. Access logs to hard copy documents are maintained. Access to data stored in the Electronic Filing System is through password protection account. The Server on which the Electronic Filing System is hosted is maintained in secure facilities.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/30/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Advanced Biomedical Computing Center (ABCC)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: Not Applicable

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NCI-15

- **7. System Name (Align with system Item name):** NCI Advanced Biomedical Computing Center ABCC
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Jack R. Collins
- **10. Provide an overview of the system:** The mission of the Advanced Biomedical Computing Center (ABCC) is to provide high performance computing for the National Cancer Institute, both for its intramural and extramural scientists.

Public Health Act, TITLE 42, CHAPTER 6A, SUBCHAPTER III, Part C, subpart 1, Sec. 285, Sec. 285a

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): No PII in the system
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: The information collected consists of name, work phone number, work address, and work e-mail of government employees. This is collected when people sign up to take a class on how to use the ABCC. None of the data collected is information subject to the Privacy Act

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No PII in this system

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No PII collected. System uses firewalls, passwords, locks, id badges, background investigations, network monitoring and an Incidence Response team.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/30/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Advanced Biomedical Computing Center IT Infrastructure [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH NCI Advanced Biomedical Computing Center IT Infrastructure
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Gregory Warth, Building 430 FCRDC, 234, 1050 Boyles Street, Frederick, MD, Phone: 301-228-4376
- **10. Provide an overview of the system:** The ABCC data center is a 3800 SQFT facility capable of handling 310KW of equipment house in a secure space accessible only by swipe card where every transaction is recorded. The NCI-Frederick network is part of and attached to the NCI network via a Firewall. All network, service, storage, and other nodes are under change control and comply with FDCC and NIH's minimum standard security configurations. There are approximately 5000 workstations and 800 servers attached to the network.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: This system consists only of infrastructure. All information is housed within applications that the infrastructure supports.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) System contains no PII data

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: This system does not contain PII data

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/30/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Agricultural Health Study --Westat (AHSW)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: No

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: 0925-0406

6. Other Identifying Number(s): AHSW

- **7. System Name (Align with system Item name):** NIH NCI Agricultural Health Study Westat (AHSW)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Michael Alavanja / Stanley Legum
- **10. Provide an overview of the system:** The Agricultural Health Study is a collaborative effort involving the National Cancer Institute (NCI), the National Institute of Environmental Health Sciences (NIEHS), and the U.S. Environmental Protection Agency (EPA). The study has four major components:
- 1. The main prospective cohort study cancer and non-cancer outcomes
 - a. linkage with cancer registries, vital statistics, United States Renal Data System (USRDS)
 - b. ongoing data collection (i.e., telephone interview, food frequency questionnaire and cheek cell collection
- 2. Cross-sectional studies including questionnaire data, functional measures, biomarkers, and GIS
- 3. Nested case-control studies
- 4. Exposure assessment and validation studies

The cohort includes 89,658 private pesticide applicators, spouses of private applicators, and commercial pesticide applicators recruited within Iowa and North Carolina. Phase I, initial cohort recruitment, began in 1993 and concluded in 1997. Phase II follow-up began in 1999 and concluded in 2003. The Phase III follow-up began in 2005 and concluded in February 2010. Phase I observation involved administration of a questionnaire to obtain information on pesticide use, other agricultural exposures, work practices that modify exposures, and other activities that

may affect either exposure or disease risks (e.g. diet, exercise, alcohol consumption, medical conditions, family history of cancer, other occupations, and smoking history). Phase II had three data collection components: a computer-assisted telephone interview (CATI), buccal cell collection, and a mailed dietary questionnaire. Phase II interviews are designed to record updated information on pesticide use since enrollment, current farming and work practices, and changes in health status. In addition, the Dietary Health Questionnaire in Phase II makes a detailed evaluation of subjects' cooking practices and dietary intake. The buccal cell collection of Phase II was implemented to assess the impact of genetic risk factors on epidemiologic outcomes. Phase III included two data collection components: a CATI interview and a buccal cell collection for selected members of the cohort. In addition to Phase II and Phase III data collection activities that include the whole cohort, a series of sub-studies involving a small number of study participants will directly measure applicator and family member exposures to selected pesticides and/or focus in greater detail on subgroups with specific diseases or exposures.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Information Management Services (IMS separately contracted by NCI performs data analyses for NCI) National Death Index (NDI) Annual match with NDI Plus files. Internal Revenue Service to obtain updated address information. This system is also covered under the Privacy Act System of Records Notice 09-25-0200.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: AHS analytic data files do not contain direct identifiers such as name, address, or SSNs. PII is shared with NDI and the IRS when we are performing matches to NDI and IRS files. Contact information (name, address, phone number) are stored in anticipation of use in future substudies, cohort maintenance purposes (e.g., possible mailings of study update newsletters), and matching with state and national vital statistics and health registries.

The AHS has four major components:

- 1. Main prospective cohort study cancer and non-cancer outcomes
 - a. linkage with cancer registries, vital statistics, United States Renal Data System (USRDS)
 - b. data collection (i.e., telephone interview, food frequeny questionnaire and cheek cell collection (no longer on-going)
- 2. Cross-sectional studies including quesitonnaire data, functional measures, biomarkers, and GIS
- 3. Nested case-control studies
- 4. Exposure assessment and validation studies

Three were also a series of sub-studies involving a small number of study participants that directly measured applicator and family member exposures to selected pesticides and/or focus in greater detail on subgroups with specific diseases or exposures. Additional substudies may be conducted in the future.

Participation is voluntary.

PII collected and maintained include name, date of birth, social security number, mailing address, phone number, and pesticide application certificate types.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) There have been no major changes in the system and none are contemplated. Our IRB would review any major changes prior to implementation and provide us with guidance on any needed notification and consent requirements.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** Extensive safeguards are in place to ensure the confidentiality of each subject is protected. Each subject is assigned a six-digit number; these IDs are used for any references to subjects on an individual basis. Names and other identifying information are kept in a separate database from the analytic files. These data are joined only for performing linkages to the mortality and cancer incidences databases and for

direct contacts with cohort members to inform them of study progress or to request their participation in substudies. Several layers of passwords exist to ensure unauthorized access to electronically stored data is not permitted. Hard copies of questionnaires that contain any personal information have been shredded. Informed consent forms, which contain subjects' names and study IDs are stored in a secure facility separate from other study data. All personnel involved with the project have signed confidentiality agreements.

Files with PII are stored in a directory accessible only to the project's lead systems manager and one programmer. Data stored in the SQL Server contact database are protected with application level security and an additional password. Data stored in other file formats are encrypted when not in use and the encryption key is known only by the same two staff members. The files are never left in unencrypted form over night so that automatic backups contain only encrypted versions.

The system is protected by firewalls, intrusion detection systems, and passwords. There are comprehensive system security and contingency plans in place. An Incident Response capability is maintained.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/30/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Automated Self-Administered 24-Hour Recall (ASA24)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH NCI Automated Self-Administered 24-hour Recall (ASA24)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Dr. Nancy Potischman
- 10. Provide an overview of the system: Self-reported dietary assessment methods are commonly used to measure food intakes for dietary surveillance, nutritional epidemiology, clinical and intervention research. We developed a 24-hour dietary recall that could be unannounced, automated, and self-administered to make feasible the administration of multiple days of recalls in large-scale epidemiological studies, surveillance sites, behavioral trials and clinical research. The format and design were modeled on the interviewer-administered Automated Multiple Pass Method (AMPM) developed by the US Department of Agriculture (USDA). The website collects information about subjects' diet for the previous day for extramural researchers doing epidemiologic or clinical research. There is no personally identifiable information collected on this site. The respondents are given a username and password by the NCI in order to gain access to the website. Participation in these studies are voluntary and nonparticipation has no impact on the subjects' care or involvement in other aspects of the studies.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): No PII in the system
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The diet information collected provides a service for outside researchers and will not be used by the agency. The system does not contain PII and the information is provided by subjects on a voluntary basis.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No PII in the system

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No PII in the system

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Automated Self-Administered 24-Hour Recall (ASA24) Researcher Website

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH NCI Automated Self-Administered 24-Hour Recall (ASA24) Researcher Website
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Nancy Potischman
- 10. Provide an overview of the system: Researchers visit this website to gain access to the subjects' website (ASA24) for their research studies. The researcher will visit the site to provide lists of subjects' IDs with their dates for visiting the subjects' website and later will monitor their study and obtain the final data files of nutrients and foods consumed by each subject. Subject IDs are not linked to personal information at NCI. The Study ID is linked at the NCI to a username and password for each subject to gain access to the ASA24. The researcher provides their name, institution and email contact information as well as similar information for other staff with permission to visit the site on thier behalf. The researcher provides only institutional information not personal email and other contact information. Participation is voluntary.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No PII in the system

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The information the researcher provides is institutional email and contact information. None of this information relates to personal information and is not shared with anyone outside of the ASA24 team. The Study ID, username and password information on respondents is not linked to any personal information. The username is linked to dietary information stored from the respondent 's reports while visiting the ASA24 website. Participation by the researcher is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No PII in the system

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No PII in the system

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Biospecimen Research Database/Biospecimen Research Network (BRD/BRN)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision: Initial PIA Migration to ProSight

1. Date of this Submission: 9/13/2011

2. OPDIV Name: NIH

- 3. Unique Project Identifier (UPI) Number:
- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): Not applicable
- 5. OMB Information Collection Approval Number: Not applicable
- **6. Other Identifying Number(s):** Not applicable
- **7. System Name (Align with system Item name):** NIH NCI Biospecimen Research Database/Biospecimen Research Network (BRD/BRN)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Andrew Breychak/Ian Fore (owner)/Ajay Nalamala/Amit Srivastava
- **10. Provide an overview of the system:** The Biospecimen Research Database (BRD) is a searchable public data repository of published papers and studies collected from PubMed that have been consistently annotated for the purposes of biospecimen science. As of June 1, 2011 there are approximately 1,140 records (each record representing a study). There are 1 system administrators and 3 curators who have access add/edit/delete the data using a secure web curation interface.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Not applicable; no PII

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: 1) No information collected, records maintained are published papers & studies gathered from PubMed, currated, and disseminated (no contact data)
- 2) NCI-OBBR uses this information to disseminate currated information about existing published papers & studies where significant findings for biospecimen science have occured
- 3) This information and application contain NO PII
- 4) Submission of personal information is NOT required and therefore neither voluntary nor mandatory
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Not applicable; no PII is collected or disseminated.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Not applicable; No PII is collected, stored, or disseminated by this system.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/21/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI California Health Interview Survey (CHIS) Information Technology System

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: 0925-0598

6. Other Identifying Number(s): N02-PC-54400

- **7. System Name (Align with system Item name):** California Health Interview Survey (CHIS) Information Technology System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Nancy Breen NCI/Sansan Lin UCLA
- **10. Provide an overview of the system:** The California Health Interview Survey (CHIS) is a population-based random-digit dial telephone survey of California's population conducted every other year since 2001 by the UCLA Center for Health Policy Research (UCLA-CHPR). UCLA-CHPR has the lead responsibility of managing the survey, preparing, maintaining, and disseminating the CHIS data files, reporting the survey findings, and disseminating the survey results. All CHIS confidential data files are maintained at the Data Access Center (DAC). No PII is contained with the CHIS confidential data files. The Data Access Center is designed to provide access to CHIS confidential files in a secured, controlled environment that protects the confidentiality of respondents.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No PII in the system.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: All data received by UCLA-CHPR is in the de-identified form with all personal identiers removed. All research participants provide verbal consent to participate in CHIS. The verbal consent script for each CHIS survey is approved by the UCLA Institutional Review Board and the California Health & Human Services Committee for the Protection of Human Services. The consent script informs respondents about the voluntary and confidential nature of the survey and assures them that their individual answers would not be linked to their identity or disclosed. There is no PII in the system. All data is given voluntarily by respondents.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No PII in the system.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No PII in the system.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI California Health Interview Survey Cancer Control Module (CHIS-CCM) 2009

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: 0925-0598

6. Other Identifying Number(s): N02-PC-54400

- **7. System Name (Align with system Item name):** NIH NCI California Health Interview Survey Cancer Control Module (CHIS-CCM) 2009
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Nancy Breen
- **10. Provide an overview of the system:** IMS is contracted by NCI to maintain CHIS microdata in a secure environment. There is no identifying information in the data. CHIS data include a range of cancer control variables for respondents including use of cancer screening, and a wide range of socio-demographic variables including health insurance status, usual source of health care. NCI analysts examine statistical patterns and trends in cancer control outcomes in California using CHIS. IMS staff develop programs to conduct statistical analyses as specified by NCI researchers.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: 1) IMS is under contract with NCI to maintain CHIS microdata files as needed for analysis by NCI. IMS programers and statisticians work under contract with NCI staff to help with programming and statistical analysis as specified by NCI staff. 2) NCI uses CHIS data to conduct statistical analysis of cancer control outcomes. These include use of cancer screening services, patterns and trends in tobacco use, physical activity and other cancer-control related behaviors. 3) No PII in the system. 4) No PII in the system.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No PII in the system.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No PII in the system.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Cancer Biomedical Informatics Grid (caBIG, caGRID) [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: None

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: None

6. Other Identifying Number(s): None

- **7. System Name (Align with system Item name):** Cancer Biomedical Informatics Grid (caBIG) caGRID
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Robert Shirley
- **10. Provide an overview of the system:** caGrid is the underlying service-oriented infrastructure that supports caBIG. Driven primarily by scientific use cases from the cancer research community, it provides the core infrastructure to compose the Grid of caBIG. caGrid provides the technology that enables collaborating institutions to share information and analytical resources efficiently and securely, while also allowing investigators to easily contribute to and leverage the resources of a national-scale, multi-institutional environment.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: caGRID does not collect, maintain or disseminate any data.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) caGRID is an infrastructure and does not contain PII.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No PII

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Cancer Central Clinical Patient Registry (C3PR)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: None

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: None

6. Other Identifying Number(s): None

- 7. System Name (Align with system Item name): NIH NCI Cancer Central Clinical Patient Registry (C3PR)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Christo Andonyadis, System Owner
- **10. Provide an overview of the system:** C3PR is a central participant registry and underlying database that will allow the management of patient clinical trials registration information and protocol information across studies, sites, systems and organizations.

C3PR operates on its own data tables with a close interface with Oracle Clinical. The implementation of the system will preserve the fundamental independence of the storage of the patient and registration information from the scientific and research data. System identifiers will be used to relate patient demographics and identifying information to eligibility, medical or treatment data.

- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes

- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The System shares PII with users of the Cancer Central Clinical Database (C3D) who are health care professionals who input patient data into the C3D System.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The Agency will collect from patients their name, date of birth, address, gender, race, and ethnicity, from patients for registry purposes for the Cancer Central Clinical Database (C3D) application. Submission of all personal information is voluntary. A medical records number will be assigned to them. This information is Personally Identifiable Information (PII) and submission of this personal information is voluntary subject to a Consent Form.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Patients voluntarily sign a consent form to voluntarily provide names, dates of birth, gender as PII and that it will be used for the registry, as well as for cancer research. The consent form obtains consent from the patient and notifies the patient of his/her rights. The patient will be notified if any major changes occur to the system. The PII will be destroyed when the system is decommissioned.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Administrative controls include annual risk assessments and the SDLC. Operational controls include personnel controls and strict account granting. Technical controls include firewalls, IDS, logon banner warnings, identification and authentication, database roles, file permissions and anti-virus/malware scanning.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Cancer Data Standards Repository-Standards Reporting-Common Data Elements (caDSR-SBR-CDE)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-4921-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NCI-31

- 7. System Name (Align with system Item name): NIH NCI Standards Based Report (caDSR)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Dave Hau
- **10. Provide an overview of the system:** One of the problems confronting the biomedical data management community is the panoply of ways that similar or identical concepts are described. Such inconsistency in data descriptors (metadata) makes it nearly impossible to aggregate and manage even modest-sized data sets in order to be able to ask basic questions. The NCI, together with partners in the research community, develops common data elements (CDEs) that are used as metadata descriptors for NCI-sponsored research. The caDSR is a database and tool set that the NCI and its partners use to create, edit and deploy the CDEs.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): No IIF in the system

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The NCI, together with partners in the research community, develops common data elements (CDEs) that are used as metadata descriptors for NCI-sponsored research. The system does not collect IIF.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No IIF

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Cancer Diagnosis Program (CDP)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: Not Applicable

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): Not Applicable

5. OMB Information Collection Approval Number: Not Applicable

6. Other Identifying Number(s): NCI-7

- **7. System Name (Align with system Item name):** NIH NCI DCTD Cancer Diagnosis Program (CDP)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Margaret M. Cavenagh, M.S.
- **10. Provide an overview of the system:** A contractor independently receives de-identified data or minimal datasets with data use agreement from cooperative agreement funded participants in NCI supported human specimen resources and makes subsets of that data available to researchers using the specimens. A contractor manages password-secure websites that provide logistics support for the research projects.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Does not share IIF
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: No IIF is collected. Deidentified information is being provided from the records of cooperative agreement funded institutions participating in NCI funded human specimen resources. The purposes and procedures of these activities have been reviewed by institutional review boards and deemed appropriate.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No IIF is collected. Only de-identifiad or a limited dataset with data use agreements under the DHHS the Privacy Rule is involved.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No IIF in the system, however username/passwords, least privilege, seperation of duties, an intrusion detection system, firewalls, locks, badge access, background investigations. A comprehensive IRT capability is also maintained,

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Cancer Genome Anatomy Project (CGAP)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: Not Applicable

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NCI-25

- **7. System Name (Align with system Item name):** NCI Cancer Genome Anatomy Project (CGAP)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Carl Schaefer
- **10. Provide an overview of the system:** The goal of the NCI's Cancer Genome Anatomy Project is to determine the gene expression profiles of normal, precancer, and cancer cells, leading eventually to improved detection, diagnosis, and treatment for the patient. By collaborating with scientists worldwide, such as the Ludwig Institute for Cancer Research and Lund University, CGAP seeks to increase its scientific expertise and expand its databases for the benefit of all cancer researchers. Public Health Act, TITLE 42, CHAPTER 6A, SUBCHAPTER III, Part C, subpart 1, Sec. 285, Sec. 285a and 44 U.S.C. 3101
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No IIF in the system

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The Cancer Genome Anatomy Project determines the gene expression profiles of normal, precancer, and cancer cells, with the goal of improved detection, diagnosis, and treatment for the patient. Gene expressions are not identified with any individual.

No IIF is collected. Data is downloaded by NIH NCI NCICB authorized users, in this case, cancer researchers.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No IIF collected. System uses firewalls, passwords, locks, id badges, background investigations, network monitoring and an Incidence Response team.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Cancer Human Biobank Comprehensive Biospecimen Resource (caHUB CBR)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision: Initial PIA Migration to ProSight

1. Date of this Submission: 3/9/2011

2. OPDIV Name: NIH

- 3. Unique Project Identifier (UPI) Number:
- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A
- **5. OMB Information Collection Approval Number:** N/A
- **6. Other Identifying Number(s):** NCI Contract No. HHSN261200800001E
- 7. System Name (Align with system Item name): NIH NCI Cancer Bioinformatics Grid (caBIG) Cancer Human Biobank Comprehensive Biospecimen Repository (caHUB CBR)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Bryon Campbell, Ph.D./Edward Suh, Sc.D. Contractors--Van Andel Research Institute
- **10. Provide an overview of the system:** The users of the CBR system are NIH/NCI personnel and contractors only. This system is not available to members of the public.

Information is organized by using metadata that includes objects, e.g. Specimen, Biohazard, Storage Container and attributes including tissue identifier (a numeric identifier that identifies the tissue sample kept in the facility. This identifier is not linked or related to any personal identifier), type, tissue site, concentration, and class.

Personal identifiers about the donors are not collected. The system implements a powerful query engine that can support any of the attributes or combination of attributes listed here if the tissue data has been collected and is available in the database. The sample ID is a coded identifier that is not linked to any Electronic Health Record (EHR) system, and cannot be used to link records in the system to any identifiable information.

- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: 1. De-identified dataset on bio-specimens (tissue)
- 2. Data supports clinical research
- 3. No PII is collected, stored, processed, or disclosed by this system. System contains only deidentified information or aggregate statistical analyses.
- 4. All data are submitted voluntary. De-indentification of the data is conducted at the tissue bank facility when the information about the tissue sample is input into the CDR node (client software) to be sent to the CDR via HTTPS protocol. The de-identification process includes the exclusion of PII data from the input of the data (manual process). In other words, fields such as donor's name, address, demographics, etc. are not available for data entry.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A - The caHUB CBR does not collect, maintain, or disseminate PII.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: This system does not collect PIA data

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 5/2/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Cancer Human Biobank Comprehensive Data Resource (caHUB CDR)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH NCI Cancer Human Biobank Comprehensive Data Resource (caHUB CDR)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: David Tabor
- 10. Provide an overview of the system: caHUB CDR is the Cancer Bioinformatics Grid (caBIG) biorepository tool for biospecimen inventory management, tracking, and annotation. This tool permits users to enter and retrieve data concerning the collection, processing, storage, quality assurance, and distribution of human biospecimens as well as clinical data about the biospecimen donor. Data will be collected about both living and deceased biospecimen donors. The Comprehensive Data Resource (CDR) is sufficiently scalable and configurable for deployment across biospecimen resources of varying size and function, and the management of multiple types of biospecimens (tissue, biofluids, nucleic acid). The tool will collect and store information about biospecimens and biospecimen donors in a format consistent with a HIPAA Privacy Rule Limited Data Set, including PII such as date of birth and other dates that are related to the clinical history of the donor and the collection, handling and processing of the biospecimens. The tool provides search functionality for both the biorepository staff and research scientists, who may be interested in searching for and requesting biospecimens for correlative science studies. Access to the system will be strictly controlled and role-based, such that individuals outside of the CDR will only have access to deidentified data.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass

through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): While the CDR will collect and store PII in the form of dates related to clinical services (e.g. date of surgery) and demographics (e.g. date of birth), all data will be completely deidentified (per HIPAA Privacy Rule) prior to being shared or disclosed. In addition, all research collaborators who receive data from the CDR will be required to sign a material transfer agreement that will include limitations on how data and biospecimens can be used and disclosed.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: 1. The CDR will collect, maintain, and store information related to the collection, processing, storage, quality assurance, and distribution of human biospecimens as well as clinical data about the biospecimen donor. Clinical data will include demographics, medical history, treatment, and outcome data for biospecimen donors.
- 2. The data is being collected and used for the purposes of biomedical research. The overall vision of caHUB is to contribute to medical advances by conducting and facilitating biobanking science and standards research. caHUB will systematically address the gaps in knowledge needed to improve the state-of-the-science and to strengthen the standards for human biobanking. Detailed information is needed about both the biospecimen and the biospecimen donor to allow a better understanding of the patient's disease as well as the how different variables associated with the collection, handling and processing of biospecimens affect overall biospecimen quality and the impact on downstream research.
- 3. The tool will collect and store information about biospecimens and biospecimen donors in a format consistent with a HIPAA Privacy Rule Limited Data Set, including PII such as date of birth. Information will include clinical data, such as dates of clinical procedures (e.g. date of surgery, date of diagnosis etc.). caHUB has entered into Material Transfer and Data Use Agreements with biospecimen source sites that provide the biospecimens and data and the agreements specify limitations on the use and disclosure of the PII.
- 4. All data are submitted voluntarily. In the case of living donors, informed consent will be required for submission of biospecimens and data to caHUB. For deceased donors, authorization will be required from the decedent's next-of-kin prior to collection of biospecimens and data). caHUB has entered into Material Transfer and Data Use Agreements with biospecimen source sites that specify limitations on the use and disclosure of the PII.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) 1. Consent will be obtained from biospecimen donors

for the collection and use of their clinical data for the caHUB project. The consent language describes the types of data that will be collected and the general types of research that will be performed as part of caHUB. The collection and submission of biospecimens and data will be overseen by the Institutional Review Board (IRB) at the collection site and re-contact for additional consent would be possible if deemed necessary.

- 2. In the case of living donors, informed consent will be required for donation of biospecimens and data to caHUB. For deceased donors, pre-consent from individuals (through living wills or registries) and authorization from the decedent's next-of-kin will be required prior to collection of biospecimens and data. The consent/authorization language describes the types of data that will be collected for caHUB. Donors or their next-of-kin will be given a paper copy of the consent/authorization for caHUB biospecimen and data submission.
- 3. The consent/authorization language for caHUB describes how the information will be used, including the types of biomedical research that are anticipated. The consent/authorization language also states that only deidentified data will be shared and describes the oversight mechanism for such sharing. All data will be completely deidentified (per HIPAA Privacy Rule) prior to being shared or disclosed.
- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The PII limited data set stored in the system is comprised of birth date, date of death, date of diagnosis, date of significant events (such as adverse events) is protected following NIST-SP800-112 "Guide to Protecting the Confidentiality of Personally Identifiable Information (PII) and NIST-SP800-53 security controls. The data has been qualified using NIST-SP800-112 criteria in the following way:

Identifiability: The information does not directly identify the individual, the data set is limited to date of birth, date of diagnosis, date of death and dates of treatment events (such as adverse events).

Quantity of PII: 1000 or more records

Data field sensitivity: the limited data set is considered low sensitivity since there are no direct identifiers or any other information linking the individual to the data.

Context of use: The release of the date of birth, date of death and date of diagnosis along with other treatment event dates would not likely cause harm to the individuals considering that it is not possible to directly identify the tissue donor by the data set collected.

Access to and location of PII: The information is accessed by NIH employees and contractors only. The data provided to end users of the system will be deidentified data per the HIPAA Privacy Rule.

Protection of the PII data policy: follows the NIH policy for PII protection found at http://oma.od.nih.gov/ms/privacy/pias.html.

Awareness, Training and Education: Follows NIH policy, yearly security awareness training.

Security Controls:

Access Enforcement (AC-3) Implements role-based access control, and data de-identification process

Separation of Duties (AC-5) De-identified data users do not have access to system administration or access to the database where PII limited data set is maintained.

Remote Access (AC-17) Remote access is protected through transport layer security (SSL) and is limited to the data contributors who are NIH / SAIC-F / sub-contractors. Other remote end users have access only to de-identified data.

User-Based Collaboration and Information Sharing (AC-21) Users who collaborate data to CDR do it under contract with the NCI-F and through transport layer security connections, end-users have access to deidentified data only through the caTissue web interface which is also protected using SSL and user name and password.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 4/1/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Cancer Imaging Program Cancer Imaging Camp application (CIP CIC)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: This is a minor app and does need a UPI

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0106

5. OMB Information Collection Approval Number: None

6. Other Identifying Number(s): NCI-79

- 7. System Name (Align with system Item name): NIH NCI Cancer Imaging Camp
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Nelya Gunina
- **10. Provide an overview of the system:** This application supports a workshop and allows potential participants of the to workshop to submit information to the workshop organizers.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The collected information is shared with the workshop 's reviewers and organizers.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: 5 U.S.C. 301; 44 U.S.C. 3101. Workshop participates post a limited ammount of work-related information and a presentation(s) to a website. IIF includes name, e-mail address, telephone number, CV,

institution, and their experiences. The information is used to identify the participants and collect their submission information. Information is submitted voluntarily.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) There are no procedures in place for notifying individuals when major changes occur to the system.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Information is secured using username/passwords, least privilege, separation of duties, an intrusion detection system, firewalls, locks, badge access, and background investigations. A comprehensive IRT capability is also maintained.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Blaise Czekalski

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Cancer Imaging Program Website (CIP)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: Not Applicable

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): Not Applicable

5. OMB Information Collection Approval Number: Not Applicable

6. Other Identifying Number(s): NCI-74

- **7. System Name (Align with system Item name):** Cancer Imaging Program http://imaging.cancer.gov
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Barbara Y Croft / Anne Menkens
- **10. Provide an overview of the system:** This is the public website for the NCI Cancer Imaging Program. It is used to provide information concerning the program to the public and research community.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No IIF in the system
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The Cancer Imaging

Program uses this website to disseminate information concerning the Program to the public. It is for information purposes. There is no IIF contained in the system. There is a webpage form used to generate an e-mail to CIP staff which allows individuals to ask questions. The information on the webpage is not kept and is the equivilant of an individual sending an e-mail to the program

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No IIF in the system

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No IIF in the system, however the site is protected by NCICB infrastructure security measures including firewalls, server password protection mechanisms and is monitored by the IRT for intrusion detection.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Cancer Information Service (CIS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH NCI CIS/Cancer.gov Sites
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Robert Zablocki
- 10. Provide an overview of the system: The system includes several search interfaces accessible through the Cancer.gov site (National Organizations That Offer Cancer-related Services, Resources for Financial Assistance for Patients and Their Families, and National Cancer Institute-designated Cancer Centers database search interfaces), and the LiveHelp Welcome Page. These are information sites meant to provide them search capabilities to retrieve list of organizations concerned with helping cancer patients and their families/friends or provide the public with access to "chat" with the NCI's Cancer Information Service.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The three search interfaces allows users to input their e-mail address in order to receive selected information via e-mail. E-mail addresses are not maintained or disseminated; e-mail addresses are provided voluntarily by users and are used only to provide requested information via this channel. Users have other print options available should they wish to have this information but not provide an e-mail address.

The LiveHelp Welcome Page provides users with access to the LiveHelp chat service manned by NCI's Contact Center staff, which is included in a separate PIA, NIH NCI CIS Extranet.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) E-mail address is not stored and so users cannot be contacted about major changes to the system. Online help files describe features/functions of the sites and are updated as changes are made.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:

 Only authenticated, authorized systems staff have access to the database.
- Controlled access to production servers; only Web administrator has this level of access.
- There is a designated deployment team and deployments are handled from a secure gateway with no connection to the Internet.
- Usernames and strong passwords are required for user access to production interface for database.
- · All production assets are in a central data center that has controlled and limited physical access.
- · Production environment is separate from development environment both logically and physically.
- Each application in the system has set user levels with different privileges assigned to each level.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Cancer Integrator (caIntegrator)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: No

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN

number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NCI-76

- 7. System Name (Align with system Item name): NIH NCI Cancer Integrator (caIntegrator)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Mervi Heiskanen
- 10. Provide an overview of the system: The caIntegrator knowledge framework provides cancer researchers with the ability to perform ad hoc querying and reporting across multiple domains of cancer data. This application framework comprises an n-tier service oriented architecture that allows pluggable web-based graphical user interfaces, a business object layer, server components that process the queries and result sets, a data access layer and a robust data warehouse. At the heart of caIntegrator is the Clinical Genomics Object Model (CGOM) that provides standardized programmatic access to the integrated biomedical data collected in the caIntegrator data system. Design of the CGOM is driven by usecases from two critical NCIsponsored studies, a brain tumor trail called GMDI (Glioma Molecular Diagnostic Initiative) and a breast cancer study called I-SPY TRIAL (Investigation of Serial Studies to Predict Your Therapeutic Response with Imaging And moLecular analysis). The model represents data from clinical trials, microarray-based gene expression, SNP genotyping and copy number experiments, and Immunohistochemistry-based protein assays. Clinical domain objects in CGOM allow access to Clinical trial protocol, treatment arms, patient information, sample histology, clinical observations and assessments. Genomic domain objects allow access to biospecimen information, raw experimental data, in-silico transformation and analyses performed on the raw experimental datasets and biomarker findings. The clinical and genomic findings domain objects have relationships to the FindingsOntology object, as the findings can be complex concepts which, in turn, can be generically represented as items occurring in an ontology (for example, WHO histopathological classification for brain tumor histology findings). caIntegrator supports the mission of the National Cancer Institute, NIH Center for Bioinformatics as a web application for cancer research.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This

question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The agency collects from authorized researchers, maintains, and disseminates via a strictly controlled process to authorized researchers de-identified medical data consisting of de-identified imaging and molecular analysis cancer data, including DNA snippets. This information is submitted on a voluntary basis. No personal information is collected.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No PII in the system.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): $\rm No$
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No PII in the system.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Cancer Therapy Evaluation System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-4902--00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: NA

6. Other Identifying Number(s): NCI-14

- **7. System Name (Align with system Item name):** NIH NCI Cancer Therapy Evaluation Program Enterprise System (CTEP-ESYS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Steve Friedman (George Redmond is alternate POC)
- 10. Provide an overview of the system: The purpose of the system is to assure patient safety and meet the NCI CTEP scientific, regulatory, administrative and operational program mission. Specifically, it is used to document, track, monitor and evaluate NCI clinical research activities. The Cancer Therapy Evaluation Program Enterprise System (CTEP-ESYS) project is the primary data collection mechanism for NCI's vast clinical trials program. CTEP-ESYS collects safety and clinical results data on ongoing cancer clinical trials (trials not yet completed). Data reporting and analysis in real time is critical to ensuring adequate monitoring of the ongoing clinical research. Timely data reporting and analysis also assures effective planning for the required successor studies, thus accelerating the evaluation of promising new agents and regimens for patients with cancer.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): CTEP-ESYS shares NCI Investigator and NCI Associates data with the Clinical Trials Support Unit (CTSU), a CTEP/NCI sponsored project to increase participation in NCI sponsored cancer related clinical trials. The CTSU system provides additional information about the clinical trials that are ongoing at various cooperative groups. With increased awareness and access to the trials information, CTEP intends to increase physician and patient participation in the NCI sponsored trials

CTEP-ESYS also shares IIF with NCI Center for Biomedical Informatics and Information Technology's Clinical Data System (CBIIT-CDS) to facilitate clinical trials related data collection functions that CBIIT-CDS application performs for CTEP-ESYS applications.

Some of the information that CTEP-ESYS shares with CTSU and CBIIT-CDS is also publicly available elsewhere.

This system falls under the guidelines of Privacy Act System of Records Notice 09-25-0200.

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Legislation authority is the Public Health Service Act (42 U.S.C. 241, 242, 248, 282, 284, 285a-j, 285l-q, 287, 287b, 287c, 289a, 289c, and 44 U.S.C. 3101.).

The types of data used are scientific and health data about cancer clinical trials, including clinical and pre-clinical data with associated regulatory and administrative supporting information. Patient participation in CTEP clinical trials is voluntary and participants in CTEP clinical trials sign an informed consent. Types of information available in the enterprise include protocols and protocol attributes, drug inventory and site distribution records, adverse event report, site audit reports, IND submission records, Investigator registration details, and Non-IIF patient accrual details. The information is used to assure patient safety, for scientific decision making, drug distribution, regulatory oversight (i.e., investigator registration, trial audits, etc.), and to facilitate administrative operations.

CTEP Staff routinely generate standard reports and request ad-hoc reports that display CTEP-ESYS data. The reports are used by CTEP Staff to analyze clinical trial operations and are also used to communicate with external collaborators. In addition to CTEP initiated reports, occasionally ad-hoc reports are created from CTEP-ESYS to support a response to a FOIA request.

In addition, CTEP has coordinated a procedure where commercial pharmaceutical companies can request reports that provide data related to adverse events and accrual of on-going cancer related clinical trials. This procedure requires review and approval by the CTEP Regulatory Affairs Branch (RAB) prior to the generation of reports.

PII collected include name, mailing address, phone number, and email.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) CTEP-ESYS collects Information in Identifiable Format (IIF) related to NCI Investigators and Associates who are aware of the intended purpose and usage of the information. NCI Investigators furnish their information to CTEP in a written application. NCI Associates furnish their information to CTEP via an online registration process. CTEP-ESYS users are required to acknowledge the NIH Privacy Policy posted on the Warning Banners prior to accessing the CTEP-ESYS.

Changes to CTEP-ESYS are managed and controlled via CMMI Level 3 compliant change management processes. All changes are discussed at and approved by Enterprise Change Management Committee (ECMC). ECMC memberships include, but not limited to, CTEP-ESYS Project Officers, CTEP Branch Chiefs, CTEP-ESYS contractors and CTEP-ESYS stakeholders.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: CTEP-ESYS data is maintained in a secure database. The following are in place as Management Controls:
- · Logon Banners
- · Rules of Behavior
- · System Security Plan
- · Configuration Management, Change Management Plans and Processes
- · Disaster Recovery Plan (tested)
- · Interconnection Security Agreement

The following are in place as Technical controls for CTEP-ESYS:

- · User ID and Passwords are required to login to CTEP-ESYS applications
- · The CTEP-ESYS application is hosted within NIH Network boundaries and is protected by NIH CIT provided Perimeter Firewall and Intrusion Detection Systems
- \cdot SSL Encryption is enabled for access to web based interfaces of CTEP-ESYS modules, where necessary
- · Proactive Systems Monitoring and Alerts Management
- · Anti-virus, security updates and patching procedures
- · Periodic SARA Scans for CTEP-ESYS systems
- · Incidence Response Procedures
- · System and Database Audit Trails and Logs

The following are in place as Operational controls for CTEP-ESYS:

· Personnel Security

- · Security Clearance Process for all contractor personnel working on CTEP-ESYS
- · CTIS Hiring and Termination Process
- · NIH Non-Disclosure Agreement for all CTIS employees working on CTEP-ESYS
- · Annual requirement by employee to take NIH CIT Security Awareness Training
- · Physical and Environmental Protection
- · Visitor Log Procedures
- · Backup Procedures
- · Offsite Storage for Tapes
- · Video Surveillance of Data Center
- · AC Maintenance Process
- · Contingency / Disaster Recovery Plan
- · Incidence Response Procedures
- · Alerts and Scans
- · Identification and Authentication
- · User Account Management Process
- · Role based user access to systems
- · Password Change Policies
- · Procedures for handling lost/compromised passwords
- · Audit Trails

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/30/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Cancer Trials Support Unit (CTSU

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: Requested

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN

number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: Requested

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): NIH NCI Cancer Trials Support Unit (CTSU)

- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Mike Montello
- 10. Provide an overview of the system: The Cancer Trials Support Unit (CTSU) is a service offered by the National Cancer Institute to enhance and facilitate access to cancer clinical trials for clinical investigators in the United States and Canada. The CTSU maintains a broad menu of trials developed by the adult cancer Cooperative Groups and other research consortia and works with these organizations to offer patient enrollment, data collection, data quality management, and enrollment reimbursement services to clinical sites entering patients in these trials. In addition, the CTSU offers a regulatory support service to all adult cancer clinical trials by collection of regulatory documents and maintenance of a national database of investigators and sites. The CTSU also provides education and training for clinical site staff and clinical trials promotion services to help increase enrollment in cancer trials. A large and complex information technology infrastructure has been developed to support CTSU operations and exchange data with other data centers involved in cancer research. Westat is the prime contractor on the project, having two subcontractors, and working with numerous other organizations.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): CTSU shares NCI Investigator and NCI Associates data with CTEP-ESYS a NCI sponsored project and other Cooperative Groups, to increase participation in NCI sponsored cancer related clinical trials

With increased awareness and access to the trials information, CTEP intends to increase physician and patient participation in the NCI sponsored trials.

CTSU shares this information, which may contain IIF, with lead research organizations for the purpose of assuring patient safety, for scientific decision making, drug distribution, regulatory oversight (i.e., investigator registration; trial audits) and to facilitate administrative operations.

CTSU also shares this information with the Cooperative Groups and with NCI Center for Biomedical Informatics and Information Technology's Clinical Data System (CBIIT-CDS). Some of this information is available to staff at Cooperative Group member sites on a limited basis

Some of the information that CTSU shares with CTEP and CBIIT-CDS is also publicly available elsewhere.

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Legislation authority is the Public Health Service Act (42 U.S.C. 241, 242, 248, 282, 284, 285a-j, 285l-q, 287, 287b, 287c, 289a, 289c, and 44 U.S.C. 3101.).

The types of data used are scientific and health data about cancer clinical trials, including clinical and pre-clinical data with associated regulatory and administrative supporting information. Patient participation in CTEP clinical trials is voluntary and participants in CTEP clinical trials sign an informed consent. Types of information available in the CTSU Enterprise include protocols and protocol attributes, Investigator registration details, and non-IIF patient accrual details. The information is used to assure patient safety, for scientific decision making, drug distribution, regulatory oversight (i.e., investigator registration; trial audits) and to facilitate administrative operations.

The CTSU collects and maintains various types of data.

Investigator and treatment site staff information is obtained from the CTEP-ESYS and maintained in the CTSU. Cooperative Group staff use this data to maintain their membership rosters. This data is used as part of the credentialing requirements for patient enrollments.

Protocol and regulatory information related to the member sites is collected and maintained in the CTSU Enterprise.

This data is disseminated to Cooperative Groups to support patient enrollment and data collection processes.

The CTSU also performs patient enrollments and will begin to collect demographic, eligibility criteria data, and other enrollment required data as part of this process. This data is collected on behalf of and shared with the organization that is leading a study.

For some studies, the CTSU performs the complete data management and collects/maintains the clinical data collected for a study and disseminates it to the organization leading the study.

Patient participation in CTEP clinical trials is voluntary.

PII collected and maintained includes name, date of birth, social security number, mailing address, phone number, medical records number, medical notes, and email address.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Users that access the systems must reregister on an annual basis and any changes would be communicated through that process.

NCI Investigators furnish their information to CTEP in a written application. IIF related to the Regulatory Support System (RSS)/Financial Management System (FMS) [JM1] are supplied to the CTSU at the time of account request via a standard application.

Participating research organizations require trial participants to sign an authorization to use or disclose identifiable health information for research. A subject cannot enroll in a study without providing one of these release forms. They can withdraw the authorization at a later time, but then must leave the study. The link to the form is

https://members.ctsu.org/readfile.asp?sectionid=1&fname=HIPAA/NSABP_HIPAA_Permission 030503.pdf&ftype=PDF

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: CTSU data is maintained in a secure database

The following are in place as Management Controls:

- · Rules of Behavior
- · System Security Plan
- · Configuration Management, Change Management Plans and Processes
- · Disaster Recovery Plan
- · Interconnection Security Agreement

The following are in place as Technical controls for CTSU:

- · User ID and Passwords are required to login to CTSU applications
- · The CTSU application is hosted within Westat Network boundaries and is protected by Westat provided Perimeter Firewall and Intrusion Detection Systems
- · SSL Encryption is enabled to access web based interfaces of CTSU modules, where necessary
- · Proactive Systems Monitoring and Alerts Management
- · Anti-virus, security updates and patching procedures
- · Periodic vulnerability scans for CTSU systems both internal and external
- · Incidence Response Procedures
- · System and Database Audit Trails and Logs

The following are in place as Operational controls for CTSU:

- · Personnel Security
- · Security Training/Clearance Process for all personnel working on CTSU
- · Westat Hiring and Termination Process
- · Non Disclosure Agreements for all employees working on CTSU
- · All employees take/review NIH CIT Security Awareness Training on an annual basis
- · Physical and Environmental Protection
- · Visitor Log Procedures
- · Backup Procedures
- · Offsite Storage for Tapes
- · Video Surveillance of Data Center
- · AC Maintenance Process
- · Contingency /Disaster Recovery Plan tested regularly (last test on 11/2/08)
- · Incidence Response Procedures
- · Alerts and Scans
- · Identification and Authentication

- · User Account Management Process
- · Role based user access to systems
- · Password Change Policies (in sync with CTEP-ESYS)
- · Procedures for handling lost/compromised passwords
- · Audit Trails

The system falls under the Privacy Act System of Records Notice 09-25-0200

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/30/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Career Development (K) Awards Outcome Evaluation

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0156

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH NCI Career Development (K) Awards Outcome Evaluation
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Julie L. Mason
- **10. Provide an overview of the system:** The NCI Center for Cancer Training has contracted with Discovery Logic to conduct a retrospective outcome evaluation of the NCI career development (K) awards program. The goal of this evaluation is to determine career outcomes, program effectiveness, and the impact of NCI K awards on career progression. For the purposes of this evaluation, Discovery Logic is collecting pre-existing information on the demographics, characteristics, and outcome metrics of NCI K applicants, grantees, and scholars. All data collected for this evaluation are extracted from extant data sources including the National Institutes of Health (NIH), National Science Foundation (NSF) and the American Association of Medical Colleges (AAMC).
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Per SORN 09-25-0156, disclosure may be made to HHS contractors and collaborating

researchers, organizations, and State and local officials for the purpose of conducting evaluation studies or collecting, aggregating, processing or analyzing records used in evaluation studies. The recipients are required to protect the confidentiality of such records and must comply with the administrative, physical, and procedural safeguards outlined in the SORN 09-25-0156 to protect the data records.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) For this evaluation, the NCI Center for Cancer Training (CCT) is not collecting any new information from the public because it is already in existence from outside sources populated by National Institutes of Health (NIH), National Science Foundation (NSF) and American Association of Medical Colleges (AAMC) data sources.
- (2) The data are used only for CCT program evaluation and reporting analysis, and are provided in aggregate form without identifying information.
- (3) The information includes PII such as NCI career development applicants/awardees/trainee names, date of birth, personal mailing address, personal phone numbers, personal email address, employment status, gender, race/ethnicity, degree, degree year, subsequent grant funding activity, publications, patents, professional society memberships, advisory committee service, faculty and career appointments.
- (4) The evaluation data are populated by existing NIH, NSF, AAMC data sources and publically available data sources that collect both voluntary and mandatory information.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.
- (Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The system does not collect any information directly from the public. The system is not publically accessible and the information is not disclosed except as permitted by the Privacy Act and in compliance with the provisions of SORN 09-25-0156. All data for the NCI Career Development (K) Awards Outcome Evaluation are pulled from extant data sources. The services contract that NCI Center for Cancer Training has with Discovery Logic for this evaluation has a one-year period of performance, and no changes will be made during that time.
- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The contractor, Discovery Logic, addresses

the operating risks of its business applications and systems by applying environmental and physical controls to all on-site information processing systems. Data are housed in a physically secure facility with protection from environmental risks such as fire and water damage, as well as protection from external breaches. Physical and environmental security controls protect the facility housing system resources, the system resources themselves, and the facilities used to support their operation. Access to Discovery Logic computing facilities is restricted using physical security and video surveillance. Employee access to Discovery Logic facilities is controlled via badge readers and video surveillance. Visitors entering the Discovery Logic facilities must sign a visitor log and be escorted at all times. Discovery Logic server rooms are protected by additional physical door locks as a secondary control. Audit logs provide additional protection. The server room has physical locks and video surveillance and only a limited number of DL staff are permitted access.

Discovery Logic maintains a secure internal network. The assets in the internal network are kept secure by a firewall, which inspects all data transmissions entering or leaving the internal network, and permits or denies network transmissions based on a set of rules. The firewall limits access to the server with the PII data to internal Discovery Logic users. No users outside of the Discovery Logic internal network will be able to access this server. A user's login ID and password has system-defined rights to specific servers and drives, determined by the System Security Officer (SSO) when the login ID and password are assigned, which means that project members can access only servers and drives within their work group and not those of other groups. Project team members are provided levels of access according to the requirements of their job function. The required level of access is dependent on the nature of the data to which access is being requested; the extent of access, such as read or write privileges; the extent of discretion in handling data; and the possibility of changing data without an audit trail. Once a decision has been made to grant access to specific project team members, appropriate system accounts and temporary passwords are created. Permission is granted to each account as required to complete job functions.

To protect sensitive data, the Discovery Logic network administration team performs network and system/application audits to protect the confidentiality, integrity, and availability of information assets. Digital information is continuously evaluated and protected against all forms of unauthorized access, use, disclosure, interruption, modification, destruction, removal, or loss.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/30/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI CB CaArray PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: Not Applicable

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NCI-28

- **7. System Name (Align with system Item name):** CaArray (Director's Challenge Toward a Molecular Classification of Cancer)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: JJ (Jeng-Jong) Pan
- **10. Provide an overview of the system:** caArray is an open-source, web and programmatically accessible array data management system. caArray guides the annotation and exchange of array data using a federated model of local installations whose results are shareable across the cancer Biomedical Informatics Grid (caBIGTM). caArray furthers translational cancer research through acquisition, dissemination and aggregation of semantically interoperable array data to support subsequent analysis by tools and services on and off the Grid. As array technology advances and matures, caArray will extend its logical library of assay management.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Clinical investigators/submitters are asked to provide their professional contact information in order to further scientific collaboration and provide a point of contact for their area of interest/research. Personal email addresses, mailing addresses and phone numbers may be unintentionally provided by the investigator/submitter in lieu of professional information.

Personally identifiable information in the form of contact information for the clinical investigator/submitter can be obtained from caArray on the Contacts tab once a particular experiment is selected/accessed. This information (which is provided voluntarily by the investigator/submitter) is shared to encourage scientific collaboration and the aggregation of semantically interoperable array data which will allow for easier subsequent analysis.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) Clinical investigators/submitters are asked to provide their business contact information, including name, mailing address, phone number, and e-mail address.
- (2) Professional contact information is collected in order to identify the researcher and associate the researcher with a particular experiment or other collected research information.
- (3) This information does ask for PII, but investigators may unintentionally provide personal contact information.
- (4) The submission of this information is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) NCI will post notices on the caArray website to inform clinical investigators/submitters of:

- (1) major changes that occur to the caArray system that may affect the use/disclosure of PII in the system;
- (2) changes in the type of PII to be collected from them;
- (3) any changes to how PII is used or shared.
- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: System uses firewalls, passwords, locks, id badges, background investigations, network monitoring and an Incident Response team.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Pla

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI CB Clinical Trials - Bioinformatics [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-4917-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): NCI-27

- 7. System Name (Align with system Item name): NCI CB Clinical Trials Bioinformatics
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Christo Andonyadis
- **10. Provide an overview of the system:** The Cancer Centralized Clinical Data System (C3DS) is leading the National Cancer Institute's (NCI) effort to create and distribute information technology infrastructure to support the conduct all aspects of NCI's supported clinical trials. Public Health Act, Title 42, Chapter 6A, Subchapter III, Part C, Subpart 1, Sec. 285, Sec. 285A And 44 U.S.C. 3101
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): PII data is limited to the doctors and nurses specifically linked to that study.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: PII includes patient initials,

DOB, Medical Notes and Medical Record Numbers. The C3D will collect clinical trial data for efficacy analysis and safety monitoring. Clinical Centers collect the data that is stored in C3D voluntarily.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Notification and consent for individuals is covered under the Privacy Policy provided on the site. All NCICB websites contain a Privacy Preference statement which enables NCICB to express its privacy practices in a standard format that can be retrieved automatically and interpreted easily by user agents to automate decision-making based on these practices when appropriate

Notices of consent is provided via an electronic notice. (in both machine- and human-readable formats).

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: System uses firewalls, passwords, locks, id badges, background investigations, network monitoring and an Incident Response team. This system falls under the Privacy Act System of Records Notice 09-25-0200.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI CB Mouse Models (CaMOD)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-4919-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NCI-30

- 7. System Name (Align with system Item name): NIH NCI CB Mouse Models
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Juli Klemm
- **10. Provide an overview of the system:** The NCI Mouse Models of Human Cancers Consortium (MMHCC) is a collaborative program designed to derive and characterize mouse models, and to generate resources, information, and innovative approaches to the application of mouse models in cancer research. In addition to the MMHCC initiative, the NCI sponsors numerous other projects to develop, analyze, and apply mouse cancer models. This NCI Mouse Model project provides the cancer research community with information about mouse models and mouse research generated by the MMHCC and other NCI-supported projects. Public Health Act, TITLE 42, CHAPTER 6A, SUBCHAPTER III, Part C, subpart 1, Sec. 285, Sec. 285a and 44 U.S.C. 3101
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Clinical investigators/submitters are asked to provide their professional contact information in order to further scientific collaboration and provide a point of contact for their area of

interest/research. Personal email addresses may be unintentionally provided by the investigator/submitter in lieu of professional information. Personally identifiable information in the form of contact information for the clinical investigator/submitter can be obtained from caMOD on the Model Characteristics page once a particular experiment is selected/accessed. This information (which is provided voluntarily by the investigator/submitter) is shared to encourage scientific collaboration and allows users to query the Cancer Models database for models submitted by researchers, and retrieve information about the making of models, their genetic description, histopathology, derived cell lines, associated images, carcinogenic agents, and therapeutic trials.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) Clinical investigators/submitters are asked to provide their business contact information, including name and e-mail address.
- (2) Professional contact information is collected in order to identify the researcher and associate the researcher with a particular experiment or other collected research information.
- (3) This information does contain PII.
- (4) The submission of this information is voluntary.

This system falls under the Privacy Act System of Records Notice 09-25-0200.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) NCI will post notices on the caArray website to inform clinical investigators/submitters of:

- (1) major changes that occur to the caArray system that may affect the use/disclosure of PII in the system;
- (2) changes in the type of PII to be collected from them;
- (3) any changes to how PII is used or shared.

This system falls under the Privacy Act System of Records Notice 09-25-0200.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No

- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: System uses firewalls, passwords, locks, id badges, background investigations, network monitoring and an Incident Response team.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI CBIIT Portfolio Manager System (CPMS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH NCI CBIIT Portfolio Management System (CPMS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Dwayne Forquer
- **10. Provide an overview of the system:** The NCI-CBIIT Portfolio Management System (NCPMS) will be the data repository for the NCI Center for Biomedical Informatics and Information Technology to maintain information related to projects and project management, contracts and contracts budgeting and finances. The system will be implemented using a phased approach. Phase One, described in this PIA will house contract information such as Contract numbers, Workspace, Budget, Status, Funding, etc. Future phases will incorporate systems inventory data, programs office data, etc.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $N\!/\!A$

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system collects project contracts information including contract status, budget, and financial information related to project contracts. The data contained in the system ONLY represents federal contact data including contact name, phone number and email. No PII in the system. This information is provided voluntarily. The collected information will be used for contracts/project management.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A - No PII in the System.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A No PII in the system.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/30/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Central European Renal Cell Cancer Follow-Up Study (CERCC)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: NA

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN

number is required for Q.4): NA

5. OMB Information Collection Approval Number: 0925-New

6. Other Identifying Number(s): CAS 10420

7. System Name (Align with system Item name): NIH NCI Central European Renal Cell Cancer Follow-Up Study (CERCC)

9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Lee E Moore

10. Provide an overview of the system: In addition to publications of benefit to the scientific community, data collected will be used to assess the 5-year survival status of kidney cancer patients that had participated in a case-control study to assess the prevalence of recurrent disease and progression, and to investigate patient, tumor and genetic determinants of survival in cases. This information will be used to identify prognostic indicators of survival that will be used to identify determinants of high-risk patients in effort to reduce disease mortality. The information will be collected in the study centers by PIs and questionnaires and abstraction forms will be immediately coded with a personal identification number before questionnaires are sent to the International Agency for Research on Cancer in Lyon France. Here they will be made into an electrnoic format and forwarded to the NCI. All disks will be mailed and require a password that will be given by phone in order to open the coded files. Information that will be collected will include patient related factors (age, sex, tobacco usage), tumor related factors (anatomic site, histology, disease staging, tumor size, extension) and treatment related factors (surgery, radiotherapy, chemotherapy, resection margins). Biologic prognostic characteristics of kidney cancer subsets will be measured and correlated with mortality to identify predictive indicators of disease outcome. The four outcomes we intend to evaluate specifically include; 1) Renal Cell Carcinoma (RCC) death, 2) Alive at 5-years with disease recurrence (same clinical stage or disease independent of primary tumor), 3) Alive at 5-years with disease progression (disease presents at higher clinical stage than primary diagnosis), and 4) Censored (alive at 5-years, lost to follow-up, or died of other causes). As in the case-control study, physicians and experienced medical staff will be employed to abstract hospital records, pathology reports, and treatment information on coded forms that do not contain personal idenfying inforantion. After we distinguish the types of follow-up protocols used and procedures followed in each country, we will develop a definition of those cases confirmed to be disease-free (using high-confidence methods, i.e. CT, PET, laboratory methods other), and patients for whom follow-up was not

confirmed, incomplete, or undetermined ("low confidence confirmation") so that we can stratify by this variable and conduct restricted analyses. We plan to collect information on methods used to evaluate disease status. Treatment variables will be grouped into broad categories and will be used as adjustment variables. Lastly, we will initiate follow-up at date of diagnosis and collect survival at 5-years, controlling for treatment and perhaps with time dependent co-variables for treatment duration as needed. We will not discount any time during cancer treatment towards survival as this could make more advanced cases with longer treatment duration incorrectly appear to have a longer disease-free survival.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): NA
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The agency will collect information as variables that is coded with a personal subject ID code that will inform us of the survival status of individuals who had previously participated in a case-control study of kidney cancer conducted in central Europe. This information includes date of death, cause of death, and date of last follow-up in a hospital by a physician. We will also receive information regarding the stage and grade of the cases tumor if they recurred or progressed. We will also receive in a coded manner information on the type of surgical and medical treatment procedures used to treat primary disease.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) This work will be conducted in the study centers in Central europe and we will not be involved nor have access to any material with names of cases. Briefly, once individuals have agreed to participate at each center, cases and next-of-kin to cases will be given a paper consent form to sign by the study center Principal Investigator. This form informs them of the procedures involved in the study, tells them about the questionnaire and how

this follow-up study related to the original study, states that there will be no compensation or payment for completion of the questionniare, described the potential discomfort, risks, and benefits. It also assures the patient or next-of-kin of confidentiality of the information collected at each study center, of their rights as a participant, and certifies that they have read the form, and whether they agree (yes/no) to participate in the interview, and whether they agree for us to access their hospital records.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: PII will never be on the system.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Central Institutional Review Board (CIRB)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: Requested

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): SORN 09-25-0200

5. OMB Information Collection Approval Number: Requested

6. Other Identifying Number(s): NCI Control No. N02CM-2008-00010

7. System Name (Align with system Item name): NIH NCI Central Institutional Review Board (CIRB)

- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Mike Montello
- **10. Provide an overview of the system:** The overall purpose of the NCI CIRB data systems is to provide comprehensive informatics support for a centralized process of facilitating Institutional Review Board (IRB) activities for National Cancer Institute (NCI) Cooperative Group clinical trials. The NCI CIRB data systems is comprised of 3 modules and fulfills multiple functions: 1) to enroll local sites with their contacts and track their local IRBs, 2) to manage study-related documents and other information, 3) to convey study and board review information to sites and collect from sites facilitated review acceptance forms via the web, 4) to track and report on CIRB help desk issues, and 5) to track and report on board membership attendance and management of board member reimbursement.

The three modules are comprised of the Membership Attendance and Tracking (MAT) internal database, and CIRB HelpDesk Application internal database (CHAD) maintained by EMMES; the CIRB Enrollment System (CES), CIRB Website hosted by CTIS; and, IRBManager webbased application hosted by BEC.

Information is sent from IRBManager to the CIRB oracle database which serves as the backend of the CIRB website. The MAT and CHAD databases are internal systems used for operations and do not exchange information.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether

provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): IRB Manager and CIRB Web Site, both of which are modules of the CIRB system, exchange study information and related documents. The CIRB web site includes both password-protected and publicly available sections. Some of the information exchanged is also publicly available elsewhere. This system falls under the guidelines of Privacy Act System of Records Notice 09-25-0200.
- **30.** Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Legislation authority is the Public Health Service Act (42 U.S.C. 241, 242, 248, 282, 284, 285a-j, 2851-q, 287, 287b, 287c, 289a, 289c, and 44 U.S.C. 3101.), CFR Title 45 Part 46 (Protection of Human Subjects), and CFR Title 21 Part 50 (Protection of Human Subjects) and Part 56 (Institutional Review Boards).

The types of data used are both scientific and administrative and used to inform board members concerning the studies under review, manage the operations and communications of Adult and Pediatric Central Institutional Review Boards, and convey information to sites concerning studies reviewed by the CIRB and decisions made by the CIRB.

The CIRB Operations Office staff routinely generates standard and ad-hoc reports, including quality control metrics that display CIRB information concerning studies, Boards, local sites, local site IRBs, and Operations Office activities.

Personal information provided by Board members is provided as part of their voluntary service to the CIRB and the NCI. Names and contact information provided by contacts at the local sites and IRBs is provided by site representatives on a voluntary basis but required for effective participation of their site in the CIRB Initiative.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The CIRB collects IIF from Board members and local sites using forms that may be completed as hard or electronic copies and mailed or emailed to the Operations Office for data entry. Board members and site representatives are aware of the purposes for which their contact information will be used. Privacy statement is available

electronically and additional privacy statement information is shared during enrollment application process.

Changes to CIRB processes, including development, utilization, or revision of CIRB information systems and using or sharing of data, are subject to review and approval by an NCI Project Officer. IT Change Management processes are in place at the respective contractor or subcontractor.

Users that access the systems must reregister on an annual basis and any changes would be communicated through that process.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: CIRB data is maintained in secure databases

The following are in place as Management Controls:

- Login Banners
- · Rules of Behavior
- · System Security Plan
- · Configuration Management, Change Management Plans and Processes
- · Disaster Recovery Plan

The following are in place as Technical controls for CIRB:

- Network security via User ID and Password login
- · User ID and Passwords required to login to CIRB applications
- The CIRB applications are hosted within Network boundaries and protected by Perimeter Firewall and Intrusion Detection
- · SSL Encryption is enabled for access to web based interfaces of CIRB modules, where necessary
- Proactive Systems Monitoring and Alerts Management
- Anti-virus, security updates and patching procedures
- Periodic scans for CIRB systems both internal and external
- Incidence Response Procedures

· System and Database Audit Trails and Logs

The following are in place as Operational controls for CIRB:

- · Personnel Security
- · Security Clearance Process for designated contractor and subcontractor personnel working on CIRB
- · Contractor and Subcontractor Hiring and Termination Process (NIH suitability investigations for key personnel)
- NIH Non-Disclosure Agreement for all contractor and subcontractor employees working on CIRB
- · Annual requirement for all employees to take/review NIH CIT Security Awareness Training
- · Physical and Environmental Protection (including individualized door entry cards and photo ID)
- · Visitor Log Procedures
- · Backup Procedures
- · Offsite Storage for Tapes
- · Video Surveillance of Data Center
- · AC Maintenance Process
- · Contingency / Disaster Recovery Plan
- · Incidence Response Procedures
- · Alerts and Scans
- · Identification and Authentication
- · User Account Management Process
- · Role based user access to systems
- Password Change Policies (for systems per NIH requirements)
- · Procedures for handling lost/compromised passwords
- Audit Trails

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI CIS Extranet PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0106

5. OMB Information Collection Approval Number: 0925-0208

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH NCI CIS Extranet
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Robert Zablocki
- **10. Provide an overview of the system:** The CIS Extranet houses documentation, resources, and applications needed by the Cancer Information Service, NCI Project Office, and CIS Central Support offices to respond to inquiries and manage operations. Access to 3rd party and custom applications are controlled through this site through a single sign-on via a CIS Extranet account.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): PII collected in the Electronic Contact Record Form (ECRF) about an interaction with the public may pass through name, mailing address, and e-mail address information to the Publications Enterprise system for fulfillment of publication requests. Information collected in ECRF for research purposes may be sent via encrypted exports to researchers for analysis and follow-up. The CIS Directory contains names and business contact information for employees and contractors working in the CIS program. The Gift Fund database contains names and addresses of NCI donors, honorees, and family contacts.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Through the various access channels (chat, e-mail, mail, and phone) clients may voluntarily provide PII and other information including name, address, phone number, e-mail address, health information, and demographic information during the inquiry response, materials ordering, or research participation processes. This information is only used to provide the requested services to the client, or shared with researchers during the course of a research study. Aggregate information that is not personally identifiable is used to describe and improve our services. The CIS Directory contains name and business contact information for employees and contractor working in the CIS program. The Gift Fund database contains names and addresses of NCI donors, honorees, and contacts to send acknowledgement of donations.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Individual public users of the Cancer Information Service cannot be contacted when major changes are made to the CIS Extranet and its applications because contact information is purged on a rolling basis every 90 days. On the LiveHelp chat welcome page, a written privacy notice is posted letting users know the service is anonymous and asking not to send PII during the chat. For PII collected during a phone call, Information Specialists read a statement to clients that information provided will be kept confidential, and research studies contain their own additional informed consent statements that are read to clients.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:

 Only authenticated, authorized systems staff have access the production database.
- Controlled access to production servers; only Web administrator has this level of access
- There is a designated deployment team and deployments are handled from a secure kiosk with no connection to the Internet
- · Usernames and strong passwords are required for user access to production interface for database

- · All production assets are in a central data center that has controlled and limited physical access
- · Production environment is separate from development environment both logically and physically
- Each application in the system has set user levels with different privileges assigned to each level

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Clinical Data System Web

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 9/13/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH NCI Clinical Data System Web
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Christo Andonyadis
- **10. Provide an overview of the system:** CDSWeb is proprietary software used by NCI clinical trial sites to report clinical trial administrative data, accrual and adverse events. Users of the CDSWeb system enter study administrative data, participant demographics data and optionally, adverse event data. This data can be entered throughout the course of the study but must be submitted at the end of each quarter. Once the data is processed and accepted by CTEP-ESYS, the finalized dataset is stored in the CTEP database, which is a system separate from CDSWeb.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\rm N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: 1) The data collected is basic demographic data, treatment course data and adverse event data. The data is de-identified and does not contain PII.

- 2) This data is collected to monitor, evaluate and administer clinical trials.
- 3) CDS Web does not contain any PII.
- 4) N/A
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) 1) N/A

- 2) N/A
- 3) N/A
- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Clinical Research Information Exchange Federal Investigator Registry (CRIX FIREBIRD) PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: Not Applicable (this is a minor application)

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: Not Applicable

6. Other Identifying Number(s): NCI-75

- **7. System Name (Align with system Item name):** Clinical Research Exchange Federal Investigator Registry CRIX FIREBIRD
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Jose Galvez, MD
- 10. Provide an overview of the system: The Federal Investigator Registry of Biomedical Informatics Research Data (FIREBIRD) is a software application that supports electronic submission of clinical trial investigator information to trial sponsors and regulatory bodies. It is the first module realized from the vision of the Interagency Oncology Task Force (IOTF), a partnership of the National Cancer Institute (NCI) and the Food and Drug Administration (FDA), to create an electronic infrastructure for the submission of regulatory data. Through a single web-based platform, investigators will be able to maintain a secure profile of the most common information required when participating in drug trials.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The IIF may be shared with Pharmaceutical companies and the Food and Drug Administration

via an Oracle link. The IIF is under SOR 09-25-0200, Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The agency collects voluntarily given data on researcher's name, birth date, mailing address, phone numbers, e-mail address, Medical license number and the State in which it was issued, and the researcher's Unique Physical ID number (UPIN) in order to identify the researcher to authorized viewers and provide contact information and credential information to authorized users. The National Cancer Institute authorizes all users.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Researchers give only their own personal information and do so voluntarily. The Firebird web site will disclose any changes to how IIF is used or shared on the website itself.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The IIF will be secured by management, operational, and technical controls. Some of these controls include user identification and authentication, public key encryption (PKI) certificates, the concept of least privilege, and firewalls. The PKI certificates will be validated by NCI. Infrastructure product, username and password, annual risk assessments, background checks on administrative employees, and key locks, cipher locks and keycards necessary to enter server rooms.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Clinical Trials Monitoring Service (CTMS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: In Process

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH NCI Clinical Trials Monitoring Service (CTMS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Gary L. Smith
- 10. Provide an overview of the system: The Clinical Trials Monitoring Service assists the Cancer Therapy Evaluation Program in fulfilling it's responsibilities to the FDA by providing:

 1). a centralized protocol patient data capture and quality control review system for clinical investigators conducting phase 0, phase 1 and selected phase 2 clinical trials. 2). an on-site auditing resource for phase 0, 1 and selected phase 2 clinical trials 3). a mechanism for assuring compliance with Clinical Trials Monitoring Branch (CTMB) Guidelines for Monitoring Clinical Trials for Cooperative Groups, Community Clinical Oncology Program, and Cancer Trials Support Unit via a co-site visitation process. 4). The DCTD that Cancer Centers and single institutions participating in clinical trials utilizing DCTD sponsored IND agents/funds are in compliance with federal regulations, and NCI policies and procedures. 5). A mechanism to provide administrative and audit support to international groups/institutions collaborating with DCTD to ensure compliance with Good Clinical Practices.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): CTMS shares data with DCTD for oversight and monitoring of clinical trials. Data from CTMS is downloaded into the Clinical Data System, a component of the CTEP-ESYS.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: CTMS collects contact information of investigators or research staff for the purpose of correspondence related to the conduct of NCI sponsored clinical trials. Most of the information that CTMS collects is non-IIF, and is publicly available elsewhere. CTMS doesn't require or collect IIF from investigators or research staff, but they may submit IIF unintentionally (such as home address, personal email accounts, etc.).

CTMS does collect patient information related to birth date (mm/dd/yy). This information is needed to ensure protocol eligibility requirements are met. Collection of any IIF related to patients participating in NCI sponsored clinical trials that CTMS may inadvertently receive in paper format is not accepted at CTMS and is returned to the institution to be redacted to ensure patient privacy and confidentiality. CTMS stores patient data in de-identified format.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) CTMS collects protocol patient data. All the data is deidentified and would not fall into the category of IIF. If IIF is accidentally submitted, which rarely occurs, it is CTMS policy to return it to the submitting institution for de-identification. The only data item that may be considered IIF is the patient's/participant's birthdate. This data element is used (particularly for pediatric patients) to ensure that protocol specified eligibility criteria relating to age restrictions are adhered to. Patients/participants are informed and sign an informed consent acknowledging that data will be collected as part of their participation in a clinical trial. The data is collected at the research institution (covered entity) and transmitted via electronic data capture system, to CTMS.

CTMS collects information on NCI Investigators in order to perform their responsibilities for oversight and monitoring of clinical trials. The information includes investigator name, address, email address and telephone number. This information is often collected through other CTEP systems, such as Investigator Registration System Filing System or CTEP-ESYS and transmitted to CTMS. Investigators are aware of the need to collect such data as part of the 1572 process required for all investigators. The information is used for correspondence purposes, reimbursement of outside physicians participating in Cancer Center Site Visits, and other activities in carrying out CTMS's mission. This data is used for internal administrative purposes

only such as site visit attendance, travel arrangements, hotel bookings and follow-up correspondence with the specific individual. It is not released to any outside entity.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: CTMS data is maintained in a secure database.

The following are in place as Administrative Controls:

- · Personnel Security
- Background Investigation Process for all personnel working on CTMS
- · CTMS Hiring and Termination Process
- Theradex Non-Disclosure Agreement for all CTMS employees working on CTMS
- Annual requirement by employee to take NIH CIT Security Awareness Training
- · Rules of Behavior
- · System Security Plan
- · Configuration Management, Change Management Plans and Processes
- · Contingency / Disaster Recovery Plan
- · Incident Report Procedures

The following are in place as Technical controls for CTMS:

- · Identification and Authentication
- User Account Management Process
- · Role based user access to systems
- Password Change Policies
- · Procedures for handling lost/compromised passwords
- · Audit Trails
- The CTMS application is hosted within Theradex Network boundaries and is protected by Theradex-provided Perimeter Firewall and Intrusion Detection Systems
- · Proactive Systems Monitoring and Alerts Management
- Anti-virus, security updates and patching procedures
- · Incidence Response Procedures
- · System and Database Audit Trails and Logs

The following are in place as Physical controls for CTMS:

- · Physical and Environmental Protection
- · Visitor Log Procedures
- · Backup Procedures
- · Offsite Storage for Tapes
- · AC Maintenance Process
- · Alerts and Scans
- · Back-up Generator
- · Alarmed Server Room
- · Limited access Server Room
- · Isolated Servers

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Consortia Data Transfer Website (CDT)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: Not Applicable

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No
- **5. OMB Information Collection Approval Number:** No
- **6. Other Identifying Number(s):** No
- **7. System Name (Align with system Item name):** NIH NCI Consortia Data Transfer Website (CDT)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Anne Ryan (Troy Budd is alternate POC)
- **10. Provide an overview of the system:** The DCP Consortia Clinical Data Transfer (CDT) Website is an Internet web portal that provides DCP and Consortia clinical data management staff with access to study-specific SAS datasets and reports of clinical data entered in DCP OC-RDC. It also provides a platform to publish any network announcements and/or updates regarding DCP Consortia clinical data management.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No IIF is present in the system
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Type of data available in CDT include adverse events, agent information, discrepancies reports and Non-IIF participant level data. The CDT Website is designed for the users from seven different clinical sites as well as DCP and Westat. Each site has an individual user content area from which the approved users can access and download the study-specific datasets and reports and view user profiles.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No IIF is present in the system

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No IIF is present in the system

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Continuation of Follow-up of Des-exposed Cohorts - IMS

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

- 3. Unique Project Identifier (UPI) Number:
- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A
- **5. OMB Information Collection Approval Number:** Clinical exemption applied for, no ID number assigned yet
- **6. Other Identifying Number(s):** No
- 7. System Name (Align with system Item name): Continuation of Follow-up of DES-exposed Cohorts
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Dr. Robert Hoover
- **10. Provide an overview of the system:** The National Cancer Institute (NCI) Combined DES Cohorts Follow-up Study is a nationwide research study following more than 21,000 women and men to learn as much as possible about the long-term health effects of DES exposure. The NCI study is the largest ongoing research study on long-term health and DES exposure. Five research centers in the United States carry out the DES Follow-up Study, coordinated by NCI. Leaders in DES research and education are responsible for the study and are dedicated to increasing scientific and medical knowledge about DES exposure. The research team includes physicians, epidemiologists, researchers, and DES advocates and educators.

IMS provides data management and analytical support for the DES followup . The support includes statistical analysis, creation and manipulation of analysis files, graphics generation, and reporting for analytical projects. The tasks covered under this PIA include:

- · Assist in the design of statistical analyses and reports.
- Design and create analysis files.
- · Program analyses using SAS software.
- · Quality Control of data and reports.
- . Document the data elements and project requirements.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system.

This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): DES Study Center Principal Investigators can view the data for research purposes.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The PII collected and stored in the system may include:
- Date of Birth
- · Date of Death
- Date of Last Contact
- Vital Status
- Gender
- · Cancer Diagnosis

The data are used to investigate the relationship between DES exposure and health outcomes.

Collection of this information is a voluntary process, as part of the study followup. This information will be used for analysis and reporting purposes.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) For this study, completing a questionnaire is voluntary. They have the option to refuse participation or complete the questionnaire. If medical records or tissue slides are necessary for disease confirmation, participants are sent a consent form with a written explanation of the purpose of the additional data. For the questionnaire, options are provided to refuse to participate in a single follow-up or to decline all future participation. Participants can contact study centers via phone, mail, or email, and through these contact options, participants can ask the study sites to have their data expunged from the study.

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No

- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The PII will be secured in a similar fashion to that of other data stored in the system. Briefly, security measures include:

System Monitoring

Automated audit trails are monitored on all server-based systems deployed at IMS. Audit records and server logs will be reviewed daily for anomalies. An automated reporting tool will be used to analyze the server logs to look for abnormal activity. Automated audit trails also play an important part in governing the access granted to users outside the Contractor's Local Area Network (LAN). A firewall is in place that logs all incoming and outgoing connections to the LAN. This includes connections to the UNIX/Linux workstations and the Windows servers. This log will be maintain and checked for evidence of attempted unauthorized access to the Contractor's LAN.

Computer Center Administrative and Physical Safeguards

IMS' Standard Operating Procedure (SOP) for Computer Resource Security details the standards and processes used to ensure the security of the computer resources and data. All IMS employees will be required to read and follow this SOP.

IMS' computer center has facilities in Silver Spring, MD and in Sterling, VA. The Sterling, Virginia site will be used for production services that require 24/7 accessibility. This site has personnel on site 24-hours a day in a facility that requires a key card and fingerprint for access. The facility also provides protection against fire and flood with highly sensitive monitoring equipment. Generators are available to provide continuous electricity in case of a main power failure.

The Silver Spring computer center is in a separate office with a key coded access lock. Each person authorized to access the computer center has a personal ID and password that must be entered each time the door is opened. A log of any attempt to enter the computer center is maintained. This log is routinely reviewed to identify any potential security risks. Visitors are never allowed into the computer center at either site. Maintenance and repair personnel will be escorted into the computer room and then monitored until all work is complete.

IMS employs firewalls with Intrusion Detection capabilities to secure the network perimeter. The firewalls are continually monitored. Reports are distributed to authorized administrators twice daily for their review. Computer center staff performs weekly security checks using Security Auditor's Research Assistant (SARA), a third generation UNIX-based security analysis

tool. IMS routinely reviews the security check results and rectifies any identified potential security vulnerabilities.

Registration of authorized users on IMS' Network is controlled by the IMS system administrator. To enter the network, the user must have an authorized user ID and a password which must be changed every 60 days. Network privileges are established which set access rights and restrictions to network resources. Access privileges to sensitive data and operating systems within the network is controlled by user ID. Authorized users have specific levels of access, such as "read only" or "read and write".

Use and disclosure policy

As part of IMS' employee orientation, each new employee reviews an overview of security policies and guidelines for IMS. Each new employee is required to sign a confidentiality agreement and complete the on-line NIH computer security and privacy awareness training courses. The confidentiality agreement requires that no data be released without the written authorization of the owner. In addition, the on-line NIH computer security refresher course will be completed annually by all employees.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Continuation of Follow-up of DES-exposed Cohorts - Westat

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): SORN 09-25-0200
- 5. OMB Information Collection Approval Number: Clinical Exemption-02-01-04
- **6. Other Identifying Number(s):** No
- **7. System Name (Align with system Item name):** NIH DES Follow-up Study Coordinating Center Management Systems
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Dr. Robert Hoover
- **10. Provide an overview of the system:** The DES Follow-up Study Coordinating Center Management System maintains participant information to support activities conducted for the Principal Investigators and staff at the study centers. Support activities include tracking the receipt of data collection forms during Follow-Ups, coordinating the review of pathology slides, coordinating submittals for National Death Index searches, coding of medical records and death certificates, receiving results from cancer registry searches, providing study status reports, and monitoring data for quality control.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): PII is disclosed to the National Center for Health Statistics (NCHS) for National Death Index (NDI) searches .

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Participants provided their name, mailing address, phone number, date of birth, and social security number to the specific study center which enrolled the participant. Participants may also provide to the study centers race, ethnicity, email addresses and updates to addresses and phone numbers during follow-ups or when contacted for other reasons. PII was voluntarily provided by participants after study consents were signed. Names and contact information are maintained by the individual study site which enrolled the participant and this PII is not disseminated to the other study sites. The study sites may send PII to the coordinating center for a specific purpose (e.g., a NDI search.) The coordinating center destroys contact information after the task is completed. Participants can decline future participation at anytime through phone calls, emails or letters to the study centers.

PII is disclosed to the NCHS for a NDI search.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Participants signed Consent Forms upon enrollment and if contacted for a Follow-up they are given a written explanation of the purpose of the follow-up. Providing any information is voluntary for this study. Options are provided to refuse to participate in a single follow-up or to decline all future participation. Participants can contact the study centers via phone, mail, or email to decline participation.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The following classes of controls are in place to protect the participant PII: access control including user account management, access enforcement, password strength, least privilege concept, session termination; security awareness and training; audit and accountability; configuration management; contingency planning; identification and authentication for users, devices; incident response including training, testing, monitoring; timely and controlled maintenance; media protection; physical and environment controls such as id badges, physical access authorization using access cards and keyed locks for building and room entry, monitoring, visitor control, emergency power, and shutoff, disaster protection and recovery; system security plan; personnel security; rules of behavior; risk assessment planning, monitoring, update; technical and communication protection including denial of service protection; boundary protection, programmable firewalls, establishment of

network zones with varying levels of restrictions; transmission integrity; security certificates, encryption, regular virus detection and monitoring; policies and procedures are in place for each control class.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI DCEG Intramural (DCEG)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-4926-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NCI-17

- **7. System Name (Align with system Item name):** NCI DCEG Information System (Intramural)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Nelya Gunina
- **10. Provide an overview of the system:** This system allows the users in the Division of Cancer Epidemiology and Genetics (DCEG) to analyze costs of scientific studies and provide more efficient and accurate reporting to both NIH and NCI. Public Health Act, TITLE 42, CHAPTER 6A, SUBCHAPTER III, Part C, subpart 1, Sec. 285, Sec. 285a and 44 U.S.C. 3101
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No PII in the system
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Work-related information is

used from other systems. This includes name, work address, e-mail address, and phone number for government employees. A limited amount is entered by staff. This includes such things as research title, research description, lead investigator, collaborators, risk factors, study type, cancer sites, research category, common scientific outlne coding, keywords, and study population accrual. Information is then available for dissemination about the research within NCI and to the NIH.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No PII collected

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No PII collected. System uses firewalls, passwords, locks, id badges, background investigations, network monitoring and an Incidence Response team.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI DCP Collaboration Repository (DCPCR)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: No

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: Not Applicable

6. Other Identifying Number(s): No

- **7. System Name (Align with system Item name):** NIH NCI DCP Collaboration Repository (DCPCR)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Anne Ryan (Troy Budd is alternate POC)
- **10. Provide an overview of the system:** The DCPCR provides the means for DCP and its contractors to centralize the management of project collateral. It serves as a single point of access from which DCP and its contractors can obtain and share timely and accurate DCP enterprise information in an organized environment. Documents are posted to topic-specific content areas to which user access is authorized by DCP based on user role/function within DCP or a DCP contractor organization.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): DCPCR information is shared with the Food and Drug Administration (FDA) to fulfill regulatory requirements. However the FDA does not interface directly with DCPCR. The IIF is under SOR

09-25-0200 Clinical, Basic, and Population-based Research Studies of the National Institutes of Health (NIH), HHS

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: DCP collects researcher's name, date of birth, mailing address, phone numbers, financial information, education records and military status in order to identify, review and approve individuals to conduct NCI DCP clinical trials.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Personally Identifiable information (PII) is provided to fulfill regulatory requirements and is for internal DCP use only.

Investigators provide PII using the FDA 1572 form and required supporting documentations (e.g., CV, financial disclosures, medical licenses, etc...). The 1572 form is signed and submitted by the investigator with the understanding that DCP will use and disclose PII information as needed to fulfill its regulatory requirements.

FDA tasks DCP with maintaining these documents to fulfill responsibilities as sponsor of clinical research trials.

Investigators can withdraw the consent provided by the 1572 but then they can no longer participate in the study. As FDA, no investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c)).

Changes are communicated at the time they are identified per DCP SOPs.

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Administrative controls includes SOPs, policies and guidelines. Technical controls includes user identification and authentication, an

Intrusion Detection System, logon warning banners, the concepts of least privilege and firewalls. Physical controls include server room, proximity card entry, an automatic fire suppression system and surveillance video. This system falls under System of Records Notice 09-25-0200.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI DCP Enterprise System Knowledgebase (DESK)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-4903-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NCI-45

- **7. System Name (Align with system Item name):** NIH NCI DCP Enterprise System Knowledgebase (DESK)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Anne Tompkins / Troy Budd
- **10. Provide an overview of the system:** DESK is an enterprise database with a suite of applications that support the scientific and administrative work of the NCI Division of Cancer Prevention (DCP) and its mission. Specifically, the DESK is used to document, track, monitor and evaluate DCP clinical research activities. DESK enables DCP to collect, analyze and report adequate clinical trials data to fulfill NCI, NIH and DHHS requirements.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No IIF is present in the system
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: Type of data available in DESK include protocol attributes, site and investigator contact information, agent information, IND records, adverse events, site audit reports, and non-IIF patient level data. The information is critical to track the receipt, abstraction, review, approval and implementation of clinical trials; it is also used to facilitate administrative operations (including reporting), support scientific decision making, regulatory oversight, and future planning of clinical trials.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No IIF is present in the system

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No IIF in the system.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Bruce Woodcock

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI DCTD Developmental Therapeutics Program (DCTD DTP)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NCI-22

- **7. System Name (Align with system Item name):** NIH NCI DCTD Developmental Therapeutics Program (DCTD DTP)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Daniel Zaharevitz
- 10. Provide an overview of the system: This is the NCI DCTD DTP Program website.

The main function of the DTP web site is to provide the research community with access to DTP data, policies and procedures. The data include over 250,000 chemical structures, growth inhibition data in human tumor cell lines for over 40,000 compounds, gene expression data measured in human tumor cell lines, results in mouse tumor models for over 100,000 compounds and much other data. Almost all of this data is freely available to all and no registration is required and no personal information is collected. The exception is for people who wish to submit compounds for testing. They must register and personal information necessary to contact them is collected (name, address, phone, email).

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No IIF in the system
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Public Health Act, TITLE 42, CHAPTER 6A, SUBCHAPTER III, PART C, subpart 1, Sec.285, Sec. 285a, and 44 U.S.C. 3101. General Program and support information for grantees and clinical trial personnel. Workplace contact information is collected for users that wish to submit compounds for screening. No IIF is collected.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No IIF, however investigating partners are emailed notification of use of information.

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No IIF collected. We have business contact information with business partners.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI DEA General Support System

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH NCI Division of Extramural Activities (DEA) General Support System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Greg Fischetti
- **10. Provide an overview of the system:** The NIH NCI DEA General Support System provides multiple applications for DEA and NCI staff which support the business processes involved with the referral and review of contract proposals and grant applications, concept tracking and reporting for the Board of Scientific Advisors, management of the National Cancer Advisory Board, and coordination of the National Advisory Act by the Committee Management Office.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\rm N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: The NIH NCI DEA General Support System provides multiple applications for DEA and NCI staff which support the business processes involved with the referral and review of contract proposals and grant applications, concept tracking and reporting for the Board of Scientific Advisors, management of the National Cancer Advisory Board, and coordination of the National Advisory Act by the Committee Management Office.

BSA: Concept/Program/Funding Opportunity meta data and approvals

CATS: Workflow and Concept meta data

CI: Offeror Name, Org. Evaluation Criteria, Meeting data

DOCS: Meeting Roster including names, degrees, grant applications, staff phone & email, standard per diem raters

ES: NCI staff Name, userId, title, org., office, phone, fax, email, classes, course attendance

FOAE: Workflow and FOA data

FOAR: FOA data, Application data, Application funding data

GL: Dictionary terms

IRG: Application data, Review recommendations and scoring

PC: Grants and contracts are coded by NCI staff to allow categorization of research dollars. The information about Principal Investigators is their person ID, name, and degree.

PRS: Meeting data, meeting roster, application data, review scores

REVCD: Application data, meeting data, meeting roster, FOA data, review guidelines, summary statements, application supplemental material, conflict of interest data

RPDU: Application data, PI name and institution, application

The DEA GSS processes only federal contact data. No PII is collected.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A - No PII in the system.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A - No PII In the System.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote **Sr. Official for Privacy Name:** Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Early Detection Research Network (EDRN)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH NCI Early Detection Research Network (EDRN)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Christos Patriotis
- **10. Provide an overview of the system:** Public face of EDRN, a project of the Cancer Biomarkers Research Group of the Division of Cancer Prevention of the National Cancer Institute. The EDRN site provides information for the general public and prospective members about EDRN research, cancer detection, and funding opportunities. EDRN members may log in to gain further information including science data and information on unreleased biomarkers.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): No PII in the system.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: Federal contact data is solely contained within the system and is generally available elsewhere through other applications and channels (such as institution/university staff directory). The purpose of repeating such information within the application is to simplify accessibility for EDRN research partners. There is no information gathered from the public. There is no public PII in the system. Submission is entirely voluntary. Information includes EDRN member name, job title, work email address, departmental home page URL, institution mailing address, institution telephone and fax number, and institution online directory photograph.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No PII in the system.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No PII in the system. Authorized personnel have physical access to server but may only access hardware. Digital information restricted to internal hard drives.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/30/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI e-Grants/web-Grants (e-Grants)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-04-00-02-4930-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NCI-38

- 7. System Name (Align with system Item name): NCI e-Grants/web-Grants
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Terry Dunne
- **10. Provide an overview of the system:** The eGrants/web-Gran-ts provides online access over the web to the official grant files including the ability to search for particular grants or documents.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The name and contact information is shared with the NIH IMPACII system. Other information is not shared. Sharing is done in accordance with SOR 09-25-0036.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Authority for collection of this information is 5. U.S.C. 301; 42 U.S.C. 217a, 241, 282(b)(6), 284a, and 288. 48 CFR

Subpart 15.3 and Subpart 42.15. IIF contained in this system consists of the following information about grantees: name, social security number, mailing address, telephone number, financial information, e-mail address, education records, and a notice of grant award. This is information is maintained as part of the grants management system. The majority of this information is not shared outside of NCI. The name and contact information is shared with the NIH IMPAC II system. Information is submitted voluntarily.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) There is no process in place to notify individuals in the event of major changes to system.

The grantees submit their information voluntarily and are made aware that it will be used in the grant funding process.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Information is secured using username/passwords, least privilege, separation of duties, an intrusion detection system, firewalls, locks, badge access, background investigations. A comprehensive IRT capability is also maintained.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Electronic Early Concurrence System (EEC)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: Not Applicable

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: Not Applicable

6. Other Identifying Number(s): NCI-41

- **7. System Name (Align with system Item name):** NCI DEA Electronic Early Concurrence System (EEC)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Greg Fischetti
- **10. Provide an overview of the system:** Records National Cancer Advisory Board concurrence and Program staff approval for early funding of highly scored grant applications. Public Health Act, TITLE 42, CHAPTER 6A, SUBCHAPTER III, Part C, subpart 1, Sec. 285, Sec. 285a and 44 U.S.C. 3101 The system downloads basic grant data from IMPACII and allows a limited number of the NCAB Members, who are special government employees, to indicate whether they concur with the initial peer review. The system also allows NCI Program Directors to indicate whether there are any reasons the grants would not be currently eligible for payment
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No Data is shared.

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: System records approvals by NCAB and program staff. The only information about the Principal Investigators that is downloaded from IMPAC II is the Principal Investigator Name. The system maintains Name and email address for the 4 NCAB members. The system also maintains a list of NCI Program Directors which has their name, email, and phone number. This information is available to the public via the NIH Web Site.

The PI names are used along with Grant Number and Title to assist staff in identifying the grant application, the NCAB Member and Staff email addresses are used to send email reminders. No information from the system is published, it is just used by NCI Grants Management staff in helping to determine whether to send early concurrence letters to applicants.

Submission of information is voluntary.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) All data is collected and maintained by the NIH Grants Management System (IMPAC II), so notifications would be handled by that system. Changes to the NIH Grants Management System are announced in the NIH Guide.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Information is secured using username/passwords, least privilege, separation of duties, an intrusion detection system, firewalls, locks, badge access, background investigations. A comprehensive IRT capability is also maintained..

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Pla

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Employee Database Internet Edition

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-90-0018

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH NCI Employee Database Internet Edition (EDie)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Bob Barber
- **10. Provide an overview of the system:** EDie is a web-based application that allows institutes to accurately maintain individual employee, contractor, and volunteer information, as well as plan for, monitor, and report on workforce staffing levels.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Information is intended for internal senior administrative use only and will not be shared with other entities. Refer to SORN 09-90-0018.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: EDie is a web-based

application that allows institutes to accurately maintain individual employee, contractor, and volunteer information, as well as plan for, monitor, and report on workforce staffing levels. All information collected is pertinent to a personnel file and represents only federal contact data. The EDie system does contain PII data as described in question 17 of the PIA. There are many uses for this information: (a) tracking a time-limited appointment to ensure renewals are done in a timely manner thereby avoiding any break in service; (b) ensuring that allocated FTE ceilings are maintained; (c) ensuring salary equality for various hiring mechanisms; (d) the ability to provide reports requested by the NIH Director; (e) maintaining lists of non FTEs, special volunteers, contractors, etc. Information is mandatory at time of hire.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Information is collected from documents provided by employees (CV, resumes, etc.) at the time of appointment; it is provided in personnel packages submitted through channels in order to effect a hire. This information is put into Capital HR and Fellowship Payment System (FPS) and subsequently downloaded into EDie. Individuals are notified of the collection and use of data as a part of the hiring process. Changes to the system or use of the information is relayed to employees via official notices from HR and the system owner.

- 1) N/A: EDie is not the point of original collection of this data.
- 2) EDie is a reporting system which inherits PII data from other official HR systems. Currently, no users have access to SSN, DOB, Home address thru the EDie application.
- 3) We do not expect any significant changes to the system functions related to PII; If this happens, HR and the system owners will notify all affected employees electronically (e-mail).
- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Access to sensitive data fields is limited on need to know basis. Each user signs a security statement and received a password. Any violations result in loss of access to system. Information is also secured by separation of duties, and intrusion detection system, firewalls, locks and background investigations. A comprehensive IRT capability is also maintained. This systems falls under System of Records Notice 09-90-0018.

EDie employs access control policies (NIHNet single sign-on) and access enforcement mechanisms (access control lists) for authentication. Additionally, access enforcement mechanisms are employed at the application level in the form of user assigned groups to further increase security within EDie. Each group has different access privileges. Access can be restricted by content and organization.

From a Physical Access perspective, the Executive Boulevard building is accessible to the public during regular business hours. There is one security guard on duty during regular business hours (8:00 AM -6:00 PM weekdays). The guard is retained by NCI to make frequent foot patrols of the entire building and surrounding areas (including the basement and garage), and one security guard desk at the entrance to the building. Due to the shared roles of offices housed in the building, it is not possible to verify that all NIH visitors to NCI offices have a proper NIH ID badge, or to require non-NIH visitors to sign a visitor log and be escorted. There is an administrative assistant stationed inside the front door of the NCI offices during regular business hours.

There is a guard on patrol duty through midnight on weekdays. Access to the building and elevators is restricted by access card on nights and weekends. Cardkeys, cipher locks, and/or keys are required for access to the NCI suites, the computer room, and rooms containing communications equipment. Access to the computer room and rooms containing communications equipment is limited to a small number of personnel.

Departing employees and contractors are required to turn in their identification badges, cardkeys, and keys as part of the exit process. NCI Administrative Officer is responsible for the control and return of keys and the reporting of stolen keys. NCI Cardkey Coordinators are responsible for the control and return of cardkeys and the reporting of lost/stolen cardkeys.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Enterprise Services and Clinical Trials Reporting Program

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: None

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: 0925-0600

6. Other Identifying Number(s): None

- **7. System Name (Align with system Item name):** NIH NCI Clinical Trials Reporting Program (CTRP)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Jose Glavez, MD
- **10. Provide an overview of the system:** The Clinical Trials Reporting Program (CTRP) is a web-based program to submit data about cancer-related clinical trials and to search for data concerning cancer-related clinical trials. The CTRP system is an electronic resource that is intended to serve as a single, definitive source of information about all NCI-supported clinical research. Deployment of this resource will allow the NCI to consolidate reporting, aggregate information and reduce redundant submissions. Information will be submitted by clinical research coordinators as designees of clinical investigators who conduct NCI-supported clinical research.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Only designated, appropriate NCI program and administrative employee and contractor staff will have full access to the data within the CTRP Database for purposes of portfolio management and

compliance with regulatory and administrative reporting obligations. Access will be limited to those with a direct need to access the data. Access will be granted to non-Federal staff under a non-disclosure agreement and staff will be given mandatory privacy and security training

Individual submitters to the CTRP Database will have full access to information they have submitted.

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) Clinical investigators are requested to provide their professional contact information, including name, business mailing address, business phone numbers, and business e-mail address. In addition, clinical investigators and/or study coordinators are requested to provide the following elements for study subject accrual information:

- submission title
- submission cut-off date (MM/DD/YYYY)
- description
- study subject ID
- study subject birth date (MM/YYYY)
- study subject gender
- study subject race
- study subject ethnicity
- study subject zip code
- study subject country
- registration date (MM/DD/YYYY)
- study subject method of payment
- disease
- participating site name

(2) The information is collected for purposes of portfolio management, compliance with regulatory and administrative reporting obligations and appropriate dissemination of cancer research information to the public. The information will be made available to designated, appropriate NCI employee and contractor staff for purposes of portfolio management and compliance with regulatory and administrative reporting obligations. Access will be limited to designated, appropriate NCI employee and contractor staff with a direct need to access the data. Access to PII will be limited to designated, appropriate NCI employee and contractor staff with a direct need to access the data. Access will be granted to non-Federal staff under a non-disclosure agreement and staff will be given mandatory privacy and security training.

- (3) The information contains the following PII: study subject birth date (MM/YYYY), study subject gender, study subject race, study subject ethnicity, and study subject zip code. Although CTRP uses a Study Subject ID to identify an accrual record on a given study, this ID is not linked to information concerning a study subject.
- (4) Submission of this information is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) NCI will post written notices on the web site portal for the CTRP system to inform clinical investigators/research coordinators of:

- (1) major changes that occur to the CTRP system that affect disclosure and/or uses of PII in the CTRP system;
- (2) changes in the type of PII to be collected from study subjects; and
- (3) any changes to how PII is used or shared (from current practice of making PII collected from study subjects available only to designated, appropriate NCI employee and contractor staff on a "need to know" basis for purposes of portfolio management and compliance with regulatory and administrative reporting obligations).
- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The PII will be secured by management, operational, and technical controls. Some of these controls include user identification and authentication, the concept of least privilege, and firewalls. Infrastructure product, username and password, annual risk assessments, background checks on administrative employees, key locks and keycards necessary to enter server rooms.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Enterprise Vocabulary System (EVS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-4920-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NCI-29

- 7. System Name (Align with system Item name): NIH NCI Enterprise Vocabulary System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Gilberto Fragoso
- **10. Provide an overview of the system:** NCI Enterprise Vocabulary Services (EVS) provides resources and services to meet NCI needs for controlled terminology, and to facilitate the standardization of terminology and information systems across the Institute and the larger biomedical community.

Two key terminology resources are produced and published by EVS:

NCI Thesaurus is a reference terminology used in a growing number of NCI and other systems. It provides rich textual and ontologic descriptions of some 50,000 key biomedical concepts.

NCI Metathesaurus is a comprehensive biomedical terminology database, connecting 2,500,000 terms from more than 50 terminologies, including some propriety vocabularies with restrictions on their use.

EVS is a partnership between the NCI Office of Communications and the NCI Center for Bioinformatics. It is a key component of the cancer Common Ontologic Resource Environment (caCORE) and the cancer Biomedical Informatics Grid (caBIG), and is used in the NCI Web Portal and Physician Data Query (PDQ) cancer information services.

A new wiki-based component of the EVS system is being constructed to facilitate collaborative vocabulary development with NCI partners.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the

character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The new wiki-based application allows end-users to create web pages to share with other end-used of the system. The end-users might do this to add additional contact information that they wish to share with other end-users, as the purpose of the wiki-based application is to foster collaborative development of vocabularies to be served by the EVS. The professional/business information is not observable by non-registered users of the application.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: 1. The system collects the end-user's email address.
- 2. The information is collected so that password information can be automatically sent on request by the end-user.
- 3. No other PII other than the email address is required for a person to register.
- 4. Entering this information is mandatory for end-users of the system.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) 1. Notifications will be posted on the wiki-based applications home page, as well as advertised on a listserv. 2. The nature of the information collected from end-users will be posted in a privacy notice on the web site, as well as 3. the use which the EVS will make of this information.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Access to raw data will be controlled through file permissions, database roles and user groups. Files will be backed up regularly and stored off site. User access with write permissions will be credentialed (username/password),

and internet access will be protected by a firewall, and encryption used where necessary (login through https). The production servers are physically secured, in facilities operated by NCI/CBIIT.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote **Sr. Official for Privacy Name:** Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Environmental and Genetic Lung Etiology (EAGLE)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: None

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: None

6. Other Identifying Number(s): NCI-80

- **7. System Name (Align with system Item name):** NIH NCI Environmental and Genetic Lung Etiology (EAGLE)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Anand Basu
- **10. Provide an overview of the system:** Environmental and Genetic Lung Etiology (EAGLE) is an interdisciplinary multi-center case-control study of lung cancer conducted in Milan, Italy, designed to explore the genetic determinants both of lung cancer and smoking. The objectives of the EAGLE study, as identified by DCEG, are as follows:
- Perform genetic profiling of study participants by 15STR markers
- · Conduct analysis of gene expression in adenocarcinoma lung cancer tissue of smokers and non-smokers
- · Identify histologic characteristics of lung cancer in relation to genotype, gene expression, somatic mutations, and smoking
- · Monitor therapy efficacy and survival of lung cancer patients
- · Identify lung cancer-affected siblings of cases and the unaffected siblings in the same sibs hips
- Perform integrative analyses of the above-mentioned datasets in the context of the epidemiological data from the study.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the

character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No IIF
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The agency voluntarily collects from authorized Researchers, maintains, and disseminates via a strictly controlled process to authorized researchers de-identified medical data consisting of de-identified molecular analysis cancer data, including DNA snippets. No personal information is collected.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No IIF is collected

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No IIF

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Fiscal Linked Analysis Research Emphasis (FLARE) [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-26-02--4920-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): NCI-18

- **7. System Name (Align with system Item name):** NIH NCI Fiscal Linked Analysis Research Emphasis (FLARE)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Elaine Taylor
- **10. Provide an overview of the system:** Supports Science Area Coding of grants and contracts for categorization of research dollars
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The system does not collect, process, or share PII.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Grants and contracts are coded by NCI staff to allow categorization of research dollars. The information about Principal

Investigators is their name, institutional address, and degree. Government POC information contains only organizational contact data. No PII is collected.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A - No PII in the system.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No PII in the System.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Genesys WFM PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH NCI Genesys WFM
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Robert Zablocki
- **10. Provide an overview of the system:** Genesys WFM uses historic contact center data concerning the various points of access (phone, chat, e-mail) to determine future volumes and staff needs. The system is used to create schedules for contact center staffing.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\rm N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: This system is used to forecast contact center staffing needs and create staff schedules. Data collected and stored in this system contains no personally identifiable information. Only information such as agent names, skill sets, and work schedules are stored in this application along with details about each interaction (i.e., handling time, time interaction arrives, time to complete interaction, etc.). The

application also allows reporting of planned and unplanned daily and intraday activities such as meetings, days off, holidays, etc. to further record events, improving forecasting and staffing assessments.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Not applicable since there is no PII in the system.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Not applicable since there is no PII in the system.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Global Specimen Identification Service (GSID)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 9/13/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH NCI Global Specimen Identification Service (GSID)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Dr. Ian Fore
- **10. Provide an overview of the system:** This system provides a single point of service to other software systems on the caBIG grid for managing Global Specimen Identifiers (GSIDs). There is no human interface. The grid service creates GSIDs, registers them with information about the requesting institute, verifies that GSIDs are unique (or reports the institute the GSID is associated with), and supports a directed graph of relations between GSIDs (e.g., parent-child relations).

No PII information can be stored, or requested, via this service.

- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: 1) The system generates unique identifiers (128 bit numbers) for software connected to this service, and stores that number, along with reference material (login information) about the institute requesting the unique identifiers. The system does not contain Federal contact data and does not collect or store any other organizations' or users' PII data. Information stored is the individual GSIDs, the relation between multiple GSIDs, and the institute which requested that individual GSID
- 2) The individual GSIDs are stored to assure uniqueness when new GSIDs are requested. The relations between GSIDs are stored to allow systems to retrieve relation data between specimens (e.g., a specimen is an aliquot of another). The institute information is stored to allow for tracking back to individual specimen repositories.
- 3) None of this information is PII.
- 4) N/A no personal information is collected.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) $\rm\ N/A$

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Health Information National Trends Survey

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH NCI Health Information National Trends Survey (HINTS) Web site
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Lewellyn Belber
- 10. Provide an overview of the system: The HINTS Web site presents data collected by the Health Information National Trends Survey. It offers the datasets for download as well as graphic data for use by journalists, policy-makers, and the general public. The survey has been fielded 3 times since 2003, and includes data from over 6000 respondents. The respondents are members of the general public, selected at random, and the survey questions have to do with how they get health information, how well they understand that information, what they know about the risks associated with various types of cancer, and other similar questions. The data is in aggregate form and includes no personally identifiable information (PII). No PII is collected or maintained by the Web site.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The system does not share or disclose PII.

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system maintains and disseminates aggregate survey results.

The information is made available to researchers in the form of downloadable datasets and to the general public, as tabluar and graphical data from individual survey questions.

The information does not include PII.

Although submission of personal information is not possible though the HINTS Web site, any survey response information provided is done so on a voluntary basis.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) There is no PII in the system.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: There is no PII in the system.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 5/6/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Health Information National Trends Survey 4 (HINTS 4)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 9/13/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200
- 5. OMB Information Collection Approval Number: 0925-0538 approval pending
- 6. Other Identifying Number(s): none
- **7. System Name (Align with system Item name):** NIH NCI Health Information National Trends Survey 4 (HINTS 4)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Terisa Davis
- **10. Provide an overview of the system:** HINTS is a survey of the adult US population authorized by the Public Health Services Act, Sections 411 (42 USC, 285a) and 412 (42 USC 285a-1.3). The HINTS system will collect information on people's cancer communication practices, information preferences, risk behaviors, attitudes, and cancer knowledge. Data will be collected via mailed paper surveys over the course of four data collection cycles. In addition, the system may collect a name, mailing address, personal phone number, military status and employment status.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The only provision under SORN 09-25-0200 for which disclosure is anticipated is for employees of Westat who are working on the study and will need access to the PII in order to complete the study. PII will not be shared with anyone outside of Westat. The routine use of records under

SORN 09-25-0200 includes the following provisions for disclosure: 1) For a research purpose (e.g., records of tumors for cancer registries); 2) To a member of Congress; 3) To the Dept. of Justice for litigation purposes; 4) To those working on the study (agency, contractors, consultants, etc); 5) To Federal agencies to obtain information on morbidity and mortality experiences; 6) Public health purposes (e.g. notifying partners of sexual disease); 7) Health service providers for reimbursement purposes; and 8) Reporting spousal or child abuse. HINTS 4 does not collect most of these categories of PII.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: 1. Government Authorization: The Public Health Services Act, Sections 411 (42 USC 285a) and 412 (42 USC 285a1.1 and 285a1.3).
- 2. Purpose of Collection: HINTS will allow NCI and the cancer communications community to refine its communication priorities, identify deficits in cancer-related population knowledge, and develop evidence-based strategies for selecting the most effective channels to reach identified demographic population groups, including typically underserved populations such as minorities and persons living in poverty.
- 3. The information collected does contain some limited PII. The PII that will be collected includes: name, mailing address, personal phone number, military status, and employment status.
- 4. Voluntary or Manditory: Information is provided on a voluntary basis only.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) 1. No changes in disclosure or data use will be permitted without explicit consent from each survey respondent. In the unlikely event that permission needs to be sought, consent forms will be sent by US Postal Service to each respondent.

- 2. Information about the study and data disclosure is provided to respondents in written form along with the survey instrument. Completion and return of the survey is considered consent to participate.
- 3. PII is used during the data collection period to accurately track study respondents. After the field period, identifying information will be removed from the database and destroyed. The PII is not shared with anyone outside of limited study staff (at Westat). Identifying information on respondents will not be shared with NCI either during or after the study.
- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:

- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: PII is secured using password-protected networks, system firewalls, and keycards/identification badges for all physical locations. Data is maintained in a secure database. Information is secured on teh system through access controls, personal security awareness and training, regular auditing of information and information management processes, careful monitoring of the information system, control of changes to the system, appropriate handling and testing of contingencies and contingency planning, ensuring that all users are properly identified and authorized for access, and that they are aware of the rules and acknowlege that fact, by ensuring that any incident is handled expeditiously, properly maintaining the system and regulating the environment the system operates in, controlling media, evaluating risks and planning for information management and information system operations, by ensuring the system and any exchange of information is protected, by maintaining the integrity of the system and the information stored in it, and by adhering to the requirements established in the contract and statement of work.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 10/11/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI IMPAC II Extensions (IMPAC II)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-04-00-02-4904-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NCI-1

- 7. System Name (Align with system Item name): NIH NCI IMPAC II Extensions (IMPAC II)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Nelya Gunina
- **10. Provide an overview of the system:** This system extends the NIH IMPACII extramural information to include the specifics of the NCI extramural business process of grant portfolio management. This includes the transition from a paper business process to an electronic process across the life cycle of an NCI sponsored grant. Comprehensive Minority Biomedical Branch (CMBB) has been rolled into IMPAC II Extensions. CMBB provides metrics to assess the success rate of the NCI CMBB program and to provide grantees information about other training opportunities.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): No information is shared. Disclosures permitted in SOR 09-25-0036 are not utilized.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Authority for collection of this information is 5. U.S.C. 301; 42 U.S.C. 217a, 241, 282(b)(6), 284a, and 288. 48 CFR Subpart 15.3 and Subpart 42.15. The IIF that the system captures on the public concerns only grantees and is obtained from the NIH IMPACII system and the NIH Data Warehouse. The IIF that the system directly collects is about individuals employed by NCI and involved in the grants business process. IIF includes, name, work address, work phone number, and financial account information. Information is given voluntarily.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) We have a agreement with IMPAC II that describes what data we will receive and limits how it will be used. If we need to change how it will be used, the agreement will be renegotiated and notification and consent issues will be part of any new agreement.

Individuals are notified and consent to the use of their information in this type of system is given when they receive grants or are hired by the government.

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Information is secured using username/passwords, database roles, least privilege, separation of duties, an intrusion detection system, firewalls, locks, badge access, background investigations. A comprehensive IRT capability is also maintained.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Inherited Bone Marrow Failure Syndrome Study (IBMFS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: CE-02-01-04

6. Other Identifying Number(s): IBMFS

- **7. System Name (Align with system Item name):** NIH NCI Inherited Bone Marrow Failure Syndrome Study (IBMFS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Blanche Alter, M.D., MPH
- **10. Provide an overview of the system:** IBMFS is an MS Access 2007 Application comprised of a user interface and database. The study aims to identify cancer prone families before the appearance of cancer, by virtue of their underlying genetic hematologic disease. The system manages the data collection activities of study participants. Contact information is maintained. Statuses for consents, clinic visits, biospecimen collections, and self-administered questionnaires are tracked. Reports list deliquent and expected events as well as summarize study progress.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): PII may be shared with collaborators, the NIH clinical center investigators and the Clinical Laboratory Improvement Amendments (CLIA) certified labs. These labs run diagnostic tests and require the use of patient name in order to meet CLIA standards.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Name, email, home addresses, and home phone numbers are collected for contact purposes. Date of birth, gender, disease and affected status are collected in order to characterize the population and to use for statistical purposes. All information collected is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.
- (Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) This is an epidemiological study. Information is collected over the phone, in writing and in person. Individuals must call into the study to begin the recruitment process and therefore implied consent for the data is received. Once a participant is deemed eligible for the study, a written consent form is mailed to them which includes information about the storage and use of the data. Those individuals who come to the NIH clinical center are reconsented in person. PII may be shared with collaborators, NIH clinical center investigators and the Clinical Laboratory Improvement Amendments (CLIA) certified labs.
- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The following classes of controls are in place to protect the APS and respondent PII: access such as user account management, access enforcement, password strength, least privilege concept, session termination, security awareness and training, audit and accountability, configuration management, contingency planning, identification and authentication for users and devices, incident response training, testing, monitoring, timely and controlled maintenance, physical and environment controls such as id badges, physical access authorization using access cards, key locks, and cipher locks for building and room entry, monitoring, visitor control, emergency power, and shutoff, disaster protection and recovery, system security plan, personnel security, rules of behavior, risk assessment planning, monitoring, update, technical and communication protection including denial of service protection, boundary protection, programmable firewalls, establishment of network zones with varying levels of restrictions, transmission integrity, security certificates, encryption, regular virus detection and monitoring, policies and procedures are in place for each family control class.

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI International Cancer Research Partnership Website

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): none

- 7. System Name (Align with system Item name): International Cancer Research Partnership (ICRP) Website
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Karen L. Parker
- 10. Provide an overview of the system: The International Cancer Research Partnership Web site (ICRP) supports a group of governmental and nongovernmental cancer research funding organizations with a mission of developing and implementing coding schema for cancer research projects, which can help identify gaps in the cancer research portfolio. The Web site includes a public internet (informational only) and an intranet component that is limited to member organizations. The public site ONLY serves as an information Web site for members of the public, providing information about the ICRP and its member organizations, access to their grants portfolio (minus funding amounts), and information for cancer-funding organizations on how to apply to the ICRP for membership. [Individuals cannot apply for membership. Member organizations must complete an application, sign a data sharing agreement, submit their data in a specific format, pay dues.] The intranet site includes the data provided by the approved member organizations (including the funding data), tools to graphically analyze the data, and space for members to share documents.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Not Applicable the system contains no PII.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: 1) Each member organization will provide data about the cancer research that they fund. This information includes the name of the member organization, type of cancer, area of research, name of the principal investigator, institution receiving the award, institution's city, state, and country, year of the award, and (for intranet site only) amount of funding
- 2) The public Web site provides all data (except for financial data) as an information service to the public. The intranet site provides additional information sharing and data analysis among the member organizations.
- 3) The system will not collect, maintain, or disseminate any PII.
- 4) The public Web site collects no information. Submission of the grant information described in question 1 is mandatory for member organizations a condition of their membership.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The system will not collect, maintain, or disseminate any PII.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: There is no PII in the system.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/30/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Investigator Registration Filing Process

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: Requested

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: Requested

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH NCI Cancer Therapy Evaluation Program (CTEP) Investigator Registration Filing Process
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Charles. L. Hall, Jr.
- **10. Provide an overview of the system:** The purpose of the CTEP Investigator Registration Filing Process is to manually collect, store, and manage data about registered investigators who are eligible to receive NCI supplied investigational agents from the Pharmaceutical Management Branch (PMB) of CTEP. The data collected is stored in hardcopy format in secure filing systems as well as secure Electronic Filing Systems operated by NCI.

CTEP contractors managing the Investigator Registration Process.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Information is shared with the FDA and pharmaceutical companies for the purposes of exchanging clinical trials data.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Information collected as part of the Investigator Registration Filing Process is that contained in the following documents collectively termed the IR packet. The information collected in the IR packet is used for the purposes of conducting clinical research. Some of the information provided in the IR packet is mandatory while some of it is voluntary.
- 1) DHHS FDA 1572 Form which collects FDA required attributes such as Investigator name, education and training experience, name and address of medical school, hospital or research facility where clinical investigation will be conducted, name and address of clinical laboratory facilities to be used in the study, name and address of Institutional Review Board responsible for review and approval, and Investigator Signature.
- 2) Supplemental Investigator Data Form which collects information such as Investigator name, Degrees, NCI Investigator Number, Month and Year of Birth, Provider number, Primary Specialties, Investigator related Training Information, Office Address for official correspondence with the Investigator, Address for Agent shipments, Shipping and Ordering Designee information and Investigator Signature.
- 3) Financial Disclosure Form which collects FDA required financial disclosure information based on four generic questions related to the Investigator's relationship to any pharmaceutical company or sponsor to the extent that the investigator has received any compensation from pharmaceutical companies, or the investigator may have any proprietary interest in any of the studies not limited to patent, trademark or licensing, or if the investigator has any equity interest in any pharmaceutical company or if the investigator or his/her institution has received any large payments in the form of funds, grants or equipment from pharmaceutical companies exclusive of the costs of supporting conducting clinical studies.
- 4) The Investigators are also required to submit an updated copy of their resume / CV.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.
- (Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) NCI Investigators who wish to participate in NCI sponsored clinical trials submit their information to CTEP Investigator Registration Process in a signed Investigator Registration (IR) packet. This investigator registration packet, along with additional cover letter, informs the investigators about intended purpose and usage of their information.
- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No

- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Policies and procedures exist to securing and providing access to IR packet information. For the hard copies of the Investigator Registration (IR) packet that are filed in the secure filing systems, the filing cabinets are secured behind double locked doors with restricted access to the facilities. Only select authorized staffs are allowed to access the hard copies. Access logs to hard copy documents are maintained. Access to data stored in the Electronic Filing System is through password protection account. The Server on which the Electronic Filing System is hosted is maintained in secure Key control based facilities. Audit Trails are kept regarding the Electronic Filing System to track data access.

Since the same hard copy documents are scanned and filed into the Electronic Filing System, no backups are maintained for the hard copy documentation. Contingency plans exist for the Electronic Filing System. Backups of tapes are not stored offsite.

The system falls under the Privacy Act System of Records Notice 09-25-0200

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Labmatrix (Labmatrix)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: none

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: none

6. Other Identifying Number(s): NCI-84

- 7. System Name (Align with system Item name): NIH NCI Labmatrix
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Jason Levine
- 10. Provide an overview of the system: Labmatrix is a system which allows for the tracking of tissue and fluid specimens obtained as part of clinical and translational research, and the tracking and collation of the results of experiments performed on those specimens. The system uses a Microsoft SQL database for its back-end data store; data entry and reporting is performed using either a web-based application or via custom-written applications which access the system via a standardized API. Labmatrix incorporates a user-based system of security and data partitioning, providing for the ability to restrict access to the system as a whole and to restrict users to the ability to view and manipulate only the data to which they have appropriate rights. Likewise, the security system incorporates a system-wide awareness of the idea of protected health information (PHI), and enforces strict access to this information on a granular basis to only those system users with both a need and the rights to know.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes

- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): IIF is shared among clinical and translational investigators who have been approved by the NIH Institutional Review Board to collaborate on any given clinical trial, such that these individuals can maintain accurate records of the specimens and results generated on their clinical trials. As stated in the SORN 09-25-0200 under Routine Uses of Records Maintained in the system, including categories of users and purposes of such uses: Disclosure may be made to agency contractors, grantees, experts, consultants, collaborating researchers, or volunteers who have been engaged by the agency to assist in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity. Recipients shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The information which will be collected within Labmatrix will be that for which collection has been approved by the NIH Institutional Review Board for any given clinical research trial. This generally includes both IIF and non-IIF, such as: a subject's name, date of birth, medical record numbers, contact information, notes about the subject's clinical care, records of all biological specimens obtained from the subject during the course of participation in the clinical research trial, and results of clinical and research tests performed on specimens obtained from the subject. Submission of this information on the part of the subjects is voluntary, and permission is provided by trial participants via the standard clinical trial consent process.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.
- (Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) If and when major changes occur to the Labmatrix system such that data is either disclosed or the use of the data changes, our standard practice would be to inform the clinical and translational research investigators who have primary contact with the participants in their trials, and ask them to notify the subjects and obtain any further consents which are needed. Likewise, we rely on these investigators to obtain the initial consent from any subjects whose IIF will be stored in Labmatrix, and expect that the IRB-approved clinical trial consent documents will contain all relevant information about how this information is both used and shared
- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Administrative: Labmatrix incorporates its own list of permitted users, and restricts administrative control of the system to only those users who are specifically granted this right within Labmatrix. Similarly, the back-end database maintains its own list of approved administrative users, and grants administrative access and control only to these approved users.

Technical: Labmatrix incorporates encryption of all communication that travels over any network interface entering or leaving the system; this includes secure HTTP for all communication with the web application, and SSL encryption of all communication using the APIs for the system.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Labrador PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): NCI Labrador

- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: William D. Figg
- **10. Provide an overview of the system:** Labrador is a system for tracking clinical samples and data related to the collected samples. It will be utilized by lab staff to catalog and barcode specimens, record information about the specimen and search existing samples.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\rm N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: We will collect limited clinical and demographic data, including name, medical record number, date of birth, date of death, date of cancer diagnosis, type of cancer, treatment protocols, drug administration, race, gender. This data will be used, along with sample analysis results to learn about cancer therapeutics and evaluate factors which predict therapy outcome. Data is associated with

individual sample records. Samples are only collected and entered into the system after patients have consented to IRB approved clinical protocol. Submission of personal information is mandatory, but enrollment in the collection protocol itself is voluntary.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Each patient has signed a consent form that allows collection of this data.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Information is secured using username/passwords, least privilege, separation of duties, an intrusion detection system, firewalls, locks, badge access, background investigations. A comprehensive IRT capability is also maintained.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI LHC-CCR-Lab Manager for Human Studies Data

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: 0925-0623

6. Other Identifying Number(s): Support Resource Contract #HHSN261201000117C/N02-RC-2010-00117

- 7. System Name (Align with system Item name): LHC-CCR-LabManager for Human Studies Data
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Glennwood E. Trivers
- 10. Provide an overview of the system: Using taped copies of the State's Motor Vehicle Administration records of licensed drivers (for Baltimore City and 12 surrounding Counties) the system identifies potential volunteers with ages, genders, races and jurisdictional locations matching those of cancer patients in our studies. These names are then placed in an original project-designed search engine (employing several commercial and well known engines) to determine if the subjects have a telephone. Those that have phones are mailed letters introducing the project and then called to ask if they will participate. If they agree to participate, they are screened during the call for eligibility and scheduled for an in-person interview. There they are consented with a written and signed statement of purpose and uses of their contributions and the contractor's interviewer obtains their histories of health, social and occupational experiences and their biological specimens for future comparison and analyses as controls for those obtained from the cancer patients recruited using similar questionnaires and biological assay procedures.

Recruitment of all cases and population controls are performed by an NCI contract (HHSN2612010-00117/N02-RC-2010-00117) for collection of human specimens from subjects with epidemiological profiles currently held by the University of Maryland School of Medicine Baltimore. These resources are used in case-control studies of cancer, making Baltimore the center of the recruitment activity for population controls used in these studies: the Medical School is the primary contractor and it arranges with the Baltimore Veterans Administration Hospital and the Johns Hopkins University Hospital (including its subsidiary Bay View Hospital) to provide access to patients with the specified diseases.

Most of the patients are residents of the state and the population controls required to complete the study designs are recruited most accurately and economically from these areas. The database of licensed drivers offers the most efficient possibility of matching the potential controls prior to

offering the opportunity to volunteer for the studies. The alternatives of surveying the population by telephone or personal contacts in a public setting is time-consuming, wrought with frustration and failure, and a comparative waste of valuable manpower and funding. Even with the advantage of the MVA database, only one in eighteen contacted agrees to participate.

- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No sharing or disclosing of PII.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system routinely collects personal information considered PII such as names, addresses, telephone numbers, and social security numbers. In addition, completed questionnaires will contain health, social and occupational histories, including diseases, surgeries, smoking habits, alcohol consumption, marriage status, parentage, jobs held, etc., and outcome of cytokine quality and quantity, presence of normal and mutated genes, etc., in test results from donated biological specimens (blood, serum, plasma, sputum and urine) to analyze environmental and or genetic risk factors when compared with results from cancer patients. Submission is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) 1. We have contact information from the time of interview and the plan is to use those data (addresses and phone numbers) to re-contact the affected subjects and obtain a revised consent. Since we are already using the Internet search engines to locate phone numbers during recruitment, we will use these same resources to obtain current addresses and phone information. If they are not found using the original information, and if we have an updated drivers' license database, we would scan that database to determine if they appear there, have moved, or have a new phone number. Depending upon the urgency of the need to make these contacts (as per IRB instructions), we could use Google, Facebook and

other engines to search or in a final effort, run searches on National Death Index and the Social Security Index to determine if they are deceased.

- 2. Subjects are sent an introductory letter describing the studies, the need for controls and the procedures for collecting information and biological specimens. Then they are called by telephone, asked to participate, given a brief screener to determine their eligibility, and asked for their choice of a time to be interviewed and to donate biospecimens. Before the interview, subjects are given a written Informed Consent to read, ask questions about, and to sign. If they do not sign, they cannot participate. The Consent Form describes the studies, the purpose, the specimens and the information they are to provide and it gives a description of the uses to be made of the information and their specimens' test results.
- 3. The Consent Form that the subjects sign describes the studies, the purpose, the specimens and the information they are to provide and it gives a description of the uses to be made of the information and their specimens' test results. Information is shared only as published summations; analyses.
- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: 1. Administratively, security is established by requiring access be granted to only the authorized with a need to know or be involved; that all authorized persons be properly trained prior to being given any access to established, on-going databases housing participant information, and in particular, databases with PII.
- 2. Technically, institutional "firewalls" and "VPN" accounts are the ultimate front line defense against exterior intruders; internally, security is achieved by requiring all users be given unique personal "user" identifiers or names, and unique and protected "system passwords" to access the most vulnerable and important databases both constructed using the most recently developed and tested techniques, for access to various system with not one of them being duplicated for use in more than one system.
- 3. Physical Controls are in place that include human guards at all major points of entry to the facility housing the system, a standard requirement for pictured ID badges to be worn by all authorized personnel granted access to the system areas; all rooms containing system IT equipment are kept routinely under lock and key, with a monitor at every main door of access to the equipment, all files, and the on-duty personnel.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI National Biomedical Imaging Archive (NBIA NCIA)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH NCI National Biomedical Imaging Archive
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Robert Shirley
- **10. Provide an overview of the system:** NBIA is a searchable repository of in vivo images that provides the biomedical research community, industry, and academia with access to image archives to be used in the development and validation of analytical software tools that support:
- Lesion detection and classification
- Accelerated diagnostic imaging decision
- Quantitative imaging assessment of drug response

NBIA provides access to imaging resources that will improve the use of imaging in today's biomedical research and practice by:

- Increasing the efficiency and reproducibility of imaging cancer detection and diagnosis
- Leveraging imaging to provide an objective assessment of therapeutic response
- Ultimately enabling the development of imaging resources that will lead to improved clinical decision support.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass

through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No PII is stored in NBIA
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) Clinical trials, physicians and other researchers submit images to NBIA using the CTP (Clinical Trial Processing) software, which is loaded on a computer at their location. Images are submitted (and stored) in the medical image standard, Digital Imaging and Communications in Medicine (DICOM). A typical DICOM file stores a digital image along with a series of tags that contain metadata about the image such as patient ID, study ID, patient weight, anatomic site, and so forth. As part of the NBIA image submission process, the CTP software, prior to uploading the images to NBIA, performs an anonymization routine to strip out any identifying metadata. Even once an image is uploaded into NBIA, curators perform quality control on submitted images to ensure no private patient data is available, the image is of good quality, and so forth. Any images found to contain identifying data in the metatags are immediately deleted from NBIA, prior to being made available via search functionality. (2) NBIA was developed to provide the biomedical research community, industry and academia with access to image archives to be used in the development and validation of analytical software tools that support lesion detection and classification, accelerated diagnostic imaging decisions, and quantitative image assessment of drug response. NBIA provides access to imaging resources that will improve the use of imaging in today's biomedical research and practice by increasing the efficiency and reproducibility of imaging cancer detection and diagnosis, leveraging imaging to provide an objective assessment of therapeutic response, and ultimately enabling the development of imaging resources that will lead to improved clinical decision support. The search interface used by researchers is also available to the general public, should they want to use it. (3) NBIA does not contain any PII. Both automated processes (Clinical Trial Processing software) and manual checks by quality control staff are used to ensure that PII does not exist in any image or its metadata. (4) Submission of DICOM images to NBIA is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No PII is stored in the NBIA system

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:

- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: There is no PII stored in the system, however the system uses firewalls, passwords, locks, id badges, background investigations, network monitoring and an Incident Response team.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/30/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI NCI Internet Website cancer.gov [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: Not Applicable

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0106

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NCI-5

- **7. System Name (Align with system Item name):** NIH NCI Internet Website www.cancer.gov
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Jonathan Cho
- **10. Provide an overview of the system:** This is the NCI's internet Web site. It disseminates cancer-related information, including information on prevention, screening, diagnosis, treatment, and survivorship. Individuals may enter their e-mail address in order to receive the NCI Cancer Bulletin.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Does not share or disclose IIF. If this changes, disclosure will be done per SOR 09-25-0106
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: SEC.407 (b) (4) of the

National Cancer Act authorizes NCI to: "collect, analyze, and disseminate all data useful in the prevention, diagnosis, and treatment of cancer, including the establishment of an international cancer research data bank to collect, catalog, store, and disseminate insofar as feasible the results of cancer research undertaken in any country for the use of any person involved in cancer research in any country." The only information collected is e-mail addresses. It is used to disseminate the e-newsletter, the NCI Cancer Bulletin. Submission of this information is voluntary.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Individuals enter their e-mail address in order to receive the NCI Cancer Bulletin. They are told this on the web site when they subscribe. This is voluntary. E-mail notifications can be sent if a major change to the system is made.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Information is secured using username/passwords, least privilege, separation of duties, an intrusion detection system, firewalls, locks, badge access, background investigations. A comprehensive IRT capability is also maintained.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Pla

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI NCI Local Network [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009 25 0200 01 3109 00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): NA

5. OMB Information Collection Approval Number: NA

6. Other Identifying Number(s): NA

- 7. System Name (Align with system Item name): NCI Local Network
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Eric Williams
- **10. Provide an overview of the system:** The system is a General Support System (GSS) and does not directly collect or store information.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{No}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system is a General Support System (GSS) and does not directly collect or store information. The applications/systems residing on the GSS collect and store information. Therefore, individual PIAs have been prepared and submitted for the applications/systems residing on this GSS.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) NA

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No Pii

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Network and Directory (eDir)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: Not Applicable

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NCI-4

- 7. System Name (Align with system Item name): NIH NCI Network & Directory
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Doug Hosier
- **10. Provide an overview of the system:** This system provides network and directory services to the NCI. It is used to control access to NCI computer resources. To accomplish this, it contains username/password information, contact information, and information about access rights.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No IIF in the system
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Collects work related /assigned information necessary for network operations. The system contains username,

password, work phone, work address, and name for NCI employees, contractors, fellows, and others who have a business relationship with NCI.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No IIF in the system

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Information is secured using username/passwords, least privilege, separation of duties, an intrusion detection system, firewalls, locks, badge access, background investigations. A comprehensive IRT capability is also maintained.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI New England Bladder Cancer Study (NEB)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200
- 5. OMB Information Collection Approval Number: Clinical Exemption #2009-06-001
- 6. Other Identifying Number(s): NEBCDS
- 7. System Name (Align with system Item name): New England Bladder Cancer Study
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Claudine Samanic
- **10. Provide an overview of the system:** A secure database containing contact information for subjects of earlier phase of New England Bladder study and next of kin; medical data collected by the study; and, health and vital status data on study participants.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The study will collect and maintain PII for the purpose of tracing and contacting study participants, and integrating medical information and records into an analytic database. PII will be used to locate and contact

individuals who already participated in a study of bladder cancer, so that we can interview them and update exposure information, and so that we can obtain medical record information about initial treatment, recurrence of bladder cancer, disease progression, and death from bladder cancer. We already have PII from these patients because of their participation in a previous study. Submission of personal information was voluntary. PII will not be analyzed or disseminated in any way, and medical and other information will be anonymized and analyzed in aggregate. Medical and demographic data will be disassociated from IIF once tracing and data collection end. In the analytic database that will be made available in whole or part to study investigators, a blinded ID will identify records for individual study subjects. The study will use analytic data to assess health outcomes of different groups of subjects and to publish disclosure-proofed findings in scientific journals and forums.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The relevant NCI and other IRB's that approve the study require formal IRB notification in the event of a disclosure of IIF not approved in advance, any changes in uses of data. The IRB's specify what information the study may collect and how the information may be used or shared. Only participants who provided consent and participated in the parent case-control study will be contacted. Participants will be contacted and enrolled by mail and telephone and verbal consent will be obtained by telephone. Participants will also be asked to sign an Authorization to Release Medical Records form that will serve as written informed consent for study personnel to obtain medical records.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** Westat requires human subject protection and data security training of all health studies staff members, and also requires that each employee sign a pledge of confidentiality. The Senior System Manager monitors compliance to these and other administrative controls. Systems containing PII and other confidential information require user authentication (ID and password) for access. Users roles limit access to need to know. Physical storage media (paper, disk, etc.) are being stored in locked containers or areas, with key or card access limited to approved individuals.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI OCE Office of Market Research and Evaluation Surveys

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: 0925-0046

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** OCE's Office of Market Research and Evaluation Surveys
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Holly A. Massett, Ph.D.
- **10. Provide an overview of the system:** The system is comprised of a web-based interface and associated backend database, plus necessary programmatic functionality to store and retrieve data, a portion of which may be provided by OMRE for a given task, and the majority of which is provided by the individual users. The primary purpose of the system is to store, compile, analyze, and output user data on a per-task/project basis; the system does not store data pertaining to individual projects past a short period following their completion.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No PII in the system. Personal information outside of work context is not colleted.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1). The system may store any or all of the following information: names, business email, mailing address of clinic or partner organization, business phone or fax information, organization name and individual's position within that organization.

- (2). This information may be tied to data collected via survey or questionnnaire within the system for which the individual has previously identified to be given access and from whom specific responses are needed.
- (3). This information collected may include any of the data listed in (1). and does not constitute PII as defined by this form as all data in question is business-related contact information.
- (4). No PII is collected. Submission is voluntary and user may opt-out of data collection.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) (1). N/A - No PII in the system.

- (2). N/A No PII in the system.
- (3). A written privacy notice is posted at the entry point of each system interface. This privacy statement states the type of data collected, how it will be used, and how data will be reported (e.g. user-specific, aggregate, etc). OMB numbers are provided where applicable and the ability of opt-out and remove all data is available to each user at any point within the system.
- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** No PII in the system. Web-baded access to the system may include (encrypted) passwords, unique urls, SSL, and other one-time login indentifiers. Privacy notices alert the individuals accessing the system what types of information are stored and how they will be used; individuals may opt-out of data collection at any point and remove all data previously input. Servers and physical backup hardware are stored in a secure data center.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Office of Acquisitions (OA)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: Not Applicable

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): no

5. OMB Information Collection Approval Number: no

6. Other Identifying Number(s): NCI-2

- 7. System Name (Align with system Item name): NIH NCI Office of Acquisition System (OA)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Anita Hughes
- **10. Provide an overview of the system:** This system collects and maintains pre- and post-award contract data for reporting to Department and Federal Contract Information Systems (DCIS & FPDS-ng). The types of information include the socio-economic classification of the contractor (small, disadvantaged, etc.) as well as information about the type of project.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The primary data collected

by the system is of a financial/budget-ary nature. Additional NIH reporting requirements relating to each project i.e., socioeconomic classification of the contractor (e.g. small disadvantaged business); information about the type of project, i.e. clinical trial; human subject research; animal research; epidemiological study; is also collected. No personally identifiable information (PII) on any individual is collected in this system. The project information collected is required by the HHS Department Contract Information System (DCIS) which transmits the information to the Federal Procurement Data System-Next Generation (FPDS-NG) which provides this budget and project information to Congress.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No PII collected.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No PII collected.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Pla

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Office of Liaison Activities Database (OLA)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-4915-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0106

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NCI-64

- **7. System Name (Align with system Item name):** NIH NCI Office of Liaison Activities Database (OLA)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Nelya Gunina
- **10. Provide an overview of the system:** The Office of Liaison Activities Database (OLA) maintains contact information for advocacy organizations and professional societies. The system also maintains information about individual advocates that serve the NCI through the Director's Consumer Liaison Group (DCLG) and the Consumer Advocates in Research and Related Activities (CARRA) program.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Does not share outside the agency. Disclosures permitted in SOR 09-25-0106 are not made.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: Legislative authority is 42 U.S.C. 203, 241, 2891-1 and 44 U.S.C. 3101), and Section 301 and 493 of the Public Health Service Act. Information is maintained for advocates that are members of the CARRA program include membership status (active or non-active), race/ethnicity/age/gender of member, occupation, highest educational degree earned, area of educational degree, primary/personal/constituency cancer type, location/race/ethnicity of constituency, activity preferences, computer skills, ability to travel, and skills/accomplishments/activities. Information is used only within the agency. Submission of information is voluntary.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Notification and consent in both cases is done via email.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Information is secured using username/passwords, least privilege, separation of duties, an intrusion detection system, firewalls, locks, badge access, background investigations. A comprehensive IRT capability is also maintained.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/19/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Oracle Clinical-Remote Data Capture (OC-RDC)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: Not Applicable

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): NIH NCI DCP Oracle Clinical-Remote Data Capture (OC-RDC)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Anne Ryan (Troy Budd is alternate POC)
- **10. Provide an overview of the system:** OC-RDC serves as the primary database and data management tool for the Division of Cancer Prevention (DCP) phase I and II clinical trial portfolio. Westat the prime contractor on this project; works with the DCP Chemoprevention Consortia Lead Orgs to develop clinical trial menus which each consortium can enter participant enrollment data and adverse events. OC-RDC also provides DCP and Consortia Lead Orgs with data quality management, including data discrepancies reports, audit trail, etc... OC-RDC is DCP effort to manage and support the data collection of clinical trials conducted under our phase I and II Chemoprevention Consortia Program.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No IIF is present in the system

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Type of data available in OC-RDC include protocol attributes, site information, agent information information, adverse events, data discrepancies information, and Non-IIF participant level data. The information is critical to for data management of DCP chemoprevention consortia clinical trials.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No IIF is present in the system

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No IIF is present in the system

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Orientation Registration (OrienReg)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-4915-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NCI-35

- **7. System Name (Align with system Item name):** NIH NCI Orientation Registration (OrienReg)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Nelya Gunina
- **10. Provide an overview of the system:** A website used to register new employees for the NCI Orientation Program.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): IIF not collected
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Employee names are entered into a database in order to register them for employee orientation. No IIF is collected. Submission of this information is voluntary.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Individuals are notified when they are hired about how the information will be used. No procedures are in place to notify individuals if major changes to the system are made.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Information is secured using username/passwords, least privilege, separation of duties, an intrusion detection system, firewalls, locks, badge access, background investigations. A comprehensive IRT capability is also maintained.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Pla

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Pathway Interaction Database (PID)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A
- **5. OMB Information Collection Approval Number:** N/A
- 6. Other Identifying Number(s): N/A
- **7. System Name (Align with system Item name):** NIH NCI Pathway Interaction Database (PID)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Jeffrey Buchoff, Tanja Davidsen
- **10. Provide an overview of the system:** The Pathway Interaction Database is a highly-structured, curated collection of information about known biomolecular interactions and key cellular processes assembled into signaling pathways. It is a collaborative project between the US National Cancer Institute (NCI) and Nature Publishing Group (NPG), and is an open access online resource.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\rm N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: 1. The agency does not collect any personal information through the system. Molecule and pathway data are entered into the system by the programmer. Web statistics are tracked as well, which included IP addresses and URLs.

- 2. The web statistics are used to determine the amount of system use.
- 3. The system does not contain PII.
- 4. No personal information is submitted.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A,

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/9/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI PLCO Research Database (PLCO)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: Not Applicable

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NCI-59

- 7. System Name (Align with system Item name): NIH NCI PLCO Research Database (PLCO)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Guillermo Marquez
- **10. Provide an overview of the system:** The system is used for monitoring, quality control, and analysis of the PLCO trial.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): No PII in the system
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: This system is used to store and monitor data from the participants in the PLCO and NLST prevention trials. Such data consists of results of screening tests such as chest x-rays, serum PSA and CA-125, sigmoisoscopy, etc. Medical history and other questionaire information is also stored. To protect

confidentially, the data in this system is referenced by a randomly assigned participant ID code only. The actual identity of the participant is known only to the screening center at which these tests were conducted. Since these participants are treated as clinical patients at these centers, their true identity is considered confidential, as with any patient, and is protected in accordance with HIPPA regulations to which all of these screening centers must adhere.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No PII in the system.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Information is secured using username/passwords, least privilege, separation of duties, an intrusion detection system, firewalls, locks, badge access, background investigations. A comprehensive IRT capability is also maintained. However, no PII in the system.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Portfolio Management Application (PMA)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: Not Applicable

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: NA

6. Other Identifying Number(s): NCI-32

- **7. System Name (Align with system Item name):** NIH NCI DCCPS Portfolio Management Application (PMA)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Everett Carpenter
- **10. Provide an overview of the system:** This application is used by NCI Extramural Division staff to manage their Research Portfolio (Grants, Contracts, Interagency Agreements) Responding to Congressional Requests (Coding, Searching, Reporting); mass mailing, Dynamic Dissemination of Research Portfolio on Public Web site etc
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Shared with NREP to identify and collect programs for the RTIPS application. Shared with Input Solutions Inc. to convert Program Products for RTIPS application. Share RTIPS contact Information with ASPEN Systems for the purpose of order fulfillment. Dissemination of Principle Investigator name on DCCPS Public web site. Share CCPlanet contact information. Information sharing is done in accordance with SOR 09-25-0036.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Public Health Act, TITLE 42, CHAPTER 6A, SUBCHAPTER III, Part C, subpart 1, Sec. 285, Sec. 285a and 44 U.S.C. 3101. The information is collected and reviewed by the Federal Program and DCCPS Management Staff to provide timely information for analysis, processing and/or dissemination. IIF collected is name, mailing address, e-mail address, and phone number. Information is submitted voluntarily.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Change in Data Use/Shared – Individuals will be notified via telephone or email to obtain consent.

Via the CCPlanet order form, individuals are told how the information will be used/not used and consent is obtained by the user entering their information and executing the submit order button.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Information is secured using username/passwords, least privilege, separation of duties, an intrusion detection system, firewalls, locks, badge access, background investigations, scheduled scan of servers and application code. A comprehensive IRT capability is also maintained.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI PRO-CTCAE PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 9/21/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 9-25-0200

5. OMB Information Collection Approval Number: #2010-02-001 clinical exemption

6. Other Identifying Number(s): Not Applicable

- **7. System Name (Align with system Item name):** NIH NCI Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Kathleen Castro
- **10. Provide an overview of the system:** The system is used by clinicians to create, schedule, and administer symptom surveys to study participants. The system is also used by study participants (i.e. patients with cancer participating in cancer clinical trials) to provide responses to these symptom surveys. The system provides the ability to notify or remind a study participant that they have a symptom survey due.

The system provides two interfaces for study participants to respond to symptom surveys:

- 1. A web interface where the study participant accesses a web site, authenticates who they are via a username and password and responds to a symptom survey via the web site. The patient reads the questions on the screen and clicks to select the appropriate responses.
- 2. A phone interface where the study participant calls or is called by a phone system, and listens to the questions on the phone and presses buttons on their phone keypad to select the appropriate response.

The responses provided by the study participant via either the web or the telephone interface are coded by the system, mapped to the CTCAE dictionary and saved directly and immediately to a database. The participant responses to survey questions are not stored anywhere except in the database. Participants may respond to the questions in either English or Spanish. The database is housed behind the NCI firewall.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the

individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The PRO-CTCAE is used by clinicians to create, schedule and administer symptoms to study participants. Study participant names and dates of birth are shared with clinicians to allow preparation and administration of surveys.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) The system collects and maintains patient responses to symptom surveys. The data is not only federal contact data.
- (2) The system will support investigator authoring of patient reported outcome case report forms (CRFs) and collect cancer patient responses to questions about their health status, symptoms, functioning and health related quality of life and integrate this information within the NCI adverse reporting system.
- (3) Yes
- (4) All data provided is voluntary
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.
- (Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) 1) Patients are enrolled on protocol which have been IRB approved. Patients are provided written consent describing the PRO-CTCAE system. Signed consent will be obtained from patients prior data entry into the system. Patients will be notified in writing if major changes occur to the system
- 2) Signed consent will be obtained from participants by members of the research team, The consent document informs the participant that study records will be kept confidential as required by law.
- 3) Participants are given written consent documents which have undergone IRB approval and are reviewed on an annual basis by the respective IRB
- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:

- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: 1. User Passwords (IA-5)

The PRO-CTCAE system account management practices shall adhere to the NCI Password Policy.

NCI Password Policy:

Users must choose passwords that have at least eight characters and include a combination of all four of the following types of characters:

Capital letters

Lower case letters

Numeric characters

Special characters (!@#\$\%^&*() + $|\sim-=\`{}[]:";'<>?,./)$

2. Passwords for Clinical Staff

Clinical staff user passwords will adhere to the NCI Password Policy.

3. Telephone Interface Passwords for Study Participants

The telephone interface passwords, hereafter known as personal identification numbers or PINs, for clinical trial participants (i.e. patients) will adhere to the following password policy:

Users must choose passwords that have exactly four numeric characters. Special characters may not be used. Alphabetic characters which correspond to the telephone keypad may be used as a pneumonic to aid users in recalling their PIN.

4. Procedures for changing/resetting passwords (IA-5)

The PRO-CTCAE system account management practices shall adhere to the NCI Password Lifetime Policy.

NCI Password Lifetime Policy:

Users must change passwords at least every 60 days to one that is different from the previous 24 passwords used;

Users must change their newly assigned system passwords the first time they log on.

Minimum password lifetime is 1 day.

5. Password Changes for Clinical Staff

Clinical staff user passwords will adhere to the NCI Password Lifetime Policy.

6. Unsuccessful Login Attempts and Account Lockout Settings (AC-11)

The following is the NCI Policy regarding unsuccessful login attempts:

When the system supports it, the maximum number of invalid user attempts during a 15 minute window is 6 (failed attempts). The account must remain locked for at least 60 minutes or until manually reset by an authorized administrator or by using a self-registration/reset website utility.

7. System Inactivity (AC-11)

The PRO-CTCAE system policy for managing idle authenticated user sessions shall adhere to the NCI policy.

NCI Policy:

Session lock mechanisms will be activated for user workstations and server consoles and other systems automatically after 15-30 minutes of inactivity, when technically and operationally feasible. Users must log out of their computers or lock their screen when they leave their desks.

8. Caching Passwords (IA-5)

The PRO-CTCAE system policy regarding caching/storing passwords shall adhere to the NCI Policy.

NCI Policy:

Users are prohibited from caching (auto-saving) NIH or NCI system passwords on the local system. Passwords should not be stored in websites, programs or scripts, if operationally feasible.

The PRO-CTCAE system does not prevent users from saving their passwords using browser enabled password saving. This policy is enforced through user compliance to the policy.

9. Separation of Duties and Least Privilege (AC-5, AC-6)

The PRO-CTCAE system supports the separation of user duties and the principles of least privilege. Users' access to the PRO-CTCAE system shall be assigned and restricted based on role or function within the system, and be limited to the minimum level of access necessary to perform the assigned duties within the system. Security related user roles will be divided between different roles through the use of role based access control (RBAC) to the extent feasible and practicable. Users will be assigned to groups or roles, which have appropriate permissions and privileges pre-assigned to them. Users must be issued and must use only non-privileged account credentials when performing non-privileged activities in the system or application.

10. Account Management (AC-2)

The PRO-CTCAE system adheres to a hierarchical method of user account administration which closely follows the hierarchy of responsibility employed for the conduct of the clinical tri

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Publications Enterprise

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 90-25-0156
- **5. OMB Information Collection Approval Number:** will be submitted as an amendment to 0925-0208
- 6. Other Identifying Number(s): N/A
- 7. System Name (Align with system Item name): NIH NCI Publications Enterprise
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Robert Zablocki
- **10. Provide an overview of the system:** Publication Enterprise is the publications ordering system that includes five interfaces to allow various user groups to order publications or manage the interfaces; a database that houses information about the publications; the interfaces available for placing orders is tied into the fulfillment and shipping systems at the NCI Distribution Center, and the Fulfillment and Shipping Systems.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): In cases where credit cards are used, credit card numbers and billing name/address are passed to credit card vendor for processing. Checks are transmitted to the bank for deposit. Shipping carriers are provided with mailing addresses for delivery of orders.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Information collected includes name, address, email, phone number, credit card information or check (if a pay order), and contents of order. The information is collected to process publication orders. Submission of this information is voluntary, and only collected from users who place orders.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Help file details information collected, purpose of these data collection, and purging routine. If changes to process are made in the system the online help file is updated to reflect those changes. The privacy policy on the public-facing interface also indicates what information is collected and for what purpose.

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:

 Only authorized, authenticated systems staff have access to database.
- · Controlled access to production servers; only Web administrator has this level of access
- There is a designated deployment team and deployments are handled from a secure kiosk with no connection to the Internet
- · Usernames and strong passwords are required for user access to production interface for database
- · All production assets are in a central data center that has controlled and limited physical access
- · Production environment is separate from development environment both logically and physically
- Each application in the system has set user levels with different privileges assigned to each level

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

Date Published: May 23, 2012

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Research Resources PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: None

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): None

5. OMB Information Collection Approval Number: None

6. Other Identifying Number(s): None

- 7. System Name (Align with system Item name): NCI Research Resources
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Elizabeth Hsu, PhD, MPH
- 10. Provide an overview of the system: NCI Research Resources is a directory of research tools and services that the National Cancer Institute (NCI) makes freely available to cancer researchers on the Web at http://resresources.nci.nih.gov/. This centralized listing of scientific tools, reagents and services developed by the NCI is provided as part of our ongoing commitment to cancer investigators to enable and expedite their research. It includes descriptions of each resource and is organized by research category and by NCI organization. The categories include animal, specimen, genomic, epidemiological, and scientific computing resources; drugs, chemicals, and biologicals; clinical trials; and statistics.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The system does not share or disclose PII
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: This public Web site will not collect any information from public users - it is simply a catalogue of services. The application will collect information from NCI staff, but it will not collect any PII. The information that will be collected from NCI staff, maintained by the application, and disseminated via the public Web site is the name of the research resource, a description of that resource, the research category to which it belongs; the NCI organization that provides the resource; and general contact information for the NCI organization.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Because the system does not collect any PII, there are no processes in place to manage PII.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Because the system does not collect, maintain, or disseminate any PII, there are no controls in place to secure PII.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Smokefree.gov Website(s) and Mobile Apps (Smokefree.gov)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 8/22/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0156

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NCI Smokefree.gov website(s) and Mobile Apps
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Lewellyn Belber
- 10. Provide an overview of the system: The system is a group of publicly accessible websites that provide evidence-based smoking cessation information to the general public and to specific target audiences. The primary website is smokefree.gov, and the sub-sites are: women.smokefree.gov, teen.smokefree.gov, and espanol.smokefree.gov. As more target audiences are identified, more sub-sites may be created. The cessation resources are provided as plain content, interactive quizzes, and printable PDFs. Some parts of the system will allow visitors to login to customize their website experience, and to record their smoking behavior in order to tailor the resources that are provided. The smartphone applications likewise display content to help people quit smoking, and allow users to track their smoking behavior and quit attempts in order to encourage and facilitate quitting.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes

- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The system does not share or disclose PII.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: 1) The system will collect email address, username, password, cell phone number, and data on smoking and other health behaviors (e.g. the number of cigarettes smoked in a day.)
- 2) The information is collected to allow a user to customize their experience on the website by logging in, with tailored content and statistics on their smoking behaviors. The e-mail address will be used for password reminders and notification of site updates. The mobile phone number will be used for a voluntary smoking cessation program delivered by text message.
- 3) The system will collect PII: email address and mobile phone number.
- 4) Submission of personal information is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) 1) If major changes to the system are made, individuals will be notified by email.

- 2) When an individual submits information, including PII, to the site, they will be notified through text on the form and a link to our privacy policy.
- 3) Users' information will not be shared. It will be used to deliver password reminders, to customize the website experience, and to deliver smoking cessation messages by text message.
- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The virtual servers are located in a locked and remotely monitored facility.

Access to the web server is granted on a limited basis to developers who need access to the system. Information is secured using username/passwords, least privilege, separation of duties, an intrusion detection system, firewalls, locks, badge access, background investigations. A comprehensive IRT capability is also maintained as part of NIH's IRT program.

All employees participate in annual security and privacy training through NIH and the contracting agency.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/9/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Starcatcher-StarGazer (Starcatcher)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-4915-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-90-0018

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NCI-12

- 7. System Name (Align with system Item name): NIH NCI Starcatcher/Stargazer (Starcatcher)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Mary Velthuis
- **10. Provide an overview of the system:** StarCatcher/Star Gazer is a web application in which the public can enter and submit resumes for referral within the NCI.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Shared within NCI with NCI hiring managers per SOR 09-90-0018. This information is further addressed in the HHS Privacy Act Systems of Record Notice 09-90-0018, published in the Federal Register, Volume 59, November 9, 1994.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Authority to collect this information is National Cancer Act of 1971, SEC.407 (b) (4). A limited amount of information

collected via StarCatcher is used by authorized NCI staff via StarGazer to identify candidates interested in working at the NCI. Submission of information is voluntary. The information specifically collected is the person's name, phone number, mailing address and e-mail address. There may or may not be other IIF on the resumes that individuals submit.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Candidates input information into StarCatcher and upon entry into the site, it is stated that: NCI maintains a resume databank of interested applicants for professional, administrative and internship positions that may have future openings. If you would like to post your resume, please choose a job category/specialty that we list.

On the website it is noted that: "The NCI StarCatcher Website accepts resumes from interested applicants for positions that may have future openings, it is not intended to solicit or accept applications for official vacancy announcements. Your contact information and resume will be kept on file in the StarCatcher Website for one year from the date you post your resume.

There are no procedures in place to notify individuals when major changes occur to the system.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Information is secured using username/passwords, least privilege, separation of duties, an intrusion detection system, firewalls, locks, badge access, background investigations. A comprehensive IRT capability is also maintained.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Status of Funds Internet Edition (SOFie)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-3199-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NCI-73

- **7. System Name (Align with system Item name):** NIH NCI Status of Funds Internet Edition (SOFie)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Bob Barber
- **10. Provide an overview of the system:** SOFie is a financial tracking tool that allows users to access financial data and download the data into spreadsheets in order to perform analysis.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: All accounting transactions are available for viewing in SOFie. The information is used to track and plan fiscal budgets. It

is necessary to have access to this data in order to comply with appropriations laws and regulations.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No IIF

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Information is secured using username/passwords, least privilege, separation of duties, an intrusion detection system, firewalls, locks, badge access, background investigations. A comprehensive IRT capability is also maintained.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Survey of Physician Attitudes Regarding the Care of Cancer Survivors (SPARCCS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: NA

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0156

5. OMB Information Collection Approval Number: 0925-0595

6. Other Identifying Number(s): NA

- **7. System Name (Align with system Item name):** Survey of Physician Attitudes Regarding the Care of Cancer Survivors (SPARCCS) Study Management System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Lynne Harlan
- **10. Provide an overview of the system:** SPARCCS is a mail survey of a national sample of practicing physicians. Physician offices are called to confirm the specialty of the physician and the mailing address. Eligible physicians are then mailed a paper survey to complete and return to Westat. After 3 mailings, physicians that have not returned a questionnaire are called and asked to participate in the study by returning a paper survey. The Study Management System tracks the physicians' contact and eligibility information. Once questionnaires are returned, they are scanned to capture responses. Individual identifying information is stripped from the response data prior to delivery to NCI.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Identifying information is provided to authorized study staff in order to make contact with respondents and to track information. The identifying information is not shared with anyone

outside of Westat. This systems falls under the guidelines of Privacy Act System of Records Notice 09-25-0156.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: 1. Authorization: The Public Health Service Act, Section 412 (42 USC 285a-1) and Section 413 (42 USC 285a-2)
- 2. Information collected: SPARCCS collects information about the beliefs, knowledge, attitudes, and practices of primary care physicians and cancer specialists regarding the care of cancer survivors.
- 3. Purpose of collection: NCI's primary objective for supporting SPARCS is to identify whether physicians are meeting the components described by the Institute of Medicine's 2005 report that described the essential components of cancer survivorship care within a health care delivery system. These data will inform the process of standardization of survivorship care practices; augment the data collected in other cancer survivorship studies such as the Cancer Care Outcomes Research and Surveillance Consortium and the Cancer Research Network; and monitor the progress made toward achieving NCI strategic goals of improving the quality of cancer care across the cancer control continuum.
- 4. Routine disclosure: There are no routine uses for which IIF would be disclosed to those not authorized to use the system (e.g., Westat employees assigned to the project).
- 5. Voluntary or mandatory? Information is provided on a voluntary basis only.
- 6. If mandatory, effects of not providing information: Not mandatory there are no effects if the information is not provided.

PII collected and maintained includes name, mailing address, phone number, email address and unique study ID number.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Information about the study and data disclosure is provided to respondents in written form along with the survey instrument. Completion and return of the survey is considered to be consent to participate. No changes in disclosure or data use will be permitted without explicit consent from each survey respondent.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: IIF is secured using password protected networks, system firewalls, and key cards/identification badges for all physical locations. Data is maintained in a secure database. Information will be secured on the system through access controls, personnel security awareness and training, regular auditing of information and information management processes, careful monitoring of the information system, control of changes to the system, appropriate handling and testing of contingencies and contingency planning, ensuring that all users are properly identified and authorized for access, and that they are aware of the rules and acknowledge that fact, by ensuring that any incident is handled expeditiously, properly maintaining the system and regulating the environment the system operates in, controlling media, evaluating risks and planning for information management and information system operations, by ensuring that the system and any exchange of information is protected, by maintaining the integrity of the system and the information stored in it, and by adhering to the requirements established in the contract and statement of work.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote **Sr. Official for Privacy Name:** Karen Plá

Sign-off Date: 9/30/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Technology Transfer Center Online Customer Survey (NCI TTC)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A
- **5. OMB Information Collection Approval Number:** 0925-XXXX (Pending approval sometime in April/May 2011)
- 6. Other Identifying Number(s): N/A
- **7. System Name (Align with system Item name):** NIH NCI Technology Transfer Center (TTC) Online Customer Survey
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: John Hewes, Ph.D.
- 10. Provide an overview of the system: The NCI TTC Online Customer Survey is a web-based data collection tool designed to assess the satisfaction of NCI Technology Transfer Center (TTC) customers and collect descriptive, non-confidential information about their company's communications and marketing. Respondents of this survey include the universe of the NCI TTC's "external customers" which includes approximately 750 managers and executives in the 320 for-profit companies who have developed biomedical research alliances with the NIH through the TTC, or made information requests concerning NIH Material Transfer Agreements (MTAs), Cooperative Research and Development Agreements (CRADAs), Confidential Disclosure Agreements (CDAs), and other instruments for developing collaborative research. Only business contact information will be used to correspond with respondents. No PII will be collected using this system. A secure url and a password will be provided to respondents to access the online survey. This website will not be available to the public.

No PII will be utilized or collected from this survey. Only company contact information will be used. There are 36 questions and none of them ask for PII. In addition, the contact information requested in company contact information only.

- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the

character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: 1 & 2. The purpose of the web-based survey is to gather critical information that will serve the goals set forth by the TTC to obtain a better understanding of the needs of its external customers in the private sector. The web-based survey will collect descriptive, non-confidential information about the characteristics of the respondents' particular company, satisfaction with TTC's customer service, preferred and expected communications channels of TTC's external customers, and strategic plans of companies to engage in external collaborations and partnerships. Respondents will not be asked to identify specific companies.
- 3. No PII will be collected
- 4. Submission is voluntary a statement at the beginning of the survey instrument indicates that participation is strictly voluntary. There will be no invitation or request for survey participants to enter or submit personal information. Survey contact information is non-confidential company contact information collected from online public and subscription databases and any NCI-internal database of companies that have negotiated collaboration agreements with NCI TTC.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No PII in the system.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No PII in the system.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/30/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Technology Transfer Center website (TTC)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision: Initial PIA Migration to ProSight

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

- 3. Unique Project Identifier (UPI) Number:
- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A
- **5. OMB Information Collection Approval Number:** N/A
- 6. Other Identifying Number(s): N/A
- **7. System Name (Align with system Item name):** NIH NCI Technology Transfer Center Website (TTC)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Bonnie Chamberlain
- 10. Provide an overview of the system: The system, the NCI TTC website, is used to disseminate information to Biotechnology and Pharmaceutical industry representatives, Academics, Non-Profit, and NIH staff about technology transfer related information. Disseminated information includes: the TTC mission; Public Health Service and NIH approved model technology transfer agreements; Technologies that are available for codevelopment/collaboration with NIH; brochures that describe technology transfer and the role of TTC in technology transfer at NCI and NIH, and intellectual property management plan templates for grantees and contractors. The system also includes a "listserv" where interested parties (who have subscribed by adding their email address to the subscription request area of the website) receive a notice by email whenever a new co-development/collaboration opportunity is added to the website. The notification is sent to the listserv subscribers automatically through a content management system for the co-development/collaboration opportunities.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: 1) We collect the email address of individuals who volunteer to add their email address to the listsery we maintain as part of the website where we send them new co-development opportunities. 2) we use the information to send new co-development opportunities which have been added to the website. 3) The information may contain PII because individuals list their e-mail addresses. 4) Submission of personal information is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.
- (Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) 1) An notice would be generated through the website and sent to all listserv subcribers' e-mail addresses. 2) Individuals voluntarily subscribe and add their e-mail addresses to the listserv. Should a major change occur, they would be given the opportunity to continue to subscribe or to unsubscribe. SHould they no longer wish to receive co-development opportunities, they can unsubscribe. An option to unsubscribe is included with every opportunity announcement they receive. 3) They would receive an electronic notice of any change in the NIH Privacy Policy.
- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls: Administrative controls: The COTR for the web development/maintenance contract controls who is assigned as a site admin user and relays the information to the web contractor.

Technical: Access to the email addresses is controlled by the use of User Names and Passwords to access the site administration area of the website where the email addresses are available. Only 2 users are allowed to access the site admin area. One is the primary user and the 2nd is the back-up.

Physical: Since the email addresses are stored electronically, no "physical access" is available.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/9/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI The Cancer Genome Atlas Data Coordinating Center (TCGA DCC)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): None

5. OMB Information Collection Approval Number: None

- **7. System Name (Align with system Item name):** NIH NCI The Cancer Genome Atlas (TCGA)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Carl Schaefer
- **10. Provide an overview of the system:** The Cancer Genome Atlas (TCGA) is a three-year pilot cancer genome characterization and sequencing project to determine the feasibility of large-scale effort to identify most of the genomic changes in three separate tumor types. The Data Coordinating Center (DCC), establishes and executes standard operating procedures, designs and implements data analysis procedures that perform quality checks on incoming data and report anomalies to the data source sites, and implements a data management pipeline to process data and prepare it for public distribution in formats and systems compatible with the caBIG program.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No IIF

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system collects medical gene data that is de-identified. The system does not collect any IIF. There are multiple de-identifying steps, so that no names, social security numbers, or none of the eighteen (18) HIPAA identifiers is collected. The system does collect de-identified gene data for research.

Patients voluntarily sign a consent form to allow their data to be used for research.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No IIF

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No IIF

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Tobacco Use Supplement to the Current Population Survey (TUS-CPS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: 0925-0368

6. Other Identifying Number(s): No

7. System Name (Align with system Item name): Tobacco Use Supplement to the Current Population Survey (TUS-CPS)

- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Anne Hartman
- **10. Provide an overview of the system:** The Tobacco Use Supplement to the Current Population Survey (TUS-CPS) is an NCI-sponsored survey of tobacco use that has been administered by the US Census Bureau as part of the Bureau of Labor Statistic's Current Population Survey in 1992-1993, 1995-1996, 1998-1999, 2000, 2001-2002, 2003, 2006-2007, and will be fielded in 2010-2011 upon OMB's approval of reinstatement with revision. The Centers for Disease Control and Prevention (CDC) co-sponsored with NCI the 2001-02, 2003, and 2006-07 survey waves.

The main data can be requested from the Census Bureau Website. A link to the Census Bureau Website ordering page is provided from the DCCPS Website: riskfactor.cancer.gov/studies/tus-cps/info.html.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: There is no PII in the system. The TUS-CPS is a key source of national and state level data on smoking and other tobacco use in the US household population because it uses a large, nationally representative sample that contains information on about 240,000 individuals within a given survey period. The TUS-CPS generally contains items covering:

cigarette smoking prevalence and history,
current and past cigarette consumption,
cigarette smoking quit attempts and intentions to quit,
medical and dental advice to quit smoking,
cigar, pipe, chewing tobacco, and snuff use,
workplace smoking policies,
smoking rules in the home,
attitudes toward smoking in public places,
opinions about the degree of youth access to tobacco in the community (1992 - 2002),
attitudes toward advertising and promotion of tobacco (1992 - 2002),
cost and purchase of cigarettes (2003-),
treatments and methods used to try to quit/quit smoking cigarettes (2003, 2010-2011),
use of harm reduction products (2003, 2006-07).

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No PII in the system.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No PII in the system.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCI Translational Science Meeting (TSMS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: None

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: No

- 7. System Name (Align with system Item name): NIH NCI Translational Science Meeting
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Nelya Gunina
- **10. Provide an overview of the system:** NIH NCI Translational Science Meeting participants register for a workshop and submit abstracts that the participants will potentially present at the meeting. There is no data on the system and no PII on the system and no data will be collected, maintained, or stored until July 2010. The information collection mechanism is disabled until July 2010.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No PII
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: 5 U.S.C. 301; 44 U.S.C.

- 3101. Meeting participants will register for the workshop and will post a limited amount of work-related information (abstracts) to a website when a conference is forthcoming. The information is used to identify the participants and collect their submission information. There is no data on the system and no PII on the system and no data will be collected, maintained, or stored until July 2010. The information collection mechanism is disabled until July 2010. Information will be submitted voluntarily.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Information is secured using username/passwords, least privilege, separation of duties, an intrusion detection system, firewalls, locks, badge access, background investigations. A comprehensive IRT capability is also maintained. There is no PII on the system.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Suzy Milliard

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCRR Clinical and Translational Science Awards [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-4803-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: No

- 7. System Name (Align with system Item name): Clinical and Translational Science Awards (CTSA)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sean Hagan
- **10. Provide an overview of the system:** CTSA is a collaborative web site facilitating robust communications among clinical and translational science communities, which enables multi-way discussions about the important new national effort to develop clinical and translational research. The CTSA system consists of the CTSA public website, the CTSA Management System for managing data, and the CTSA-Wiki (for information sharing among grantees funded under the CTSA program).
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No IIF ${\sf No}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Control and Oversight - Program Monitoring Information; Public Affairs – Customer Services; Public Affairs – Product Outreach; and, Public Affairs – Public Relations. The system does not collect or maintain IIF.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No IIF

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No IIF

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name:

Josephine Kennedy (NCRR ISSO, delegated by the NCRR Privacy Coordinator, Cindy McConnell)

Josephine Kennedy (NCRR ISSO, delegated by the NCRR Privacy Coordinator, Cindy McConnell)

Josephine Kennedy (NCRR ISSO, delegated by the NCRR Privacy

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCRR Clinical and Translational Science Awards Study Management System [System] PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: TBD

6. Other Identifying Number(s): Westat internal Project ID 8668

7. System Name (Align with system Item name): NIH NCRR National Evaluation of the Clinical and Translational Science Awards (CTSA) Initiative

Study Management System

- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Patricia Newman
- **10. Provide an overview of the system:** The CTSA Initiative is directed at transforming the way biomedical research is conducted nationwide by reducing the time it takes for basic science or laboratory discoveries to become treatments for patients, and for those treatments in turn to be incorporated and disseminated throughout community practice. The CTSA-SMS will include a variety of data to support an evaluation of the first four cohorts of CTSA awardee institutions and the CTSA Consortium. The system stores, processes, and transmits all information related to the study including data submitted by awardees in Non-Competing Continuation Progress Reports (PHS 2590), surveys and responses, staff and agency contact information, study data and reports, and other electronic and hardcopy information.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes

- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The CTSA-SMS collects and maintains a variety of information types. Data submitted to NIH in award applications, Non-Competing Continuation Progress Reports (PHS 2590), and other routine award reporting include award numbers, names, professional email addresses, telephone contact information, and NIH commons ID and person ID. In addition to the identifying information used to locate and contact survey participants, the system will store, process, and transmit basic data respondents volunteer regarding employment, education, and demographics. Information in the CTSA-SMS will be used to provide analytical and policy support to NCRR, assisting NIH in making decisions about current CTSA programming, future funding, and other initiatives to improve clinical and translational science. It may also provide information for NIH's Government Performance and Results Act (GPRA) report. At least one journal article based on the findings will be developed and submitted for publication. Information collected constitutes PII such as name, mailing addresses, personal email address, and employment status. Disclosure of personal information is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The CTSA-SMS will be used only to collect survey data, analyze data, and produce reports for the CTSA evaluation study. The CTSA-SMS will be retired upon conclusion of the study. No major changes to the CTSA-SMS affecting disclosure and/or data use are anticipated. In the unlikely event of future major change to the CTSA-SMS affecting status or use of personally identifiable information (PII), privacy notice of consent is provided in writing or via email to affected individuals.

Notification and consent from individuals for collection of PII is provided in the survey: "Pursuant to 5 CFR 1320.5(b), an agency may not conduct or sponsor, and a person is not required to respond to an information collection unless it displays a valid OMB control number. The OMB control number for this collection is 0348-XXXX."

Each survey is preceded by a message to the individual which specifies why the information is being collected and how it will be used (i.e., The NIH leadership is interested in learning more about the use of CTSA resources.)

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:

- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Information will be secured on the system through access controls, personnel security awareness and training, regular auditing of information and information management processes, careful monitoring of a properly accredited CTSA-SMS information system, control of changes to the system, by appropriate planning and testing of configuration management and contingency processes, by ensuring that all users of the CTSA-SMS are properly identified and authorized for access and are aware of and acknowledge the system rules of behavior, by ensuring that any contingency or incident is handled expeditiously, properly maintaining the system and regulating the environment it operates in, by controlling media, by evaluating risks and planning for information management and information system operations, by ensuring that the system and any exchange of information is protected, by maintaining the confidentiality and integrity of the CTSA-SMS, and by adhering to the requirements established in the contract and statement of work.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name:

Josephine Kennedy (NCRR ISSO, delegated by the NCRR Privacy Coordinator, Cindy McConnell)

Josephine Kennedy (NCRR ISSO, delegated by the NCRR Privacy Coordinator, Cindy McConnell)

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 2/16/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCRR Construction Grants Management System (CGMS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-4803-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: No

- **7. System Name (Align with system Item name):** NCRR Construction Grants Management System (CGMS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Josephine Kennedy
- 10. Provide an overview of the system: The system is used to track C06 Construction grants.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{No}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: CGMS only contains Grant data, not financial data and not Privacy Act data: Grants Financial Management Reporting and Information; Grants Planning and Resource Allocation Budget Formulation Information; Program Monitoring Control and Oversight. No IIF is collected or maintained in the system.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No IIF

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No IIF

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name:

Josephine Kennedy (NCRR ISSO, delegated by the NCRR Privacy Coordinator, Cindy McConnell)

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCRR Electronic Funds Management System (eFMS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-4803-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: No

- 7. System Name (Align with system Item name): NCRR Electronic Funds Management System (eFMS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sean Hagan
- **10. Provide an overview of the system:** The eFMS is a web-enabled fiscal planning tool of the current fiscal year for the Office of Financial Management (OFM) and NCRR managers. Both dynamic data from IMPAC II and local non-enterprise data are available. Grant data are displayed in a variety of formats, including web pages, web summary tables, Excel spreadsheets and formal reports. This system provides the Budget Officer with a means to ensure appropriate fiscal control, monitor obligations to verify compliance, and provide accurate, current information to NCRR management for the NCRR extramural portfolio.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No IIF

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: eFMS only contains Grant data, not financial data and not Privacy Act data: Grants Financial Management Reporting and Information; Grants Planning and Resource Allocation Budget Formulation Information; Program Monitoring Control and Oversight. No IIF is collected or maintained in the system.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No IIF

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No IIF

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Josephine Kennedy (NCRR ISSO, delegated by the NCRR Privacy

Coordinator, Cindy McConnell)

Josephine Kennedy (NCRR ISSO, delegated by the NCRR Privacy Coordinator, Cindy McConnell)

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCRR Employee Database Internet Edition (EDie)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-90-0018, 09-90-0024, 09-25-0216

5. OMB Information Collection Approval Number: N/A

- **7. System Name (Align with system Item name):** NIH NCRR Employee Database Internet Edition (EDie)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Bonnie Richards
- 10. Provide an overview of the system: EDie is a web-based application that allows Institutes to accurately maintain individual employee, contractor, fellow, guest, and volunteer information, as well as plan for, monitor, and report on workforce staffing levels. To minimize duplicate data entry, the standard business systems from which EDie currently downloads are the NIH Human Resources Database (HRDB), the Fellowship Payment System (FPS), the NIH Enterprise Directory (NED), and FSA Atlas. HRDB is EDie's source for information about general hire employees, including General Schedule, General Wage, Commissioned Officers, and others. The official data that is stored in HRDB, including payroll information, is available for each employee and can be viewed by those users with corresponding access privileges. FPS is the source for information about visiting fellows, including their stipend and sponsorship information. NED is the source for information about contractors and other special volunteers. Because these are not direct hire employees, there is no payroll or FTE information available for these employees. EDie also pulls in locator information from NED for every employee that is stored in EDie and who has a corresponding NED ID. FSA Atlas is the source for Visa information. EDie provides an efficient and effective way to manage and report on the workforce of the Institute/Center (IC). It provides the ability to track and report on planning records. It allows users to update staff information for future actions while also having the ability to view the official source information, staffing summary and trend information.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether

provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\rm N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: EDie tracks all information pertinent to a personnel file for the purpose of personnel management activities. Information is collected from employees via the Human Resources Database (HRDB) system, Fellowship Payment System (FPS), nVision Data Warehouse and NIH Enterprise Directory (NED). Uses consist of the following: a) tracking a time-limited appointment to ensure renewals are done in a timely manner, thereby avoiding any break in service; b) ensuring that allocated FTE ceilings are maintained; c) ensuring salary equity for various hiring mechanisms; d) providing reports requested by the NIH Director, the IC Director, and other management staff, as requested; and e) maintaining lists of non-FTEs, special volunteers, contractors, and other hiring appointments. Information collected constitutes PII such as name, date of birth, social security number, personal mailing address, personal phone numbers, personal email address, education records and employment status. It is mandatory for employees to submit personal information.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.
- (Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) PII in the system is downloaded from the HRDB, FPS, nVision Data Warehouse and NED. Changes to HRDB or changes in the way information is used is relayed to employees via official notices from the NIH Office of Human Resources (OHR). Individuals are notified of the collection and use of the data as part of the hiring process. This is a mandatory requirement of potential job applicants seeking employment at NIH.
- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: PII stored in EDie is accessed by a very limited number of administrative staff with a "need-to-know" status. EDie is password protected and sensitive data is encrypted. The system is located on a server in a secure server room behind the NIH firewall.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name:

Josephine Kennedy (NCRR ISSO, delegated by the NCRR Privacy Coordinator, Cindy McConnell)

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 1/11/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCRR Grants Workflow Information System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-4803-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: No

- **7. System Name (Align with system Item name):** Grants Workflow Information System (GWIS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Gregory Farber, Ph.D.
- **10. Provide an overview of the system:** GWIS provides web-based and Microsoft Outlook integration to help authorized NCRR personnel automate and improve the grant management processes/workflows.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No IIF
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: GWIS is an internal grants workflow solution. Information is obtained from the IMPAC II and eFMS (NCRR Electronic

Funds Management System). This information is for internal use only, and only the minimal necessary data is collected to support the NCRR internal grants workflow process. GWIS is integrated with Microsoft Outlook for authorized NCRR users. Workflows have been identified and are being developed to process Unsolicited Administrative Supplements, Carry-Over Requests, Funding Opportunity Announcements (FOAs)/ Program Announcements, Annual Progress Report Approvals, National Advisory Research Resources Council (NARRC) Processes, New and Competing Continuation Awards, and Competitive Administrative Supplements.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No IIF

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No IIF

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name:

Josephine Kennedy (NCRR ISSO, delegated by the NCRR Privacy Coordinator, Cindy McConnell)

Josephine Kennedy (NCRR ISSO, delegated by the NCRR Privacy Coordinator, Cindy McConnell)

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCRR Internet PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 3/30/2012

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-4803-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

- **5. OMB Information Collection Approval Number:** No
- 6. Other Identifying Number(s): No
- 7. System Name (Align with system Item name): NCATS Internet Website
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Josephine Kennedy
- **10. Provide an overview of the system:** NCATS Public Website used to disseminate information about NCRR resources and grant programs to biomedical researchers with NIH or other peer-reviewed funding via the world wide web.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $No \ IIF$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The NCATS website will disseminate information on NCATS initiatives and activities of relevence to the research community. Shares employee office contact information: name, title, position description, office location and phone numbers to expedite communication with the public. This information is not

considered IIF because it is publically available and in the context of how it is presented cannot cause harm to the individual.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No Information in Indentiafiable Form. NCATS employees are notified that their office contact information is made publically available in the course of their duties.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: NA

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name:

Josephine Kennedy (NCRR ISSO, delegated by the NCRR Privacy Coordinator, Cindy McConnell)

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCRR Intranet PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-4803-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

- **5. OMB Information Collection Approval Number:** No
- **6. Other Identifying Number(s):** No
- 7. System Name (Align with system Item name): NCRR Intranet
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sean Hagan
- **10. Provide an overview of the system:** To disseminate relevant information and useful dynamic applications to Center employees.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No IIF
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The NCRR Intranet is used internally to disseminate useful information to authorized NCRR employees and contractors. Shares employee information: name, title, position description, office location and phone numbers (internally only) to increase organizational communication and efficiency. This information is not considered IIF because it is publically available and in the context of how it is presented cannot cause harm to the individual. This information is "opt out" for each employee.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No IIF

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No IIF

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name:

Josephine Kennedy (NCRR ISSO, delegated by the NCRR Privacy Coordinator, Cindy McConnell)

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCRR NCRR General Support System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-4802-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: No

- 7. System Name (Align with system Item name): NCRR General Support System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sean Hagan
- **10. Provide an overview of the system:** The system is a General Support System (GSS) and does not directly collect or store information.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system is a General Support System (GSS) and does not directly collect or store information. The applications/systems residing on the GSS collect and store information. Therefore, individual PIAs have been prepared and submitted for the applications/systems residing on this GSS.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Josephine Kennedy (NCRR ISSO, delegated by the NCRR Privacy

Coordinator, Cindy McConnell)

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCRR Science Information System (SIS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-4802-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: No

- 7. System Name (Align with system Item name): NCRR Science Information System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: R. Jean Babb
- **10. Provide an overview of the system:** A database system used by NCRR staff to review annual progress report data, code the research activites, and prepare reports highlighting scientific accomplishments. This information is invaluable in supporting GPRA, PART, and other materials used to inform the Administration, Congress, interested parties and the general public. NCRR is working to integrate and strengthen clinical informatics.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): NCRR and NIH budget officials for reporting to Congress. Shares information internally for generating funding reports for NIH OD and congress. Ref: 09-25-0036
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: Information is obtained from the IMPAC II system and populates this database for internal use only. Information collected is the minimal necessary to code and report on research projects for funding the grantees and investigators. Mandatory for eRA submission. In addition, SIS now collects the name, email address, phone number (and Fax) for external users needed for the Federated Login process of registering users in the external active directory.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The process in place is governed by IMPAC II, an NIH Enterprise System maintained by eRA. SIS has no additional processes in place.

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Policy and procedures are in place for administrative management of the system. Technical control is: username and password login, firewalls, IDS, antivirus, and audit logs. Physical access to the server room is protected by double set of locked doors and must be accessed using a key fob and pass code (cipher lock).

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name:

Josephine Kennedy (NCRR ISSO, delegated by the NCRR Privacy Coordinator, Cindy McConnell)

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCRR Status of Funds Internet Edition (SOFie)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-3199-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

- 7. System Name (Align with system Item name): NCRR SOFIE
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Bonnie Richards
- **10. Provide an overview of the system:** Manage expenditures and obligations. The purpose of the system is to monitor expenditures. Program helps project the budget; allows users to know how much money is left in the FY to spend.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No IIF
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: All accounting transactions are available for viewing in VSOF. The information is used to track and plan fiscal budgets. It is necessary to have access to this data in order to comply with appropriations laws and

regulations. Data elements stored are: arbitrary Document #, Object Class Code, Vendor, Description of Expenses, and Purchase Amount.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No IIF

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No IIF

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Josephine Kennedy (NCRR ISSO, delegated by the NCRR Privacy

Coordinator, Cindy McConnell)

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NCRR Visual Employee Database System (VEDS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-09-02-3196-00-403-131

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-90-0018

5. OMB Information Collection Approval Number: No

- 7. System Name (Align with system Item name): NCRR Visual Employee Database System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Bonnie Richards
- **10. Provide an overview of the system:** VEDS is a windows based application primarily used to track personnel information.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The data is shared internally for administrative use only and will not be shared with other entities. Ref: 09-90-0018
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The NETCOMM application collects personal information from the NIH Human Resource Database (HRDB) through bi-weekly downloads. Social security numbers, names, grades, salaries, addresses,

telephone numbers, and job titles are included in the data collected. The data collected is used to manage the organization's personnel information. Under authority 42 USC 287c-21

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) IIF in the system is gathered from the HRDB and NED systems. Changes to the system or changes in the way the information is used is relayed to employees via official notices from NCRR or the System Owners. Individuals are notified of the collection and use of data as part of the hiring process and is mandatory if the potential job applicant wishes to seek employment at NIH.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** Access to sensitive data fields is limited to those that need to know. Each user signs a security statement, and any violations results in loss of access to system. Policy and procedures are in place for administrative management of the system. Technical control is: username and password login, firewalls, IDS, antivirus, and audit logs. Physical access to the server room is protected by double set of locked doors and must be accessed using a key fob and pass code (cipher lock).

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name:

Josephine Kennedy (NCRR ISSO, delegated by the NCRR Privacy Coordinator, Cindy McConnell)

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Pla

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NEI AMB Survey PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 1/7/2011

2. OPDIV Name: NIH

- 3. Unique Project Identifier (UPI) Number:
- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A
- **5. OMB Information Collection Approval Number:** N/A
- 6. Other Identifying Number(s): N/A
- **7. System Name (Align with system Item name):** NIH NEI Administrative Management Branch (AMB) Survey
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Felicia Powell
- **10. Provide an overview of the system:** Administrative Managing Branch (AMB) Survey is an online survey to record how AMB has been serving its NEI clients. The survey asks about topics such as the types of services provided, level of interaction, professionalism in the office, etc. The system does not collect, store, or disseminate PII.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A: The system does not collect, store, or disseminate PII.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: This voluntary survey collects information from NEI staff about services provided and quality ratings. It includes names of Administrative Officers and optional user names and organizational information (they

can leave these fields blank and submit the survey anonymously). Data is analyzed to evaluate administrative services. The system does not contain PII--only business contact info for NEI staff.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A: The system does not collect, store, or disseminate PII

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A--The system does not collect, store, or disseminate PII.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Trevor Peterson

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 2/24/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NEI Animal Order and Support

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 6/27/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH NEI Animal Order and Support
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: James Raber
- **10. Provide an overview of the system:** NEI Animal Order and Support is used to track all animal orders coming in and out of NEI. The system does not collect, store, or disseminate PII.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A: The system does not collect, store, or disseminate PII.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system collects biological details about animals, care and housing information, and associates them with investigators. The system collects this information for tracking and ordering laboratory animals and their protocols. There is no PII, and submission is voluntary.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A: The system does not collect, store, or disseminate PII.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The system does not collect, store, or disseminate PII. All relevant administrative, technical, and physical controls are inherited from the NEI GSS.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Trevor Peterson

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 8/4/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NEI CAF Animal Order and Support

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 6/27/2011

2. OPDIV Name: NIH

- 3. Unique Project Identifier (UPI) Number:
- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A
- **5. OMB Information Collection Approval Number:** N/A
- 6. Other Identifying Number(s): N/A
- **7. System Name (Align with system Item name):** NIH NEI Central Animal Facility (CAF) Animal Order and Support
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: James Raber
- **10. Provide an overview of the system:** Central Animal Facility (CAF) Animal Order and Support is a NEI run tracking system. This system tracks animal orders for the CAF for multiple NIH ICs: NIDCR, NICHD, NIMH, NHGRT, NINDS, NEI, NCI, and OD. The system does not collect, store, or disseminate PII.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A: The system does not collect, store, or disseminate PII.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system collects

biological details about animals, care and housing information, and associates them with investigators. The system collects this information for tracking and ordering laboratory animals and their protocols. There is no PII, and submission is voluntary.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A: The system does not collect, store, or disseminate PII

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The system does not collect, store, or disseminate PII. All relevant administrative, technical, and physical controls are inherited from the NEI GSS.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Trevor Peterson

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 8/4/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NEI Calcium Calendar PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 1/7/2011

2. OPDIV Name: NIH

- 3. Unique Project Identifier (UPI) Number:
- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A
- **5. OMB Information Collection Approval Number:** N/A
- 6. Other Identifying Number(s): N/A
- 7. System Name (Align with system Item name): NIH NEI Calcium Calendar
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Robert Fariss
- **10. Provide an overview of the system:** The Calcium Calendar is a commercial off-the-shelf, web-based scheduling software that allows the administrator to create calendars that users of the system can access for reserving equipment or services. The Calcium Calendar is hosted on an NEI server provided by NEI's IT branch. The Calcium Calendar hosts equipment pages for the Biological Imaging Core, Flow Cytometry Core, and Visual Function Core. Only NEI employees with a valid NIH login and password are able to access the calendars, because the login authentication uses the NEI employee roster, which is constantly updated. The system does not collect, store, or disseminate PII.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A: The system does not collect, store, or disseminate PII.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: The only information collected about the user is federal contact data--the user name and work telephone number--for managing scheduling of equipment in National Eye Institute core facilities. The Calcium system does not collect PII about members of the public, only business contact info for federal employees, which is required for proper scheduling.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A: The system does not collect, store, or disseminate PII.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A--The system does not collect, store, or disseminate PII.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Trevor Peterson

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 2/24/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NEI Cogan Collection Website

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 1/31/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH NEI Cogan Collection Website
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Fausto Vela
- **10. Provide an overview of the system:** An extensive collection of clinical ophthalmic cases and their pathology for use by researchers and clinicians to aid in preventing, diagnosing, and treating diseases of the eye and visual system. The system does not collect, store, or disseminate PII.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A: The system does not collect, store, or disseminate PII.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The Cogan Collection website is an extensive collection of clinical ophthalmic cases and their pathology for use by

researchers and clinicians to aid in preventing, diagnosing, and treating diseases of the eye and visual system. The cases and the pathology were collected by the late Dr. David Glendenning Cogan during his career and are now posted to the internet. There are no access restrictions (i.e. public access) to the website as it is designed to be available to all doctors, students, etc. for learning/research purposes. The cases do not identify patients and are intended to be used as a teaching collection of ophthalmic pathology. The only information provided for any case is age and gender (i.e, 45-yr old male). Photographs are of different parts of the eye and cannot be used to identify individuals. PII is not collected, shared, or maintained.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A: The system does not collect, store, or disseminate PII.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The system does not collect, store, or disseminate PII. All relevant administrative, technical, and physical controls are inherited from the NEI GSS.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Trevor Peterson

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 3/7/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NEI Computer Inventory PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 1/31/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH NEI Computer Inventory
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Don Smith
- **10. Provide an overview of the system:** Dynamic form for collection of NEI computer inventory information and data. The system does not collect, store, or disseminate PII.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A: The system does not collect, store, or disseminate PII.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The NEI Computer Inventory is a dynamic form used to help NEI maintain and track computer inventory and data. The Inventory form collects information such as serial numbers, computer names, MAC addresses, IPs, etc. This information is mandatory to maintain an accurate inventory. The inventory does not collect, store, maintain PII.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A: The system does not collect, store, or disseminate PII.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The system does not collect, store, or disseminate PII. All relevant administrative, technical, and physical controls are inherited from the NEI GSS.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Trevor Peterson

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 3/2/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NEI Employee Database Internet Edition (EDie)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 6/27/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-90-0018

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH NEI Employee Database Internet Edition (EDie)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Felicia Powell
- **10. Provide an overview of the system:** NEI EDie is a system that pulls HR information from the NIH system HRDB. This data is then used by NEI for HR and administrative purposes.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The NEI EDie system only discloses information within NIH during transfers, terminations, and hires of new employees within NIH/NEI.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: EDie pulls existing HR data from HRDB, FPS, NED, and FSA Atlas. This includes business contact information for all NIH

employees and contractors, and more specific payroll information for NIH employees only. Its function is to consolidate the data from these various sources and allow easily customizable reporting for personnel data analysis. The information includes PII for government employees only; submission in the original systems is mandatory. Only 6 members of NEI have access to this data.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) There is not a notification process yet. Will develop one with the new NEI EDie C&A.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** Logical access to EDie is primarily via the web site. Specific roles are managed by EDie. Access to the server running EDie is limited to authorized system administrators via active directory (AD). SQL access is limited to authorized system administrators via AD and to three SQL accounts. NetComm support staff and the EDie web application have read/write access to the database information. A SoFie/EDie direct database link has read only access to EDie. Two system administrators assign access roles to a restricted group based on job function. Only AOs and ATs (and the sysadmins) have access to PII.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Trevor Peterson

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NEI Eye Bank (NEIBank) PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 6/27/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-8710-00-110-219

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No
- **5. OMB Information Collection Approval Number:** No
- **6. Other Identifying Number(s):** 2004 UPI=009-25-01-26-02-8710-00-202-069, Older UPI=009-25-01-26-02-8710-00
- 7. System Name (Align with system Item name): NIH NEI Eye Bank (NEIBank)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Graeme Wistow
- **10. Provide an overview of the system:** NEIBank is a web-based resource for the ocular genomics community.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The data presented includes annotated, public domain expressed sequence tag (partial cDNA sequences) collections for multiple eye tissues from human and several other species; public domain eye-related human SAGE data; a database of known human eye disease genes from the published literature; and visualization tools for the genomic loci of as yet unmapped eye diseases. These resources

provide an overview of the known transcriptional repertoire of the eye with visualization of specific clones, splice variants, human SAGE tag counts and candidate disease regions.

There is no IIF or personal information.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) There are no processes in place. The system does not collect, maintain or store IIF or any user solicited material.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Trevor Peterson

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Pla

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NEI Grants Management PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 6/27/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-04-00-02-8712-00-110-219

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): 2004 UPI=009-25-04-00-02-8712-00-205-080, Older UPI= 009-25-01-03-02-8703-00

- 7. System Name (Align with system Item name): NIH NEI Grants Management
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Fausto Vela
- **10. Provide an overview of the system:** Support management of NEI's grants.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): This system shares IIF with NIH IMPACT II. Information is shared to allow grants management administration data to be synchronized with IMPACT II.

09-25-0036

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: This system shares IIF with

NIH IMPACT II. Information is shared to allow grants management administration data to be synchronized with IMPACT II.

IMPACT II states that Information is given to IMPACT II voluntarily.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) All information is extracted from IMPAC II - all consent and notification is handled by IMPAC II.

The system does not have any notification and consent processes in place in addition to the IMPAC II procedures.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Physical access to the NIH campus requires an identification badge or as a registered visitor. Physical access to all server rooms is restricted, brass key required.

Data is stored on the system in folders with permissions appropriate to the data. Active directory enforces access. Folder owners are responsible to authorizing access for individuals and adding to existing permission groups.

Access to the files and databases is through userid and password as enforced by NIH active directory. An additional userid/password challenge is presented when logging in to the database.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Trevor Peterson

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Pla

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NEI Histology Lab Database

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 1/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0099

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH NEI Histology Lab Database
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Chi Chao Chan
- **10. Provide an overview of the system:** Referring physicians send the patient's name, age, and clinical history as part of request for histological analysis; lab staff enter data; senior lab staff add test results and generate reports to send back (in hard copy) to the referring physician.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Analysis report is sent back to the referring physician for treatment.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: NEI collects patient name, age, and clinical history from the referring physician; NEI adds a record number and a write-up

of analysis results. The information contains PII, and participation is voluntary, though PII is required if patients choose to participate.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) A detailed consent form is provided to the referring physician and must be returned with the patient's signature. Patient consent is necessary *before* samples are sent for analysis, and the referring physician is the logical point of contact. Also, the analysis is provided to the referring physician for diagnosis and treatment. Because there is no direct contact between NEI and patients, and because the analysis is a one-time service, no changes are anticipated after the fact, and no notification process is in place.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Physical access to the NIH campus requires an identification badge or as a registered visitor. Physical access to all server rooms is restricted, brass key required.

Data is stored on the system in folders with permissions appropriate to the data. Active directory enforces access. Folder owners are responsible to authorizing access for individuals and adding to existing permission groups.

Access to the files and databases is through userid and password as enforced by NIH active directory. An additional userid/password challenge is presented when logging in to the database.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Trevor Peterson

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 2/24/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NEI 121 PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 1/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): NIH NEI I2I

- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Lore Anne McNicol
- **10. Provide an overview of the system:** I2I is a readily-searchable NEI grant application database based on NIH's IMPAC II system. NEI extramural research staff use it to retrieve information in managing their grant portfolios.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): This system shares PII with NIH IMPAC II. Information is shared to allow grants management administration data to be synchronized with IMPAC II.

09-25-0036

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: I2I imports grant data from

IMPAC II for simpler, more customized viewing. We use the information to analyze, review, and decide which grants we are going to fund. Applicant name, birthdate, phone number, e-mail, and address are included; contact info could be business or personal. Submission is voluntary.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) All information is extracted from IMPAC II - all consent and notification is handled by IMPAC II.

The system does not have any notification and consent processes in place in addition to the IMPAC II procedures.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Everyone who comes on the NIH campus must have an identification badge or register as a visitor. Physical access to all server rooms is restricted, brass key required.

Data is stored on the system in folders with logical access appropriate to the data. Domain controls restrict access. Folder owners are responsible to authorizing access for individuals and adding to existing permission groups.

Access to the files and databases is through userid and password as enforced by NIH active directory. An additional userid/password challenge is presented when logging in to the database.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Trevor Peterson

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 2/24/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NEI Internet Website PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 6/27/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: Not Applicable

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0106

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): Old:

2004 UPI 009-25-01-27-02-8711-00-305-109, Old UPI: 009-25-02-01-02-3036-00

- 7. System Name (Align with system Item name): NIH NEI Internet Web site
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Kym Collins-Lee
- **10. Provide an overview of the system:** To share information with the public about vision research and eye diseases and disorders.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Mailing list and contact information for those requesting information from NEI's Office of Communications. 09-25-0106

A separate email list is maintained by the subscribers. It contains only the email address of the subscriber.

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: Contact information is voluntarily collected. Information collected is only the information necessary to mail pamphlets or other printed information. Email address is voluntarily entered if the user joins an email list.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Information is submitted voluntarily, consent is assumed when contact information is submitted. Individuals may request corrections to or be removed from the email list.

There are no processes in place to notify users when major changes occur to the system.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Requests for information, name and address, are only available to NEI staff.

Email addresses on the email list are maintained by NEI staff and by specific request of the subscriber.

The system is monitored daily for intrusion by Big Brother, system logs, disk usage, and other indications of intrusion. MacAfee Outbreak Manager is used to control any possible virus outbreaks.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Trevor Peterson

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Pla

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NEI Intranet Website PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 6/27/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): National Eye Institute (NEI) Intranet
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Anna Harper
- **10. Provide an overview of the system:** The NEI Intranet Website is an information sharing site dedicated to providing only NEI users with vital information about NEI as an organization as well as useful administrative information.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\rm N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: N/A No PII collected or dissemenated
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g.,

disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) All security controls can be found in the NEI GSS C&A SSP. The NEI Intranet falls under the NEI GSS and inherits all its controls.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: All controls can be found in the NEI GSS SSP.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Trevor Peterson

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NEI NEI eyeGENE [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 6/27/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0099

5. OMB Information Collection Approval Number: None

6. Other Identifying Number(s): None

- 7. System Name (Align with system Item name): NIH NEI eyeGENE v4
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Santa Tumminia
- **10. Provide an overview of the system:** The eyeGENE system stores phenotype, genotype, patient demographic, and other administrative data collected from various types of participating users. Sharing this information among clinicians and researchers allows the analysis of larger datasets that are necessary to identify novel genetic risk factors for ocular diseases, and answer pharmaco-genetic and epidemiologic questions of ocular disease.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The eyeGENE system is accessed by four classes of users: clinical, CLIA Lab, central administrators, and researchers viewing anonymized data through the analytical interface. The last category of user never has access to any PII.

Clinical users have full access to PII for the patients of their own clinic. This PII would be maintained and accessible to all such users via medical records in their clinic.

All CLIA users have IRB clearance that requires close protection for any PII they may view. Nevertheless, CLIA users do not see the name, address, phone number, or other related identifying information concerning a patient for whom DNA has been shipped for processing. The only identifying information that a CLIA lab sees for a patient is race, sex, and date of birth. Race and sex are required to be accessible as these are related to the genetic test results being processed. DOB is required to ensure that the DNA tube being processed is in fact for the correct patient. Once again, all CLIA lab users must have IRB clearance, which ensures protection of these small pieces of PII data.

eyeGENE central administrators, all of whom are staff of the NEI, have access to full name, address, phone number, race, sex, and DOB for patients, as these are needed for various eyeGENE functions. All such staff who have access to this data are subject to rigorous security screening and all are authorized to view such PII data.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The eyeGENE system collects data for phenotypes, genotypes, tissue specimens, medical images, consent forms, patient demographics, specifications for event-triggered emails to selected eyeGENE users, dynamic metadata defining clinical questions for each diagnosis, plus supporting administrative and additional data. This data is collected to allow researchers to analyze correlations between phenotypes and genotypes for inherited eye disorders, and also to manage the real-time collection and validation of such data as entered by multiple eyeGENE partners. This information is shared with individually identifiable data fields only by those authorized users directly involved in handling this information, including clinicians who perform exams on this patient. Aggregated and anonymized data, containing no PII data, will be made available to authorized users with a research interest in this data. A limited set of PII is collected for patients, primarily in fields for name, address, phone number, race, sex and date of birth. Access to PII is carefully controlled and protected, with access only by authorized users and multiple layers of security protection as well as audit tracking for all system functions. Submission of this limited set of PII for patients is mandatory, as clinicians must have access to such information for appropriate patient care.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) A written, signed consent form is required for patients to participate. For each participating clinical organization collecting data, the phone number of the organization and the email of at least one staff member of the organization will be kept as a

contact information should some intrusion into eyeGENE that could compromise privacy be detected

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The eyeGENE system is accessed by four classes of users: clinical, CLIA Lab, central administrators, and researchers viewing anonymized data through the analytical interface. Each class has its own distinct level of access and verification.

Technically, the system design of eyeGENE contains multiple protections to ensure that all data, including PII, is available only to authorized users. These security protections are designed to high government standards, and are closely reviewed for each new release of the eyeGENE system. In addition, an audit log is maintained tracking each time any user accesses PII, which serves as a double-check to track who viewed such data.

Physically, all eyeGENE data is stored on CIT servers, hosted at NIH, behind the NIH firewall.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Trevor Peterson

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NEI NEI GSS [System] PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 6/27/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** National Eye Institute General Support System (NEI GSS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Fausto Vela
- **10. Provide an overview of the system:** NEI's mission for the NEI GSS is to support eye research for public health by providing services to its users and the public. NEI GSS also holds these systems under its C&A package:

AMB Survey

CAF AFMS

Calcium Calendar

Clinical Studies Update System

Cogan Collection Website

Grist

I2I

LabTrack

Microarray Support

NEI AFMS

NEI Internet Website

NEI Intranet Website

NEI TGMDB

NEIBank

NEIPro

NEI New User Form

Oracle Password Changer

OAM Survey

Property Forms

Staff Directory

VISION Network

- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N_0
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The NEI GSS only collects internal business and research data for use with its program areas. This includes information that is work related such as work email, phone number, etc. No personal information is collected or disseminated.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The NEI GSS does not collect, store, or disseminate PII. All administrative, technical, and physical controls are described in full in the

NEI GSS SSP. There are multiple levels of security for the NEI GSS, starting with the operating system to weekly checks for accuracy by the ISSO.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Trevor Peterson

Sr. Official for Privacy Approval: Promote **Sr. Official for Privacy Name:** Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NEI NextGen PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 6/27/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH NEI NextGen
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Elizabeth Murphy
- **10. Provide an overview of the system:** The NextGen system (COTS from NextGen Healthcare Information Systems, Inc.), is a highly customizable system for the capture of clinical data. The NEI has implemented this system as a clinical research database, which is used by all authorized clinical personnel for the real-time capture of clinical research data in the NEI outpatient clinic. This data includes demographic, medical history, medication and ophthalmic data. All data in the system is collected as part of IRB approved clinical research protocols which govern its use.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Data is shared for the purpose of clinical research, as part of IRB approved protocols involving members of different ICs.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: The NextGen system is used for the real-time capture of clinical research data in the NEI outpatient clinic. This data includes demographic (including PII), medical history, medication and ophthalmic data. All data in the system is collected as part of IRB approved clinical research protocols which govern its use. The collection of personal information is mandatory for enrollment in a clinical protocol, however said enrollment is completely voluntary.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Within an ongoing clinical protocol, changes to the protocol, including changes in how the data from the protocol will be used, can trigger the need to re-consent the patient. This re-consenting process informs the patient of the changes. Data from a terminated clinical protocol can be re-used with the permission of the IRB, although it would be de-identified before re-use unless the patient was contacted to re-consent. The method for contacting the patient would be determined by the IRB based on the information which was to be included in the research analysis.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** Access to the PII on the system is managed through the process of only granting login accounts (user name, password and/or PIN) to authorized clinical personnel. Logins are managed as security groups to further manage the level of access, ranging from read-only for low-level support staff to full access for system administrators. However, because of the interface from the hospital admissions department, all local changes (changes by users with login access) to demographic information (name, address, DOB, etc) will be over-written by the patient authorized changes transmitted from the NIH CC admissions department.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Trevor Peterson

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NEI Oracle Password Changer

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 1/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH NEI Oracle Password Changer
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Don Smith
- **10. Provide an overview of the system:** Enable users to change their own Oracle passwords without logging on to Oracle. This application runs internally and adheres to the NIH password policy. The system does not collect, store, or disseminate PII.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A: The system does not collect, store, or disseminate PII.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system requires the user's Oracle username and password, so they can update their password periodically for good IT security. Users can be NEI staff, including employees and contractors. The information contains

no PII. No PII can be used to substitute for a username or password, and rules are strict enough that it is unlikely anyone will use PII for their password.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A: The system does not collect, store, or disseminate PII.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The system does not collect, store, or disseminate PII. All relevant administrative, technical, and physical controls are inherited from the NEI GSS.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Trevor Peterson

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Pla

Sign-off Date: 2/16/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NEI Property Forms PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 1/28/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH NEI Property Forms
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Cheyanne Keene
- **10. Provide an overview of the system:** This system allows NEI staff to electronically request a property pass, property transfer, move request, or surplus request. This system was designed as a means of speeding up the process of these requests. The requests do not require the collection of personal information.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A: The system does not collect, store, or disseminate PII.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Basic information such as name, location and phone number are gathered. Information is imported from the NIH Enterprise Directory for NEI staff only. Other information collected includes lab/branch, property custodian, specific property item details (decal, manufacturer, model, and serial) and

CAN number. This information is used to process the specific request within the NBS Property. Contact information is required for the process, but this system does not contain PII.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A: The system does not collect, store, or disseminate PII.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The system does not collect, store, or disseminate PII. All relevant administrative, technical, and physical controls are inherited from the NEI GSS.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Trevor Peterson

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 3/11/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NEI Recognizing Extraordinary Work and Rewarding Distinguished Service (REWARDS) PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 6/27/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: none

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): none

- **7. System Name (Align with system Item name):** NEI Recognizing Extraordinary Work And Rewarding Distinguished Service (REWARDS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Angelia Neal
- **10. Provide an overview of the system:** database and web interface to submit, route, and approve incidental award nominations
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: staff names, work contact info, and award justification and approval information, to automate workflow of the award nomination and approval process; there is no PII

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Trevor Peterson

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NEI Status of Funds Internet Edition (SOFie)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 6/27/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-3199-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): NA

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- **7. System Name (Align with system Item name):** NEI Status of Funds Internet Edition (SOFie)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Marilyn Laurie
- **10. Provide an overview of the system:** SOFie is a Web-based financial reporting/tracking tool that enables NIH ICs to manipulate and report on financial transactions downloaded from the Budget & Finance database in the NIH Data Warehouse. (The NIH DW Budget & Finance database comprises data downloaded from the NIH Business System.) Appointment and authority is given to the National Institutes of Health under 5 U.S.C. 301 and 302, 44 U.S.C. 3101 and 3102, Executive Order 9397.

The SOFie application supports the efforts of several offices and branches within NEI, allowing budget offices to track expenditures of direct, reimbursable, and non-appropriated funds in a fiscal year. Additionally, SOFie is used to reflect budget allocations and projected expenditures at the operating level.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): No sharing or disclosures at this time. Refer to the Privacy Act systems notice 09-25-0217 section entitled ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES for the allowed disclosures of IIF.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Grantee and contractor (NIH grant recipient and contractor) information maintained comprises: name and financial account information. User (NIH employee) information maintained comprises: name, business phone numbers, email addresses. NEI accounting transactions are downloaded from the Budget & Finance database in the NIH Data Warehouse. (The NIH DW Budget & Finance database comprises data downloaded from the NIH Business System.) The data is used to plan, track, and report on NEI fiscal budgets.

The SOFIE system collects First Names, Last Names, Business Phone Numbers, Fax Numbers, and Email Addresses of its users voluntarily.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No processes are in place to notify and obtain consent from the individuals whose information is in the system when major changes, as defined in Section 208 of the E-Government Act of 2002, occur to the system.

When applying for grants or contracts, applicants are informed that information is collected for accurate identification, referral and review by program managers. Refer to the system of record 09-25-0217 section entitled ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES for a summary of the notice of uses of information.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls: Physical controls: Guards, Identification badges, key cards and closed circuit TV

Technical controls: User ID, passwords, firewall, Virtual Private Network (VPN)

Administrative controls: Weekly backups, weekly log file checks, warning banners, database management

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Trevor Peterson

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NEI Telework PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 6/27/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: no

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0216

- 5. OMB Information Collection Approval Number: no
- 6. Other Identifying Number(s): no
- 7. System Name (Align with system Item name): NEI Telework Application
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Trevor Peterson
- **10. Provide an overview of the system:** NEI Telework Application is a NEI Automated System that allows for the submission, routing, and approval of telework requests. It is an institute-wide, mandatory, automated system that replaces a manual process.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Disclosures are made in accordance with SOR # 09-25-0216

Names contact information of individuals are collected and may be shared within the Institute or division in order to carry out the business process.

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: This system is used to request approval for telework and store agreement (schedule, work arrangement, justifications)

and necessary contact information (name, work org, address, phone, fax, e-mail, home address, phone, fax). Other than names and contact information of applicant employees, and the names and e-mail addresses of the approving officials, it tracks no other personally identifiable information. The workflow process involved allows the position and disposition of a task or activity (with whom, when) to be identified in the organization. Information is obtained voluntarily.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The IIF contained in the system is that of employees and contractors of the Institute. This information was obtained voluntarily from the employees and is used to manage administrative tasks within the department. There is no process in place to notify individuals of how their IIF will be used or if major changes occur.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Physical access to the NIH campus requires an identification badge or as a registered visitor. Physical access to all server rooms is restricted; combination or brass key is required.

Data is stored on the system in directories with permissions appropriate to the data and reviewed by the system administrator. The operating system enforces access based on the userid.

Access to the files and databases is through userid and password as enforced by the operating system. An additional userid/password challenge is presented when logging in to a database.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Trevor Peterson

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NEI Transgenic Mouse Database

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 1/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH NEI Transgenic Mouse Database
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Eric Wawrousek
- 10. Provide an overview of the system: The transgenic mouse database is a central repository for information about transgenic mice we are maintaining, and have maintained, in the NEI Intramural Research Program (IRP). It also tracks frozen mouse lines. Since the NEI Genetic Engineering Core tracks thousands of mice, and thousands of frozen samples, it is absolutely essential to have this information in an orderly database from which data can easily be retrieved. The database consists of multiple data tables in an Oracle database. The front end is accessed via a set of programs in MSAccess, and there is a web interface which allows IRP investigators to retrieve information about their mice directly from the database. The system does not involve PII.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A: The system does not collect, store, or disseminate PII.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) Most of the information in the database is generated by the Genetic Engineering Core (GEC). It deals only with investigators' mice and frozen mouse lines, and all information is only for government use. We do have investigators' names and their NIH laboratory and section affiliation. No personal information is maintained. (2) We use the information internally only to track GEC services provided to individual investigators. (3) As stated in (1), the system contains only the name of the federal investigator and his/her NIH laboratory/section affiliation. (4) Not applicable.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A: The system does not collect, store, or disseminate PII.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A--The system does not collect, store, or disseminate PII.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Trevor Peterson

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 2/28/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NEI VISION Network Members Only

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 6/27/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0106

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): VISION Network Members Only
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Kym Collins-Lee
- 10. Provide an overview of the system: The purpose of the VISION Public Information Network is to communicate vision research results to the public through its grantee institutions. Public Information Officers from NEI grantee institutions work with the NEI to develop ongoing programs to educate the public about the benefits of vision research. The Members Only section allows members to access special media materials and to post news release, projects and events; and advertise job opportunities.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s):
- (1) Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

- (2) Disclosure may be made from this system of records by the Department of Health and Human Services (HHS) to the Department of Justice, or to a court or other tribunal, when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has any interest in such litigation, and HHS determines that the use of such records by the Department of Justice, court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however, that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Names and e-mail addresses are used by the NEI staff and grantees to access the system to update the information and add new study descriptions. Names and e-mail address are required for the user to access the VISION Network Members Only section. Contact information of list members is available only to each other.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) A statement is included on the web site indicating the only usage is for the subscribers to communicate with each other. The only information collected is that supplied by the subscriber. If any change of information usage is made the subscribers will be contacted via email.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The server containing the VISION Network Members Only section is maintained by an NEI contractor who follows guidance from NSA, NIST, SANS, and CERT to maintain the security and integrity of the system.

Information contained in the lists is maintained by NEI staff and by specific request of the subscriber.

The system is monitored daily for intrusion by Big Brother, system logs, disk usage, and other indications of intrusion. MacAfee Outbreak Manager is used to control any possible virus outbreaks.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Trevor Peterson

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NHGRI Attention Deficit Hyperactivity Disorder Database [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/27/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-9199-00-404-138

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: not applicable

6. Other Identifying Number(s): not applicable

- **7. System Name (Align with system Item name):** NHGRI Attention Deficit Hyperactivity Disorder Database (ADHD)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Maria Acosta, MD
- **10. Provide an overview of the system:** Database of demographic and clinical research data on ADHD (Attention Deficit Hyperactivity Disorder).
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Data is shared among members of the ADHD research team. This information is further addressed in the NIH Privacy Act Systems of Record Notice 09-25-0200, published in the Federal Register, Volume 67, No. 187, September 26, 2002.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Name, date of birth, mailing

address, phone numbers, medical notes, email address, family and blood sample accession numbers, questionnaires completed by study subjects. Information is given voluntarily.

This research study on the genetics of Attention Deficit/Hyperactivity Disorder is collecting information from families with affected children in order to better understand the impact of genetics on the transmission of the disorder, and its manifestations.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Patients and/or parents sign an IRB (Internal Review Board) informed consent form mailed to them and mailed back to the research study coordinator. Patients and/or parents are informed that protocol related information will be used for research purposes and restricted to study team members only. Families that agree to participate are contacted by the study coordinator. No changes in the system or modifications in the database have been done from the original design. No modifications are expected. Currently no reason to re-contact families that have finished the data collection part of the study.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Access is limited to research team members only; files backed up regularly and back up files stored offsite; user ID and password required; firewall present; accounts locked after five minutes of inactivity, computers in locked offices

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Carol S. Martin, 301-402-5348

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NHGRI Career Resource Website

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 6/27/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 0

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): no

5. OMB Information Collection Approval Number: 0

6. Other Identifying Number(s): 0

- 7. System Name (Align with system Item name): NHGRI Career Resource Web Site
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Carla Easter
- **10. Provide an overview of the system:** The National Human Genome Research Institute (NHGRI) has developed an interactive on-line Genetic and Genomic Careers Resource Tool. The main goals of the web site are to educate and engage the audience in understanding what "genomics" is and to identify and describe the careers that exist now and may exist in the future in these highly active and emerging fields of science.

The web site is designed to provide Internet access to:

Inform students about possible careers in genetics and genomics;

Show the relationship between genetic careers and other disciplines (i.e., science writing);

Provide a resource for students, career counselors, parents, and teachers;

Provide viewers with a basic understanding of important information about genetics and genomics research; and

Expose the audience to professionals doing cutting-edge science.

Web site visitors will have the option to create their own "personal" web page within the site (which will be password protected) by setting up a logon profile. Personal pages will allow owners to create their own personalized list of the careers that they are most interested in and to rank their site preferences. Users will have the option to utilize this feature of the web, but will not be required to create a profile in order to use the site itself. Users may create a profile by creating a username and password that will allow them to access the site. User login information will not be managed by this site. If the user name and password is forgotten, the user will have to establish a new set of credentials. The user has full control of his/her personal page; NIH will not collect any information to manage these pages.

Users of this site can not customize their personal pages to contain any contact information, links or photos. The personal page only tracks choices made from the site while the person is on the site.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{No}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Registration information for setting up a personal profile/web page includes a user defined username and password of the user's choice which will be maintained on the server. This information is needed only if the user creates a personal web page, and wants to access it at another time. Creating a personal profile is not required (is voluntary). No IIF is collected or stored on the system. The information provided is about genetic careers and other disciplines (i.e., science writing).
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: Yes

50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Carol S. Martin, 301-402-5348

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NHGRI Community of Genetic Educators (CoGE)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/1/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: No

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN

number is required for Q.4): 09-25-0156

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

7. System Name (Align with system Item name): Community of Genetic Educators (CoGE) NIH

- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Jeff Witherly
- **10. Provide an overview of the system:** The "Community of Genetic Educators" web site was created to help connect genetic educators online. It is a forum for information sharing. With so many resources available, it is sometimes difficult for educators to know what will work in the classroom. This web site may be used to find resources, to recommend resources, learn from other members in similar situations, act as a mentor to other members, submit helpful lessons learned and resources, and work with the education team at the NIH Genome Institute (NHGRI) in reviewing and refining learning tools.

Each site visitor is asked to register on the first visit. Registration includes setting up an account with password, name, email address, state/country, zip code, language, time zone, current education position, type of school info, teaching experience and instructional focus. Voluntary information that further defines the visitor includes affiliations, a text box for a biography and the option to add a photograph.

After registration the visitor is given immediate access to the site which includes many resources and a messaging forum.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the

character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: To register for site access, the following information is mandatory: First and last name, email address, country, state, zip code, language, time zone, current education position, other positions, type of school, minority serving institution, location, school level, teaching experience, and instructional focus. Of the information required, name and email address are considered to be information in identifiable form (IIF).

The following information is voluntary: affiliations, biography, photo. A photo is considered to be information in identifiable form (IIF).

The "Community of Genetic Educators" web site was created to help connect genetic educators online. It is a forum for information sharing. With so many resources available, it is sometimes difficult for educators to know what will work in the classroom. This web site may be used to find resources, to recommend resources, learn from other members in similar situations, act as a mentor to other members, submit helpful lessons learned and resources, and work with the education team at the NIH Genome Institute (NHGRI) in reviewing and refining learning tools.

Each site visitor is asked to register on the first visit. Registration includes setting up an account with password and includes the mandatory information listed above. Voluntary information that further defines the visitor and will better introduce this person to others visiting the site.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) There is an extensive Privacy statement displayed on the registration page. Additional information is made available through a link called "Privacy" displayed on each web page, which includes the following:

Personally Provided Information

Information Required For Membership:

We require each member to enter a limited amount of personal information as part of the registration process of the CoGE web site. This information is typically required as part of our NHGRI educational course registrations, and will be used at the CoGE for contacting CoGE members about events, opportunities, and new educational products of value.

We have made every attempt to make the required information as minimal as possible for members. This information includes: your name, your email address, country, state, zip code, and current educational position (teacher, administrator, other). We will also ask you to choose a member name and a member password.

Your real name, and your email address are not shared online in the CoGE. Only CoGE administrators have access to this personal information. Members will only know your member name and your CoGE email address.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The amount of IIF collected is minimal, only that which is absolutely needed to meet the needs of the system's purpose.

Registration information is not available to the users of this site unless they chose to share with one another. This voluntary sharing of information is not being managed by the system.

From an administrative point of view, only a limited number of staff have access to the IIF. Support personnel will have access for maintenance purposes. The system owners and administrators will have access for the creation of aggregate reports. A well constructed set of rules of behavior are in place for all who have access to the IIF.

The technical and physical aspects are properly cared for by placing the system on a secured server, in a secured location. A separate C&A was completed for the server that houses this application by the IT staff.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Carol S. Martin, 301-402-5348

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NHGRI Edie PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/14/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-90-0018, 09-90-0024, 09-25-0216

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): None

- 7. System Name (Align with system Item name): NIH NHGRI Edie
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Patricia Messick
- **10. Provide an overview of the system:** Employee Database System Internet Edition (EDie) is the web-based and enhanced version of the VEDS. EDie, a client server application, provides integrated, next generation solutions with web-based access to employee management data. Personnel information is funneled through the HRDB, NED, and FPS databases to EDie, thus providing administrative staff with up-to date information on all personnel. This information is important to ensure renewals are processed in a timely fashion, new hires are captured, FTE/Non-FTE projections, as well as ensuring NHGRI remains equitable in our pay structure for all positions.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Information is intended for internal administrative use only and will not be shared by other entities. Refer to SORN 09-90-0018, SORN 09-90-0024 and SORN 09-25-0216.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: EDiE tracks all information pertinent to a personnel file for the purpose of personnel management activities. Information is collected from employees via the Human Resources Database (HRDB) system, Fellowship Payment System (FPS), nVision Data Warehouse and NIH Enterprise Directory (NED). Uses consist of the following: a) tracking a time-limited appointment to ensure renewals are done in a timely manner, thereby avoiding any break in service; b) ensuring that allocated FTE ceilings are maintained; c) ensuring salary equity for various hiring mechanisms; d) providing reports requested by the NIH Director, the IC Director, and other management staff, as requested; and e) maintaining lists of non-FTEs, special volunteers, contractors, and other hiring appointments. The information collected constitutes IIF and is mandatory for all employees.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) IIF in the system is downloaded from the HRDB, FPS, nVision Data Warehouse and NED. Changes to HRDB or changes in the way information is used is relayed to employees via official notices from the NIH Office of Human Resources (OHR). Individuals are notified of the collection and use of the data as part of the hiring process. This is a mandatory requirement of potential job applicants seeking employment at NIH.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: IIF stored in EDiE is accessed by a very limited number of administrative staff with a "need-to-know" status. EDiE is password protected and sensitive data is encrypted. The system is located on a server in a secure server room behind the NIH firewall.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Carol S. Martin, 301-402-5348

Sr. Official for Privacy Approval: Promote **Sr. Official for Privacy Name:** Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NHGRI LabMatrix PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 6/24/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: no/a

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

- 5. OMB Information Collection Approval Number: not applicable
- **6. Other Identifying Number(s):** not applicable
- 7. System Name (Align with system Item name): Labmatrix
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Dr Gretchen Gibney
- **10. Provide an overview of the system:** Research and clinical database which contains information related to clinical and research laboratory data collection and findings from Institutional Review Board study protocols. NHGRI professional medical staff (MD, RN, Genetic Counselor) and scientific laboratory personnel (PhDs, technicians, data managers) access for research purposes only.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Restricted to research. This information is further addressed in the NIH Privacy Act Systems of Record Notice 09-25-0200, published in the Federal Register, Volume 67, No. 187, September 26, 2002.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Research and clinical

database of patient PII including demographics (e.g., address, date of birth, gender), study enrollment and consent information, medical records, test results, medical record number, photographic identifier, email address, employment data. IIF contained. Information submission is voluntary. Information is used for research purposes only.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Individuals whose PII is in the system have provided it voluntarily for research purposes with implicit consent and/or explicit consent by way of an Institutional Review Board (IRB) approved consent form. In the event of significant changes in disclosure or usage of data collected under the authority of an IRB consent process, individuals would be re-consented per IRB guidance.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Access is PIV card/PIN restricted to authorized users, and administrative and technical access controls for each user are specified individually on a least privilege basis. All data transmissions are encrypted, all transactions are monitored, and application and database server are housed in a locked, secure setting.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Carol S. Martin, 301-402-5348

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NHGRI NHGRI Twinbrook Data Center [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 6/30/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: no

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): no

5. OMB Information Collection Approval Number: no

6. Other Identifying Number(s): no

- 7. System Name (Align with system Item name): NHGRI Twinbrook Server Room
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Ed Whitley
- **10. Provide an overview of the system:** The system is a General Support system (GSS) and does not directly collect or store information.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system is a General Support System (GSS) and does not directly collect or store information. The applications/systems residing on the GSS collect and store information. Therefore, individual PIAs have been prepared and submitted for the applications/systems residing on this GSS.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval:

PIA Reviewer Name: Carol S. Martin, 301-402-5348

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NHGRI NHGRI Two Democracy Data Center [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 6/30/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: No

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): NHGRI Two Democracy Server Room
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Ed Whitley
- **10. Provide an overview of the system:** The system is a General Support System (GSS) and does not directly collect or store information.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system is a General Support System (GSS) and does not directly collect or store information. The applications/systems residing on the GSS collect and store information. Therefore, individual PIAs have been prepared and submitted for the applications/systems residing on this GSS.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Carol S. Martin, 301-402-5348

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NHGRI Status of Funds Internet Edition (SOFie)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 6/27/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-09-02-3199-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): no

5. OMB Information Collection Approval Number: no

6. Other Identifying Number(s): no

- **7. System Name (Align with system Item name):** NHGRI Status of Funds Internet Edition (SOFie)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Ann Fitzpatrick
- **10. Provide an overview of the system:** An organizational reporting tool that allows an organization to manipulate and report on financial transactions downloaded from the NIH Central Accounting System. The information is general accounting info by category, with totals by category, and has no info specific to employees.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): no
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Accounting data and related

document information is downloaded from CAS/Central Accounting System mainframe and is specific to NHGRI/OD Office for its fiscal year operations. The information is general accounting info by category (ex. wages), with totals by category, and nothing specific to individual employees. The system contains no PII.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Carol S. Martin, 301-402-5348

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Pla

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NHGRI Trainee Tracking Database

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/13/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: not applicable

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-90-0018

5. OMB Information Collection Approval Number: not applicable

6. Other Identifying Number(s): not applicable

- 7. System Name (Align with system Item name): Trainee Tracking Database
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Dave Kanney and/or Bill Pavan
- **10. Provide an overview of the system:** The system supports the overall training mission of the intramural program through the monitoring and tracking of trainees at all levels. The database enables the ITO (Intramural Training Office) to create and manage records for all trainees. A record of each trainee contains name, degree, gender, race, department and mentor and is maintained to capture aggregate demographic information, to track the progress of individual trainees, and to manage follow-up surveys, annual reviews, and exit interviews critical for the evaluation of the training program. The information in the database aggregated across the data set, presents a snapshot of the size and demographics of the trainees each year.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Annual review dates, branch, position title, EOD (Enter on Duty) date, merit award data, mentor's name, name, gender, race/ethnicity for diversity and evaluation purposes. The system contains IIF and submission of gender, race/ethnicity is voluntary.

The information is used to track the progress of individual trainees, and to manage follow-up surveys, annual reviews, and exit interviews.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Any changes in the system would not change the data, therefore, there is no need to notify and obtain consent.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Database secured behind locked doors, login/password/ ID protected with very limited 'need-to-know' users.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Carol S. Martin, 301-402-5348

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Pla

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NHGRI Undiagnosed Disease Program (UDP)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/11/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: no

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: no

6. Other Identifying Number(s): no

- 7. System Name (Align with system Item name): NIH Undiagnosed Disease Program (UDP)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: David Adams, M.D., Ph.D., Building 10, Room 10C103B, NIH Bethesda Campus, 20892. Phone 301 402 6435
- **10. Provide an overview of the system:** Microsoft SharePoint will be used as a tool to store data so that medical information related to the Undiagnosed Disease Program (UDP) can be shared easily with medical staff involved in the UDP program. Those who will have access are NIH credentialed clinical providers and administrative persons who handle identifiable clinical data in other forms (for example, UPD-associated non-clinical CRIS users).
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): no
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: 1. Collected information will include such items as scanned medical records sent to the NIH, participant photographs, and binary files from tests that cannot be stored in the available clinical information system, e.g. electroencephalogram data.

- 2. The information will be stored in order to provide access to NIH clinical staff who need to review the extensive medical histories associated with typical UDP participants. Such review will allow the users to make decisions about accepting individual participants, and to plan for the care of participants who will travel to the NIH to participate in the UDP program.
- 3. The information will contain PII
- 4. Participation in the UDP program is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The data contained in this system is collected in accord with the clinical consent used for the UDP program. The original copy if the information is the hard-copy that is sent by the participant to the NIH. The Sharepoint copy of the data will be used for the same purpose the original is used for, i.e. review by NIH clinical providers. If new uses of the information are proposed by the UDP investigators, the mechanism of those new uses will involve the hard copies and not the electronic copies on this system. To summarize, the rules for this Sharepoint resource will be forced to be equal to or more restrictive than the rules for the medical record hard copies, thereby allowing the resource to be used within the constraints of the original clinical consent process. Individuals will be given notice of consent electronically.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: This application is on a server in our data center. Access is granted by userid and password (the user must be in the NIH employee database). This program inherits all the security controls which are in place at our data center.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Carol S. Martin, 301-402-5348

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NHLBI Clinical Data System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-26-02-7213-00-202-069

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): NIH NHLBI Clinical Data System (CDS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Zeyad Mobassaleh
- **10. Provide an overview of the system:** The NHLBI-CDS collects and manages data emanating from clinical studies and allows for monitoring recruitment and tracking patients. It is a multi-tiered, Web-based system where research-related data are entered to facilitate the generation of regulatory reports and data sets for analyses.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The NHLBI-CDS produces Medical Record reports that are filed in the Clinical Center Medical Records Department and are also used to send to the patient's referring physician. SOR number is 09-25-0200.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: The NHLBI-CDS collects and manages data emanating from clinical studies and allows for monitoring recruitment and tracking patients and analyzing results. Collection of this information is authorized under sections 301, 319F-1, 402, and 405 of the PHS Act which authorize the HHS Secretary to conduct and support research.

The primary use of this information is to track clinical research results for studies conducted at the National Institutes of Health. Information such as patient name, address, medical history, test and procedure results, and other research related information is collected and maintained. NHLBI-DIR uses this information to analyze and report the results of clinical research being conducted within the division. The information collected includes IIF and all patients enrolled on clinical studies sign an informed consent related to their participation in clinical research. Some of the information is used for Medical Record reporting and for providing the patient's referring physicians with the test results and assessments related to the patient's visit. Information is provided on a voluntary basis as participation in clinical trial research is voluntary.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) All patients sign an informed consent (paper) related to their participation in clinical research and how their data will be used. There is no process for obtaining consent from individuals whose IIF is in the system when major system changes occur, however this system is an internal system (only available within NIH) and data are de-identified for the purpose of summarizing and publishing research results.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** Data is maintained in a secure database. Routine access is restricted to authorized employees and contractors only according to the principal of least privilege by the use of user name and password access controls. Additional technical and administrative controls are also employed, including badge access, intrusion detection system, firewalls, virtual private networks, encryption, etc. The NHLBI-CDS staff monitors system access for intrusion detection and reviews audit logs to identify inappropriate browsing or inappropriate database access. Computer security incidents are referred to the NIH Incident Response Team (NIH IRT). Contractors are required to have employment suitability determinations, National Agency Checks, credit checks, and/or background investigations, commensurate with the position. Contractors are also required to sign an NIH non-disclosure

agreement prior to being given access to the NHLBI-CDS. Contractors must take the NIH security awareness training.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Suzanne Freeman Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NHLBI Council PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): 009-25-01-26-02-7204-00-202-069 (UPI)

7. System Name (Align with system Item name): NIH NHLBI Council

- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Zeyad Mobassaleh
- **10. Provide an overview of the system:** The Council web site assists the NHLBI extramural staff and the council board members in preparing for council meetings. The Council system extracts the grant application information from NHLBI Tracking and Budget System (TABS) database and the members assigned to applications from IMPAC II (eRA) database. Council related documents are provided in the system by the divisions. The council members review the applications, view the summary statements and abstracts and make recommendations on the scientific merit of applications.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The system does not share or disclose PII data.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The Council system does

not collect any information. Council is a National Heart Lung and Blood Institute (NHLBI) intranet website that enables NHLBI Council Advisory Board members to review and review their assignments and the NHBLI staff to track the applications discussed at the Council meetings. Council meetings are held 4 times a year. The Council system extracts the grant application information from TABS database and the members assigned to applications from IMPAC II (eRA) database. The council members review the grant applications, view the summary statements and abstracts, and make recommendations on the scientific merit of applications. The website contains only Federal grant data and it does not collect, maintain, or disseminate PII data. Council does not require the submission of personal information.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Not Applicable.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Not Applicable

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Suzanne Freeman Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/30/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NHLBI EDie PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-90-0018

5. OMB Information Collection Approval Number: None

6. Other Identifying Number(s): None

- **7. System Name (Align with system Item name):** NIH NHLBI Employee Database Internet Edition (EDie)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Christopher Bourdeau
- **10. Provide an overview of the system:** EDie is an intranet based application primarily used to manage and track personnel information. The application downloads this information from the Human Resources Database (HRDB) weekly. Information entered into the EDie database is not uploaded into the HRDB. Due to the sensitivity of the personnel data in this system, access to the EDie database is limited to specific users within the IC. Users are assigned roles that restrict what data they may view and what functions they can perform. Access privileges are enforced through authentication within the database.

Authority for maintenance of the system: 5 U.S.C. 1302, 2951, 4118,4308,4506,7501,7511,7521 and Executive Order 10561

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes

- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Information is intended for internal senior administrative use only and will not be shared with other entities. Please refer to SOR # 09-90-0018, Personnel Records in Operating Offices, HHS/OS/ASPER
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: EDie tracks all information pertinent to a personnel file for the purposes of personnel management activities. Information is collected from employees via the Human Resources Database (HRDB) system. Uses consist of the following: a) tracking a time-limited appointment to ensure renewals are completed in a timely manner, thereby avoiding any break in service; b) ensuring that allocated FTE ceilings are maintained; c) ensuring salary quality for various hiring mechanisms; d) providing report as requested by the NIH Director, the IC Director, and other management staff; and e) maintaining lists of non-FTEs, special volunteers, contractors, and other hiring appointments. The information collected constitutes IIF and is mandatory for all employees.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) IIF in the system is downloaded periodically from the HRDB. Changes to the HRDB or changes in the way information is used are relayed to employees via official notice from the NIH Office of Human Resources (OHR). Individuals are notified of the collection and use of the data as part of the hiring process. This is a mandatory requirement of potential job applicants seeking employment at NIH.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: IIF data is maintained in a secure database. Routine access is restricted to authorized employees and contractors only according to the principle of least privilege by the use of user name and password access controls. Additional technical and administrative controls are also employed, including badge access, intrusion detections systems, firewalls, virtual private networks, encryption, etc.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Suzanne Freeman

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NHLBI Extramural Program Development (EP)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-26-02-7204-00-202-069

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): NHLBI Extramural Program
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Zeyad Mobassaleh
- **10. Provide an overview of the system:** Manage NHLBI Extramural Research Programs.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Grant data is available to reviewers during submission/evaluation of potential grants. See SOR 09-25-0036
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Collection of this information is authorized under 5 U.S.C 301. Information collected by the system includes: funding applications, awards, trainee appointments and advisory committee records. The PII collected to contact business partners includes name, personal address, personal phone number,

and personal email. The primary use of this information is for government personnel to conduct grant application reviews, approvals, and to create reports related to grant applications. Submission of this information is mandatory for grant applications to be processed.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) There is no process to notify or obtain consent when there is a major change to the system that affects disclosure and/or data uses since the notice at the time of the original collection.

Applicants are notified data is collected when they enter it into the system, or fill in the paper application.

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: This system has been subject to a Certification and Accreditation (C&A) process, during which, all technical, administrative and physical controls were evaluated. These controls are defined in NIST publication 800-53 Recommended Security Controls for Federal Information Systems.

The system is housed in a secure server room, which is located in a building protected by security personnel 24/7 (door locks, key badge, etc...). Technical controls ensure that no unauthorized access is permitted (passwords, certificates, encryption, firewalls, etc...). Strict administrative controls are in place to ensure the system is operated in a safe, consistent manner (least privilege, separation of duties, background investigations, etc...).

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Suzanne Freeman Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NHLBI Internet Animal Study Proposal

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A
- **5. OMB Information Collection Approval Number:** No
- **6. Other Identifying Number(s):** No
- **7. System Name (Align with system Item name):** NIH NHLBI Internet Animal Study Proposal (IASP)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Zeyad Mobassaleh
- **10. Provide an overview of the system:** The IASP application supports the creation and management of NIH compliant animal study proposals. This program is used by all intramural researchers at NHLBI to create and submit animal study research proposals. IASP is also used by the Animal Care and Use Committee (ACUC), Veterinarians, Investigators and research support staff to comply with requirements regarding research conducted at NIH.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: The IASP application supports the creation and management of NIH compliant animal study proposals. This program is used by all intramural researchers at NHLBI to create and submit animal study research proposals. IASP is also used by the Animal Care and Use Committee (ACUC), Veterinarians, Investigators and research support staff to comply with requirements regarding research conducted at NIH with respect to animals. It does not contain any PII data.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Not Applicable.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Not Applicable

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Suzanne Freeman

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NHLBI Internet Website PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-27-02-7299-00-305-109

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0106, 09-90-0024

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): NHLBI Web Site
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Matt Raschka
- **10. Provide an overview of the system:** Disseminates health information and information and policies related to NHLBI Extramural and Intramural Programs.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Credit Card information is transferred to Verisign for cost recovery.

Information from Techfinder may be shared the NIH Office of Technology Transfer, which is responsible for licensing NIH technology. SOR is 09-25-0106 and 09-90-0024.

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Voluntary; contains IIF:

o names and mailing addresses, email addresses, phone and FAX numbers for delivery of purchased items, purchase confirmation, verification, and updating information,

- o credit card numbers for: purchase of items (cost recovery),
- o Login credentials needed to update staff profiles

Voluntary; does not contain IIF

- o Names of organizations and description, general job titles, organizational unit, research interests, contact information, information about an activity (including dates), expected audience, and setting (e.g., healthcare, work site, community, media, etc.) for posting on the Web, publicizing local activities, or developing interest in NHLBI activities, also for staff recruitment of new postdocs and principal investigators.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The individuals are contacted by either email or US Post, depending on the information in that particular system

Notification of intent to use information is available on the Web application or Web sites.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: Yes
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Information is secured using username/passwords, least privilege, separation of duties, an intrusion detection system, firewalls, locks, badge access, background investigations. A comprehensive IRT capability is also maintained.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Suzanne Freeman Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NHLBI Intramural Research Application Development (IR)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-26-02-7203-00-202-069

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0099

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): NHLBI Intramural Program
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Zeyad Mobassaleh
- **10. Provide an overview of the system:** Manage NHLBI Intramural Research Programs.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Clinical test results are available to authorized researchers and caregivers. See SOR 09-25-0099
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Collection of this information is authorized under 42 U.S.C. 241, 248. The system collects medical treatment record data. This information is used to provide evaluations and treatments to patients, and for subsequent medical research. The researchers and caregivers will have access to this information. Submission of this information is mandatory for all medical research patients.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) All patients sign an informed consent (paper) related to their participation in clinical research and how their data will be used. There is no process for obtaining consent from individuals whose IIF is in the system when major system changes occur, however this system is an internal system (only available within NIH) and data are de-identified for the purpose of summarizing and publishing research results.

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: This system has been subject to a Certification and Accreditation (C&A) process, during which, all technical, administrative and physical controls were evaluated. These controls are defined in NIST publication 800-53 Recommended Security Controls for Federal Information Systems.

The system is housed in a secure server room, which is located in a building protected by security personnel 24/7 (door locks, key badge, etc...). Technical controls ensure that no unauthorized access is permitted (passwords, certificates, encryption, firewalls, etc...). Strict administrative controls are in place to ensure the system is operated in a safe, consistent manner (least privilege, separation of duties, background investigations, etc...).

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Suzanne Freeman Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NHLBI Lab of Cardiac Energetics

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200 (research)

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): None

- **7. System Name (Align with system Item name):** NIH NHLBI Laboratory of Cardiac Energetics (LCE)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Zeyad Mobassaleh
- **10. Provide an overview of the system:** The LCE MRI Database is used by the Magnetic Resonance Imaging (MRI) section of LCE at NHLBI. The system was initially developed by the LCE group as a Microsoft Access database. The system was converted by the Application Development Support Branch (ADSB) to a secure web based clinical database that collects data for patients in Hjartevernd Hospital (Iceland), Suburban Hospital (Bethesda, MD) and NIH Clinical Center (Bethesda, MD). The system adheres to HIPAA standards and includes external interfaces to the NIH Central Fax Service and DICOM Nodes on the network.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Hospital personnel for clinical and research purposes.

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system collects the following data elements: First Name, Middle Name, Last Name, Medical Record Number, Medical Record number for Suburban Hospitals, Medical Record number for Baltimore Hospitals, Date of Birth, Gender, Street, City, State, Zip, Home Phone, Work Phone, Email, Ethnic Group, Race.

The data is used for clinical operations and research purposes. The above listed Data Elements do contain PII data. The primary use of this information is to track clinical research results for studies conducted at the National Institutes of Health. Information such as patient name, address, medical history, test and procedure results, and other research related information is collected and maintained. NHLBI-LCE investigators use this information to analyze and report the results of clinical research being conducted within the division. The information collected includes some PII and all patients enrolled on clinical studies sign an informed consent related to their participation in clinical research. Some of the information is provided to the patient's referring physicians with the test results and assessments related to the patient's visit. Information is provided on a voluntary basis as participation in clinical trial research is voluntary.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Each subject that participates on a clinical trial and provides data as a result must sign a consent form that indicates what PII is being collected and how that data will be used or shared. Once received, the forms are scanned into the system. The original form is kept on file in the patient's medical file and a copy is provided to the patient for their own records as well.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** Data is maintained in a secure database. Routine access is restricted to authorized employees and contractors only according to the principal of least privilege by the use of user name and password access controls. Additional technical and administrative controls are also employed, including badge access, intrusion detection system, firewalls, virtual private networks, encryption, etc. The NHLBI-LCE support staff monitors system access for intrusion detection and reviews audit logs to identify inappropriate browsing or inappropriate database access. Computer security incidents are referred to the NIH Incident Response Team (NIH IRT). Contractors are required to have

employment suitability determinations, National Agency Checks, credit checks, and/or background investigations, commensurate with the position. Contractors are also required to sign an NIH non-disclosure agreement prior to being given access to the NHLBI-LCE. Contractors must take the NIH security awareness training.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Suzanne Freeman Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NHLBI Status of Funds Internet Edition (SOFie)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: No

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

7. System Name (Align with system Item name): NHLBI SOFie

- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sandra Gault
- **10. Provide an overview of the system:** SOFie is a web-based application for internal use only to manage expenditures and obligations. The purpose of the system is to monitor expenditures. Program helps project the budget; allows users to know how much money is left in the FY to spend.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No IIF
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: All accounting transactions are available for viewing in SOFie. The information is used to track and plan fiscal budgets. It is necessary to have access to this data in order to comply with appropriations laws and regulations. Data elements stored are: arbitrary Document #, Object Class Code, Vendor, Description of Expenses, and Purchase Amount.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No IIF

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No IIF

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Suzanne Freeman Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NHLBI Survey of NHLBI Constituents' Health Information Needs and Preferred Formats

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): SORN 09-25-0156

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** Survey of NHLBI Constituents' Health Information Needs and Preferred Formats
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Ann Taubenheim
- 10. Provide an overview of the system: A Web-based survey tool, WebSurveyor, will be used to contact and collect data from NHLBI constituents who have contacted the NHLBI Health Information Center website within the past 3 years. These previous customers will be invited by e-mail to participate in a short online survey. Survey questions ask about respondents' health information and education needs and format preferences. No personally identifiable information (PII) will be collected from survey respondents. Constituents who choose to complete the survey are identified by e-mail address. Upon completion of the survey, all data tying the assigned identifier to an e-mail address will be destroyed; namely, the contents of the e-mail fields will be erased.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Survey questions ask about respondents' health information and education needs and format preferences. No personally identifiable information (PII) will be collected from survey respondents.

The survey data will be used to support the NHLBI Office of Communications and Legislative Activities' efforts in developing a strategic plan. All survey responses are voluntary.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) All e-mails to potential respondents, as well as each page of the survey will contain the message: "Your answers will be kept completely confidential and not linked to personal or identifying data of any kind. Moreover, your information will not be shared with any other party."

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Administrative Security: Only contractor personnel whose duties require the use of the information in the system have access. This includes the system administrator only.

Technical Security: The multiserver architecture is isolated on a dedicated internal subnet separated from both the internal AIR network and the public Internet by an enterprise-grade firewall managed by the AIR Web Hosting Services team. In addition to the firewall, Web Hosting Services has deployed an intrusion prevention system appliance that can employ granular security policies commensurate with the level of risk on a per-host basis. For security purposes, only the Web server itself is accessible from the Internet, and even then, solely over ports 80 and 443 for HTTP and SSL-encrypted HTTP, respectively. The databases are not Internet-accessible, and furthermore, are accessible strictly from within the internal AIR network only to those users whose roles require that they be expressly granted access to these systems. Internal access to the servers may take the form of SFTP to the Web server, Terminal services to any servers, directly via the local console, or via an installed eEnterprise client. Authorized

internal users are able to access only those servers to which they need access and only via the methods that are applicable to their specific roles.

The WebSurveyor tool will assign a unique identifier to each potential respondent in the study tied to his/her e-mail address to ensure one response per respondent. That identifier will not be accessible to anyone but the AIR system administrator for the WebSurveyor tool. Upon completion of the survey, all data tying the assigned identifier to an e-mail address will be destroyed; namely, the contents of the e-mail fields will be erased.

Physical Safeguards: The system administrator's role is to ensure a stable and secure operating environment within which the WebSurveyor tool can function. This includes establishing and executing a long-term vision that guards the security and reliable operation of the system. This includes managing backups of system files and data; installation of patches to ensure system security and stability; monitoring system log files for suspicious activity; assigning server-level access rights to users as needed; and coordinating with vendors to replace and enhance system hardware as needed.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Suzanne Freeman Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIA Aging Data Administration Management System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/9/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-04-00-02-4302-00-101-001

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036 Extramural Awards and Charted Advisory Committees

- **5. OMB Information Collection Approval Number:** No
- **6. Other Identifying Number(s):** No
- **7. System Name (Align with system Item name):** NIH NIA Aging Data Administration Management System (ADAMS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Chris Porter
- **10. Provide an overview of the system:** The NIH NIA Aging Data Administration Management System (ADAMS) is a tracking and recording system for grants. It allows the user to code competing applications before council meetings, scientifically code grants based on their study, perform ad hoc queries, and generate reports. Legislation to authorize this activity is under 5. U.S.C.301;42U.S.C.217a.241,282(b)(6),248a, and 288.48 CFR Subpart
- 15.3 and Subpart 42.15. More specific functions include: allocation and adjusting funding estimates for grants based on their budgets, summarizing grant funding by specific categories for reporting to Congress, and reporting committed, pending, and obligated records with future year commitments.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes

- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No sharing or disclosures at this time. Refer to the system of record 09-25-0036 section entitled ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES http://oma.od.nih.gov/ms/privacy/pa-files/0036.htm for the allowed disclosures of IIF.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system stores information on grant applications and contracts awarded by the NIH, including performance evaluations. The information is used to support centralized grant programs and contract management. PII in the system includes name, mailing address, email address, telephone number, financial account information, and grant and/or contract number. Submission of personal information is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No processes are in place to notify and obtain consent from the individuals whose IIF is in the system when major changes, as defined in Section 208 of the E-Government Act of 2002, occur to the system.

When applying for grants, applicants are informed that personal information is collected for accurate identification, referral and review by grants program managers. Refer to the system of record 09-25-0036 section entitled ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES http://oma.od.nih.gov/ms/privacy/pa-files/0036.htm, for a summary of the notice of uses of information.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls: Physical controls: Guards, Identification badges, key cards and closed circuit TV.

Technical controls: User ID, passwords, firewall, Virtual Private Network (VPN).

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Taryn Ayoub

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Pla

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIA Baltimore Longitudinal Study of Aging [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02--4303-00-110-219

- **4.** Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200 Clinical, Basic and Population-based-Research Studies
- **5. OMB Information Collection Approval Number:** CE 08-01-01 clinically exempt, per NIH OMB Project Clearance Branch
- 6. Other Identifying Number(s): Westat PID 8807
- **7. System Name (Align with system Item name):** NIH NIA Baltimore Longitudinal Study of Aging (BLSA)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Luigi Ferrucci
- 10. Provide an overview of the system: The NIA supports the Baltimore Longitudinal Study of Aging (BLSA), America's longest-running scientific study of human aging, begun in 1958. BLSA scientists are learning what happens as people age and how to sort out changes due to aging from those due to disease or other causes. More than 1,400 men and women are study volunteers. They range in age from their 20s to their 90s. BLSA study data comprises clinical data, data from questionnaires, cognitive tests, physical exams, and medical histories and other diagnostic test and images. BLSA databases are used by researchers at the NIA Clinical Research Branch's Longitudinal Studies Section. BLSA data comprises both Personally Identifiable Information (PII) and de-identified data used in analysis by NIA researchers. Appointment and authority is given to the National Institutes of Health under the Public Service Act.

IDEAL is an extension of the Baltimore Longitudinal Study on Aging (BLSA). NIA's goal for the IDEAL recruitment effort is to enroll 500 healthy individuals aged 80 or older over the 5-year term of the contract. The IDEAL Study cohort will be compared to current BLSA participants over age 80 who are no longer healthy or fully functional. IDEAL subjects will be followed for life with yearly visits. A secondary objective of the IDEAL Study is to identify physiological, environmental, and behavioral characteristics that are risk factors for loss of a person's healthy aging status over time. The IDEAL-SMS stores, processes, and transmits all information related to the study including data gathered from individuals enrolled in the study, staff and agency contact information, study data and reports, and other electronic and hardcopy information.

The IDEAL-SMS collects and maintains a variety of information types. Volunteers identified through this recruitment effort will participate in up to two rounds of eligibility screening: Stage One is a telephone interview, and Stage Two is a home visit that includes physical examination, cognitive testing, a resting electrocardiogram, and a blood draw. In addition to the identifying information used to locate and contact study participants, the system will store, process, and transmit examination and testing results, electrocardiogram hardcopy and data, and blood analysis data. Contact information is not submitted by the participants. Participation in the study is voluntary.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): No sharing or disclosures at this time. Information regarding potential disclosure practices is further addressed in the NIH Privacy Act Systems of Record Notice 09-25-0200, published in the Federal Register, Volume 67, No. 187, September 26, 2002.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The personal information collected includes: name, mother's maiden name, date of birth, (voluntary) SSN, mailing address, phone number, medical record numbers, notes and email address. Information is used in examining the clinical questions addressed by the study, and to contact the consenting participants with the results of testing and to collect clinical follow-up information. The information collected is the minimum required to accomplish the stated mission. The information collected contains PII. Submission of personal information is voluntary.

The IDEAL-SMS collects and maintains a variety of information types. Volunteers identified through this recruitment effort will participate in up to two rounds of eligibility screening: Stage One is a telephoneinterview, and Stage Two is a home visit that includes physical examination, cognitive testing, a resting electrocardiogram, and a blood draw. In addition to the identifying information used to locate and contact study participants, the system will store, process, and transmit examination and testing results, electrocardiogram hardcopy and data, and blood

analysis data. Contact information is not submitted by the participants. Participation in the study is voluntary.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Noprocesses are in place to notify and obtain consent from the individuals whose IIF is in the system when major changes, as defined in Section 208 of the E-Government Act of 2002, occur to the system.

All participants sign an informed consent form acknowledging their voluntary participation in the study and their rights under HIPAA. (Refer to the Privacy Act systems notice 09-25-0200 section entitled ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES for a summary of the notice of uses of information.)

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls: Physical controls: Guards, Identification badges, key cards and closed circuit TV

Technical controls: User ID, passwords, firewall, Virtual Private Network (VPN)

Information will be secured on the system through access controls, personnel security awareness and training, regular auditing of information and information management processes, careful monitoring of a properly accredited IDEAL-SMS information system, control of changes to the system, by appropriate planning and testing of configuration management and contingency processes, by ensuring that all users of the IDEAL-SMS are properly identified and authorized for access and are aware of and acknowledge the system rules of behavior, by ensuring that any contingency or incident is handled expeditiously, properly maintaining the system and regulating the environment it operates in, by controlling media, by evaluating risks and planning for information management and information system operations, by ensuring that the system and any exchange of information is protected, by maintaining the confidentiality and integrity of the IDEAL-SMS, and by adhering to the requirements established in the contract and statement of work.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Taryn Ayoub

Sr. Official for Privacy Approval: Promote **Sr. Official for Privacy Name:** Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIA Clinical Research System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/9/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-4303-00-110-219

- **4.** Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200 Clinical, Basic and Population-based Research Studies
- **5. OMB Information Collection Approval Number:** Not Applicable
- **6. Other Identifying Number(s):** No
- 7. System Name (Align with system Item name): NIH NIA Clinical Research System (CRS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Linda Jo Byrd
- **10. Provide an overview of the system:** The Clinical Research System is a product of the Clinical Research Branch of the NIA Intramural Research Program. It collects personal information on the participants of the Baltimore Longitudinal Study on Aging as well as clinical research studies. The system is physically located on the 5th floor of the Harbor Hospital Center in Baltimore, Maryland.

Appointment and authority is given to the National Institute on Aging under Public Service Act, Public Service Act, 42 U.S.C. 241, 242, 248, 282, 284, 285a, 285b, 285c, 285d, 285e, 285f, 285g, 285h, 285i, 285j, 285l, 285m, 285n, 285o, 285p, 285q, 287, 287b, 287c, 289a, 289c, and 44 U.S.C. 3101.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes

- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No sharing or disclosures at this time. Refer to the system of record 09-25-0200 section entitled ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm for the allowed disclosures of IIF.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The information is collected during the initial and subsequent visits to the clinical research branch. The PII includes: name, mother's maiden name, date of birth, social security number, mailing address, phone number, medical record numbers, notes and email address. Information is used to contact the consenting participants with the results of testing, to collect follow-up information, and as part of the clinical research. The information collected is the minimum required to accomplish the stated mission. Submission of personal information is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No processes are in place to notify and obtain consent from the individuals whose IIF is in the system when major changes, as defined in Section 208 of the E-Government Act of 2002, occur to the system.

All participants sign an RRB-approved informed consent form acknowledging their voluntary participation in the study and their rights under HIPAA. (Refer to the system of record 09-25-0200 section entitled ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm, for a summary of the notice of uses of information.)

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls: Physical controls: Guards, Identification badges, key cards and closed circuit TV

Technical controls: User ID, passwords, firewall, Virtual Private Network (VPN)

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Taryn Ayoub

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Pla

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIA CollectionPro PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-90-0024

5. OMB Information Collection Approval Number: None

6. Other Identifying Number(s): None

- 7. System Name (Align with system Item name): NIH NIA CollectionPro
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Chris Porter
- 10. Provide an overview of the system: The NIA CollectionPro is a Web-based application that facilitates management of non-appropriated accounts, comprising unconditional and conditional gift fund contributions as well as payments related to cooperative research and development agreements (CRADA). The system includes the ability to manage gift fund and CRADA accounts, record individual collections, upload NIH Business System (NBS) obligations summed at the NIH common accounting number (CAN) level, reconcile advice of allotments, track Investment information, and generate routing documents and letters of acceptance or acknowledgement. The included reports provide a real time balance available for each of the accounts, offer insight into the relationship between the advice of allotment, investments, and funds available for obligation, and identify the new collections included in each of the reconciled advice of allotments received from the NIH Office of Financial Management (OFM). Donors do not have access to the NIA CollectionPro website.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes

- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) Donor's check number, donor's name or company name, donor's address, donor type (private, etc.), and donor's account name.
- (2) The information is used to manage, reconcile, and report gift funds made to the NIA.
- (3) The information contains PII.
- (4) Submission of PII is voluntarily provided to NIA personnel over the phone.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) (1) There is no formal procedure in place to notify individuals when the system changes.

- (2) Donors initiate the process and voluntarily provide their PII by phone to NIA personnel. NIA personnel enter the donor's PII into the system.
- (3) If the donor asks, NIA personnel will explain by phone that a) the PII is used to manage non-appropriated accounts and b) the PII is not shared, but is used to generate letters back to the donor and, if requested, also to the honored person or recipient research program.
- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls: Administrative controls: Security Plan, file backups, offsite storage, security awareness training, role-based access, and policies for retention and destruction of PII.

Technical controls: User ID, passwords, firewall, VPN, encryption, IDS, and PKI. Physical controls: Guards, Identification badges, key cards and closed circuit TV.

PIA Approval

PIA Reviewer Approval: Promote PIA Reviewer Name: Taryn Ayoub

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 2/28/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIA Echocardiology PACS [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: Not Applicable

6. Other Identifying Number(s): none

- 7. System Name (Align with system Item name): NIH NIA Echocardiology PACS
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Linda Jo Byrd
- **10. Provide an overview of the system:** The NIA Echocardiology Picture Archiving and Communications System (PACS) provides acquisition, archiving, transmission, display, and management of imaging exams and studies. Compliant with DICOM and HL-7 standards, the NIA Echocardiology PACS eliminates ultrasound films and enables simultaneous access to digital images and research data at multiple locations. The system features Web-based access to digital images and text for off-site viewing.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No sharing or disclosures at this time. Refer to the system of record 09-25-0200 section entitled ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm for the allowed disclosures of PII.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The personal information collected during the initial and subsequent visits to the clinical research branch. This information includes: name, mother's maiden name, date of birth, social security number, mailing address, phone number, medical record numbers, notes and email address. Information is used to contact the consenting participants with the results of testing, to collect follow-up information, and as part of the clinical research. The information collected is the minimum required to accomplish the stated mission. The information contains PII. Submission of personal information is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No processes are in place to notify and obtain consent from the individuals whose PII is in the system when major changes, as defined in Section 208 of the E-Government Act of 2002, occur to the system.

All participants sign an IRB-approved informed consent form acknowledging their voluntary participation in the study and their rights under HIPAA. (Refer to the system of record 09-25-0200 section entitled ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm, for a summary of the notice of uses of information.)

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls: Administrative controls: data access policies

Physical controls: Guards, Identification badges, key cards and closed circuit TV Technical controls: User ID, passwords, firewall, Virtual Private Network (VPN)

PIA Approval

PIA Reviewer Approval: Promote PIA Reviewer Name: Taryn Ayoub

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIA ERP Web PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 11/8/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-03-00-02-3109-00-304-104

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

- **5. OMB Information Collection Approval Number:** No
- **6. Other Identifying Number(s):** No
- 7. System Name (Align with system Item name): NIH NIA ERP Web
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Mike Valdez
- **10. Provide an overview of the system:** The NIA Extramural Research Program (ERP) Web comprises the NIA public Websites. The NIA public Website http://www.nia.nih.gov/ provides Web-based worldwide access to NIA public information. The public portion of the NIA website has no identification/authentication of visitors or encryption of traffic between the Web server and user browsers. Appointment and authority is given to the National Institute on Aging under Public Service Act, 42 U.S.C. 241, 242, 248, 282, 284, 285a, 285b, 285c, 285d, 285e, 285f, 285g, 285h, 285i, 285j, 285l, 285m, 285n, 285o, 285p, 285q, 287, 287b, 287c, 289a, 289c, and 44 U.S.C. 3101.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No PII collected, stored, or processed.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: No PII collected, stored, or processed. No Submission of personal information.

Information on the ERP Web website http://www.nia.nih.gov/ comprises NIA health information publications, clinical trials descriptions, public service ads, links to related sites, links to health and aging organizations, extramural research program descriptions, intramural research descriptions, materials from NIA conferences, workshops, and meetings, information on NIH's inclusion policies, and descriptions of scientific resources.

No PII on ERP Web site.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A--No PII collected, stored, or processed.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No PII collected, stored, or processed.

PIA Approval

PIA Reviewer Approval: Promote PIA Reviewer Name: Taryn Ayoub

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIA Healthy Aging in Neighborhoods of Diversity across the Life Span [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/9/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-4303-00-110-219

- **4.** Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200 Clinical, Basic and Population-based Research Studies
- 5. OMB Information Collection Approval Number: Not applicable
- **6. Other Identifying Number(s):** No
- **7. System Name (Align with system Item name):** NIH NIA Healthy Aging in Neighborhoods of Diversity across the Life Span System (HANDLS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Alan Zonderman
- **10. Provide an overview of the system:** The HANDLS system is a product of the Research Resources Branch of NIA Intramural Research Program. It collects personal information on the participants in the HANDLS study. The system is physically located in the Biomedical Research Center in Baltimore, Maryland. Appointment and authority is given to the National Institute on Aging under Public Service Act, 42 U.S.C. 241, 242, 248, 282, 284, 285a, 285b, 285c, 285d, 285e, 285f, 285g, 285h, 285i, 285j, 285l, 285m, 285n, 285o, 285p, 285q, 287, 287b, 287c, 289a, 289c, and 44 U.S.C. 3101.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): No sharing or disclosures at this time. Refer to the system of record 09-25-0200 section entitled ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING

CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES

http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm for the allowed disclosures of PII.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The personal information collected includes: name, date of birth, social security number, mailing address, phone number, medical record numbers, notes and email address. Information is used in examining the clinical questions addressed by the study, and to contact the consenting participants with the results of testing and to collect clinical follow-up information. The information collected is the minimum required to accomplish the stated mission. The information contains PII. Submission of personal information is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No processes are in place to notify and obtain consent from the individuals whose PII is in the system when major changes, as defined in Section 208 of the E-Government Act of 2002, occur to the system.

All participants sign an RRB-approved informed consent form acknowledging their voluntary participation in the study and their rights under HIPAA. (Refer to the system of record 09-25-0200 section entitled ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm, for a summary of the notice of uses of information.)

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls: Physical controls: Gards, Identification badges, key cards and closed circuit TV.

Technical controls: User ID, passwords, firewall, VPN, IDS.

Administrative controls: system security plan, contingency plan, files are backed up regularly, backups are stored offsite, contract clauses ensuring adherence to privacy provisions and practices, least privilege through role-based access, and policies for retention and destruction of PII.

PIA Approval

PIA Reviewer Approval: Promote PIA Reviewer Name: Taryn Ayoub

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Pla

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIA IRP SSH Gateway PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-3109-00-110-219

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No
- **5. OMB Information Collection Approval Number:** No
- 6. Other Identifying Number(s): No
- 7. System Name (Align with system Item name): NIH NIA IRP SSH Gateway
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Alan Zonderman
- **10. Provide an overview of the system:** The IRP SSH Gateway system provides access to sensitive NIA IRP information on private shares for collaboration between NIA IRP and non-NIH investigators. Appointment and authority is given to the National Institute on Aging under Public Service Act, 42 U.S.C. 241, 242, 248, 282, 284, 285a, 285b, 285c, 285d, 285e, 285f, 285g, 285h, 285i, 285j, 285l, 285m, 285n, 285o, 285p, 285q, 287, 287b, 287c, 289a, 289c, and 44 U.S.C. 3101.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No PII collected, stored, or processed
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: De-identified clinical

research data, non-human research data, statistical reports, and study reports. No PII collected, stored, or processed.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A--No PII collected, stored, or processed.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No PII collected, stored, or processed.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Taryn Ayoub

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIA IRP Web PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/9/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-4303-00-110-219

- **4.** Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200 Clinical, Basic and Population-based-Research Studies
- 5. OMB Information Collection Approval Number: Not Applicable
- 6. Other Identifying Number(s): No
- 7. System Name (Align with system Item name): NIH NIA IRP Web
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Alan Zonderman
- **10. Provide an overview of the system:** NIA Intramural Research Program (IRP) Web is a suite of Web-enabled applications in Baltimore, MD, that supports NIA IRP clinical research and administrative activities. Appointment and authority is given to the National Institute on Aging under Public Service Act, 42 U.S.C. 241, 242, 248, 282, 284, 285a, 285b, 285c, 285d, 285e, 285f, 285g, 285h, 285i, 285j, 285l, 285m, 285n, 285o, 285p, 285q, 287, 287b, 287c, 289a, 289c, and 44 U.S.C. 3101.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): No sharing or disclosures. While this system does not intend to share or disclose any PII, the system of record 09-25-0200 indicates some potential disclosure of information practices.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: The personal information is collected from a Website. This information includes: name, street address, telephone number, email address, date of birth, gender, height, weight, ethnic background, medications currently taken, and comments. The information is used to screen the potential participants in clinical research. The information collected is the minimum required to accomplish the stated mission. The information contains PII. Submission of personal information is voluntary.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Participants supply basic personal identifying information during the intake process to the Clinical Research Branch. All participants sign a consent form acknowledging their anonymity and rights under HIPAA. Refer to system of record 09-25-0200 for a detailed summary. No process for notifying individuals when major changes occur to the system.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls: Physical controls: guards, identification badges, key cards, and closed circuit TV.

Technical controls: user IDs, passwords, firewall, VPN, IDS.

Administrative controls: system security plan, contingency plan, files are backed up regularly, backups are stored offsite, contract clauses ensuring adherence to privacy provisions and practices, least privilege through role-based access, and policies for retention and destruction of PII.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Taryn Ayoub

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIA Magnetic Resonance Imaging Picture Archiving and Communications System of NIA [System] PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: Not Applicable

6. Other Identifying Number(s): none

- 7. System Name (Align with system Item name): NIH NIA MRI PACS
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Linda Jo Byrd
- **10. Provide an overview of the system:** The NIA MRI Picture Archiving and Communications System (PACS) provides acquisition, archiving, transmission, display, and management of imaging exams and studies. Compliant with DICOM and HL-7 standards, the NIA MRI PACS eliminates radiological films and enables simultaneous access to digital images and research data at multiple locations. The system features Web-based access to digital images and text for off-site viewing.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No sharing or disclosures at this time. Refer to the system of record 09-25-0200 section entitled ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm for the allowed disclosures of PII.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The personal information collected during the initial and subsequent visits to the clinical research branch. This information includes: name, mother's maiden name, date of birth, social security number, mailing address, phone number, medical record numbers, notes and email address. Information is used to contact the consenting participants with the results of testing, to collect follow-up information, and as part of the clinical research. The information collected is the minimum required to accomplish the stated mission. The information contains PII. Submission of personal information is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No processes are in place to notify and obtain consent from the individuals whose PII is in the system when major changes, as defined in Section 208 of the E-Government Act of 2002, occur to the system.

All participants sign an IRB-approved informed consent form acknowledging their voluntary participation in the study and their rights under HIPAA. (Refer to the system of record 09-25-0200 section entitled ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm, for a summary of the notice of uses of information.)

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls: Administrative controls: data access policies

Physical controls: Guards, Identification badges, key cards and closed circuit TV Technical controls: User ID, passwords, firewall, Virtual Private Network (VPN)

PIA Approval

PIA Reviewer Approval: Promote PIA Reviewer Name: Taryn Ayoub

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIA Microsoft Office SharePoint Services of NIA [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-03-00-02-3109-00-304-104

- **4.** Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0216 "Administration: NIH Electronic Directory (NED), HHS/NIH"
- 5. OMB Information Collection Approval Number: none
- 6. Other Identifying Number(s): none
- **7. System Name (Align with system Item name):** NIH NIA Microsoft Office SharePoint Services (MOSS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Mike Valdez
- 10. Provide an overview of the system: The NIH NIA MOSS is a Microsoft Office SharePoint Services-based NIA Intranet portal. MOSS provides collaboration and data organization tools for users at the NIA Office of the Director (OD) and Office of Administrative Management (OAM). MOSS facilitates sharing of OD and OAM business processes, including employee administration, purchase ordering, and asset management tracking. MOSS document workflow sites support management of administrative policies and procedures as well as administrative requests and actions. MOSS search capabilities enable cross-site searching that speeds access to critical administrative documentation.NIA MOSS comprises the NIA Intranet Websites.

The NIA intranet Website provides Web-based local (NIHnet) access to NIA private information and applications. (ADAMS Web-based applications are located on the intranet Website. See the ADAMS PIA.)

- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): No sharing or disclosures at this time. Refer to the system of record 09-25-0216 section entitled ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES http://oma.od.nih.gov/ms/privacy/pa-files/0216.htm for the allowed disclosures of PII.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: All PII in the system is queried from the NIH Enterprise Directory (NED) system. PII needed to facilitate NIA Office of the Director (OD) and Office of Administrative Management (OAM) collaboration includes name, work phone number, and work email address of NIA employees and contractors. Submission of information to NED is mandatory.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No processes are in place to notify and obtain consent from the individuals whose PII is in the system when major changes, as defined in Section 208 of the E-Government Act of 2002, occur to the system. All PII in the system is queried from the NIH Enterprise Directory (NED) system.

Refer to the system of record notice 09-25-0216 section entitled ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES for a summary of the notice of uses of NED information.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls: Physical controls: guards, identification badges, key cards and closed circuit TV.

Technical controls: user IDs, passwords, firewall, VPN, encryption, IDS.

Administrative controls: system security plan, contingency plan, files are backed up regularly, backups are stored offsite, user manual, contract clauses ensuring adherence to privacy

provisions and practices, least privilege through role-based access, and policies for retention and destruction of PII.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Taryn Ayoub

Sr. Official for Privacy Approval: Promote **Sr. Official for Privacy Name:** Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIA NIA ERP Data Centers [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/8/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-03-00-02-3109-00-304-104

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No
- **5. OMB Information Collection Approval Number:** No
- **6. Other Identifying Number(s):** No
- 7. System Name (Align with system Item name): NIH NIA ERP Data Centers
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Mike Valdez
- **10. Provide an overview of the system:** NIA Extramural Research Program (ERP) Data Centers in Bethesda, MD. These data centers support NIA ERP administrative activities. Appointment and authority is given to the National Institute on Aging under Public Service Act, 42 U.S.C. 241, 242, 248, 282, 284, 285a, 285b, 285c, 285d, 285e, 285f, 285g, 285h, 285i, 285j, 285l, 285m, 285n, 285o, 285p, 285g, 287, 287b, 287c, 289a, 289c, and 44 U.S.C. 3101.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No PII collected, stored, or processed.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Server configuration and

event log data is collected and maintained to support data center operations. Data is collected and maintained as needed to administer servers, SAN, and tape backup system. No PII collected, stored, or processed.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A--No PII collected, stored, or processed.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No PII collected, stored, or processed.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Melissa Fraczkowski Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIA NIA IRP Data Centers [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/8/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-3109-00-110-219

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No
- **5. OMB Information Collection Approval Number:** No
- **6. Other Identifying Number(s):** No
- 7. System Name (Align with system Item name): NIH NIA IRP Data Centers
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Alan Zonderman
- **10. Provide an overview of the system:** NIA Intramural Research Program (IRP) Data Centers in Baltimore, MD. These data centers support NIA IRP clinical research and administrative activities. Appointment and authority is given to the National Institute on Aging under Public Service Act, 42 U.S.C. 241, 242, 248, 282, 284, 285a, 285b, 285c, 285d, 285e, 285f, 285g, 285h, 285i, 285j, 285j, 285n, 285n, 285o, 285p, 285q, 287, 287b, 287c, 289a, 289c, and 44 U.S.C. 3101.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): No PII collected, stored, or processed.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: Server configuration and event log data is collected and maintained to support data center operations. Data is collected and maintained as needed to administer servers, SAN, and tape backup system. No PII collected, stored, or processed.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A--No PII collected, stored, or processed.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A--No PII collected, stored, or processed.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Melissa Fraczkowski Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/20/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIA NIA NACAnet [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/9/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-03-00-02-3109-00-304-104

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0217 "NIH Business System (NBS), HHS/NIH"
- **5. OMB Information Collection Approval Number:** No
- **6. Other Identifying Number(s):** No
- 7. System Name (Align with system Item name): NIH NIA NACAnet
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Robin Barr
- **10. Provide an overview of the system:** The National Advisory Council on Aging Network (NACAnet) is an NIA web application that supports the National Advisory Council on Aging (NACA) by providing a repository of council-related documents. No transactions are collected or accomplished on the website, only display of NACA information. NACAnet users comprise NIA employees and the current NACA council members, some of whom are located outside NIH at academic facilities. Appointment and authority is given to the National Institute on Aging under Public Service Act, 42 U.S.C. 241, 242, 248, 282, 284, 285a, 285b, 285c, 285d, 285e, 285f, 285g, 285h, 285i, 285j, 285l, 285m, 285n, 285o, 285p, 285q, 287, 287c, 289a, 289c, and 44 U.S.C. 3101.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): No sharing or disclosures at this time. Refer to the Privacy Act systems notice 09-25-0217 section entitled ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM,

INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES for the allowed disclosures of PII.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Grantee (NIH grant recipient) personal information maintained comprises: name, mailing address, phone number, financial account information, and employment status. The data is used for NACA planning. The information contains PII. Submission of personal information is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No processes are in place to notify and obtain consent from the individuals whose PII is in the system when major changes, as defined in Section 208 of the E-Government Act of 2002, occur to the system.

When applying for grants or contracts, applicants are informed that personal information is collected for accurate identification, referral and review by program managers. Refer to the system of record 09-25-0217 section entitled ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES for a summary of the notice of uses of information..

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls: Physical controls: guards, identification badges, key cards and closed circuit TV.

Technical controls: user IDs, passwords, firewall, VPN.

Administrative controls: system security plan, contingency plan, files are backed up regularly, backups are stored offsite, contract clauses ensuring adherence to privacy provisions and practices, least privilege through role-based access, and policies for retention and destruction of PII.

PIA Approval

PIA Reviewer Approval: Promote PIA Reviewer Name: Taryn Ayoub

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIA Position and Employee Tracking (PET)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-03-00-02-3109-00-304-104

- **4.** Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0216 "Administration: NIH Electronic Directory (NED), HHS/NIH": 09-90-0018 "Personnel Records in Operating Offices, HHS/OS/ASPER"
- 5. OMB Information Collection Approval Number: none
- 6. Other Identifying Number(s): none
- **7. System Name (Align with system Item name):** NIH NIA Position and Employee Tracking (PET)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Melissa Fraczowski
- **10. Provide an overview of the system:** The NIA Position and Employee Tracking (PET) application is owned and maintained by the Workforce Strategic and Planning Branch (WSPB) of the NIA Office of Administrative Management (OAM) and is located in Building 31 on the NIH main campus in Bethesda, MD. The PET application consolidates NIA personnel information into one location, reducing WSPB reliance on maintaining separate Microsoft Excel spreadsheets for different categories of personnel information. The PET will be used to maintain administrative and status information on NIA federal FTE and non-FTE contractors, special volunteers, intramural research training award recipients (IRTAs), visiting fellows, guest researchers, and detailees.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes

- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No sharing or disclosures at this time.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Some PII in the system is queried from the NIH Enterprise Directory (NED) and the HHS Capital HR systems and entered into the PET application. Additional PII comes from spreadsheets maintained by the Workforce Strategy and Performance Branch (WSPB). Types of PII include name, NIH badge number, Capital HR Employee ID, and start and separation dates of NIA employees and contractors. The information contains PII. Submission of personal information is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No processes are in place to notify and obtain consent from the individuals whose PII is in the system when major changes, as defined in Section 208 of the E-Government Act of 2002, occur to the system. All PII in the system is queried from the NIH Enterprise Directory (NED) and HHS Capital HR systems and entered into the PET application.

Refer to the system of record notice 09-25-0216 section entitled ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES for a summary of the notice of uses of NED information.

Refer to the system of record notice 09-90-0018 section entitled ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES for a summary of the notice of uses of Capital HR information.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Physical controls for Building 31 and the Gateway Building include: guards, identification badges, key cards and closed circuit TV. Technical controls for the server and PET applications include: user ID, passwords.

PIA Approval

PIA Reviewer Approval: Promote PIA Reviewer Name: Taryn Ayoub

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIA Social Research System (SRS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/5/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): none
- 5. OMB Information Collection Approval Number: none
- 6. Other Identifying Number(s): none
- 7. System Name (Align with system Item name): NIH NIA Social Research System (SRS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Partha Bhattacharyya
- **10. Provide an overview of the system:** The NIH NIA Social Research System (SRS) is a general purpose workstation (Dell Precision T7500 PC with Windows 7) with statistical programs STATA and SAS for analysis of deidentified Medicare and Social Security Administration data by Partha Bhattacharyya, PhD, of the National Institute on Aging (NIA) Division of Social and Behavioral Research (DSBR). Dr. Bhattacharyya will personally conduct all analyses performed on the SRS and share aggregate, de-identified results with collaborators.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A. No PII.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: The information in the system comprises deidentified Medicare claims records data (diagnosis codes, reimbursement, and date of service), deidentified Social Security earnings file data (income), and deidentified hospital discharge data (diagnosis codes, reimbursement, and date of service). The information is used in examining the clinical questions addressed by the study. The information does not contain PII.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A. No PII.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A. No PII.

PIA Approval

PIA Reviewer Approval: Promote PIA Reviewer Name: Taryn Ayoub

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIA Status of Funds Internet Edition (SOFie)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/9/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-09-02-3199-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): NIH NIA Status of Funds Internet Edition (SOFie)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Chris Porter
- **10. Provide an overview of the system:** SOFie is a Web-based financial reporting/tracking tool that enables NIH ICs to manipulate and report on financial transactions downloaded from the Budget & Finance database in the NIH Data Warehouse. (The NIH DW Budget & Finance database comprises data downloaded from the NIH Business System.) Appointment and authority is given to the National Institutes of Health under 5 U.S.C. 301 and 302, 44 U.S.C. 3101 and 3102, Executive Order 9397.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A. No PII.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: NIA accounting transactions are downloaded from the Budget & Finance database in the NIH Data Warehouse. (The NIH DW Budget & Finance database comprises data downloaded from the NIH Business System.) The data is used to plan, track, and report on NIA fiscal budgets.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A. No PII.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A. No PII.

PIA Approval

PIA Reviewer Approval: Promote PIA Reviewer Name: Taryn Ayoub

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIA Telework NIA [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/9/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-09-02-3109-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-90-0018 "Personnel Records in Operating Offices, HHS/OS/ASPER"

- **5. OMB Information Collection Approval Number:** N/A
- **6. Other Identifying Number(s):** no
- 7. System Name (Align with system Item name): NIH NIA Telework
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Melissa Fraczkowski
- **10. Provide an overview of the system:** The Telework system in an enterprise system hosted by NIA. This enterprise system is also used by CSR, NHGRI, NIMHD, NIDA and NHLBI. The system supports the federal Telework initiative by providing an online Telework application repository and approval workflow. After an employee completes an online Telework application form, the application moves through an electronic approval process. Upon approval of the application, the applicant receives an email notification of their application status. The applicant then completes an online Home Office Evaluation form. The Telework system also enables automatic renewals, automatic changes, and online termination of telework approval.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): No sharing or disclosures at this time. Refer to the system of record 09-90-0018 section entitled ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING

CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES

http://oma.od.nih.gov/ms/privacy/pa-files/09900018.htm for the allowed disclosures of PII.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The Telework system collects and maintains voluntarily submitted PII needed to support the federal Telework initiative, including employee name, supervisor name, NIH employee badge number, job title and grade, IC, division, building and room numbers, work phone and fax, email address, home address, and home phone and fax numbers. The information is used to manage Telework applications, approvals, renewals, changes, and terminations. The information contains PII. Submission of personal information is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) All PII in the Telework system is submitted by Telework applicants during the application process. At login, the Telework system displays a Privacy Statement that describes use of collected data.

No processes are in place to notify and obtain consent from the individuals whose PII is in the system when major changes, as defined in Section 208 of the E-Government Act of 2002, occur to the system.

Refer to the system of record 09-90-0018 section entitled ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES for a summary of the notice of uses of information.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls: Physical controls: guards, identification badges, key cards and closed circuit TV. Technical controls: user ID, passwords, firewall, Virtual Private Network (VPN).

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Taryn Ayoub

Sr. Official for Privacy Approval: Promote **Sr. Official for Privacy Name:** Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIAAA Clinical Research Database (CRDB)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIAAA Clinical Research Database (CRDB)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Etienne Lamoreaux
- **10. Provide an overview of the system:** NIAAA CRDB collects and acquires data from CRIS (Clinical Research Information System) and NIAAA intramural laboratories. Authority for the maintenance of the system: 42 U.S.C. 241, 42 U.S.C. 290dd-2, 42 CFR Part 2, and where applicable, nondisclosures will be made consistent with authorization of confidentiality under 42 U.S.C. 241 and 42 CFR Part 2a.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The system does not share or disclose PII. Refer to SORN 09-25-0200.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: CRDB collects patient data that is used to conduct clinical protocols. The information collected from subjects constitutes PII. Information and patient data is obtained from subjects who sign written informed consent forms. Rules and regulations are in agreement with standard practices at the NIH Clinical Center.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) PII in the system is downloaded from NIH CRIS (Clinical Research Information System); therefore, the notification and consent processes associated with CRIS apply. This data is merged with patient data (PII) collected by NIAAA intramural laboratories. Information and patient data is obtained from subjects who sign written informed consent forms. Rules and regulations for the collection of patient data by NIAAA laboratories are in agreement with standard practices at the NIH Clinical Center.

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** PII stored in NIAAA CRDB is accessed by a very limited number of staff with a "need-to-know" status, mostly consisting of principal investigators and scientific staff responsible for data input and validation. Only authorized users have access to PII data. PII contained in the system is protected through NIH Active Directory account and password management, and inheritied NIH policies and procedures. Secure socket layer protocol (SSL) is used to encrypt data in transit. The system is located in a secure network room behind a firewall. Users receive NIH rules of behavior training. All personnel not having card key access to the server room are escorted and required to sign in. Access to the building and its hallways is recorded on video 24 hours a day (recorded not CCTV).

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Pamela Anderson Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIAAA EMPLOYEE DATABASE internet edition (EDiE)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-3196-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-90-0018, 09-90-0024, 09-25-0216

5. OMB Information Collection Approval Number: None

6. Other Identifying Number(s): None

- 7. System Name (Align with system Item name): Employee Database Internet Edition
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Patricia Scullion
- **10. Provide an overview of the system:** EDiE is an intranet based application primarily used to manage and track personnel information. Authority for maintenance of the system: 5 U.S.C. 1302, 2951, 4118, 4308, 4506, 7501, 7511, 7521 and Executive Order 10561.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Information is intended for internal senior administrative use only and will not be shared by other entities. Refer to SORN 09-90-0018, SORN 09-90-0024 and SORN 09-25-0216.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: EDiE tracks all information pertinent to a personnel file for the purpose of personnel management activities. Information is

collected from employees via the Human Resources Database (HRDB) system, nVision Data Warehouse and NIH Enterprise Directory (NED). Uses consist of the following: a) tracking a time-limited appointment to ensure renewals are done in a timely manner, thereby avoiding any break in service; b) ensuring that allocated FTE ceilings are maintained; c) ensuring salary equality for various hiring mechanisms; d) providing reports to the NIH Director, the IC Director, and other management staff as requested; and e) maintaining lists of non-FTEs, special volunteers, contractors, and other hiring appointments. The information collected constitutes PII and is mandatory for all employees.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) PII in the system is downloaded from the HRDB, nVision Data Warehouse and NED. Changes to HRDB or changes in the way information is used is relayed to employees via official notices from the NIH Office of Human Resources (OHR). Individuals are notified of the collection and use of the data as part of the hiring process. This is a mandatory requirement of potential job applicants seeking employment at NIH.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** PII stored in EDiE is accessed by a very limited number of administrative staff with a "need-to-know" status. Only authorized users have access to PII data. PII contained in the system is protected through NIH Active Directory account and password management, and inheritied NIH policies and procedures. Secure socket layer protocol (SSL) is used to encrypt data in transit. The system is located in a secure network room behind a firewall. Users receive NIH rules of behavior training. All personnel not having card key access to the server room are escorted and required to sign in. Access to the building and its hallways is recorded on video 24 hours a day (recorded not CCTV).

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Pamela Anderson Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIAAA FINEX PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-04-02-8610-00-404-136

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): NIAAA FinEx

- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Donna Casady
- **10. Provide an overview of the system:** The FinEx application is a centralized, internet-based relational database environment that stores data and business rules (procedures) required to maintain the Extramural grant budget. The FinEx application includes the tools necessary to estimate, award, obligate, forecast and report on grant budgets in the Extramural program.

In its in-production state, FinEx resides on the NIAAA-FINSOF server as a .Net, web-developed application. Its interdependences on other resources (or dynamically-linked libraries (DLLs)) are fully compiled into the installed version of FinEx on NIAAA-FINSOF. NIAAA-FINSOF serves as the web application. The database on which FinEx is dependent resides on NIAAA reosurces, SQL Server 2000 database server. FinEx utilizes, but is not dependent on NIH CIT resources for supplemental data (e.g. IRDB-an Oracle database warehouse server and DataWarehouse-an IBM mainframe finance data warehouse).

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes

- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): PII is obtained from the eRA system in the administration of research grants IAW SOR#09-25-0036
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Financial Grant information. The FinEx application is a centralized, Internet-based relational database environment that stores data and business rules (procedures) required to maintain the extramural grant budget. The FinEx application includes the tools necessary to estimate, award, obligate, forecast and report on grant budgets in the extramural program. The type of PII collected and contained in NIAAA FinEx are applicant "names" and is obtained from the eRA system and is a required part of the grants submission process. Since PII is required for the grants submission process, it is a mandatory requirement of FinEx. This PIA is only viewed by the NIAAA Budget Office.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) PII is submitted as a part of the grants application process. Information used by the NIAAA FinEx is taken from the eRA grant application. Notification and consent from the individual is assumed when the grant application is submitted. All notification and consent is taken care of via the grant application submission process and eRA systems.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** Role based security and NIH Active Directory authentication with a user name and password are used, and group access permissions are used to secure the application and it's data. Users are only allowed access on a least privilege, need-to-know basis, and receive NIH rules of behavior training. The system resides behind a firewall and is in a server room with no external access. All personnel not having card key access to the server room are escorted and required to sign in. Access to the building and its hallways is recorded on video 24 hours a day (recorded not CCTV).

PIA Approval

PIA Reviewer Approval: Promote
PIA Reviewer Name: Pamela Anderson

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/30/2011

Approved for Web Publishing: Yes

Date Published: May 23, 2012

06.3 HHS PIA Summary for Posting (Form) / NIH NIAAA NESARC3 Study Management System

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: TBD

6. Other Identifying Number(s): Westat Internal Project ID 8690

- **7. System Name (Align with system Item name):** NIH NIAAA National Epidemiologic Survey on Alcohol and Related Conditions III Study Management System (NESARC3-SMS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Bridget Grant, Ph.D, Ph.D
- **10. Provide an overview of the system:** The information is collected under 42 USC 285n and participation in the NESARC-III is voluntary. The information contains PII and information is shared in accordance with the guidance in the System of Records Notice 09-25-0200. The NESARC-III is a nationally representative survey of the U.S. population (N=46,500). The NESARC-III will collect information on alcohol use practices and alcohol use disorders and their associated physical (e.g. liver cirrhosis) and psychological (e.g. depressed mood) disabilities and also DNA through saliva samples. There are two small methodological components (N=1700) that collect information on reliability and validity. The major purpose of the information is to determine the prevalence, distribution, treatment and health disparities and economic costs and to identify environmental and genetic risk factors and their interactions for these conditions.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes

- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Information stored in the system is shared in accordance with the routine uses outlined in NIH Systems of Record Notice 09-25-0200.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The information is collected under 42 USC 285n and participation in the NESARC-III is voluntary. The information contains PII and information is shared in accordance with the guidance in the System of Records Notice 09-25-0200. The NESARC-III is a nationally representative survey of the U.S. population (N=46,500). The NESARC-III will collect information on alcohol use practices and alcohol use disorders and their associated physical (e.g. liver cirrhosis) and psychological (e.g. depressed mood) disabilities and also DNA through saliva samples. There are two small methodological components (N=1700) that collect information on reliability and validity. The major purpose of the information is to determine the prevalence, distribution, treatment and health disparities and economic costs and to identify environmental and genetic risk factors and their interactions for these conditions. Information collected includes background information, including sociodemographic variables; alcohol use practices, disorders and alcohol related social, psychological and physical consequences; symptoms scales indexing major mood, anxiety, and eating conditions that frequently co-occur with alcohol and drug use disorders; tobacco, medicine and drug use and disorders and related social, psychological, and physical consequences; selected personality traits, including behavior; alcohol, drug, and mental health treatment utilization; medical conditions related to alcohol consumption; care giving roles; discrimination in health care; race-ethnicity; gender; income; sexual orientation; physical disability; acculturation; perceived stress and social support; adverse childhood experiences and intimate partner violence; nativity; generational status; sexual orientation; age at first intercourse; presence of HIV/AIDS and other medical disease; health insurance coverage; and executive functioning.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Individuals whose information is in the system only interact with the system to respond to the surveys. No changes will be made to the information that they provide. Respondents are notified and consent is obtained regarding PII collected from them through advance letters, informational study materials and written notice on consent. The information will be used for research purposes and shared in accordance with the guidance in System of Records Notice 09-25-0200.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No

- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Information will be secured on the system through access controls, personnel security awareness and training, regular auditing of information and information management processes, careful monitoring of a properly accredited NESARC3-SMS information system, control of changes to the system, by appropriate planning and testing of configuration management and contingency processes, by ensuring that all users of the NESARC3-SMS are properly identified and authorized for access and are aware of and acknowledge the system rules of behavior, by ensuring that any contingency or incident is handled expeditiously, properly maintaining the system and regulating the environment it operates in, by controlling media, by evaluating risks and planning for information management and information system operations, by ensuring that the system and any exchange of information is protected, by maintaining the confidentiality and integrity of the NESARC3-SMS, and by adhering to the requirements established in the contract and statement of work.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Pamela Anderson Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIAAA NIAAA General Support System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-0200-01-3109-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIAAA General Support System (GSS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Jonathan Folkers
- **10. Provide an overview of the system:** The system is a General Support System (GSS) and does not directly collect or store information.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system is a General Support System (GSS) and does not directly collect or store information. The applications/systems residing on the GSS collect and store information. Therefore, individual PIAs have been prepared and submitted for the applications/systems residing on this GSS.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Pamela Anderson Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIAAA SOFie PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): Status of Funds internet edition (SOFie)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Donna Casady
- **10. Provide an overview of the system:** SOFie is a Web based application employing Microsoft's IIS and SQL server software. The SOFie application supports the efforts of several offices and branches within NIAAA, allowing budget offices to track expenditures of direct, reimbursable, and non-appropriated funds in a fiscal year. Additionally, SOFie is used to reflect budget allocations and projected expenditures at the operating level. The program also contains a tracking mechanism to track prior year funds. The application downloads this information from the NIH Data Warehouse weekly. Information entered into the SOFie database is not uploaded into the NIH Data Warehouse database. SOFie is not a source database for other information systems.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Accounting data and related document information is downloaded from the Central Accounting Mainframe (Data Warehouse Budget and Finance) and is relevant or specific to NIAAA for its fiscal year operations. No IIF information is contained in SOFIE.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Pamela Anderson

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIAID ARAC Review (ARAC)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/18/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-01-02-8520-00-110-249

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- **7. System Name (Align with system Item name):** NIH NIAID AIDS Research Advisory Committee (ARAC) Review
- **9.** System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Joe Croghan, 301.443.8439, croghanj@niaid.nih.gov
- **10. Provide an overview of the system:** The ARAC system serves as a communication tool for committee members and the NIAID office that coordinates the meetings. It provides a web accessible interface for DAIDS to:
- post timely information on upcoming ARAC meetings
- receive feedback on concepts from meeting participants (members)
- send emails containing system related information to active users
- · maintain a searchable archive of past meetings, concepts, and participants

The ARAC system is a role based secure tool with three different levels of users; administrators, members, and viewers.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass

through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Information on committee members who participate in the application review process will be maintained, and may be shared with other authorized users. This includes the user name, degree, title, work address, work phone number, and work email address. Per SORN 09-25-0036, Disclosure may be made to qualified experts not within the definition of Department employees as prescribed in Department regulations for opinions as a part of the application review process. Disclosure may be made to a private contractor or Federal agency for the purpose of collating, analyzing, aggregating or otherwise refining records in this system. The contractor or Federal agency
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Information on committee members who participate in the application review process will be maintained, and may be shared with other authorized users. This includes the user name, degree, title, work address, work phone number, and work email address. Per SORN 09-25-0036, Disclosure may be made to qualified experts not within the definition of Department employees as prescribed in Department regulations for opinions as a part of the application review process. Disclosure may be made to a private contractor or Federal agency for the purpose of collating, analyzing, aggregating or otherwise refining records in this system. Committee members whose names and contact information is contained on the system have submitted it voluntarily and are informed that it will be used to assist in communication and the review process.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Written consent is obtained from members when personal (contact) information is collected.

The intended use for the information is described in writing at the time of collection.

Members are informed of the use of the application (ARAC), that it will contain their names and contact information. Changes to the system are discussed with all members during business communications, including written correspondence.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No

- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Authorized Users: Employees who maintain records in this system are instructed to grant regular access only to NIH extramural and advisory committee staff, NIH contract management staff, and Federal acquisition personnel. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the System manager.

Physical Safeguards: Physical access to NIH work areas is restricted to employees. Physical access to the Office of Technology Information Systems (OTIS) work areas is restricted to OTIS employees. Physical access to Office of Federal Advisory Committee Policy (OFACP) work areas is restricted to OFACP employees. Access to the contractor performance files is restricted through the use of secure socket layer encryption and through an IBM password protection system. Only authorized government contracting personnel are permitted access. Access is monitored and controlled by OTIS.

Procedural Safeguards: Access to source data files is strictly controlled by files staff. Records may be removed from files only at the request of the System manager or other authorized employee. Access to computer files is controlled by the use of registered accounts, registered initials, keywords, and similar limited access systems.

PIA Approval

PIA Reviewer Approval: Promote PIA Reviewer Name: Natasha Taylor

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIAID Biological Specimen Inventory II (BSI-II)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/18/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: No

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN

number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): NIH NIAID Biological Specimen Inventory II (BSI-II)

- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Tram Huyen, 301.451.2898
- 10. Provide an overview of the system: NIAID is a data-intensive organization, highly reliant on the effective and efficient management of large volumes of clinical biospecimen data to accomplish its research mission. To address the tracking and management of its clinical biospecimens while ensuring compliance with recent Congressional reporting requirements and other Federal regulations, NIAID is seeking to implement the Biological Specimen Inventory-II (BSI-II) system. This system is operated by a contractor working on NIAID's behalf; Information Management Services, Inc. (IMS),

The BSI-II system is designed to track laboratory specimen inventories from a single laboratory up to an enterprise-level biorepository. The system provides the following capabilities:

- · Specimen Management
- · Requisition/Workflow Tracking
- · Freezer/Inventory Management
- · Comprehensive Reporting
- · Shipment and Discrepancy Tracking

The BSI-II system runs on all major operating systems and can accommodate a large number of records and concurrent users. The system can be accessed via two implementations: a Javabased client application and a Web-based application.

13. Indicate if the system is new or an existing one being modified: Existing

- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Researchers who are Authorized users can view the data for research purposes. Note that this system does not match IIF against other computer systems, and no other organizations or systems are dependent upon the IIF contained in this system. Additionally, per SORN 09-25-0200, routine uses of records maintained in the system, including categories of users and the purposes of such uses, are as follows:

A record may be disclosed for a research purpose, when the Department: (A) has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; e.g., disclosure of alcohol or drug abuse patient records will be made only in accordance with the restrictions of confidentiality statutes and regulations 42 U.S.C. 241, 42 U.S.C. 290dd-2, 42 CFR Part 2, and where applicable, no disclosures will be made inconsistent with an authorization of confidentiality under 42 U.S.C. 241 and 42 CFR Part 2a; (B) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law; and (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by, these provisions. Disclosure may be made to a Member of Congress or to a Congressional staff member in

response to an inquiry of the Congressional office made at the written request of the constituent about whom the record is maintained.

The Department of Health and Human Services (HHS) may disclose information from this system of records to the Department of Justice when: (a) The agency or any component thereof; or (b) any employee of the agency in his or her official capacity where the Department of Justice has agreed to represent the employee; or (c) the United States Government, is a party to litigation or has an interest in such litigation, and by careful review, the agency determines that the records are both relevant and necessary to the litigation and the use of such records by the Department of Justice is, therefore, deemed by the agency to be for a purpose that is compatible with the purpose for which the agency collected the records.

Disclosure may be made to agency contractors, grantees, experts, consultants, collaborating researchers, or volunteers who have been engaged by the agency to assist in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity. Recipients shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

Information from this system may be disclosed to Federal agencies, State agencies (including the Motor Vehicle Administration and State vital statistics offices, private agencies, and other

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The collection of IIF is a voluntary process that is routinely done as a part of a clinical protocol. The collection of this information and the subsequent handling of that information is detailed in the consent forms associated with a given clinical protocol.

The IIF collected and stored in the BSI-II system may include:

- · Adoption Status
- · Age
- Date of Birth
- · Date of Death
- Date of Last Status
- · Deceased Status
- · Diagnosis
- Email Address
- · Ethnicity
- · Family Information
- Medical Notes
- Medical Records Numbers
- · Patient Name
- · Clinician Name
- · Phone Number
- Sex
- Suffix
- · Vitals status

- Medications
- · Protocol #(s)
- · Confidentiality Agreement # or exemption
- Collection Site Name
- Collection Site Address
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Informed Consent is obtained from all participants in writing before they are enrolled in a clinical protocol. The informed consent documents what information is collected and how it will be used, as well as providing a point of contact for each protocol.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The IIF will be secured in a similar fashion to that of other data stored in the system. Briefly, security measures include:

Transmission

All communication between the client application and the BSI transaction servers will be encrypted using a 128-bit algorithm. All HTTPS communications, including the web-based client application, will use ASE 256-bit encryption between the client and the server. In addition, IMS will maintain both production HTTP and HTTPS (secure) servers on the Internet for file transfers. The HTTP servers are utilized for day to day file transfers of publicly available data.

System Monitoring

Automated audit trails are monitored on all server-based systems deployed at IMS. File usage logging will be done for files specified by the NIAID. Audit records and server logs will be reviewed daily for anomalies. An automated reporting tool will be used to analyze the server logs to look for abnormal activity. Automated audit trails also play an important part in governing the access granted to users outside the Contractor's Local Area Network (LAN). A firewall is in place that logs all incoming and outgoing connections to the LAN. This includes connections to the UNIX/Linux workstations and the Windows servers. This log will be maintain and checked for evidence of attempted unauthorized access to the Contractor's LAN.

Client Application

The BSI-II system maintains a full audit-trail on all data and meta-data modified in the system. This includes what was changed, when, how, and by whom. These logs will be maintained within the database and will be not editable, but will be available for query and review by authorized staff. Access to the system requires a valid username and password. All communication between the client and server uses encrypted sockets to protect the data. Access to system functions are granted by role-based assigned privileges.

Computer Center Administrative and Physical Safeguards

IMS' Standard Operating Procedure (SOP) for Computer Resource Security details the standards and processes used to ensure the security of the computer resources and data. All IMS employees will be required to read and follow this SOP.

IMS' computer center has facilities in Silver Spring, MD and in Sterling, VA. The Sterling, Virginia site will be used for production services that require 24/7 accessibility. This site has personnel on site 24-hours a day in a facility that requires a key card and fingerprint for access. The facility also provides protection against fire and flood with highly sensitive monitoring equipment. Generators are available to provide continuous electricity in case of a main power failure.

The Silver Spring computer center is in a separate office with a key coded access lock. Each person authorized to access the computer center has a personal ID and password that must be entered each time the door is opened. A log of any attempt to enter the computer center is maintained. This log is routinely reviewed to identify any potential security risks. Visitors are never allowed into the computer center at either site. Maintenance and repair personnel will be escorted into the computer room and then monitored until all work is complete.

IMS employs firewalls with Intrusion Detection capabilities to secure the network perimeter. The firewalls are continually monitored. Reports are distributed to authorized administrators twice daily for their review. Computer center staff performs weekly security checks using Security Auditor's Research Assistant (SARA), a third generation UNIX-based security analysis tool. IMS routinely reviews the security check results and rectifies any identified potential security vulnerabilities.

Registration of authorized users on IMS' Network is controlled by the IMS system administrator. To enter the network, the user must have an authorized user ID and a password which must be changed every 90 days. Network privileges are established

PIA Approval

PIA Reviewer Approval: Promote PIA Reviewer Name: Natasha Taylor

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIAID Chem Database PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/11/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A
- **5. OMB Information Collection Approval Number:** N/A
- 6. Other Identifying Number(s): N/A
- 7. System Name (Align with system Item name): NIH NIAID Chem Database
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Joe Croghan
- **10. Provide an overview of the system:** The NIAID ChemDB system provides for the management of chemical and biological databases which serve as tools for the rational selection and discovery of potential therapies for AIDS and opportunistic infections (OIs). The databases contain pertinent published literature and NIAID confidential data and information on the chemical, virological, immunological and microbiological aspects of therapeutic agents for HIV, OIs, and TB, and on microbicides.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The data collected, maintained and disseminated in the NIAID Chemdb is preclinical chemical and biological testing

data abstracted from publicly available journal articles, patents from the US Patent and World Patent offices and professional association meetings. The data includes chemical structures, molecular weights, molecular formulas, chemical names, compound identifiers, trivial compound names, names of companies and institutes where the compound was developed, CAS# and NSC# for each compound. Also stored in the database are estimated parameters such as logP, number of H bond donors, number of H bond acceptors and Phia, which might indicate a compounds suitability as a drug. These parameters are generated using publicly available third party software such as the FDA's Kowwin, MDL's QSARIS and Symyx's Isentris. The biological data stored in the database is EC50, IC50, CC50, SI, testing methods, virus tested, cell line tested, enzyme tested and other data which elucidates the environment in which the data was collected.

This data base does not contain any IIF data.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) $\rm\,N/A$

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Natasha Taylor/Margaret Moore

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIAID Clinical Research Information Management System of NIAID [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: New Interagency Uses

1. Date of this Submission: 8/11/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: No

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0099

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH NIAID Clinical Research Information Management System of NIAID (CRIMSON)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Bill Barrick
- **10. Provide an overview of the system:** The Clinical Research Information Management System of the NIAID (CRIMSON) is a Major Application used by the NIAID outpatient clinics in support of their clinical research trials. CRIMSON was developed around a novel model that reduces or eliminates duplicate data entry of research study participant information. CRIMSON combines electronic medical record functionality with clinical trials management functionality into one system. CRIMSON automatically integrates laboratory data from multiple sources, along with entered clinical observation data, into one data repository of clinical research protocol information. Information is then available to investigators for clinical and research usage via standard reports, monitoring reports, ad-hoc queries, statistical analysis, graphical display, etc.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Sharing is limited to medical consultation within the organization. In addition, PII (progress

notes and lab data) are shared with the NIH Clinical Center Medical Records Department for patient care and clinical research.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) The system is an electronic health record. The program will collect patient encounter information including medical histories, examinations, treatment plans, interventions and the outcomes of those interventions. Documentation of family histories and health events may include identifiers of both the individual and family members. Documentation of common contact information (e.g., address, phone number, e-mail address) is required for safety purposes and to maintain continuity of the provider-patient relationship. The system does not collect Social Security numbers. (2) The information is used in the conduct of clinical research, health management, health education of the individual patient or family, and teaching in a professional program of medical education. (3) The information contains PII, including name, date of birth, address, phone number, e-mail address, and medical data. (4) All information submitted by patients is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) A number of federal and local agencies oversee and direct this process including the Institutional Review Board for Human Subjects Protection, the Clinical Center Medical Records Department, and the Office of Human Subjects Protections.

- (1) When an initiative arises in which historical data or specimens are desired for use in ways not covered by prior consent, the Institutional Review Board reviews and advises on the scope of consent. In many cases the IRB requires re-consent with the patient or requires that program refrain from data or specimen uses not previously consented. (2) Patients in this program undergo a informed consent counseling from no fewer than two separate allied health professionals. Consent is obtained in an interview with a physician and affirmed by the patient in writing. Notification and consent to obtain information and specimens is managed in the Consent to Treat and Consent to Participate in Clinical Study procedures. Patients are extensively counseled on the meaning and implications of both and then affirm their understanding in writing. (3) Patients are notified during the consent process how their information will be used and that it may be shared with health care professionals and research staff.
- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:

- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** System access is granted by the Project Officer (COTR) for purposes of conducting health care or clinical research. Allied Health care professionals with direct patient contact and access to the system are credentialed by the appropriate hospital authorities. Other logistical and scientific staff are granted access based on a "least permissions" model appropriate to their role in the care or research process. All persons with access to the system are covered by appropriate nondisclosure agreements, have completed NIH security training, and been instructed in the appropriate management of IIF.

Electronic access to the system is restricted to persons with credentials that include a password and logon. NIH policies apply to password complexity and change frequency. Access lists are reviewed every 6 months to ensure currency. Individual access may be reviewed on an as needed basis. Data travels only over secured NIH networks. Servers are located in secure physical locations certified and accredited for appropriate physical access controls.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Natasha Taylor/Margaret Moore

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIAID DAIT Studies System (DSS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/18/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-8534-00-110-249

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH NIAID DAIT Studies System (DSS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Joe Croghan, 301.443.8439, croghani@niaid.nih.gov
- **10. Provide an overview of the system:** This is a management oversight system designed to assist the Division of Allergy, Immunology and Transplantation (DAIT) Project Officers (POs) in managing research projects that include human subjects.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The information will not be shared. Per SORN 09-25-0036, disclosures may be made for the following uses:

Disclosure may be made to the cognizant audit agency for auditing.

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

Disclosure may be made to qualified experts not within the definition of Department employees as prescribed in Department regulations for opinions as a part of the application review process.

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Name, Mailing address, telephone number, and email address are the PII that the agency will collect. It will be used for management oversight to assist DAIT Project Officers (POs) who manage research projects that include human subjects.

Submission of the information is voluntary as it is part of the application process, but applications that are submitted without the information could be hindered from processing and could be declined for insufficient information.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Information is provided by individuals who are applying for grants. Participation is at the discretion of the individual who applies for the grant or award. The applicants are informed on the application that the information collected will be used solely for the management of the grants process and will not be shared. There is no process in place to notify individuals in the event of a major change to the system.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** Authorized Users: Employees who maintain records in this system are instructed to grant regular access only to NIH extramural and advisory committee staff, NIH contract management staff, and Federal acquisition personnel. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the System manager.

Physical Safeguards: Physical access to Office of Extramural Research (OER) work areas is restricted to OER employees. Physical access to the Office of Acquisition and Policy (OAMP) work areas is restricted to OAMP employees. Physical access to Office of Federal Advisory Committee Policy (OFACP) work areas is restricted to OFACP employees. Access to the contractor performance files is restricted through the use of secure socket layer encryption and

through an IBM password protection system. Only authorized government contracting personnel are permitted access. Access is monitored and controlled by OAMP.

Procedural Safeguards: Access to source data files is strictly controlled by files staff. Records may be removed from files only at the request of the System manager or other authorized employee. Access to computer files is controlled by the use of registered accounts, registered initials, keywords, and similar limited access systems.

These practices are in compliance with the standards of Chapter 45-13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45-13, and the HHS Automated Information Systems Security Program Handbook.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Natasha R. Taylor/Margaret Moore

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIAID Employee Database Internet Edition (EDie)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: Significant Merging

1. Date of this Submission: 9/19/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-90-0018

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH NIAID Employee Database Internet Edition (EDie)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Joe Croghan
- **10. Provide an overview of the system:** EDie is an intranet based application primarily used to manage and track personnel information. Authority for maintenance of the system: 5 U.S.C. 1302, 2951, 4118, 4308, 4506, 7501, 7511, 7521 and Executive Order 10561.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Information is intended for internal administrative use only and will not be shared by other entities. Refer to SORN 09-90-0018, SORN 09-90-0024 and SORN 09-25-0216.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: EDie tracks all information

pertinent to a personnel file for the purpose of personnel management activities. Information is collected from employees via the Human Resources Database (HRDB) system; Fellowship Payment System (FPS); nVision Data Warehouse and NIH Enterprise Directory (NED). Uses consist of the following: a) tracking a time-limited appointment to ensure renewals are done in a timely manner, thereby avoiding any break in service; b) ensuring that allocated FTE ceilings are maintained; c) ensuring salary equity for various hiring mechanisms; d) providing reports requested by the NIH Director, the IC Director, and other management staff, as requested; and e) maintaining lists of non-FTEs, special volunteers, contractors, and other hiring appointments. The type of information collected constitutes PII and includes, but is not limited to the following data elements: name, home address, home phone number, social security number and date of birth. The PII collected is mandatory for all employees.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) PII in the system is downloaded from the HRDB, FPS, nVision Data Warehouse and NED. Changes to HRDB or changes in the way information is used is relayed to employees via official notices from the NIH Office of Human Resources (OHR). Individuals are notified of the collection and use of the data as part of the hiring process. This is a mandatory requirement of potential job applicants seeking employment at NIH.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Authorized Users: The NIAID system manager(s) authorize access to the system based upon an employee's official role and job function within the organization in addition to management approval.

Physical Safeguards: Physical access to Office of Extramural Research (OER) work areas is restricted to OER employees. Physical access to the Office of Acquisition and Policy (OAMP) work areas is restricted to OAMP employees. Physical access to Office of Federal Advisory Committee Policy (OFACP) work areas is restricted to OFACP employees. Access to the contractor performance files is restricted through the use of secure socket layer encryption and through an IBM password protection system. Only authorized government contracting personnel are permitted access. Access is monitored and controlled by OAMP. The NIAID Data Center is restricted by badge access whereby permissions are only provided to limited employees with job

functions requiring such access. In addition, entry to the building is controlled via badge access and visitors are required to sign in at the guard's desk and be escorted around the building.

Procedural Safeguards: Access to source data files is strictly controlled by files staff. Records may be removed from files only at the request of the System manager or other authorized employee. Access to computer files is controlled by the use of registered accounts, registered initials, keywords, and similar limited access systems.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Natasha R. Taylor Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIAID Facility Management System

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

- **3.** Unique Project Identifier (UPI) Number: This system does not meet the requirements for a UPI number.
- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A
- **5. OMB Information Collection Approval Number:** N/A
- 6. Other Identifying Number(s): N/A
- 7. System Name (Align with system Item name): NIH NIAID Facility Management System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Joe Croghan
- **10. Provide an overview of the system:** The Office of Research Operations (ORO) uses the Facility Management System to manage the NIAID space inventory and associated facility assets. It is used to track the office and laboratory space allocations for all NIAID staff, fellows, and contract employees.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Information on this system is for internal use only, and is used by the Office of Research Operations (ORO) to plan space and office allocations. Disclosure may be made to a congressional office from the records of an individual in response to an inquiry from the congressional office made at the request of that individual.

Disclosure may be made to representatives of the General Services Administration or the National Archives and Records Administration who are conducting records management inspections under the authority of 44 U.S.C. 2904 and 2906.

Disclosure may be made to agency contractors, experts, consultants, or volunteers who have been engaged by the agency to assist in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity. Recipients are required to maintain Privacy Act safeguards with respect to these records.

Disclosure may be made to respond to a Federal agency's request made in connection with the hiring or retention of an employee, the letting of a contract or issuance of a security clearance, grant, license, or other benefit by the requesting agency, but only to the extent that the information disclosed is relevant and necessary to the requesting agency's decision on the matter.

Disclosure may be made to the Department of Justice, or to a court or other adjudicative body, from this system of records when (a) HHS, or any component thereof; or (b) any HHS officer or employee in his or her official capacity; or (c) any HHS officer or employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the officer or employee; or (d) the United States or any agency thereof where HHS determines that the proceeding is likely to affect HHS or any of its components, is a party to the proceeding or has any interest in the proceeding, and HHS determines that the records are relevant and necessary to the proceeding and would help in the effective representation of the governmental party.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: 1. This system only contains information on NIAID employees, fellows, and contractors. Information is pulled monthly from NIH NED Public Data and includes:
- · NED ID
- · Name
- · Organization
- · E-Mail
- · Location Building, Floor, Room
- 2. The employee information is used to associate employees with facility space information in order to calculate space utilization, and track vacant underutilized space.
- 3. The information does contain PII.
- 4. Submission of employee data to NED is mandatory under federal guidance.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Prospective employees/staff are informed of the privacy act statement upon receipt of official employment forms. The privacy act statement informs

prospective employees of the routine purpose for collecting the information that is being requested. The information in the system is based upon official information that is provided as a condition of employment.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The system is password protected with role based security that provides a separation based on need to know. Only space data managers will have access to information. The system is protected by firewalls, both NIH and NIAID controlled. The server is located within a NIAID facility, protected by guards who require ID badges for entry. The server is further contained in a locked server room that requires special access for entry.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Natasha Taylor/Margaret Moore

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/21/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIAID iMedRIS PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

- 3. Unique Project Identifier (UPI) Number: N/A Minor Application
- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A
- **5. OMB Information Collection Approval Number:** N/A
- 6. Other Identifying Number(s): N/A
- 7. System Name (Align with system Item name): NIH NIAID iMedRIS
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Bill Barrick, Clinical Research Program Analyst
- **10. Provide an overview of the system:** Submission and management of documents associated with Institutional Review Board business of the NIAID.

NIAID IRB Submissions (iMedRIS/iRIS) is a commercial software solution intended for use by the NIAID Institutional Review Board (IRB) Office and its customers including IRB members and clinical research Investigators. The purpose of the solution is to manage the online submissions associated with clinical research protocols and the work of those whose responsibility it is to assure human subjects protections.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\rm N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Clinical research protocols, documents supporting human subjects protections as they relate to clinical research protocols including adverse events that occur during the conduct of such protocols and information items about clinical research protocols and the business of the Institutional Review Board. No IIF is contained in any of the documents.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A -

No IIF in system

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Natasha Taylor/Margaret Moore

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIAID NIAID Acquisition Management and Budget Information System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-09-02-8513-00-405-143

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH NIAID Acquisition Management and Budget Information System (AMBIS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Joe Croghan, 301.443.8439, croghanj@niaid.nih.gov
- **10. Provide an overview of the system:** The Acquisition Management Budget Information System (AMBIS) is a Web based acquisition system that effectively and securely allows filing purchase requests that are further processed and entered into the NIH Business System (NBS).
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): none
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) The information the

agency will collect, maintain, or disseminate contains only federal contact data: Name, business mailing address, business telephone number, and business email address; (2) the information collected is an identifier for requesters; (3) The information does not contain PII; and (4) The submission of personal information is mandatory.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) AMBIS contains a combination of information about users of the system collected at the time the user (federal employee, contractor, or fellow) is authorized to access the system, and information maintained by each individual user. This includes: i) name, ii) mailing address, iii) telephone number, iv) NED ID and v) email address. The data is contained only in the system and not disseminated. The data is required to authorize a user for access to AMBIS. This information is Federal contact data only. The information does NOT contain PII. Submission of this information is mandatory.

In addition, business contact information including i) name, ii) company telephone number, iii) company address, and iv) company email address is collected for vendor contacts. The data is required to contact the vendor regarding order status. The information does NOT contain PII. Submission of this information is voluntary.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

No IIF

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Natasha Taylor/Margaret Moore

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIAID NIAID Division of AIDS Enterprise System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/11/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-8523-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH NIAID NIAID Division of AIDS Enterprise System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Joe Marci
- **10. Provide an overview of the system:** The Enterprise System (ES) is a comprehensive system that supports DAIDS' business functions, management, and oversight responsibilities. It is exclusively for the use of administrators and research staff, and contains no clinical trials data, which are maintained in other systems not connected to the ES. Its components include:
- SharePoint Portal a common access point for DAIDS staff inside NIAID; not reachable from outside the NIH firewall.
- · Protocol Management central repository for DAIDS network and non-network protocols.
- · Protocol Registration manages registration of sites on protocols.
- · IND Management Investigational New Drug tracks and manages IND submissions to the FDA.
- Master Contact centralized system for contact info for stakeholders engaged in clinical research (.e.g., investigators, collaborators, institutions, labs, agencies, pharmaceutical sponsors, manufacturers). The ES Data Collection Center (EDCC), which is run under a contract managed by DAIDS, gathers publicly available contact information for staff and enters it for professional purposes.
- Expedited Adverse Experience Reporting System (DAERS) expedited reporting of adverse events in DAIDS sponsored clinical trials. These events are tracked using general information about trials participants, not specifics such as names or traceable IDs.

Clinical Site Monitoring System – official info source for Clinical Site Monitoring activities (e.g., tracking of monitoring schedules, assignment requests, site monitoring reports, & issues identified during site visits).

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The ES requires medical officers to provide CVs. For information about protocol registrations, clinical trials, trial sites, etc., the system relies upon the ES Data Collection Center (EDCC), managed by an external contractor, to provide business contact information for DAIDS administrative staff, such as workplace address, institutional affiliation, workplace e-mail, business phone number and so on. As part of the protocol registration, site management, etc. processes, the EDCC inputs work contact information supplied by individuals, along with other information supplied as part of these business processes.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) The information the agency will collect, maintain, or disseminate

Organization: Displays the Organization with which the person is affiliated.

Type: Displays the Organization type associated with the organization name, e.g., Clinical Trials Unit, Clinical Research Site, Pharmacy, etc.

Organization ID: Displays the DAIDS-assigned Organization ID associated with the organization name, for all organization types except Clinical Research Sites.

Site ID: Displays the DAIDS-assigned Site ID associated with the Clinical Research Sites. The Site ID will only display if the Organization Type is Clinical Research Site.

Participant Name: Displays the full name of the person meeting the search criteria. The name appears as an e-mail hyperlink.

Participant Type: Displays the person type associated with the person name, e.g., Federal Personnel, Site Personnel, Network Personnel, etc.

Participant ID: Displays the Participant ID associated with the Person's name. This is a number assigned by the ES to keep track of the person's work information and status.

Role (Title): Displays the role of the person at the displayed organization and the title in parentheses.

Address: Displays the business address of the person at the organization.

Contact: Displays the business phone numbers of the person at the displayed organization.

(2) Why and for what purpose the agency will use the information

The Division of AIDS and NIAID collects CVs only in the ES for regulatory purposes.

(3) Explicitly indicate whether the information contains PII.

The PII consists of the contact information which the EDCC may gather from previously self-submitted data.

(4) Whether submission of personal information is voluntary or mandatory

Mandatory. There is no form or field in the ES for anyone to input or adjust their personal information.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) (1) Notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system

Medical officers are responsible for uploading their CVs as part of the regulatory process.

(2) Notify and obtain consent from individuals regarding what PII is being collected from them

Beginning with its next formal release, the ES will include a notice on its Master Contact search results pages. The notice will read: "This system does not solicit Personal Identifiable Information (PII). It is intended strictly for business use. However, if an individual has provided PII on a contact form in the past, and that PII is publicly available, that PII may be reflected in the contact information displayed as a result of a DAIDS-ES search.

(3) How the information will be used or shared

Work information, the CVs will be used to verify the status and credentials of a medical officer.

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes

- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The ES permits only authorized and authenticated user access. Additionally, there are Federal (NIST, FIPS, OMB, GAO, agencylevel HHS/NIH guidelines and directives compliant) and industry-best practices security measures in place to ensure the system utilizes and ensures the effective use of security controls and authentication tools to protect privacy to the extent feasible. Risk of unauthorized access is, therefore, considered low.

Authorized user access to information is limited to authorized personnel in the performance of their duties. Authorized personnel include system managers and their staffs, and NIH contractors and subcontractors, all of whom are responsible for administering the DAIDS-ES. Physical safeguards: Rooms where data servers are kept are continually monitored. During all hours, rooms are locked and controlled by on-site personnel. Security guards perform random checks on the physical security of the storage locations after duty hours, including weekends and holidays. Procedural and Technical Safeguards: A password is required to access the Portal and all its applications, and a data set name controls the release of data to only authorized users. Codes by which automated files may be accessed are changed periodically. This procedure also includes deletion of access codes when employees or contractors leave. New employees and contractors are briefed and the security department is notified of all staff members and contractors authorized to be in secured areas during working and nonworking hours. This list is revised as NIH requires the completion of a computer-based training (CBT) course entitled 'Computer Security and Awareness' for NIH staff and contractors. This CBT provides an overview of basic IT security practices and the awareness that knowing or willful disclosure of any sensitive information can result in criminal penalties associated with the Privacy Act, Computer Security Act, and other federal laws that apply. This CBT can be found at http://irtsectra-ining.nih.gov/. User access may be requested only by personnel authorized by the Executive Officer. Users are not permitted system access until the required system training prerequisites are completed and they demonstrate the competencies required to fulfill their work responsibilities-. Individuals remotely accessing the secured areas of the ES Internet sites have separate accounts and passwords, and all data transmitted between the server and workstations is encrypted.

These practices are in compliance with the standards of Chapter 45-13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS 45-13, and the Department's Automated Information System Security Handbook.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Natasha R. Taylor/Margaret Moore

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 8/24/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIAID NIAID Intramural NIAID Research Opportunities Program [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/11/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-8529-00-110-249

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0014

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH NIAID NIAID Intramural NIAID Research Opportunities Program (INRO)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Joe Croghan, 301.443.8439, croghanj@niaid.nih.gov
- **10. Provide an overview of the system:** INRO introduces minority students to research and training opportunities in NIAID's Division of Intramural Research and the Vaccine Research Center. To support this endeavor, SEB created the INRO system. INRO provides an on-line application process for students interested in the INRO Program, and enables reviewers to assign ratings and select students for participation. It serves as a resource for INRO program administrators.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Per SORN 09-25-0014. Information may be used to respond to congressional inquiries regarding constituents who have applied for training programs. Information may be used to respond to

hospitals and other healthcare institutions seeking verification of training for physicians who trained in NIH clinical programs.

Information may be used to respond to congressional inquiries regarding constituents who have applied for training programs.

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Students will enter the following data. Submission is voluntary and used to manage selections for the intern program.

- Name
- Date of Birth
- Alien Registration Number
- Medical Notes
- Mailing Address
- ·Phone Numbers (e.g., phone, fax, and cell)
- · Email Address
- · Education Records
- · Race
- · National Origin
- · Country of birth
- · Gender
- · Emergency Contact Name
- · Emergency Contact Phone
- · Dates of Winter Break
- Sponsor Name
- · Sponsor E-mail
- · Sponsor Telephone
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Students supply information voluntarily as part of the application process for a internship opportunity at the NIH. IIF is collected at the time of application for the internship. Students are informed of the need and intended use of the IIF at the point of collection, and they are given the choice to opt out by not completing and submitting the application for an internship.

They are advised that the information collected is to be used strictly for administering the INRO program.

They may opt out of the submission by not submitting an application.

Notification is made electronically, and in some cases by mail, if changes occur that warrant notification to enrollees.

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Data security in accordance with the HHS, NIH, and NIAID IT security guidelines, and the guidelines of the Office of Training and Special Emphasis Programs (OTSEP).

Measures to prevent the unauthorized disclosure of information covered under the Privacy Act are implemented for each training program administered through the Office of Education.

Authorized Users: Staff in the Office of Education are instructed to disclose information only to NIH personnel who are involved in the evaluation and selection of candidates for intramural training programs.

Physical Safeguards: Paper files and disks are stored in cabinets in a locked room that is under constant surveillance by security personnel. Electronic databases are accessible only with a password on secure web sites.

Procedural safeguards: Access to the paper files is strictly controlled by the Office of Education staff. Files may be removed only with the approval of the system manager or other authorized official(s).

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Natasha Taylor/Margaret Moore

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIAID NIAID Planning and Reporting System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/12/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-09-02-8504-00-301-092

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH NIAID Planning and Reporting System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Joe Croghan, 301.443.8439, croghanj@niaid.nih.gov
- **10. Provide an overview of the system:** NIAID Planning and Reporting System (NPARS) is a web based application that enables NIAID staff to monitor, process, and report on the status of competing and noncompeting grant applications. NIAID division offices use it internally to track and manage grant applications processes, such as review, approve, release and award grant applications. It is segmented into the following modules: NIAID Funding Plan, RFA/PA Award System, Bridge Awards System, Select Pay Awards System,

Merit Pay System, Merit Extensions, FY Grants Tracking System, GrayZone Comments Select Pay and Bridge, Request For Administrative Supplement, and GMB Special Actions. The system also has a number of council reports.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Does Not Share

Per SORN (09-25-0036) disclosures may be made to a Federal Agency, The Department, or another NIH organization according to the guidelines stipulated in the SORN.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: As part of the Institute's research management business function, this system contains Names, Mailing Addresses, and Phone numbers of Principal Investigators involved in research funded by the Institute. This information is voluntarily submitted by principal investigators seeking NIH funding for research. There is an opt out choice. The information collected is used to manage NIH business functions.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Grant applicants are given copies of NIAID's Privacy Policy during the application process. Consent is obtained upon application. IIF within this system is not disclosed or utilized outside of the functions of managing the Institute's business. Individuals are notified of changes in writing per NIAID's Privacy Policy.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** Administrative Access Controls: Employees who maintain records in this system are instructed to grant regular access only to NIH extramural and advisory committee staff, NIH contract management staff, and Federal acquisition personnel. One-time and special access by other employees is granted only when specifically authorized by the System manager.

Technical Controls: Access to the contractor performance files is restricted through the use of secure socket layer encryption and through an IBM password protection system. Only authorized government contracting personnel are permitted access. Access is monitored and controlled by OAMP. Access to source data files is strictly controlled by files staff. Records may be removed from files only at the request of the System manager or other authorized employee. Access to computer files is controlled by the use of registered accounts, registered initials, keywords, and similar limited access systems. NPARS system has been through a full C&A and received an

ATO from NIAID's CIO. The system benefits from double firewall, user authentication, least access privileges, and controlled access points.

Physical Controls: Physical access to Office of Extramural Research (OER) work areas is restricted to OER employees. Physical access to the Office of Acquisition and Policy (OAMP) work areas is restricted to OAMP employees. Physical access to the Office of Federal Advisory Committee Policy (OFACP) work areas is restricted to OFACP employees. The system resides on servers that are in a locked server facility with restricted access.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Natasha Taylor/Margaret Moore

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIAID Program Management Tool (PMT)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/18/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-09-02-8508-00-301-092

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH NIAID Program Management Tool (PMT)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Joe Croghan, 301.443.8439, croghanj@niaid.nih.gov
- **10. Provide an overview of the system:** The Program Management Tool (PMT) is an Intranet, web-based application that was developed for Program Officers (PO) within the Division of Microbiology and Infectious Diseases (DMID) of the extramural branch as an aid for organizing and managing their grants and project applications portfolio. The primary purpose of the application is to assist POs in performing various administrative tasks associated with portfolio management.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system integrates all electronic information resources required to perform the activities of portfolio management. It captures information about the application, awards, and grants. It contains indicators from basic laboratory science to Phase III clinical trials. It has biodefense program information. This system does not collect PII.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) This system contains no PII.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: NA

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Natasha Taylor/Margaret Moore

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIAID Reviewer Support Site (RSS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/18/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-8534-00-110-249

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH NIAID Reviewer Support Site (RSS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Joe Croghan, 301.443.8439, croghani@niaid.nih.gov
- **10. Provide an overview of the system:** The Scientific Review Program (SRP) conducts meetings to perform technical evaluation (a.k.a. peer review) of grant applications and contract proposals. The NIAID Reviewer Support Site (RSS) enhances the communication of information between meeting coordinators and participants throughout the process.

RSS is a secure, Internet-accessible administrative support system that provides a centralized repository of documents and information related to review meetings. The system was updated to provide:

- § Online active forms for collection of pre-review data from reviewers
- § Pre-review reports for meeting staff
- § Electronic review function (assignment tools, collection and management of evaluations, etc.)
- § Improvement to the management, configuration, and presentation of meeting-related files
- § Improvement to the overall user interface
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The system does not share it with any other system.

Disclosure may be made to qualified experts not within the definition of Department employees as prescribed in Department regulations for opinions as a part of the application review process.

A record may be disclosed for a research purpose, when the Department: (A) has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained.

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Very limited IIF is maintained for user identification and communication, and reporting.

Reviewers:

Full name (from NIHExt or NED)

Academic degrees (required)

Rank or title (required)

Work address (from NIHExt or NED)

Work phone # (from NIHExt or NED)

Work fax #

Home address (required)

Home phone # (required)

Cell phone #

Phone # for teleconference

Email address (from NIHExt or NED)

Alternate contact (e.g., assistant's name, phone #, email address)

Federal employee status

Other appointments or professional affiliations

Gender

Race/Ethnicity

Used for:

Contact info

Meeting management

Submission in government-mandated reports

Submission of IIF is voluntary. Consent is implicit in the reviewer's agreement to serve on a peer review committee

Meeting Staff:

Full Name (from NED)

Work email address

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Information about NIAID staff will be entered by system administrators or the individuals themselves. Some information about reviewers will be collected via telephone conversation or hardcopy submission and entered by NIAID staff; the rest will be entered online by the individuals themselves. Reviewers are instructed by initial telephone interview that information about them will be used for internal administrative purposes only and will not be shared. Consent is implicit in a reviewer's agreement to serve on a peer review panel.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The system resides on a secure server behind a firewall. Communications between the web browser and system server are encrypted (TLS). User access is by invitation only, via authenticated user ID and password. Passwords comply with HHS/NIH policy (expiration, format, etc.). Permissions are governed by the user's assigned system-wide and meeting-specific roles. Access to individual meetings (files and other data) terminates after specified dates. Physical access controls include guards, ID badges, and key cards.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Natasha Taylor

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIAID Scientific Initiative Management System (SIMS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/18/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-8536-00-110-249

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH NIAID Scientific Initiative Management System (SIMS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Joe Croghan, 301.443.8439, croghanj@niaid.nih.gov
- **10. Provide an overview of the system:** The Scientific Initiative Management System (SIMS) is designed to integrate the creation of concepts for initiatives, and the review and approval of selected concepts for development as PFAs, RFPs, PAs and Contracts. It enables phasing (scheduling) and tracking of initiatives from approval through completion stages.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Does Not Share

Per SORN 09-25-0036, disclosure to Congress, Federal Agencies, and within the Department are permitted according to specified guidelines.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system contains Names, Email addresses and Phone numbers. The information is used to support centralized grant programs of the Public Health Service. Services are provided in the areas of grant application assignment and referral, initial review, council review, award processing and grant accounting. Submittal of this information is voluntary. The applicant has the choice to opt out.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Consent is gained at the point of application. The Institute's Privacy Policy is included with application materials and includes intended use of the data by the Institute. An applicant 's consent to the disclosure and use of personal information by submitting an application. The intended use of the information is disclosed at the application process. Applicants are notified via electronic means, postal service, or telephone of all changes that effect their grant or contract status. This includes their file information.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** Authorized Users: Employees who maintain records in this system are instructed to grant regular access only to NIH extramural and advisory committee staff, NIH contract management staff, and Federal acquisition personnel. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the System manager.

Physical Safeguards: Physical access to Office of Extramural Research (OER) work areas is restricted to OER employees. Physical access to the Office of Acquisition and Policy (OAMP) work areas is restricted to OAMP employees. Physical access to Office of Federal Advisory Committee Policy (OFACP) work areas is restricted to OFACP employees. Access to the contractor performance files is restricted through the use of secure socket layer encryption and through an IBM password protection system. Only authorized government contracting personnel are permitted access. Access is monitored and controlled by OAMP.

Procedural Safeguards: Access to source data files is strictly controlled by files staff. Records may be removed from files only at the request of the System manager or other authorized employee. Access to computer files is controlled by the use of registered accounts, registered initials, keywords, and similar limited access systems.

PIA Approval

PIA Reviewer Approval: Promote PIA Reviewer Name: Natasha Taylor

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIAID Scientific Reporting Suite (SRS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/18/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-8535-00-110-249

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIAID Scientific Reporting Suite (SRS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Joe Croghan, 301.443.8439, croghanj@niaid.nih.gov
- **10. Provide an overview of the system:** A series of software support tools for the DEA primarily scientific reporting tools regarding research, science, grants management, and data analysis.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): There is no PII in this system.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: This system does not collect or contain any IIF.

It consists of a suite of software support tools for OSPFM. It identifies the scientific codes employed by NIAID to define the type of research employed on research efforts. Each discipline and sub-discipline has specific codes which are used to track the work; primarily scientific reporting tools regarding research, scientific coding, science, grants management, and data analysis.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote PIA Reviewer Name: Natasha Taylor

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIAID Vaccine Research Center Study Manager (VRCSM) [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/11/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0012

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH NIAID Vaccine Research Center Study Manager (VRCSM)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Huyen, Yentram
- **10. Provide an overview of the system:** This is a clinical trial recruitment and scheduling system for vaccine research. It is used to collect information from individuals who wish to volunteer to participate as healthy participants in clinical trials.

Legislative authority is: 5. U.S.C. 301; 42 U.S.C. 217a, 241, 282(b)(6), 284a, and 288. 48 CFR Subpart 15.3 and Subpart 42.15

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Does not disclose or share PII.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) The following PII is collected:

- · Name (Mandatory)
- · Age and date of birth (Mandatory)

ONE method of contact is mandatory (participants choice of):

- Mailing address or
- Telephone number and alternate phone number or
- · Email address

Additional information is collected AFTER volunteer provides verbal consent. People who do not wish to provide information are not eligible to participate in voluntary studies.

- · Generic medical history of healthy volunteers
- · History of sexual behavior (if applicable to the trial)
- (2) The information is collected to track potential clinical trial volunteers and determine their suitability for participation in various clinical trials.
- (3) The information collected does contain PII.
- (4) The submission of personal information is mandatory only if volunteers decide to pursue enrollment.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Individuals agree to have information collected as part of clinical trial screening. Major changes are not contemplated for this system, and data is not shared. The data will never be used for other purposes. Individuals call in and self volunteer for studies.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: User accounts grant access only to those individuals who have a need to know the information in the performance of their duties. Data is not available outside of the dedicated group. System is housed in a locked server room with strict access control kept. Duties are divided to ensure access monitoring. Management review ensures compliance with procedures.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Natasha R. Taylor/Margaret Moore

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/30/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIAID Vaccine Research Center Support Suite (VRC) [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/11/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-8541-00-110-249

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH NIAID Vaccine Research Center Support Suite (VRC)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Tram Huyen
- **10. Provide an overview of the system:** This is a suite of software applications built for use by Vaccine Research Center (VRC) research scientists and laboratory staff. These systems include features for sophisticated data analysis, information storage, retrieval and sharing, and reporting. The data is scientific in nature and does not have any patient or clinical identifiers.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A This system contains no IIF
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: 1. The information is

collected and maintained for use by scientists, and consists of plasmid maps, laboratory protocols, and lists of cell lines. It is for internal use only.

- 2. This information serves as a repository of resources for scientists.
- 3. There is no PII contained within the system.
- 4. There is no personal information contained within the system.

No IIF collected.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No IIF is collected or maintained in this system.

Authorized Users: Employees who maintain records in this system are instructed to grant regular access only to NIH extramural and advisory committee staff, NIH contract management staff, and Federal acquisition personnel. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the System manager.

Physical Safeguards: Physical access to Office of Extramural Research (OER) work areas is restricted to OER employees. Physical access to the Office of Acquisition and Policy (OAMP) work areas is restricted to OAMP employees. Physical access to Office of Federal Advisory Committee Policy (OFACP) work areas is restricted to OFACP employees. Access to the contractor performance files is restricted through the use of secure socket layer encryption and through an IBM password protection system. Only authorized government contracting personnel are permitted access. Access is monitored and controlled by OAMP.

Procedural Safeguards: Access to source data files is strictly controlled by files staff. Records may be removed from files only at the request of the system manager or other authorized employee. Access to computer files is controlled by the use of registered accounts, registered initials, keywords, and similar limited access systems.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Natasha Taylor/Margaret Moore

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIAID Visual Status of Funds (VSOF)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/12/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-01-02-3198-00-402-125

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH NIAID Visual Status of Funds (VSOF)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Joe Croghan
- **10. Provide an overview of the system:** This application is used to monitor, track, query and report the Institute's fiscal and budgetary data in order to monitor obligations and expenditures associated with the current fiscal year.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): System does not collect PII.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Accounting data and related document information is downloaded from the budget module of the NIH Data Warehouse and is relevant or specific to NIAID for its fiscal year operations. The system contains no IIF.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A - System does not collect PII.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: This system does not contain IIF.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Natasha R. Taylor Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIAID WAN/Internet/Remote Access [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/11/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: Does not exist.

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH NIAID WAN/Internet/Remote Access GSS
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Alex Rosenthal
- **10. Provide an overview of the system:** The NIAID WAN provides a platform for all network functionality. This includes application hosting, network resources, network connectivity to greater NIH resources, internet access, and file storage capabilities. All information that may be utilized by NIAID personnel is potentially stored and/or transmitted via the NIAID WAN. Access to the NIAID WAN is restricted to NIAID facilities; remote access may only be obtained through systems that traverse NIH and NIAID firewalls. Means of remote access consist of Citrix and Virtual Private Network.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Does not share.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: This is a GSS system and does not collect, maintain, or disseminate PII as a separate system. Minor applications residing on the network each have their own Privacy Impact Assessment which details this information.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Each major application which resides on the network and which also contains PII has its own processes.

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: There is no PII on the network.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Natasha Taylor/Margaret Moore

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIAMS Apex Applications (Apex)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 8/3/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): None

- **7. System Name (Align with system Item name):** NIH NIAMS Oracle Application Express (APEX)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Janet David
- **10. Provide an overview of the system:** The system displays IMPAC II data based on a specific query. IMPAC II Information for Management, Planning Analysis, and Coordination is an NIH enterprise application consisting of a series of modules that allow the Extramural Program community to input, track, analyze, manage, and report grant portfolio data. The data pulled is: full grant number, grant title, PI Name, PI Organization, PI Email address, PI Organization address, grant status, Program Class Code, Program Official, budget start date, budget end date, awarded amount, abstract. The legislation authorizing this activity is 5 U.S.C 1302, 2951, 4118, 4308, 4506, 7501, 7511, 7521, and Executive Order 10561.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\rm N\!/\!A$

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: NIAMS collects the Name, Address, Telephone Number, FAX Number, and Email Address for Program Officials, Grants Management Officers, and Grants Management Specialists, and Scientific Review Officers. In addition to these fields, the Education/Degree field is captured for the Principal Investigator. Information is used for creating various reports on grant data. The information is for contact purposes and for Freedom of Information Act (FOIA) requests. Contact information is gathered from other systems such as IMPAC II, the NIH global address list, and legacy Administrative Management Budget System (AMBIS) data. The information is necessary if the persons intend on conducting business with the NIH.

Legislation authority: 5. U.S.C. 1302, 2951, 4118, 4308, 4506, 7501, 7511, 7521, and Executive Order 10561

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) (1) Individuals provide consent for the use of their information, including when major changes occur to the system, at the time they provide their information into the database.

- (2) The Program Official, Grants Management Officer, Grants Management Specialist, and Scientific Review Officer are required to provide their names, addresses, telephone numbers, fax number, and email address to be posted for their assigned grants." Individuals are notified at the point of entry into the system regarding the PII that is being collected from them and they voluntarily provide consent when entering their data.
- (3) Information is used and shared electronically.
- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Admin Controls The information is maintained on-line by the system and may be accessed and printed by those authorized access to the information. Access to this data is limited to those persons whose official duties require such access

Physical controls - Access to the system requires an NIH Login userid and password, The system is further restricted to only NIAMS users and the NIAMS domain (servers, and PCs etc residing in NIAMS). The servers are secured in a locked, controlled environment.

Technical controls - The NIAMS ISSO and Server Team monitor and control access to all NIAMS machines, including the Intranet server using system monitoring and intrusion detection tools.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Lillian Cosme, 301-496-8296

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/28/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIAMS Coding System for Special Emphasis Areas (SEA)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-26-02-8801-00-202-069

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: 0925-0001

6. Other Identifying Number(s): None

- **7. System Name (Align with system Item name):** NIAMS Coding System for Scientific Emphasis Areas (SEA)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Janet David
- **10. Provide an overview of the system:** In order to respond to the NIH Budget Office requests and congressional inquiries regarding awarded information in relation to disease reporting areas, awarded data on grants, research contracts and intramural projects are "coded" by disease or special emphasis areas (SEA). This system allows the record to be coded and reports generated to respond to requests. The principal investigator's name and address are included on reports for reference. Data is tallied by fiscal year and comparisons made. The purpose of this system is to code the grant, contract or intramural project to obtain the data.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Information is collected under SOR 09-25-0036. Information is compiled in report format to respond to queries from Congressional offices, scientific associations and for NIH disease reporting information. Data is provided to show projects funded to support the numerous NIAMS

disease categories. The data is displayed to show dollars awarded to Institutions/Principal Investigators broken down by disease categories. IIF data is used to identify and credit the project to the specific investigator.

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Legislation authority: 5. U.S.C. 301; 42 U.S.C. 217a, 241, 282(b)(6), 284a, and 288. 48 CFR Subpart 15.3 and Subpart 42.15.

The name and address information associated with the grant, contract or project is listed on the generated reports as a reference. The grant, contract or project is coded for special emphasis areas (SEA) as it relates to disease reporting. Information is collected to respond to congressional inquiries and budget office requests. Information is usually aggregated for each special emphasis area as well as reports listing the specific grant, contract, and project. Information is mandatory under the parent eRA/NIH system. (NIAMS is not making it mandatory).

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) This system is an extension of the enterprise system (eRA/ImpacII) which is authorized to collect data under 0925-0001. If major changes in the enterprise system ocurred, the notification and consent would be through the enterprise system. Changes to the forms or systems that collect the data would notify the individuals when they enter their own data. This system does not collect or use any other data on the individual except what is available through the enterprise system.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Admin Controls The information is maintained on-line by the system and may be accessed and printed by those authorized access to the information. Access to this data is limited to those persons whose official duties require such access.

Physical controls - Access to the system requires an NIH Login userid and password. The system is further restricted to only NIAMS users and the NIAMS domain (servers, and PCs etc residing in NIAMS). The servers are secured in a locked, controlled environment.

Technical controls - The NIAMS ISSO and Server Team monitor and control access to all NIAMS machines, including the Intranet server using system monitoring and intrusion detection tools.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Lillian Cosme, 301-496-8296

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIAMS Employee Database Internet Edition (EDie)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: Conversions

1. Date of this Submission: 7/21/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-90-0018

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): None

- **7. System Name (Align with system Item name):** NIH NIAMS Employee Database Internet Edition (EDie)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Ms. Valerie Green
- **10. Provide an overview of the system:** EDie is an intranet based application primarily used to manage and track personnel information. Authority for maintenance of the system: 5 U.S.C. 1302, 2951, 4118, 4308, 4506, 7501, 7511, 7521 and Executive Order 10561.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Information is intended for internal administrative use only and will not be shared by other entities. Refer to SORN 09-90-0018, SORN 09-90-0024 and SORN 09-25-0216.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: EDie tracks all information

pertinent to a personnel file for the purpose of personnel management activities. Information is collected from employees via the Human Resources Database (HRDB) system, Fellowship Payment System (FPS), nVision Data Warehouse and NIH Enterprise Directory (NED). Uses consist of the following: a) tracking a time-limited appointment to ensure renewals are done in a timely manner, thereby avoiding any break in service; b) ensuring that allocated FTE ceilings are maintained; c) ensuring salary equity for various hiring mechanisms; d) providing reports requested by the NIH Director, the IC Director, and other management staff, as requested; and e) maintaining lists of non-FTEs, special volunteers, contractors, and other hiring appointments. The type of information collected constitutes PII and includes, but is not limited to the following data elements: name, date of birth, SSN, race, address, phone numbers, race, etc.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The Information is derived from information supplied by the individual, which is placed in the HRDB or EHRP, or is provided by Department officials. Information is initially supplied by the individual to Human Resources, in writing, at the time of employment. The information is required to process payroll, taxes, benefits, and other actions and determinations. Consent is provided as part of the initial data collection process, for input into HRDB/EHRP and NED.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: PII stored in EDie is accessed by a very limited number of administrative staff with a "need-to-know" status. EDie is password protected and sensitive data is encrypted. The system is located at One Democracy Plaza, 6701 Democracy Blvd, Suite 704, Bethesda, MD behind the NIH firewall.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Lillian Cosme

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 8/4/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIAMS Internet Multi-IC Contract Tracking System (MCTS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-26-02-8801-00-202-069

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: 0990-0115

6. Other Identifying Number(s): None

- **7. System Name (Align with system Item name):** Internet Multi-IC Contract Tracking System (MCTS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Janet David
- **10. Provide an overview of the system:** This system is used to monitor and track deliverables and administrative paperwork on awarded research contracts. System is used to facilitate the work processes within the contract management office and to provide the data for reports for internal sources.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Information is collected under 09-25-0036. Data is for internal purposes to track and manage the contract paperwork with the office. IIF data is used to identify the principal investigator of the contract.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Legislation authority: 5. U.S.C. 301; 42 U.S.C. 217a, 241, 282(b)(6), 284a, and 288. 48 CFR Subpart 15.3 and Subpart 42.15.

Information collected is from the awarded research contract paperwork and is for internal administration of the contract. A contact person's name and mailing address is included for reference and to generate correspondence. The contact name & address is mandatory.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) If major changes in the enterprise system ocurred (request for contract data), notification and consent would be through the enterprise system. Changes to the forms or systems that collect the data would notify the individuals when they enter their own data and apply for a contract. This system does not collect or use any other data on the individual except what is available through the enterprise system.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Admin Controls The information is maintained on-line by the system and may be accessed and printed by those authorized access to the information. Access to this data is limited to those persons whose official duties require such access.

Physical controls - Access to the system requires an NIH Login userid and password, The system is further restricted to only NIAMS users and the NIAMS domain (servers, and PCs etc residing in NIAMS). The servers are secured in a locked, controlled environment.

Technical controls - The NIAMS ISSO and Server Team monitor and control access to all NIAMS machines, including the Intranet server using system monitoring and intrusion detection tools.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Lillian Cosme, 301-496-8296

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIAMS Internet Website PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-04-02-8812-00-312-165

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): Not applicable

5. OMB Information Collection Approval Number: Not applicable

6. Other Identifying Number(s): None

- 7. System Name (Align with system Item name): NIAMS Internet Website
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Danny Heise
- **10. Provide an overview of the system:** Information Dissemination NIAMS receives calls requesting various literature related to the NIAMS mission. In order to send the information, the caller's name, address and, optionally, their email address and telephone number are captured.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Information is shared with the NIAMS Clearing House that sends out requested literature.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: NIAMS collects the caller's name and address, and optionally their email and telephone number, plus a description of the information requested. We also collect IP addresses and pages visited in the log.

The data is used to send the requested information to the requestor. The data is shared with a Clearing House who mails out the information. Once the information (brochure, literature, etc.) is mailed, the data is deleted.

The requestor would need to furnish their name and address (or email address) in order for the requested literature to be mailed.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) When/if major changes occur to the system that could affect or change how the individuals information would be shared, each of the existing individuals would be notified, via mail or email, and requested to consent to the new process. All new users would be made aware of the change when they supply or enter their information.

Under the Privacy Statement tab located on the web site, the requestor is notified of what information will be collected and how it will be used.

The requestor's information is deleted after the materials have been mailed. Changes to the system would not affect the requestor.

The name, address, and optionally an email address and telephone number, are collected from the individual who requests literature from the NIAMS. Without the name and address, the literature could not be mailed.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Admin Controls The information is maintained on-line by the system and may be accessed and printed by those authorized access to the information. Access to this data is limited to those persons whose official duties require such access.

Physical controls - Access to the System requires an NIH Login userid and password. The system is further restricted to only NIAMS users and the NIAMS domain (servers, and PCs etc residing in NIAMS). The servers are secured in a locked, controlled environment.

Technical controls - The NIAMS ISSO and Server Team monitor and control access to all NIAMS machines, including the Intranet server using system monitoring and intrusion detection tools.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Lillian Cosme, 301-496-8296

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIAMS Intranet Website PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-04-02-8812-00-312-165

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0106

5. OMB Information Collection Approval Number: Not applicable

6. Other Identifying Number(s): None

- 7. System Name (Align with system Item name): NIAMS Intranet Site
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Danny Heise
- 10. Provide an overview of the system: Information dissemination to the NIAMS staff.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Reference SOR # 09-25-0106

The information is shared internally amongst NIAMS Staff. It is used to complete administrative processes/functions.

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The agency collects the individual's name, photo, Lab/Branch/Office address, phone numbers, and email address for administrative processes/functions. The photo is voluntary and the other information obtained is mandatory.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) When/if major changes occur to the system that affect or change how the individuals information will be shared, each of the existing individuals would be notified, via mail or email, and requested to consent to the new process. All new users will be made aware of the change when they enter or supply their information.

The Directory information is mandatory and is provided by the Administrative Office. The photo is voluntary. Staff members must sign a consent form before the photo is taken and placed on the Intranet. The site contains a privacy notice that states, "This is a U.S. Government Internal (Intranet) Web site, which may be accessed and used only for authorized Government business by authorized personnel. Unauthorized access or use of content on this Web site may subject violators to criminal, civil, and/or administrative action. All information on this site may be intercepted, recorded, read, copied, and disclosed by and to authorized personnel for official purposes, including criminal investigations. Such information includes sensitive data encrypted to comply with confidentiality and privacy requirements. Access or use of this Web site by any person, whether authorized or unauthorized, constitutes consent to these terms. There is no right of privacy when accessing this site. Information on this site relates only to work and data related to NIAMS activities. No information related to non-business activities of personnel will be collected or presented on this site without the explicit written permission of the personnel involved."

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Admin Controls The information is maintained on-line by the system and may be accessed and printed by those authorized access to the information. The data is indexed by employee name. Access to this data is limited to those persons whose official duties require such access.

Physical controls - Access to the Intranet requires an NIH Login userid and password, The NIAMS Intranet is further restricted to only NIAMS employees and the NIAMS domain (servers, and PCs etc residing in NIAMS). The servers are secured in a locked, controlled environment.

Technical controls - The NIAMS ISSO and Server Team monitor and control access to all NIAMS machines, including the Intranet server using system monitoring and intrusion detection tools.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Lillian Cosme, 301-496-8296

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIAMS NIAMS General Support System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 9/13/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-0200-01-3109-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH NIAMS Local Area Network (LAN)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: George Brown
- **10. Provide an overview of the system:** The system is a General Support System (GSS) and does not directly collect or store information.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Not applicable
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system is a General Support System (GSS) and does not directly collect or store information. The applications/systems residing on the GSS collect and store information. Therefore, individual PIAs have been prepared and submitted for the applications/systems residing on this GSS.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Not applicable. The system is a GSS and does not directly collect or store information. The applications/systems residing on the GSS collect and store information. Therefore, individual PIAs have been prepared and submitted for the applications/systems residing on this GSS.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Not applicable no PII data.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Lillian Cosme

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIAMS Oxford/Cambridge Scholars Program

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/3/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: None

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN

number is required for Q.4): None

5. OMB Information Collection Approval Number: None

6. Other Identifying Number(s): None

- 7. System Name (Align with system Item name): NIH-NIAMS Oxford/Cambridge Scholars Program (OXCAM)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Bridget Lampert, 301-496-6083
- 10. Provide an overview of the system: The OXCAM system consists of a web-based application called Lean Project Manager, which serves as a document/file management system to enable the doctoral students of the NIH-Oxford University Scholars in Biomedical Research Program and the NIH-Cambridge University Health Sciences Research Scholars Program to participate in an inter-disciplinary training program and collaborative research project. The students work under the joint mentorship of intramural faculty of two institutions: NIH and either Oxford or Cambridge University. The students spend equal time in NIH and U.K. laboratories as they progress towards their degree. The students submit training plans, research proposals, and other related files for archival. The Lean Project Manager application is installed on a NIAMS server secured with an SSL certificate. The OXCAM Program Director and NIAMS Server Administrator serve as the system gatekeepers. They use the application for document storage and retrieval and grant user access, as appropriate. Students working to earn a D.Phil. degree in biomedical and health research are granted access to post and view their own records for which they must provide a valid NIH email address, username and password. Faculty advisors, in their advisory capacity, are granted access to view the training plans, progress reports and research proposals submitted by the students assigned to them for the purpose of scheduling meetings and monitoring progress.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the

character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The system does not share or disclose IIF
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system does not contain PII. The only attributes tied to each of the US/UK student folders uploaded to the Lean Project Manager IT system are the student's name, valid NIH email address, and NIH phone number.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The users of the system (students) do not provide any information (PII) that is not publicly available via NIH (e.g. NED). No processes are in place because the system only contains files posted by the author (i.e. the students), along with the author's name, NIH email address and NIH phone number. As noted previously, the information students upload to the system is developed by them and shared with faculty to help inform the advising process.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The application can not be accessed by individuals who do not possess a current NIH password and who have not been granted access to the server by the NIAMS administrator. The OXCAM program director and the NIAMS server administrator are the gatekeepers for who can be permissioned to use the application for document storage and retrieval. Individual tickets must be submitted for each person to be granted access. The server administrator controls what level of access various types of users have. The only information a student may see is what he/she has uploaded to the server. Faculty advisors may view training plans, progress reports and research proposals the students submit.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Lillian Cosme

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIAMS Resource Management Services Budget (RMS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/3/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-02-01-02-8806-00-

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): Not applicable

5. OMB Information Collection Approval Number: Not applicable

6. Other Identifying Number(s): None

- **7. System Name (Align with system Item name):** NIAMS Resource Management Services (RMS) Budget System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Janet M. David
- **10. Provide an overview of the system:** Create and maintain budget data for the NIAMS Office of the Director programs. The legislation authorizing this activity is 5 U.S.C 1302, 2951, 4118, 4308, 4506, 7501, 7511, 7521, and Executive Order 10561.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Reference SOR # 09-90-0018. This information is further addressed in the HHS Privacy Act Systems of Record Notice 09-90-0018, published in the Federal Register, Volume 59, November 9, 1994.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: NIAMS collects Employee Last and First Names with the salary, grade, and step. Information is used for creating the OD Division budget for each fiscal year.

Data is not matched with any personal identifiers, sensitive data, or Privacy Act data. Data is required to project and create an accurate budget for FTEs.

This information is collected as backup data to create the salary line item for the NIAMS OD budget for the fiscal year.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) When/if major changes occur to the system that affect or change how the individuals information will be shared, each of the existing individuals would be notified, via mail or email, and requested to consent to the new process. All new users will be made aware of the change when they are asked to supply information.

The information is provided by Department officials, only Employee Name, Grade, Step, and Salary information is gathered via biweekly download from the Visual Employment Database System (VEDS).

It is supplied via data download in a separate Oracle table from VEDS.

The information is required, as a condition of employment, to process payroll, taxes, benefits, and other actions and determinations made about an individual while employed.

Written notice is provided to the subject at the time of employment.

Notification procedures include the immediate supervisors of individuals or the administrative offices of the organizational units in which employed. HR may also provide further information concerning the existence of this SOR. Individuals should provide their name, SSN, and organization in which employed.

The information is used by operating officials in carrying out their management responsibilities.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Admin Controls The information is maintained on-line by the system and may be accessed and printed by those authorized access to the information. Access to this data is limited to those persons whose official duties require such access.

Physical controls - Access to the system requires an NIH Login userid and password. The system is further restricted to only NIAMS users and the NIAMS domain (servers, and PCs etc residing in NIAMS).

Technical controls - The NIAMS ISSO and Server Team monitor and control access to all NIAMS machines, including the Intranet server using system monitoring and intrusion detection tools.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Lillian Cosme, 301-496-8296

Sr. Official for Privacy Approval: Promote **Sr. Official for Privacy Name:** Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIAMS SF-52 (SF-52) PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/3/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-26-02-8801-00-202-069

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-90-0018

5. OMB Information Collection Approval Number: Not applicable

6. Other Identifying Number(s): None

- 7. System Name (Align with system Item name): NIAMS SF-52 Tracking
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Janet M. David
- **10. Provide an overview of the system:** The systems is used to create, modify, route, and track SF-52 (personnel) actions. IIF data collected/used is the employee's name, DOB, SSN, mailing address, and salary. The information is required, as a condition of employment, to process payroll, benefits, taxes, and other actions and determinations made about an individual while employed.

Reference SOR # 09-90-0018.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Reference SOR # 09-90-0018.

The Office of Personnel Management, Merit System Protection Board, Equal Employment Opportunity

Commission, and the Federal Labor Relations Authority in carrying out their functions. Appropriate federal, state or local agencies as deemed relevant or necessary to the Department.

Other individuals performing functions for the Department but technically not having the status of agency employees, if they need access to the records in order to perform their assigned agency functions. Used by the NIAMS Administrative Officers (AOs) to track SF52 data. Data collected is required for all SF-52 personnel actions.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The legislation authorizing this activity is 5 U.S.C. 1302, 2951, 4118, 4308, 4506, 7501, 7511, 7521, and Exec Order 10561. NIAMS collects employee name, date of birth, SSN, mailing address and salary. The data is needed to create SF-52 actions. Human Resources uses the SF-52 actions to input information into EHRP. Required statistical reports to upper management and higher headquarters are generated from this information. Data collection is mandatory.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) When/if major changes occur to the system that affect or change how the individuals information will be shared, each of the existing individuals would be notified, via mail or email, and requested to consent to the new process. All new users will be made aware of the change when they supply their information.

- (a) The information comes from the individual to whom it applies, is derived from information supplied by the individual, or is provided by Department officials. (b) It is initially supplied by the individual to HR in writing at the time of employment. (c) The information is required, as a condition of employment, to process payroll, taxes, benefits, and other actions and determinations made about an individual while employed.
- (d) Written notice is provided to the subject at the time of employment. (e) Notification procedures include the immediate supervisors of individuals or the administrative offices of the organizational units in which employed. HR may also provide further information concerning the existence of this SOR. Individuals should provide their name, SSN, and organization in which employed. The information is used by operating officials in carrying out their personnel management responsibilities.
- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Admin Controls The information is

maintained on-line by the system and may be accessed and printed by those authorized access to the information. Access to this data is limited to those persons whose official duties require such access.

Physical controls - Access to the system requires an NIH Login userid and password. The system is further restricted to only NIAMS users and the NIAMS domain (servers, and PCs etc residing in NIAMS).

Technical controls - The NIAMS ISSO and Server Team monitor and control access to all NIAMS machines, including the Intranet server using system monitoring and intrusion detection tools.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Lillian Cosme, 301-496-8296

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIAMS Sharepoint PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: New Interagency Uses

1. Date of this Submission: 11/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0106

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): NONE

- 7. System Name (Align with system Item name): NIH NIAMS SharePoint
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Janet David
- **10. Provide an overview of the system:** This system's main function is to provide an electronic workspace for NIAMS document collaboration, repository, workflow, and tracking in order to assure timely and appropriate attention of any document that needs to be completed or approved by a specified due date. Examples of these documents include Science Advances, data calls, Funding Opportunity Announcement clearances, meeting notes, application requirements, travel requests, and controlled correspondence. The legislation authorizing this activity is The Health Research Extension Act of 1985, P.L. 99-158.

NIAMS' SharePoint system is strictly an "Employee System" (see Q.17 in this Section) in that the system is restricted to obtaining information to "permit the physical or online contacting of a specific individual employed by the Federal Government" (see Q.30 in this Section).

- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A
- **30.** Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: As a condition of employment, NIAMS collects Employee Name, Work Phone Number, and Work E-Mail Address. This information is provided and verified by the Employee. his/her supervisor, and/or the Microsoft Outlook Global Address List. This information can only be accessed by authorized NIAMS staff, and selected and specifically authorized NIH staff (see Q.54 in this Section and Q.32 in the Website Hosting Section. Note that access will not be expanded beyound NIH).

NIAMS uses this information to provide point-of-contact information and to route and track documents in workflows. Data is not matched with any personal identifiers, sensitive data, or Privacy Act data. The information is needed to streamline document approval processes so that data calls and other documents that need approval are tracked, routed, and completed on time.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Information is supplied via employee or supervisor and may be verified using the Microsoft Outlook Global Address List. The information is required, as a condition of employment, to communicate with the individual while employed. Written notice is provided to the subject at the time of employment. Notification procedures include the immediate supervisors of individuals or the administrative offices of the organizational units in which the individual is employed. The information is used by operating officials in carrying out their management responsibilities.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Administrative Controls are in place to ensure that system owners, operators, contractors, and program managers who use the system have been trained and are made aware of their responsibilities for protecting any personal information collected and maintained. Initial training is required in order to allow access to the

system and refresher training is conducted annually. Training is conducted electronically and those who don't complete the training as specified will have their access revoked.

The SO ensures that user access is restricted to the appropriate site Administrator, and the site Administrator ensures that all users granted access follow all applicable requirements and the Institute's sensitive data policy (2800-NIAMS-OD-SITB-008).

Physical controls - Access to the system requires an NIH Login userid and password. The system is further restricted to only NIAMS users and the NIAMS domain (servers, and PCs etc residing in NIAMS). The servers are secured in a locked, controlled environment. Physical Access Controls to the building, suite, and server room are by identification badges and key cards (fobs).

Technical Controls are in place to minimize the possibility of unauthorized access, use or dissemination of the data. The NIAMS ISSO and Server Team monitor and control access to all NIAMS machines, including the Intranet server using system monitoring and intrusion detection tools. These technical controls include userids and roles, passwords, firewalls, Virtual Private Network (VPN), and an intrusion detection system.

Additional safeguards have been implemented as of November 7, 2011. While most users of the system are NIAMS staff, the SO recently allowed selected NIH staff to have access, too. Because of this, the SO has ensured that additional safeguards have been implemented. The firewall was opened for the selected NIH-level users, SSL was added, additional auditing has been implemented, and additional training is provided. Selected NIH employees can be granted access to a specific site provided that site owner utilizes limited access via a Help Desk ticket. If access is granted, access is monitored and removed when no longer required. (Note - system access will not be expanded beyond NIH.)

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Lillian Cosme, 301-496-8296

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/9/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIAMS Status of Funds Internet Edition (SOFie)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/8/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: TBD (was 09-25-01-01-02-3198-00-402-125 for predecessor, VSOF)

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): Not applicable
- **5. OMB Information Collection Approval Number:** No
- **6. Other Identifying Number(s):** No
- 7. System Name (Align with system Item name): Status of Funds Internet Edition (SOFie)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Valerie Green
- **10. Provide an overview of the system:** SoFiE is the Institute's budget reporting system used to track costs and generate status reports. It is a multi-user integrated database of financial transactions from the NIH Central Accounting System used by multiple NIH Institutes and centers to monitor the financial status of programs they support.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The system does not share or disclose PII.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Accounting data and related

document information is downloaded from Accounting and is relevant or specific to NIAMS for its fiscal year operations.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Not applicable. No PII is collected, shared, or disclosed.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Not applicable as no PII is collected, shared, or disclosed. Controls are in place for the system.

Admin Controls - The information is maintained on-line by the system and may be accessed and printed by those authorized access to the information. Access to this data is limited to those persons whose official duties require such access.

Physical controls - Access to the system requires an NIH Login userid and password. The system is further restricted to only NIAMS users and the NIAMS domain (servers, and PCs etc residing in NIAMS). The servers are secured in a locked, controlled environment.

Technical controls - The NIAMS ISSO and Server Team monitor and control access to all NIAMS machines, including the Intranet server using system monitoring and intrusion detection tools.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Lillian Cosme, 301-496-8296

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIBIB Employee Database Internet Edition (EDie)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 9/8/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-90-0018, 09-90-0024, 09-25-0216

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): None

- **7. System Name (Align with system Item name):** NIH NIBIB Employee Database Internet Edition (EDie)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Truc Le
- **10. Provide an overview of the system:** EDie is an Intranet based application primarily used to manage and track personnel information. Authority for maintenance of the system: 5 U.S.C. 1302, 2951, 4118, 4308, 4506, 7501, 7511, 7521 and Executive Order 10561.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Information is intended for internal administrative use only and will not be shared by other entities. Refer to SORN 09-90-0018, SORN 09-90-0024 and SORN 09-25-0216.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: EDie tracks all information

pertinent to a personnel file for the purpose of personnel management activities. Information is collected from employees via the Human Resources Database (HRDB) system, Fellowship Payment System (FPS), nVision Data Warehouse and NIH Enterprise Directory (NED). Uses consist of the following: a) tracking a time-limited appointment to ensure renewals are done in a timely manner, thereby avoiding any break in service; b) ensuring that allocated FTE ceilings are maintained; c) ensuring salary equity for various hiring mechanisms; d) providing reports requested by the NIH Director, the IC Director, and other management staff, as requested; and e) maintaining lists of non-FTEs, special volunteers, contractors, and other hiring appointments. The type of information collected constitutes PII and includes, but is not limited to the following data elements: name, home address, home phone number, social security number and date of birth. The PII collected is mandatory for all employees.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) PII in the system is downloaded from the HRDB, FPS, nVision Data Warehouse and NED. Changes to HRDB or changes in the way information is used is relayed to employees via official notices from the NIH Office of Human Resources (OHR). Individuals are notified of the collection and use of the data as part of the hiring process. This is a mandatory requirement of potential job applicants seeking employment at NIH.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** PII stored in EDie is accessed by a very limited number of administrative staff with a "need-to-know" status. EDie is password protected and sensitive data is encrypted. The system is located on a server in a secure server room behind the NIH firewall.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Kai Kamerow

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/9/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIBIB Internet Website PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-00-0000-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): Internal Website
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Mary Beth Kester
- **10. Provide an overview of the system:** The NIBIB Internet provides mission-related information to multiple constituencies that include other federal agency staff, extramural researchers, health professionals, educators, students, and professionals.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): does not disclose IIF
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The only data collected are for web site usage statistics and are not retrieved by personal identifier.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g.,

disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) NIBIB website is in compliance with federal law and NIH web policies. The web site does not collect personal data and the privacy notification statement and disclaimers are used and visible from every page, including web pages directed to children. We do not use persistent cookies.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: Yes
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: We do not collect information in identifiable form.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Kai Kamerow

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIBIB NIBIB General Support System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-04-00-0000-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH NIBIB General Support System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Lawrence Morton
- **10. Provide an overview of the system:** The system is a General Support System (GSS) and does not directly collect or store information.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system is a General Support System (GSS) and does not directly collect or store information. The applications/systems residing on the GSS collect and store information. Therefore, individual PIAs have been prepared and submitted for the applications/systems residing on this GSS.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Kai Kamerow

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIBIB Status of Funds Internet Edition (SOFIE)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: In development

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): Status of Funds Internet Edition (SOFie)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Pamela Galpin
- **10. Provide an overview of the system:** SOFie is a web database application that allows institutes to track expenses and the balance of accounts.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The SOFie system gathers financial data together from NIH systems in order to view and manipulate financial information for the ICs needs. The system does not include any personal information or information in identifiable form.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: System is password protected. Individuals only view accounts pertinent to their area.

PIA Approval

PIA Reviewer Approval: Promote PIA Reviewer Name: Kai Kamerow

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NICHD Certification of Confidentiality [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: Not applicable.

6. Other Identifying Number(s): Not applicable.

- **7. System Name (Align with system Item name):** NICHD Extramural Clinical Certificate of Confidentiality System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Rodney Rivera
- **10. Provide an overview of the system:** The NICHD Extramural Clinical Certificate of Confidentiality System enables investigators who are conducting research in line with NICHD's mission to apply for a Certificate of Confidentiality from the NICHD and supports the internal processes for finalizing and issuing the Certificate.

The system automates the cumbersome paper-based process of applying for and issuing certificates by providing a public web interface for users to request a certificate and a staff-side module used by staff in the Clinical Director's office to track and modify the submission and generate the official document for signature.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes

- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Not applicable.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: NICHD will collect the name, email address, mailing address, and phone number of individuals applying for applications for NICHD Extramural Certificates of Confidentiality. The information will contain PII and submission of personal information is voluntary, but necessary if the applicant chooses to apply.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) If a major change were to occur to the information system, individuals would be notified via telephone calls regarding any potential changes to their PII. At that time, they would be able to provide consent acknowledging the change. Individuals are notified of the information that is being collected from them, and consent is obtained twice: (1) via a pop-up notification where they agree t to certain statement regarding their study before the individual is able to access the application and (2) when they submit their information for the certificate of confidentiality. The first portion of the application indicates how the information the individual(s) submit will be used.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Access to and use of these records is limited to those persons whose official duties require such access. Secured via sign-on and authentication methods. Administrative controls include system security plan, contingency plan, files backed-up and stored off site, user training, and least privilege accesses. Technical access controls include user identification, password, firewall, VPN, encryption, intrusion detection system, common access cards, and public key infrastructure. Physical access controls include guards, identification badges, key cards, cipher locks, and closed circuit TV.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Aubrey Callwood Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NICHD Child Health Information Retrieval Program [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-04-00-02-4401-00-202-069

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): Not Applicable

5. OMB Information Collection Approval Number: Not Applicable

6. Other Identifying Number(s): NICHD-0002

- 7. System Name (Align with system Item name): Child Health Information Retrieval Program (CHIRP)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Aubrey Callwood
- **10. Provide an overview of the system:** The Child Health Information Retrieval Program (CHIRP) provides support for grant application and award processing, tracking, scientific coding and report retrieval for the NICHD Extramural program
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Not Applicable
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: No Information in

Indentifiable Form (IIF) is collected or stored. CHIRP Pull grants and Contract Related data from IMPACII.

The Referral and Program Analysis Branch (RPAB) of NICHD's Office of Scientific Policy, Analysis, and Communication (OSPAC) assigns each project funding application to the appropriate NICHD branch for review. Once funding has been approved, RPAB then applies extensive scientific coding to the grant record based on the areas of research involved. Throughout the pre- and post-funding process, RPAB maintains summary information about each project for reporting purposes. All project records are then given pre-funding preliminary coding and post-funding scientific coding for detailed and accurate classification. Based on all available project data, highly-flexible querying options allow users to generate various standard and customized reports as necessary for interested internal and external entities.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No IIF is collected

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Not Applicable

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Aubrey Callwood Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NICHD Contracts Module (CM)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): Not applicable

5. OMB Information Collection Approval Number: Not applicable

6. Other Identifying Number(s): Not applicable.

7. System Name (Align with system Item name): NICHD Contracts Module (CM)

- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Rodney Rivera
- **10. Provide an overview of the system:** The NICHD Contracts Module is a web-based system designed to allow NICHD staff with contracts responsibilities to more efficiently monitor the contracts budget, as well as provide a high level budget view for discussions with NICHD senior management. The system will be designed to capture contracts financial data at key points in the business process from the relevant NICHD and NIH financial systems and link the data together. The system is initially intended for use by the Finance and Contracts branches, with future extension to Program staff.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Not applicable

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: 1) The system does not collect PII information. Specifically, the system stores information about each contract for which NICHD is providing funding (contractor name, contract title, and dollar amounts).
- 2) The system is designed to capture contracts financial data at key points in the business process from the relavant NICHD and NIH financial systems and link the data together in order to more efficiently monitor the contracts budget.
- 3) The system does not collect or store PII information.
- 4) User do not submit any personal information to the system. The system does not collect data or PII from users.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No IIF is collected

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Not Applicable

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Aubrey Callwood Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NICHD Council Member Website [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): Not Applicable
- 5. OMB Information Collection Approval Number: Not Applicable
- **6. Other Identifying Number(s):** Not Applicable
- 7. System Name (Align with system Item name): Council Member Website (CMW)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Aubrey Callwood
- **10. Provide an overview of the system:** CMW provides NICHD Advisory Council members with online access to a variety of Council-related information, both for the current council and an archive of data from prior councils. The site also provides Council members with the ability to review and vote on individual applications as well as an En Bloc review which would allow the Council to fulfill their business function without physically meeting at National Institute of Health (NIH).
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Not Applicable
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: 1) The system does not collect or store PII information. The system provides NICHD advisory council members with online access to a variety of Council related information. Current council and archive data from prior council is available on the site.

- 2) The information available on the Council Member Website is used by NICHD staff to access general council information.
- 3) The system does not collect or store PII information.
- 4) Not Applicable Users do not submit PII information.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No IIF is collected

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Not Applicable

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Aubrey Callwood Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NICHD Diversity Development Database (3D)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: Not Applicable

6. Other Identifying Number(s): Not Applicable

- **7. System Name (Align with system Item name):** NICHD Diversity Development Database (3D)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Rodney Rivera
- **10. Provide an overview of the system:** The Diversity Development Database (3-D) system is a web-based application providing a central mechanism for collecting and reporting on data for programs within the Division of Special Populations (DSP). It allows program participants (e.g., Principal Investigators, Mentors, and Scholars) to more easily meet their program's funding and assessment requirements by providing a centralized location where they can submit relevant data on their progress and achievements at any time. It also aids NIH staff in their duty to evaluate training programs at grantee institutions by increasing data uniformity, decreasing data duplication, and enabling up-to-the-minute reporting, allowing them to see a program's or individual's progress at any given time in history.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Not Applicable

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: 1) 3D maintains business information on individuals requesting grants from NIH (this includes: Name, Personal Mailing Address, Personal Phone Numbers, Personal Email Address, and Educational Information). The name of the individual is requested along with education information such as the school and degree earned (no formal transcripts are requested) as well as the individual's military history (such as their position and dates in that position), but no formal request is made to the military to obtain this information. The information is also used for the purpose of monitoring progress in one of the diversity related programs.
- 2) The information is used to contact individuals requesting grants from NIH
- 3) The system does contain PII
- 4) THe information submission is voluntary, but necessary in order to participate
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) If a major change were to occur to the system, individuals would be notified via e-mail. Individuals are notified, and consent is obtained, regarding what PII is being collected from them at the time of information collection. During that time, they are also notified how that information is going to be used. At that point, they can determine whether they will participate.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Access to and use of these records is limited to those persons whose official duties require such access. Secured via sign-on and authentication methods. Administrative controls include system security plan, contingency plan, files backed-up and stored off site, user training, and least privilege accesses. Technical access controls include user identification, password, firewall, VPN, encryption, intrusion detection system, common access cards, and public key infrastructure. Physical access controls include guards, identification badges, key cards, cipher locks, and closed circuit TV.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Aubrey Callwood Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 10/11/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NICHD Insider 2 [System] PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

- 3. Unique Project Identifier (UPI) Number:
- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): Not Applicable
- 5. OMB Information Collection Approval Number: Not Applicable
- **6. Other Identifying Number(s):** Not Applicable
- 7. System Name (Align with system Item name): Insider Intranet 2 (Insider2)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Aubrey Callwood
- **10. Provide an overview of the system:** The Insider provides an Intranet for NICHD Staff to use to view general administrative information online. In addition, program and extramural staff have access to several applications that allow them to submit recommendations for grants funding, reporting, and document tracking
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: 1) The system does not collect or store PII information. The system provides general administrative information to staff.

The system allows extramural staff to submit non PII information such as recommendation for grants funding, reporting and document tracking.

- 2) The information available on the Insider Intranet site is used by the NICHD staff to access general administrative information.
- 3) The system does not collect or store PII information.
- 4) Not Applicable Users do not submit PII information.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No IIF is collected

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The system does not collect PII, however there are controls in place on the system including the following: administrative controls include a system security plan, a contingency plan, the backing up of files and storing them offsite, as well as methods in place to ensure least privilege access; technical controls include user identification, passwords, firewall, and an intrusion detection system; and physical access controls include identification badges, key cards, and cipher locks.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Aubrey Callwood

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NICHD Menkes Disease and Occipital Horn Syndrome International Registry [System] PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200
- **5. OMB Information Collection Approval Number:** N/A
- **6. Other Identifying Number(s):** N/A There are no Other Identifying Numbers the Agency uses.
- **7. System Name (Align with system Item name):** NIH NICHD Menkes Disease and Occipital Horn Syndrome International Registry
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Rodney Rivera
- 10. Provide an overview of the system: Menkes allow doctors around the world to seek referrals for patients with Menkes or Occipital Horn syndromes via a public website. Dr. Stephen Kaler is the leading expert on these diseases and is not only the sole source for treatment referrals, but is also the only person who can confirm that the patient has these diseases. This website allow doctors to enter in basic patient personal information as well as data about their symptoms to allow Dr. Kaler to provide referrals for treatment. The registry also allows follow-up information to be posted. Currently, this data is sent to Dr. Kaler via telephone, email, or fax.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The information is only shared between Dr. Stephen Kaler and his assistant Maryellen Rechen.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: 1) Information is sent to Dr. Kaler regarding patients symptoms (this includes: Name, Date of Birth, Personal Mailing Address, Personal Phone Number, Medical Noters, and Personal Email Address)
- 2) The information is sent in order for Dr. Kaler to fully assess the patients symptoms and make approprirate for treatment of the specified disease
- 3) Yes the information contains PII
- 4) The submission is voluntary because the patients and doctors enter the information themselves in the website
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The information is entered voluntarily, and therefore consent is given by the patients when the information is entered.

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Administrative controls include a system security plan, a contingency plan, backing up files and storing them offsite, user manuals, and least privilege access. Technical controls include user identification, passwords, firewall, virtual privacy network (VPN), encryption, and an intrusion detection system (IDS). Physical controls include guards, identification badges, key cards, and cipher locks.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Aubrey Callwood Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NICHD NICHD General Support System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

- **4.** Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): Not applicable. System does not retrieve PII by one or more personal identifiers.
- **5. OMB Information Collection Approval Number:** Not applicable.
- **6. Other Identifying Number(s):** Not applicable. System does not retrieve PII by one or more personal identifiers.
- 7. System Name (Align with system Item name): NICHD General Support System (GSS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Rodney Rivera
- 10. Provide an overview of the system: The NICHD GSS is managed out if the NICHD Information Resources Management Branch (IRMB) office. The size of the NICHD GSS is equated to the size of networks found in mid-size corporations. The NICHD GSS is used for internal administrative and scientific purposes, as well as to provide services to the general external public. Additionally, specific extranet projects are supported via NICHD GSS as well. Systems within this GSS include: nichddirsfs1.nichd.nih.gov, nichddirsfs2.nichd.nih.gov, nichdzfish3.nichd.nih.gov, searchdir.nichd.nih.gov, nichdvm10, nichdvm11, nichdvm12, nichdvm13, nichdvm18, nichdvm19, nichdvm20, nichdvm21, nichdmic.nichd.nih.gov, nichdmica.nichd.nih.gov, nichd32t21.nichd.nih.gov (attached to a electron microscope), nichdsws.nichd.nih.gov, zfish.nichd.nih.gov, stbb-lr.nichd.nih.gov, tango.nichd.nih.gov, zfish2.nichd.nih.gov, rafisher.nichd.nih.gov, stbbrock.nichd.nih.gov, nichddevdb.nichd.nih.gov, nichddbprod.nichd.nih.gov, nichdetdbproddb.nichd.hih.gov, nichd-cedb.nichd.nih.gov, trypsin.nichd.nih.gov, nichdapptest1.nichd.nih.gov, nichdappdev1.nichd.nih.gov, nichdappprod1.nichd.nih.gov, nichdappprod2.nichd.nih.gov, nichd-etdbapps.nichd.nih.gov, nichddirdevdb.nichd.nih.gov, nichd-rs.nichd.nih.gov, metis.nichd.nih.gov, nichdexp.nichd.nih.gov, nichdetdbldap, nichddesprdev1, nichdapps1, nichd6prts, nichdrocklapps, nichdtripmon, nichdtissuebank, ceres, nichd-webtest, nichdinsidrtst, nichdehirptrain, nichdsp01, nichdsp02, nichdelsgl01, nichdelsgl02, nichdnmsgl01, nichdwsus, nichdmrsd, nichdintnettest, nichdorstest, nichdorptest, nichdmrsdtest, nichdbizobj02, nichdbizobj01, nichdbackup03, nichdextrtst, nichdreport01, nichdmssql02, nichdmsmom, nichdinsightmgr, nichdshareptest, nichdtwtst, nichdtw01, nichdorp, nichdors, nichdpatchscan01, nichdmssql01, nichdmssql03, nichdora1, nichdora2, nichdora3, nichdora4, nichdora5, nichdora6, nichdoramgr, nichdnascan1, nichdnascan2, nichdnascan3, nichdstorage2, nichd49dc1, nichdehirp, nichdextranet1, nichd6100dc1, nichdtermsrv1, nichd6100e, nichdvm08, nichdvm02,

nichdsharepoint, nichdpoolesvlle, nichdoramgrts, nichdreport, nichdvm09, nichd6100fs1, nichdinsider, nichdcc1, nichdcc3, nichd9fs1, nichd31fs1, nichd6fs1, nichd49fs1, nichd49fs1, nichd49fs1, nichd49fs1, nichd49fs1, nichd49fs1, nichd49fs1, nichd49fs1, nichdbackup01, nichdbackup02, nichdrds, nichd31dc, nichdnav, nichdsav, nichdoramgrp, nichdoramgrt, nichdora7, nichdora8, nichdapps2, eroom, and HPBL01C700.

- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Not applicable.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: As the NICHD GSS is the principle component for administrative, scientific, and business data, individual applications may have specific configurations and/or data storage requirements and classifications beyond the scope of this document. Such applications are individually documented by their respective owners. NICHD GSS management personnel continue to provide the platform support, administration, backup, etc., for the systems comprising such applications. This system does not collect, maintain or disseminate PII.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) As the NICHD GSS is the principle component for administrative, scientific, and business data, individual applications may have specific configurations and/or data storage requirements and classifications beyond the scope of this document. Such applications are individually documented by their respective owners. NICHD GSS management personnel continue to provide the platform support, administration, backup, etc., for the systems comprising such applications. This system does not collect, maintain or disseminate PII.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Administrative controls include system security plan, contingency plan, files backed-up and stored off site, user training, and least privilege accesses. Technical access controls include user identification, password, firewall, VPN, encryption, intrusion detection system, common access cards, and public key infrastructure. Physical access controls include guards, identification badges, key cards, cipher locks, and closed circuit TV.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name:

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NICHD Operational Planning and Scientific Initiatives System of Tracking (OP-ASIST)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): Not Applicable
- 5. OMB Information Collection Approval Number: Not Applicable
- **6. Other Identifying Number(s):** Not Applicable
- **7. System Name (Align with system Item name):** NIH NICHD Operational Planning and Scientific Initiative System of Tracking
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Li Huang
- **10. Provide an overview of the system:** OP-ASIST is an automated, web-based tool that supports the Eunice Kennedy Shriver- National Institute of Child Health and Human Development (NICHD) research initiative user community. OP-ASIST provides NICHD with the ability to manage the planning process for grant and contract related scientific initiatives. It facilitates tracking the progress of all scientific initiatives from initial concept development through grant and contract approval.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Not Applicable
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: 1) The information collected, maintained, and disseminated are proposed contract and grant information including the organizations, the background and scope of contract, peer reviews of the initiative, financial information (who's providing funding, how much, and mechanism), decisions that are made throughout approval process, and the audit of all changes that any user makes

- 2) Information is collected to provide NICHD with a mechanism to plan future contracts and grants
- 3) The system does not contain PII
- 4) Not applicable, there is no submission of personal information by users
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Not applicable. System will not collect, maintain, or disseminate any PII.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Not Applicable

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name:

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NICHD Reproductive Tissue Sample Repository [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 8/22/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: Not Applicable

6. Other Identifying Number(s): Not Applicable

- **7. System Name (Align with system Item name):** NIH NICHD Reproductive Tissue Sample Repository (RTSaR)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Rodney Rivera
- **10. Provide an overview of the system:** The RTSaR is a centralized, Web-based system that may be used to track and retrieve information about tissue availability. RTSaR may be used by the tissue banks to enter and maintain current data regarding the availability of tissue samples at their facility to query, the availability of tissue, and to order tissue samples on-line.

RTSaR has been implemented using Java, JSP, HTML, and XML technologies. Data persistence is achieved using an Oracle database. Secure Socket Layer (SSL) has also been put in place to provide security of data being sent across the Internet.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Not Applicable

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: 1) The system holds basic information about Tissue in various repository (size, date, generic statistic about source of tissue). Users that have access to (name, institution, email address, and grant users are funded through). The information collected is includes information about users that are outside the Federal Government.
- 2) The information is used for scientist to request a sample tissue to perform an NIH funded research. The user information (name, email address, and phone number) is kept so that access information can be granted to users by the system admins.
- 3) The system does contain PII
- 4) If users need access to the system, they must submit their name, email address, and phone number. Therefore the submission is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The information is entered voluntarily, and therefore consent is given by the users when the information is entered.

- 1) An email may be sent out to all users to let them know of change.
- 2) The information is entered voluntary by users. The users provide their name, email address, and phone numbers in order to gain access to the system.
- 3) The user information (name, email address, and phone number) is used to contact users, specifically when system admins need to verify their user information (name, email address, and phone number)
- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Records are maintained on-line by the system and may be printed by authorized requesters. Access to and use of these records is limited to those persons whose official duties require such access. Secured via sign-on and authentication methods. Administrative controls include system security plan, contingency plan, files backed-up and stored off site, user training, and least privilege accesses. Technical access

controls include user identification, password, firewall, VPN, encryption, intrusion detection system, common access cards, and public key infrastructure. Physical access controls include guards, identification badges, key cards, cipher locks, and closed circuit TV.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Aubrey Callwood Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 10/28/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NICHD Sponsored Dashboards (NSD)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 9/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): Not Applicable

5. OMB Information Collection Approval Number: Not Applicable

6. Other Identifying Number(s): Not Applicable

- 7. System Name (Align with system Item name): NIH NICHD Sponsored Dashboards (NSD)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Rodney Rivera
- **10. Provide an overview of the system:** The NICHD Dashboard tool was designed to enhance the decision-making efficiency of NICHD senior management by providing simplified, timely access to required information through a set of key performance indicators. Analogous to the way information is displayed on a vehicle dashboard; the Dashboard was intended to allow users to quickly analyze performance across multiple "gauges". These "gauges" or measures are grouped in categories of interest to NICHD senior management: Extramural, Intramural, Financial, Human Capital and Administration.

The project was originally spearheaded by the prior Executive Officer. The project was intended to be released to Center Directors to allow them to view their portion of the financial budget, their grants portfolio and contracts portfolio. While several of these measures were completed, changes to the financial structure and systems at NICHD and NIH have occurred so several measures have been removed from the system.

NICHD Sponsored Dashboards (NSD) consists of the NIH Dashboard, NCI Dashboard, the NICHD Dashboard and Telework Application and Review System (Telework) applications. NSD is an internal application and is accessible to NIH users via the NIH Intranet only. The dashboards are designed for senior managers and executives and the dashboard information is read only from the source, Human Resources Database (HRDB).

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the

individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Not Applicable
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: 1) The NSD contains Extramural, Intramural, Financial, and Administration Information
- 2) The information is used to enhance the decision-making efficiency of NICHD senior management by providing simplified, timely access to required information through a set of key performance indicators
- 3) The system does not contain PII
- 4) Not Applicable
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No PII is collected

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The system does not collect PII, however there are controls in place on the system including the following: administrative controls include a system security plan, a contingency plan, the backing up of files and storing them offsite, as well as methods in place to ensure least privilege access; technical controls include user identification, passwords, firewall, and an intrusion detection system; and physical access controls include identification badges, key cards, and cipher locks.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Aubrey Callwood Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 10/11/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIDA Animal Care Research Solutions

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A
- **5. OMB Information Collection Approval Number:** N/A
- 6. Other Identifying Number(s): N/A
- **7. System Name (Align with system Item name):** NIH NIDA Animal Care and Research Solutions
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Pei-Li Chao
- **10. Provide an overview of the system:** Applications included in this system are Animal Care Database, Animal Study Protocol (ASP), and Animal Research Information System (ARIS). They are designed to facilitate and make ease of the day to day operation of the animal research.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) This information system

contains animal purchasing/ordering information, animal research protocols, and animal research logistics. The information contained in the system ONLY represents federal contact data.

- (2) the information is used for scientific research and its logistics.
- (3) It does not contain PII.
- (4) Not applicable. This system does not ask for submission of personal information.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Mark Green

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIDA BIS Collaboration and Scheduling System

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH NIDA BIS Collaboration and Scheduling system
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Pei-Li Chao
- **10. Provide an overview of the system:** Included in this system are applications designed to increase the efficiency of NIDA IRP day to day operation, promote collaborations among researchers for information sharing, and for information distribution. They are office/conference room booking system, BIS Web, BIS Sharepoint and Wiki.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\rm N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) The system collects

scheduling information, shared scientific information, serve as entry point for other systems, and store/display documents for administrative purpose for IT and Administrative branch. The information contained in the system ONLY represents federal contact data.

- (2) the information is used in aid of scientifc research.
- (3) It does not contain PII.
- (4) Not applicable. This system does not ask for submission of personal information.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) $\rm\ N/A$

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Mark Green

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIDA BIS Inventory and Change Control System

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIHNIDA BIS Inventory and Change Control System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Pei-Li Chao
- **10. Provide an overview of the system:** This information system contains two parts. One is for system inventory tracking; the other is for change control tracking. The information system is an in-house application built for BIS to record server configurations along with the changes made to each server and to document the approving process before the actual change is done to the servers.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: (1)The system collects server configurations, server function, and change control information on servers maintained by the BIS. It is used by the IT department for server tracking. It does not contain contact data.

- (2) the information is used for maintaining NIDA IRP Servers.
- (3) It does not contain PII.
- (4) Not applicable. This system does not ask for submission of personal information.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) $\rm\ N/A$

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Mark Green

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIDA Criminal Justice Drug Abuse Treatment Studies (CJDATS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 8/12/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: n/a

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN

number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: n/a

6. Other Identifying Number(s): n/a

7. System Name (Align with system Item name): NIH NIDA Criminal Justice Drug Abuse Treatment Studies

- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sarah Duffy
- 10. Provide an overview of the system: The system supports the CJDATS Research Collaborative, which funds 9 research centers (RCs) through a cooperative agreement mechanism. The RCs conduct three multi-center and multi-site studies to test organizational and professional change strategies to implement evidence-based approaches to assessing and treating drug abuse within criminal justice settings. The three projects include one to improve assessment of clinical needs, one to improve linkages to HIV services, and another to improve practices related to medication-assisted therapy. The system facilitates the processing and aggregation of the study data collected by the RCs; coordination of research-related activities, dissemination of non-identifiable data, and general dissemination of public CJDATS information. Most information is collected by the RCs via survey from employees of correctional institutions and community-based treatment centers. This information includes demographic and position information about the respondents, as well as study-related information such as their perception of functioning of their workplaces, their attitudes towards change, and their perceptions of the interventions being tested. It also collects data about the respondents' perceptions of the interventions being studied. PDF versions of paper forms are uploaded by the RCs to a secure website provided under contract to AMAR International (AMAR). The forms are then fed into Teleforms and converted to SPSS (Statistical Package for the Social Sciences) files. These SPSS files are provided to RCs on an as needed and approved basis so they can conduct statistical analyses. The RCs will also collect information on the quality of patient-level case plans from administrative data. These data will not be linkable to the patient for whom the case plan was created, and will not contain any personal information on the patient him- or herself. The system also contains a website which contains the names of RC, contractor, and NIDA personnel who are working on the project. At the end of the research project, AMAR will make available public use versions of these files for posting in a data archive hosted under a separate contract.
- 13. Indicate if the system is new or an existing one being modified: New

- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The system processes data records that in some cases contain non-informative personal identification numbers, which are included in data records to facilitate linking. These personal identification numbers can be linked by the RC who originally collected the information to personally-identifying information (which is kept under lock and key). A given respondent may fill out several forms, information from which needs to be linked to create a respondent-specific record for use in statistical analysis. Employment status information is implicit, because respondents are all employees. The records containing these non-informative IDs may be shared with others in the Criminal Justice Drug Abuse Treatment Studies (CJDATS 2 - "2" refers to the fact that this is the second CJDATS program funded by NIDA. The first, CJDATS 1 is complete) research cooperative, including designated and approved personnel in any of the 9 RCs, as well as appropriate contractor and NIDA staff. Under SORN 09-25-0200, these records may be disclosed for routine uses and under conditions and contexts specified in the SORN notice such as for research purposes, response to an inquiry by Members of Congress or their staff, litigation purposes to the Department of Justice, to agency contractors, grantees, experts, consultants, collaborating researchers, and volunteers to assist in the performance of a service related to this system of records. Other uses specified in the SORN notice are likely not relevant to this system, because the data needed to inform those uses is not contained in these records. Names of RC, contractor, and NIDA personnel who are working on the project are on the Website for purposes of collaboration, administration, etc. These are not reserach subjects.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1). The study data, which are processed and maintained by the agency's contractor, AMAR International, and its subcontractors, but collected by the RCs, contains survey responses from employees of criminal justice organizations and community-based treatment agencies to a variety of surveys that are conducted as part of the research. These surveys collect information on the characteristics of the individuals, their worksites, and their perceptions about the various professional and organization change strategies under study. The RCs will also collect information on the quality of patient case plans, but this information will not be linkable to individual patients and does not contain information about the patients themselves. Finally, the website contains the names of the RC, contractor, and NIDA staff who are working on the project. (2). This information is being collected to support research conducted under a cooperative agreement. The findings from the

studies will be disseminated via peer-reviewed publication and conference presentations, and the purpose of the project is to improve treatment received by drug abusers involved in the criminal justice system. At the end of the study, public use versions of the data files (i.e. de-identified and modified according to findings from a disclosure analysis) likely will be posted on a a public website (likely here http://www.icpsr.umich.edu/icpsrweb/NAHDAP/index.jsp) (3). The data submitted by the RCs to the data processing contractor contain a unique, non-informative respondent identifier to facilitate linking that individuals' responses to various surveys to allow for statistical analysis. Each RC keeps under lock and key information that could be used to link the identifier to an individual. Names of NIDA, RC, and contractor staff working on the project are contained on the website (4). Submission of personal information, and any other survey response, is voluntary.

This activity is authorized under Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) (1). There are no plans to make major changes to the system, including disclosure and use of the data, beyond what was originally consented, in this time-limited research project.. (2). Respondents are notified and consented at each wave of study data collection via individual RC IRB and correction or community services site approved consent forms. For example, the following requirements are from the State of Connecticut:

A. Before commencing a research project requiring participation by staff or inmates, the researcher shall give each participant a written informed consent statement containing the following information: 1. Identification of the researcher; 2. Objectives of the research project; 3. Procedures to be followed in the conduct of research; 4. Purpose of each procedure; 5. Anticipated uses of results of the reserach; 6. A statement of benefits reasonably to be expected; 7. A declaration concerning discomfort and risk, including a description of anticipated discomfort and risk; 8. A statement that participation is completely voluntary and that the participant may withdraw consent and end participation in the project at any time without penalty or prejudice; 9. A statement regarding the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law; 10. A statement that participation in the research project will have no effect on the inmate's release date or parole eligibility; 11. An offer to answer questions about the research project; and 12. Appropriate additional information as needed to describe adequately the nature and risks of the research project. A researcher in addition to presenting the statement of informed consent to the participant, shall also obtain the participant's signature on the statement of informed consent prior to initiating the research activity. (3). The processed data will be shared with designated and approved members of the CJ DATS reserach consortium for statistical analyses for use in publications and conference presentations. De-identified data that has been modified according

to the results of a disclosure analysis may be posted here http://www.icpsr.umich.edu/icpsrweb/NAHDAP/index.jsp.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Administrative Controls: Only selected data processing contractor and subcontractor staff, selected NIDA staff, and RC staff specifically identified by the Principal Investigators have access to the data containing PII on the system, which are hosted on a non-public part of the website. Technical Controls: Access to PII database is protected by strong passwords (MS Windows Server 2008 password policy) and the assignment of access rights and permissions. Passwords are changed at 6 month intervals. Windows Authentication is used. Authentication information is required every time the user logs into the website and every time the user opens a document on the website. McAffee Total Protection, Windows Forefront Security, and Windows Firewall are enabled to protect the site, in addition to firewalls provided by the hosting site (FPWeb.net), a subcontractor to the prime (AMAR international). The firewall is set up to reject all outside connections on ports not used by the CJ-DATS website. Physical controls: traditional locks, access controls, and biometric surveillance systems; fire suppression, HVAC, power feeds, hot-swappable servers and routers as provided by FP Web. FP Web has SAS 70 Type II Certification.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Mark R. Green, 301.435.1431

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIDA Drug Inventory Supply and Control System (DISCS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/19/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: Unknown

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0210

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NIDA3

- **7. System Name (Align with system Item name):** Drug Inventory Supply and Control System (DISCS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Anita LoMonico
- **10. Provide an overview of the system:** This system accounts for research grade drugs made available for distribution for research and analytical purposes. Materials are provided on request from persons authorized by the DEA (Drug Enforcement Administration) and following procedures specified by that agency. This system maintains (1) records of quantities in inventory by DEA classification and locally assigned catalog information, (2) records of all distributions of quantities of materials by inventory account, order number and requesting individual. If shipment is to a secondary address because of DEA registration or radiation safety requirements, that information is also maintained.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): System does not collect, store or share PII as defined by NIH

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Types of information contained in the records are: researchers name, DEA (Drug Enforcement Administration) registration numbers, business address (location of research project), telephone number and e-mail address, requests for substance(s), name and amount of each compound requested and shipped, date material is shipped and received, shipment numbers, and DEA order form numbers. Data collected are the minimum necessary to satisfy DEA record requirements, to allow contact with requestor and, finally, to ship materials to requestor.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) There are no procedures to notify users of changes in use of IIF collected. This system serves the single purpose of accounting for drugs distributed primarily for research and analytical purposes and providing the distributor with contact and shipping address information to comply with requests for materials from NIDA supplies. Additional information is collected for the sole purpose of accounting for the drug materials in accordance with law and regulations pertaining.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** Authorized users only. The "hard copy" records arephysically located at the Neuroscience Center, Bethesda, Maryland, the main server is physically located at 6116 Executive Blvd, Rockville, MD.. The computerized records are kept in a room with controlled access. The room is locked at all times. The "hard copy" records are stored in locked file cabinets in a room with controlled access. This room is locked when not occupied. The Neuroscience Center has a 24-hour guard patrol service. The terminals are housed in a secured work area with limited admittance. Contract personnel use a password identification system to obtain access and encrypted connections to ensure data security.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Mark Green, 301-435-1431

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIDA Employee Database Internet Edition (EDiE)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-9318-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-90-0018

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- **7. System Name (Align with system Item name):** NIH NIDA Employee Database Internet Edition (EDiE)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Pei-Li Chao
- **10. Provide an overview of the system:** The Employee Database Internet Edition system (a.k.a. EDie) provides an efficient method for data gathering, tracking and analysis, and reporting to allow for basic workforce planning in the areas of:
- FTE and cost projections
- FTE Personnel Actions (including renewals of appointments and visas)
- Employee Ratings
- Employee Awards
- FTE Personnel training data
- FTE Census Data
- FTE Education Level and Degree type
- FTE "Tickler" Alerts for WIGIs, promotions, visa renewals, retention bonus, etc.
- FTE Employment dates (EOD, NTE, Termination, etc.)
- FTE Salary History (mostly T5 & T42 employees, but can also be useful for awards)

In general it is a consolidated or one stop place for employee information (FTEs, Non-FTEs, and Contractors)

The authority for maintenance of the system is: 5 U.S.C. 1302, 2951, 4118, 4308, 4506, 7501, 7511, 7521 and Executive Order 10561.

13. Indicate if the system is new or an existing one being modified: Existing

- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Information is intended for internal senior federal government administrative staff and their delegates, for the purpose of performing their personnel management duties and responsibilities, and information will not be shared by other entities.

Refer to SORN 09-90-0018.

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: EDie tracks all information pertinent to a personnel file for the purpose of personnel management activities. Information is collected from employees via the Human Resources Database (HRDB) system, Fellowship Payment (FPS) system, NIH Enterprise Directory (NED) system. The information contains IIF, and submission of the data by personnel is mandated by each hiring mechanism.

Primary usage consists of the following:

- a) tracking a time-limited appointment to ensure renewals are done in a timely manner, thereby avoiding any break in service;
 - b) ensuring that allocated FTE ceilings are maintained;
 - c) ensuring salary equality for various hiring mechanisms;
 - d) providing reports requested by the NIDA Director, and other management staff as requested;
- e) maintaining lists of non-FTEs, special volunteers, contractors, and other hiring appointments.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) IIF in the system is downloaded from the HRDB, Data Warehouse, and NEDs. Changes to HRDB, Data Warehouse, and NED or change's in the way information is used is relayed to employees via official notices from the NIH Office of Human

resources (OHR). Individuals are notified of the collection and use of the data as part of the hiring process. This is a mandatory requirement of potential job applicants seeking employment at NIH.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Access and permission are granted based on the "need to know" and "least privilege" principles based on the authorized user role. All users of this system have taken mandatory annual Information Security Awareness training and Privacy Awareness Course.

The system is resided on NIHnet which binds to NIH network security controls and all its policies and procedures, including password policy and procedures. The website uses SSL for encrypted communication between the server and the client.

The system reside in a building with 24x7 security guards, badge identification, visitor escort, CCTv, and key cards access at restricted area.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Mark R. Green

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIDA External Collaboration System

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH NIDA External Collaboration System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Pei-Li Chao
- **10. Provide an overview of the system:** External collaboration System hosts several web applications, which don't include PII and have all been assessed with their own PIAs, to facilitate the collaboration efforts between IRP and the outside entities. It utilizes NIH external AD accounts to grant access to the collaborators. There are three applications included in this system. Data Safety Monitory Board (DSMB)/ IRB Protocol, Image Read, and AgMednet.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\rm N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) This information system

either collects or disseminates information from or to outside entities that are collaborating with NIDA IRP. The contact information contained in the system ONLY represents federal contact data.

- (2) the information is used for collaboration with non-NIH entities
- (3) It does not contain PII.
- (4) Not applicable. This system does not ask for submission of personal information.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) $\rm\ N/A$

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Mark Green

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 12/9/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIDA Extramural Project System (NEPS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/19/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-26-02-9301-00-202-069

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): NIDA 1

- **7. System Name (Align with system Item name):** National Institutes on Drug Abuse Extramural Project System (NEPS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Anita LoMonico
- **10. Provide an overview of the system:** NEPS is a NIDA corporate extension system to IMPAC II. This system provides online management, reporting, and tracking of grant data.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): PII is not shared nor disclosed with other divisions within this agency, external agencies, or other people or organizations outside the agency
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Authority for collection of this information is 5. U.S.C. 301; 42 U.S.C. 217a, 241, 282(b)(6), 284a, and 288. 48 CFR

Subpart 15.3 and Subpart 42.15. The IIF that the system captures on the public is obtained from the NIH IMPACII system. This system does not directly collect information but rather retrieves the information from the NIH IMPACII system. The IIF that the system retrieves is about individuals employed by NIDA and involved in the grants business process. IIF includes name, address, phone number, and financial account information. Most information supplied is mandatory as it is needed to process a grant application.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) There are no processes in place to notify and obtain consent from individuals regarding the IIF used in this system when major changes have occurred.

Forms used by NIH to collect Privacy information (such as PHS 398) clearly state the purpose of the information being collected.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Information is secured using username/passwor-ds, least privilege, separation of duties, firewalls, locks, badge access, background investigations.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Mark Green, 301-435-1431

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIDA Internet Website PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/12/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-02-00-01-3109-00-109-026

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

- **5. OMB Information Collection Approval Number:** No
- **6. Other Identifying Number(s):** No
- 7. System Name (Align with system Item name): NIH NIDA Internet Server
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Mark Fleming
- **10. Provide an overview of the system:** Website for the National Institute on Drug Abuse for public use.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Yes with contractors for order fulfillment.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Log files for statistical purposes.

The webserver logfile logs the following information

The Internet domain (for example, "xcompany.com" if you use a private Internet access account, or "yourschool.edu" if you connect from a university's domain), and IP address (an IP address is

a number that is automatically assigned to your computer whenever you are surfing the Web) from which you access our website

The type of browser and operating system used to access our site,

The date and time you access our site,

The pages you visit, and

If you linked to our website from another website, the address of that website.

Ordering information for product fulfillment. This information is collect through an online form and is only kept long enought to fullfill the obligation. Upon completion, this information is deleted immediately. Voluntary submission by user.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The information is not stored for any length of time and is deleted once completed. No need for notification of change and there are no processes in place to notify individual when major changes occur. The information is sent to the contractor for order fulfillment only.

There are processes in place to obtain consent and information is stored as described in privacy policy.

from privacy policy *

"If you choose to provide us with additional information about yourself through an e-mail message, form, survey, etc., we will only maintain the information as long as needed to respond to your question or to fulfill the stated purpose of the communication."

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: Yes
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Secured through cipher locked office, badge entry to building, passwords, and key card usage.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Mark Green, 301-435-1431

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

Date Published: May 23, 2012

06.3 HHS PIA Summary for Posting (Form) / NIH NIDA Intranet Website PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-02-00-01-3109-00-109-026

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): NIH NIDA Intranet Server
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Mark Fleming
- 10. Provide an overview of the system: Internal resources for NIDA staff.

The SOP has confirmed that there is no linkable PII.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Log files for statistical purposes.

The webserver logs the following information

The Internet domain (for example, "xcompany.com" if you use a private Internet access account, or "yourschool.edu" if you connect from a university's domain), and IP address (an IP address is a number that is automatically assigned to your computer whenever you are surfing the Web) from which you access our website

The type of browser and operating system used to access our site,

The date and time you access our site,

The pages you visit, and

If you linked to our website from another website, the address of that website.

There is no IIF data.

The SOP has confirmed that there is no linkable PII.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Mark Green, 301-435-1431

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/30/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIDA IRP BSC Review PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/8/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-90-0018

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH NIDA Intramural Research Program BSC Review
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Pei-Li Chao
- **10. Provide an overview of the system:** Board of Scientific Counselors (BSC), developed inhouse, is hosted at a secure website to allow authorized external scientific review board members to access NIDA IRP primary investigator's (PI) curriculum vitae (CV), achievements, budget, performance, and publications. Through this system, the initial performance review of a PI is conducted by the scientific review board.

The goal of the BSC review process is to assist the Scientific Director by providing a rigorous external scientific review of the Intramural Research Program, including the performance of the intramural scientists and the quality of their research programs. To assure that the BSCs' evaluations will be most useful to the Scientific Directors in their decision making, the BSCs must be composed of individuals who themselves have outstanding scientific credentials and who are committed to providing rigorous, objective reviews.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes

23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The goal of the Board of Scientific Counselor (BSC) review process is to assist the Scientific Director by providing a rigorous external scientific review of the Intramural Research Program, including the performance of the intramural scientists and the quality of their research programs.

BSC composed of individuals who themselves have outstanding scientific credentials and who are committed to providing rigorous, objective reviews. Such as professors from Universities.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) NIDA IRP Primary investigators' CV, achievements, budgets, performance, and publications.
- (2) For preliminary performance review of the PIs by the scientific review board.
- (3) It contains PII
- (4) The application does not ask for submission of personal information. PIs are instructed to remove all personal and personal contact information from their CVs. The submission of information is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) PI's are notified about how the information will be used or shared at the time their information (CV, budget, employment status, etc...) is submitted into the system. By PI's voluntarily submitting their information into the system they are providing consent regarding the use of their PII.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Access and permission are granted based on the "need to know" and "least privilege" principles. Authentication is handle by NIH External Active Directory that also dictates strong password protection.

The system resids on NIHnet which binds to NIH network security controls and all its policies and procedures, including password policy and procedures. The website uses SSL for encrypted communication between the server and the client.

The system resides in a building with 24x7 security guards, badge identification, visitor escort, CCTv, and key cards access at restricted area.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Mark Green, Deputy Director, OEA, NIDA 301.435.1431

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 8/4/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIDA NIDA HQ GSS [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/12/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: No

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH NIDA HQ Network
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Jeff Weiner
- **10. Provide an overview of the system:** This is a local area network (LAN) that hosts NIDA HQ servers and workstations to support the NIDA HQ mission. This LAN is an extension of NIHnet. The system is a General Support System (GSS) and does not directly collect or store information.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\rm N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system is a General Support System (GSS) and does not directly collect or store information. The

applications/systems residing on the GSS collect and store information. Therefore, individual PIAs have been prepared and submitted for the applications/systems residing on the GSS.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) $\rm\ N/A$

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Mark Green

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIDA NIDA IRP Human Research Information System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-9318-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0203

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NIDA 5

- **7. System Name (Align with system Item name):** Human Research Information System (HuRIS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Pei-Li Chao
- **10. Provide an overview of the system:** To collect and maintain a database for research activities at NIDA/IRP. To enable Federal drug abuse researchers to evaluate and monitor the subjects' health during participation in a research project. The areas of research include, but are not limited to, biomedical, clinical, behavioral,

pharmacological, psychiatric, psychosocial, epidemiological, etiological, statistical, treatment and prevention of narcotic addiction and drug abuse.

Authority: Public Health Service Act, Section 301(a) (42 U.S.C. 241(a)); Sections 341(a) and 344 (d) (42 U.S.C. 257(a) and 260

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The authorized users at the NIDA/IRP and other authorized individuals according to the Privacy

Act System of Records (SOR) Number 09-25-0203. This information is further addressed in the NIH Privacy Act Systems of Record Notice 09-25-0203, published in the Federal Register, Volume 67, No. 187, September 26, 2002.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The National Institute on Drug Abuse (NIDA) recruits volunteers and screens these individuals for their acceptability to participate in specific research projects. For this purpose, HuRIS is used to collect, manage and maintain information on these participants. The collected data contains information in identifiable form (IIF) and includes, but is not limited to: name, study identification number, address, relevant telephone numbers, social security number, date of birth, weight, height, sex, race, and social, economic and demographic data. In compliance with relevant regulations, NIDA may disclose information to State or local public health departments. Submission of all information by research participants is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The information is strictly used for the purposes for which consent has been obtained. No other use of the data is allowed which is outside the scope of the existing consent; a major change in the research requires new consent. The participants are made well aware of the usage of the information they provide and sign consent for which it is obtained by Federal personnel that they are eligible to participate and consent.

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** Only authorized NIDA Intramural Research Program staff are allowed access to these files. Physical Safeguards: Files and file rooms are locked after business hours. Building has electronic controlled entry at all times with a 24-hour security guard and television surveillance

system. The computer terminals are in a further secured area.

Procedural Safeguards: All users of personal information in connection with the performance of their jobs protect information from

unauthorized personnel. Access codes to the research records are available only to the Principal Investigator and his/her research team. Access to the records is strictly limited to those staff members trained in

accordance with the Privacy Act. The contractor staff members are required to secure the information in accordance with the Privacy Act. Project Officer and contracting officials will monitor contractor compliance.

Access to the Human Research Information System (HuRIS): The NIDA IRP computerized medical and research record is strictly limited. All staff must be authorized to use the system and be granted an access code

(user name and password) by the system sponsor (NIDA, IRP Chief of Biomedical Informatics). Passwords are required to be changed every sixty days. Access is limited by job classification and is on a need to know basis only. Data entered is time and date stamped by the staff member's name. Data is not altered once entered. While logged into the system, the

name of the staff member is displayed on the screen. An activity log of each use is kept. Data is backed up on a daily basis. Implementation

Guidelines: These practices are in compliance with the standards of Chapter 45-13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45-13, and the HHS Automated Information Systems Security Program

Handbook. In addition, because much of the data collected in these esearch projects are sensitive and confidential, special safeguards have been established. Certificates of confidentiality have been issued under Protection of Identity - Research Subjects Regulations (42 CFR Part 2a) to those projects initiated since February 1980. This authorization enables

persons engaged in research on mental health, including research on the use and effect of psychoactive drugs, to protect the privacy of research subjects by withholding their names or other identifying characteristics

from all persons not connected with the conduct of the research. Persons so authorized may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding to identify such individuals. In addition, these records are subject to 42 CFR Part 2, the Confidentiality of Alcohol and Drug Abuse Patient Records Regulations (42 CFR 2.56), which state: "Where the content of patient records has been disclosed pursuant to these regulations for the purpose of conducting scientific research...information contained therein which would directly or indirectly identify any patient may not be disclosed by the recipient thereof either voluntarily or in response to any legal process whether Federal or State."

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Mark Green, 301-435-1431

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIDA NIDA IRP Local Area Network [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/8/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-02-01-02-9315-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH NIDA IRP Network
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Pei-Li Chao
- **10. Provide an overview of the system:** This is a local area network (Ethernet) that hosting NIDA IRP servers and workstations to support IRP's mission. This LAN is an extension of NIHnet with private T3 line connection. The system is a General Support System (GSS) and does not directly collect or store information.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\rm N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system is a General Support System (GSS) and does not directly collect or store information. The

applications/systems residing on the GSS collect and store information. Therefore, individual PIAs have been prepared and submitted for the applications/systems residing on this GSS.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) $\rm\,N/A$

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote
PIA Reviewer Name: Mark R. Green

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIDA Status of Funds Internet Edition (SoFIE)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): SOFIE
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Stacy Gardner
- **10. Provide an overview of the system:** The SOFie application supports the efforts of several offices and branches within the IC, allowing budget offices to track expenditures in appropriate funds in a fiscal year. The program contains a tracking mechanism to track prior year funds as well. The application downloads this information from the NIH Data Warehouse weekly. Information entered into the SOFie database is not uploaded into the NIH Data Warehouse database. SOFie is not a source database for other information systems.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\rm N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: The application downloads this information from the NIH Data Warehouse weekly. Information entered into the SOFie database is not uploaded into the NIH Data Warehouse database.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Mark Green,

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIDA WebEvent PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A
- **5. OMB Information Collection Approval Number:** N/A
- 6. Other Identifying Number(s): N/A
- 7. System Name (Align with system Item name): NIH NIDA WebEvent
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Pei-Li Chao
- **10. Provide an overview of the system:** A web based calendar application allows event scheduling using Internet Explorer and calendar sharing among multiple users. It is a commercial off the shelf application, purchased and used by IRP to better utilize its resources.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\rm N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) The system collects scheduling data for resource (rooms, instruments, or personnel) allocation. The information contained in the system ONLY represents federal contact data.
- (2) the information is used in aid of scientific research.

- (3) It does not contain PII.
- (4) Not applicable. This system does not ask for submission of personal information.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Mark Green 301.435.1431

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIDCD Content **Management System (CMS)**

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: No

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0106

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): NIDCD Content Management Server (CMS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Jenny Wenger, 301-496-7243
- 10. Provide an overview of the system: The CMS System is a comprehensive solution for managing web content and support's NIDCD's mission to the general public. CMS allows creation of dynamic web sites using extensible CMS controls. Users can create, publish, and manage their own web content through the appropriate CMS control. NIDCD General public sites are Internet and StemCell. Internal sites are NIDCD Intranet, NIDCD Board of Scientific Counselors

and Advisory Council.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Information is used internally to NIDCD only. SOR # 09-25-0106 safeguards are used to ensure only appropriate people have access to the information, and that they are aware of their

responsibilities for proper handling of the information. Contractors run and maintain the system and are aware of the above.

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Employee contact information is pulled from the NIH Employee Database (NED) system for all NIDCD employees. Fields pulled are: First name, Last name, Phone number, e-mail address, org. unit, Building number, room number, Fax number, NED Classification (employee, fellow, contractor etc) and Mail Stop Code.

The information is displayed on the Intranet site and is used to facilitate communication between employees. The NIDCD CMS system does not feed into any system.

The information is stored in identifiable form.

Inclusion is mandatory since inclusion in NED is mandatory for all people working at NIH who require an ID badge and or AD account.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Consent for the listing of personal information in the NIH Employee Database (NED) is given at the time they are hired \ begin working at the NIH. No additional processes are employed by NIDCD to inform individuals when major system changes are made to the CMS System, or to inform them how their information will be used or shared on the CMS System.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Information is in an electronic system on NIH secure network infrastructure and is password protected with access limited to only authorized users. NIDCD periodically reviews and implements policies in line with HHS guidelines.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Luis Ochoa (NIDCD ISSO - 301.402.1128) or Debbie Washington (NIDCD Privacy Coordinator - 301-451-9806)

Sr. Official for Privacy Approval: PromoteSr. Official for Privacy Name: Karen Pla

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

Date Published: May 23, 2012

06.3 HHS PIA Summary for Posting (Form) / NIH NIDCD Employee Database Internet Edition (eDie)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 3/28/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-90-0018

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIDCD Employee Database Internet Edition (NIDCD EDIE)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Luis Ochoa (NIDCD ISSO, 301-402-1128)
- **10. Provide an overview of the system:** NIDCD EDie system is a personal tracking system for internal use only PHS Act Section 301. The NIDCD EDie system application supports the efforts of the Office of Resource Management's (ORM) Administrative and Financial Management Branches with tracking employee information. The application downloads this information from the Human Resource Database (HRDB) weekly. Information entered into the NIDCD EDIE system database is not uploaded into the HRDB.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The information collected is all information pertinent to a personnel file.
- (1) The information contained in the system ONLY represents federal contact data. (Employee Name, Date of Birth, Employee Status, Organizational Unit, Employment End Date, and Salary Information)
- (2) There are many uses for this information: (a) tracking a time-limited appointment to ensure renewals are done in a timely manner thereby avoiding any break in service; (b) ensuring that allocated FTE ceilings are maintained; (c) ensuring salary equality for various hiring mechanisms; (d) the ability to provide reports requested by the NIH Director; (e) maintaining lists of non FTEs, special volunteers, contractors, etc. Information is mandatory at time of hire.
- (3) The information contains PII. (Employee Name, Date of Birth, Employee Status, Organizational Unit, Employment End Date, and Salary Information)
- (4) Submission of personal information is mandatory.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.
- (Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Information is collected from documents provided by employees (CV, resumes, etc) at the time of appointment. It is provided in personnel packages submitted through channels in order to affect a hire. This information is put into the EHRP system and subsequently downloaded into NIDCD EDIE system. Individuals are notifed of the collection and use of data as a part of the hiring process. Changes to the system or use of the information is relayed to employees via official notices from HR.
- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: This information is provided to key staff by the administrator. The system is authorized only with a person who has a proper access rights with user name and password. The system is secured in an office with locks and the building is secured by the security guard.

Information is in an electronic system on NIH secure network infrastructure and is password protected with access limited to only authorized users. NIDCD periodically reviews and implements policies in line with HHS guidelines.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: NIDCD ISSO (Luis Ochoa, 301.402.1128) & NIDCD Privacy

Coordinator (Debbie Washington, 301.451.9806)

Sr. Official for Privacy Approval: Promote **Sr. Official for Privacy Name:** Karen Plá

Sign-off Date: 4/1/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIDCD LMG (Olioga) (LMG)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/11/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: No

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- **7. System Name (Align with system Item name):** NIDCD Laboratory Molecular Genetics Intranet [LMG Intranet] Minor Application of NIDCD GSS
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Robert Morelll (5RC Staff Scientist, 301.402.4249)
- **10. Provide an overview of the system:** The NIDCD Laboratory of Molecular Genetics (LMG) database system is a comprehensive solution for managing, tracking laboratory specimens\supplies stored in laboratory freezers. The LMG Intranet system supports approximately 32 users in the NIDCD LMG Group located at the 5 Research Court facility.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Information is used internally only. SOR # 09-25-0200 safeguards are used to ensure only appropriate people have access to the information, and that they are aware of their responsibilities for proper handling of the information.

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The information contained in the LMG System includes patient first name, last name, close familial relation to other individuals contained in the system (such as father, mother, brother, sister, aunt, uncle etc), Hearing loss status (affected vs. not affected), Gene mutation information, only where it relates to the hearing loss trait.

The information is used as part of an IRB approved study to identify, and better understand the relationship between hearing loss and genetics.

The information is stored in Identifiable Form

Inclusion in the study and therefore this database is completely voluntary and there is a process by which a subject can request that they no longer be included in the study \ database.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Patients are informed in writing concerning how their information will be collected, used, and shared during the course of the study. Patient consent for the use of their information is obtained prior to inclusion in the study.

No additional processes are employed by NIDCD to inform individuals when major system changes are made to the LMG System.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The IIF is secured using layered security practices. The information is contained in a password protected database. Physical security of the building does not allow unauthorized people to enter, and the computer facilities are further protected by locked doors. Multiple layers of firewalls also ensure that only appropriate network traffic is allowed to pass.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Luis Ochoa (NIDCD ISSO, 301.402.1128) / Debbie Washington (301-451-9806)

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Pla

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIDCD Microsoft Office SharePoint Server Intranet (MOSS Intranet)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 9/20/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- **7. System Name (Align with system Item name):** NIDCD Microsoft Office SharePoint Server Intranet (NIDCD MOSS Intranet)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Jennifer Wenger 301-496-7243
- **10. Provide an overview of the system:** The (NIDCD MOSS Intranet) system is a comprehensive solution for managing web content and support's NIDCD's mission. The (NIDCD MOSS Intranet) system allows creation of dynamic web sites using extensible MOSS controls. Users can create, publish, and manage their own web content through the appropriate MOSS controls. The (NIDCD MOSS Intranet) system is for NIDCD internal office use. (Currently in developement; 08-01-10)
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: System is currently not in production. Q14. Identify the life-cycle phase of this system: Initiation phase.

The system does not feed into any system. (DOES NOT COLLECT PII)

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) System is currently not in production. Q14. Identify the life-cycle phase of this system: Initiation phase.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** Curently, this system (NIDCD MOSS Intranet) is not in production. Q14. Identify the life-cycle phase of this system: Initiation phase. Information is in an electronic system on NIH secure network infrastructure and is password protected with access limited to only authorized users. NIDCD periodically reviews and implements policies in line with HHS guidelines.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Luis Ochoa (NIDCD ISSO - 301.402.1128) or Debbie Washington

(NIDCD Privacy Coordinator - 301-451-9806) **Sr. Official for Privacy Approval:** Promote

Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIDCD NEI/NIDCD Usher Database

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 3/28/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: No, the system does not meet the requirements for a UPI.

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200
- **5. OMB Information Collection Approval Number:** N/A
- **6. Other Identifying Number(s):** No
- 7. System Name (Align with system Item name): NEI / NIDCD Usher Database
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Julie Schultz borkj@nidcd.nih.gov, Jackie Jones (NIDCD CIO, 301-402-1128)
- **10. Provide an overview of the system:** Centralized repository for storage and analysis of clinical data produced by NEI and NICDC researchers studying Usher Syndrome. FileMaker Pro database that will store clinical and genetic data from Usher Syndrome research subjects collected by NIH investigators
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Information is used internally only. Safeguards are used to ensure only appropriate people have access to the information, and that they are aware of their responsibilities for proper handling of the information.

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Investigators will collect patient history, clinical evaluations (audiologic testing, vestibular testing, and ocular testing) and molecular testing. The data and test results will be entered into and stored in the Usher Database

This database will allow the investigators to share and analyze said data and will improve researcher efficiency versus using a paper-based data collection system.

Yes. the information is PII. (Name, Personal Mailing Address, Personal Telephone Number, Medical Record Numbers, and Medical Notes)

Research subjects sign informed consent to participate in the study and are able to withdraw from the study at any time.

Inclusion in the study and therefore this database is completely voluntary and there is a process by which a subject can request that they no longer be included in the study database.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Investigators will collect patient history, clinical evaluations (audiologic testing, vestibular testing, and ocular testing) and molecular testing.

Patients are informed in writing concerning how their information will be collected, used, and shared during the course of the study.

Patient consent for the use of their information is obtained prior to inclusion in the study.

No additional processes are employed by NIDCD to inform individuals when major system changes are made to the system.

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The IIF/PII is secured using layered security practices. The information is contained in a password protected database. Physical security of the building does not allow unauthorized people to enter, and the computer facilities are further protected by locked doors. Multiple layers of firewalls also ensure that only appropriate network traffic is allowed to pass

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Privacy Coordinator, Debbie washington 301-451-9806

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 4/1/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIDCD NIDCD General Support System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: Not Applicable

1. Date of this Submission: 3/28/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: No, the system does not meet the requirements for a UPI.

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200
- **5. OMB Information Collection Approval Number:** N/A
- **6. Other Identifying Number(s):** No
- 7. System Name (Align with system Item name): NIDCD General Support System [NIDCD GSS]
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Walter Mehlferber (Network Chief, 301-402-1128)
- 10. Provide an overview of the system: NIDCD General Support System [NIDCD GSS] is an interconnected set of information resources under the same direct management control that share common functionality. Examples of interconnected information resources include data centers, local area networks, workstations and servers that support multiple NIDCD applications. These systems provide information processing services for National Institute of Deafness and Other Communications Disorders' (NIDCD) medical research programs and management programs as well as Department of Health and Human Services (DHHS) and other government agency management programs. The information technology equipment supporting these services are operated and maintained by NIDCD's Information Systems Management Branch.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\rm N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: N/A
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Debbie Washington (NIDCD Privacy Coordinator) 301-451-9806 & Luis

Ochoa (NIDCD ISSO) 301-402-1128

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 4/1/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIDCD Otobase PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 3/28/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): NIDCD Otobase Database
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Carmen Brewer (NIDCD Clinic Audiologist, 301.496.5294), ChristopherZalewski (NIDCD Clinic Audiologist, 301.496.5145)
- **10. Provide an overview of the system:** The Otobase system is used to collect hearing test data directly from the audiometer. It is used to a) generate an audiogram (which would otherwise be hand written), b) store hearing test data. Storing the data in this way provides instant access to past audiograms, and a searchable data base for purposes of research. The computers are all password protected and in addition, access to otobase requires entry of another password.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Information is used internally only. SOR # 09-25-0200 safeguards are used to ensure only appropriate people have access to the information, and that they are aware of their responsibilities for proper handling of the information.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

- **submission of personal information is voluntary or mandatory:** (1) NIDCD clinicians will collect patient history and clinical evaluations (audiologic testing notes). The data and test results will be entered into and stored in the NIDCD Otobase Database.
- (2) This database will allow the clinicians/researchers to share and analyze data and will improve researcher efficiency versus using a paper-based data collection system.
- (3) Yes. the information is PII (Name, Date of Birth, Medical number, Medicate notes)
- (4) Patient subjects sign informed consent to participate in the study and are able to withdraw from the study at any time. Inclusion in the study and therefore this database is completely voluntary and there is a process by which a subject can request that they no longer be included in the study \ database.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.
- (Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Clinicians/Researcher will collect patient history, clinical evaluations (audiologic testing). Patients are informed in writing concerning how their information will be collected, used, and shared during the course of the study. Patient consent for the use of their information is obtained prior to inclusion in the study. No additional processes are employed by NIDCD clinician/researchers to inform individuals when major system changes are made to the system.
- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The IIF/PII is secured using layered security practices. The information is contained in a password protected database. Physical security of the building does not allow unauthorized people to enter, and the computer facilities are further protected by locked doors. Multiple layers of firewalls also ensure that only appropriate network traffic is allowed to pass.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Debbie Washington 301-451-9806 (Privacy Coordinator) & Luis Ochoa

ISSO 301-402-1128

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 4/1/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIDCD Status of Funds Internet Edition (SOFie)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/12/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 0

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- **7. System Name (Align with system Item name):** NIDCD Status of Funds Internet [NIDCD SOFIE]
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Mark Rotariu (NIDCD Budget Officer, 301-402-0497)
- **10. Provide an overview of the system:** SOFie is a Web based application. The SOFie application supports the efforts of several offices and branches within NIDCD, allowing budget offices to track expenditures of direct, reimbursable, and non-appropriated funds in a fiscal year. Additionally, SOFie is used to reflect budget allocations and projected expenditures at the operating level. The program also contains a tracking mechanism to track prior year funds. The application downloads this information from the NIH Data Warehouse weekly. Information entered into the SOFie database is not uploaded into the NIH Data Warehouse database. SOFie is not a source database for other information systems.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No PII is collected.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: No PII is collected. Accounting data and related document information is downloaded from a central accounting mainframe and is relevant or specific to an institute or center for its fiscal year operations.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No PII is collected.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: NO PII IS COLLECTED BY THIS SYSTEM

Information is in an electronic system on NIH secure network infrastructure and is password protected with access limited to only authorized users. NIDCD periodically reviews and implements policies in line with HHS guidelines.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Debbie Washington NIDCD Privacy Coordinator 301-451-9806

(8/12/2011)

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIDCR Employee Database Internet Edition (EDie)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 9/30/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-90-0018

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): None

- **7. System Name (Align with system Item name):** NIH NIDCR Employee Database Internet Edition (EDie)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Ginger Betson
- **10. Provide an overview of the system:** EDie is an intranet based application primarily used to manage and track personnel information. Authority for maintenance of the system: 5 U.S.C. 1302, 2951, 4118, 4308, 4506, 7501, 7511, 7521 and Executive Order 10561.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Information is intended for internal administrative use only and will not be shared by other entities. Refer to SORN 09-90-0018.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: EDie tracks all information

pertinent to a personnel file for the purpose of personnel management activities. Information is collected from employees via the Human Resources Database (HRDB) system, Fellowship Payment System (FPS), nVision Data Warehouse and NIH Enterprise Directory (NED). Uses consist of the following: a) tracking a time-limited appointment to ensure renewals are done in a timely manner, thereby avoiding any break in service; b) ensuring that allocated FTE ceilings are maintained; c) ensuring salary equity for various hiring mechanisms; d) providing reports requested by the NIH Director, the IC Director, and other management staff, as requested; and e) maintaining lists of non-FTEs, special volunteers, contractors, and other hiring appointments. The information collected constitutes PII and is mandatory for all employees. The following PII is included in the system name, date of birth, social security number, personal mailing address, personal phone numbers, personal email address, education records and employment status

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) PII in the system is downloaded from the HRDB, FPS, nVision Data Warehouse and NED. Changes to HRDB or changes in the way information is used is relayed to employees via official notices from the NIH Office of Human Resources (OHR). Individuals are notified of the collection and use of the data as part of the hiring process. This is a mandatory requirement of potential job applicants seeking employment at NIH.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: PII stored in EDie is accessed by a very limited number of administrative staff with a "need-to-know" status. EDie is password protected and sensitive data is encrypted. The system is located on a server in a secure server room behind the NIH firewall. Physical controls include cipher locks, key cards, CCTV and identification badges for access to servers.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Kajuana Canady (301) 594-4855

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 10/28/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIDCR Internet Website PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-02-00-01-3109-00-109-026

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0106
- **5. OMB Information Collection Approval Number:** 42 U.S.C. 203, 241, 2891-1 and 42 U.S.C. 3101 and Section 301 of the Public Health Act. (*Periodically we run the American Customer Satisfaction Index (ACSI) survey on the NIDCR website).
- 6. Other Identifying Number(s): NIDCR-8
- 7. System Name (Align with system Item name): NIDCR Internet Website
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Jody Dove
- **10. Provide an overview of the system:** The web site disseminates information about oral health, research advances, funding and training opportunities, and Institute priorities to researchers, patients, health care providers, policymakers, and the public.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): SOR 09-25-0106; The SOR on file for this system contains language which details potential disclosure of information practices. NIDCR will comply with the SOR. A) The information collected through the publication order form is disclosed only to specific clearinghouse staff so they can process the orders and mail out publications to those who have requested them.
- B) The NIDCR website also offers users the option to sign-up for the Institute E-Newsletter. This Listserv list -- NIDCR-NEWSLETTER -- is hosted by the NIH Listserv facility at CIT and has the same privacy policy as all Listserv lists they host:

https://list.nih.gov/LISTSERV_WEB/privacy.htm. The NIDCR-NEWSLETTER listserv list is only disclosed to the owners of the list for the purpose of managing, validating, and maintaining the subscriptions with the subscribers' consent.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: A) If someone wishes to order a publication they must supply the following IIF information: name, address, and phone number. This information is required to mail the publication. But it is entirely up to individuals to decide if they wish to order publications.
- B) If someone wishes to subscribe to our e-newsletter, they must supply the following IIF information: name and e-mail address. This information is required to e-mail them the newsletter. The sign-up is entirely voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) NIDCR does not plan to make any changes to the system. However, if a change were to occur:

- A) NIDCR would post a written notice directly on the publication order form to inform individuals of this change. The publication order form makes clear what information is being collected (name, address, and telephone number) and why (to mail out publications that an individual requests). The order form states that this information is shared only with our clearinghouse for the purpose of complying with the individual's publication request.
- B) Likewise, NIDCR does not plan to make any changes to the e-newsletter sign-up. However, were a change to occur, a notice would be placed directly on the sign-up page to inform individuals of this change. The e-newsletter sign-up page makes clear that the individual's name and e-mail address will only be used for the purpose of e-mailing the newsletter.
- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: Yes
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: A) If someone wishes to order a

publication, they must supply their name, address, and phone number through the publication order form on the NIDCR web site. The information is stored and managed by our clearinghouse, IQ Solutions. Access to IIF requires a password for system access. Such access is limited to authorized system users, administrators, developers, and information technology support personnel.

B) The following security controls are in place for the NIDCR-NEWSLETTER Listsery: IIF will be secured on the system using Listserv basic administrative access control. Only the Listserv designated owners with valid e-mail accounts can manage specific Listserv lists through the NIH Listserv Secured Web User Interface (https). Except for the Listserv system administrators, no one can have access to the Listserv console. Every issued command is validated and confirmed via email (smtp) from/to listserve@list.nih.gov. The Listserv system also is secured inside the data center following the NIH Security for NIH servers:

http://www.cit.nih.gov/ServiceCatalog/DATACENTERSECURITY.HTM

In addition, e-mail distribution to the Listserv is scanned using the best possible virus protection from the NIH Central e-mail system.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Kajuana Canady / 451-3392

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIDCR Intramural Research Training Awards Database (IRTA)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/27/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: No

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): NIH 09-25-0158

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NIDCR-05

- **7. System Name (Align with system Item name):** NIDCR Intramural Research Training Awards Database (IRTA)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Deborah Philp
- **10. Provide an overview of the system:** Records of Appicants and Awardees of the NIH Intramural Research Training Awards Program
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): IRTA does not currently share or disclose IIF information. It is covered by the SOR 09-25-0158 for potential disclosures.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Name, Mailing Address, Phone numbers, email Address, Education Records.

This information will be used in generating reports for our programs, but no personal information will be given in these reports. The information does contain IIF and the submission of personal information is voluntary.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No process is in place.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The IIF will be secured using role based assignments and limited computer access. Password controls are inplace for this IIF and I am the only person with access to this system. Technical controls for this system include strong password authentication and fire wall protection. Physical controls include cipher locks, key card access and Identification badges for access to database servers.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Kajuana Canady / 451-3392

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIDCR NIDCR GSS [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 9/28/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): NIDCR LAN
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: John Prue (301) 594-7552
- **10. Provide an overview of the system:** The system is a General Support System (GSS) and does not directly collect or store information.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system is a General Support System (GSS) and does not directly collect or store information. The applications/systems residing on the GSS collect and store information. Therefore, individual PIAs have been prepared and submitted for the applications/systems residing on this GSS.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name:

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/30/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIDCR Science Coding and Reporting System (SCORE)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/18/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-26-02-7304-00-202-069

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): NIH 09-25-0036

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NIDCR-03

- 7. System Name (Align with system Item name): Scientific Coding and Reporting (SCORE)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Timothy Iafolla
- **10. Provide an overview of the system:** SCORE is a scientific coding system that assigns science coding terms to specific grants, projects, and contracts funded by NIDCR. SCORE draws information about funded grants from the NIH enterprise system on grants (IMPAC II), and then adds NIDCR-specific science coding information. SCORE is used primarily for budget reporting, program evaluation, and other analysis.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The SCORE system does not currently share or disclose IIF information. It is covered by the SOR NIH 09-25-0036 for potential disclosures.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: All IIF in the SCORE system is collected and maintained by the NIH enterprise system IMPAC II. SCORE stores this information but does not collect or disseminate it.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) This process occurs through the NIH enterprise system IMPAC II. SCORE does not have separate procedures for this activity because all IIF in the SCORE system is downloaded from IMPAC II.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls: Administrative controls include role-based assignments and limited access. Technical controls include strong password authentication, firewall protection, and administrative logs. Physical controls include cipher locks, key cards, CCTV, and identification badges for access to database servers.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Kajuana Canady/451-3392

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIDCR SOFie PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/18/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No
- **5. OMB Information Collection Approval Number:** No
- **6. Other Identifying Number(s):** No
- **7. System Name (Align with system Item name):** NIH NIDCR Status of Funds Internet Edition (SOFie)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: George J. Coy
- **10. Provide an overview of the system:** SOFie is a Web-based financial reporting/tracking tool that enables NIH ICs to manipulate and report on financial transactions downloaded from the Budget & Finance database in the NIH Data Warehouse. (The NIH DW Budget & Finance database comprises data downloaded from the NIH Business System).
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No sharing or disclosures at this time.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Accounting transactions related to payroll, grants, contracts, and procurement of goods and services. IC accounting

transactions are downloaded from the Budget & Finance database in the NIH Data Warehouse. The data contains no IIF information and it used to plan, track, and report on IC fiscal budgets.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) $\rm\,N/A$

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Kajuana Canady/301-451-3392

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIDDK CellManage PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/11/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-0727-00-110-249

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): CellManage
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Frank L. Holloman
- **10. Provide an overview of the system:** CellManage is a database system that allows for efficient wireless communication procurement and management. The system allows a singular procurement purchase to cover the needs across several wireless providers/vendors. CellManage allows increased maintenance and oversight through consolidated reporting features. Database compiles multiple bills in one platform.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: NIDDK will be collecting the same information that is already listed on each wireless communication bill; i.e. call details such as minutes used. Instead of certifying paper bills, employees will certify bills via the

electronic system. No IIF is contained. NIDDK will be collecting the information to gain more oversight on its wireless devices.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) NO IIF is contained in the system therefore there is no policy in place in regards to notifying individuals about changes to the new system.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: NO IIF is contained in the system but administratively, access to the data will be limited to a system administrator who will assign access to individuals to review their own account. The server for the system is located within NIDDK's server room, which follows federal guidelines for technical and physical security.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Frank L. Holloman - 301-496-3670

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIDDK Clinical Research Core

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 09-25-01-05-02-0727-00-110-249

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0099

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): None

- 7. System Name (Align with system Item name): NIDDK Clinical Research Core
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Bethel Stannard
- **10. Provide an overview of the system:** The Clinical Research Core is an intramural NIDDK system that manages the clinical research patient samples and tracks their location and quantity used by Principal Investigators (PIs), or sent for testing at other clinical laboratories at NIH or outside NIH. At a future time, the database may be linked to CRIS by the patient's medical record number (MRN). The CRC addresses the needs of the intramural research staff and is tailored to meet the needs of a diverse range of studies.

The driving factors for use of the CRC are:

- Provide a means to handle the specialized requirements of NIDDK study processes and samples;
- Provide a mechanism for tracking the locations of the large volume of clinical samples; and,
- Allow for retrieval of data and samples for research purposes.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes

- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Yes, within NIH for clinical research only. This information, voluntary and consenual by the patient, regards diagnostic problems with scientific value that is only disclosed to appropriate medical researchers in connection with treatment of patients. The primary use of this information is to provide medical treatment at NIH. This information may be disclosed to researchers for research purposes and to HHS personnel to monitor personnel to assure that safety standards are maintained. Submission of this information is voluntary. In addition, the patient is notified that some notification or counseling of current and/or ongoing partners may be carried out through arrangements with, or referral to, local public health agencies. This includes the physician who referred them for treatment, and for certain communicable diseases, including AIDS and symptomatic HIV infection, to appropriate State and Federal government agencies, in accordance with the routine uses cited by SORN 09-26-0099. Recipients are required to maintain Privacy Act safeguards with respect to these records at all times.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The information and samples are collected from patients, outside medical entities, and the NIH Clinical Center. This information is voluntary with the consent of the patient for clinical research only within NIH. The collected data is used as an aid for clinical personnel as well as the basis for research in various diverse groups. The data consists of first name, last name, and middle initial; MRN (patient's medical record number); diagnosis and medication (liver group only); protocol number; study number; physician name; type of sample; storage location (room, freezer, shelf, rack, box, position in box); release of samples, including amount, date, to whom sent, and sample return date. Identifiable samples are released to the responsible PIs for research testing and to NIH clinical laboratories for clinical testing. Coding samples may be sent outside NIH for clinical or research testing without disclosure of the patient's identity.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Collections and use: Prior to any treatment and collection of medical data and samples, the patient signs a protocol consent form. Via consent to medical treatment and study, the patient is implicitly acknowledging the collection of medical data. The protocol consent form explicitly addresses the use and distribution of the data and samples with respect to confidentiality and the Federal Privacy Act.

System changes: There is a mechanism to amend the consent based on protocol changes. Patients are required to sign any new approved amendments. This mechanism could be used to cover changes in data policy and/or usage.

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No

- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** Technical, physical, and administrative controls are in place to ensure the security of the information. The application enforces assigned authorizations for controlling role-based access torecords at the application level using user identification and password. Role-based access is limited to the nurses and doctors conducting patient data and sample collection and research. Restricted access to privileged functions are additionally enforced by limiting such access to only system administrators, programmers, and database administrators supporting the Clinical Research Core application.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Cyrus Karimian

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIDDK EDie PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/11/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-0727-00-110-249

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0106

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): EDie
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Gwendolyn Proctor
- **10. Provide an overview of the system:** EDie is an n-tiered, web-based Intranet application consisting of server hardware and operating system software to maintain two databases for interface with the target SQL server.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): System does not share, only download employee information.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The Employee Database Internet Edition (EDie) application is a web-based employee management tool for access to NIH human resource data as an enhanced version of VEDS (Visual Employee Database System) that it replaces. It is used by multiple Institutes within NIH to track NIDDK employee information on salary, benefits, education, awards, disabilities, retirement eligibility, and other human

resource information. Access to information through EDie is restricted to specific users to perform their assigned functions and access privileges are enforced through authentication through the NIH Active Directory access controls for authorized access.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Collection and use: Information from NIH human resource records used to perform various HR activities to benefit employee. The employee provides data and consent during initial employment process upon hiring for employment with the Federal government.

System changes: Employees are notified of any system protocol changes based on data policy and/or usage with associated updating of employee consent if required.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** Technical, physical and administrative controls are in place to ensure the security of the information as described within the System Security Plan, with regular backup of data and contingency planning to restore information from any disruption and annual security awareness training refresher sessions for personnel. The system is certified and accredited as a minor application within the general support system providing IT services to NIDDK.

The information is secured through multiple levels of security and access controls established to verify the user's identity and authentication to determine user authorization for access and to perform actions requested. The access controls are supplemented with secure network services at both the NIH and NIDDK levels.

PIA Approval

PIA Reviewer Approval: Promote
PIA Reviewer Name: Cyrus Karimian

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIDDK Internet Website PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-0727-00-110-249

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0106

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): NIH NIDDK Internet Web site
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Roberta Albert
- **10. Provide an overview of the system:** The NIDDK Internet Web site system includes the development and mainentance environment for all public Web sites hosted by NIDDK. These Web sites serve as communication tools for disseminating information to support the mission of the Institute.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): On http://intramural.niddk.nih.gov IIF from Intramural researchers is displayed to the general public in order to provide contact information and a description of the research conducted. Ref.SOR #: 09-25-0106
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system hosts web based forms that offer one way the public can communicate with NIDDK. These forms are designed to

collect a name, mailing address, phone number, comment, or email address; however, the user is never required to provide this information. This information is then forwarded via email to either NIDDK's webmaster or the Office of Public Liaison. (This information is never captured, stored or maintained on the web system.) The forwarded email communication, when received by the designated office, is addressed and then promptly deleted. The Office of Public Liaison may keep email for several months in order to provide follow up actions.

IIF from Intramural researchers (name, photograph, lab location, email address, lab phone, lab fax, research statement, education info, and publications) is collected and stored through NIDDK's Intranet system and displayed on the Internet system (public access web pages). For example please see http://intramural.niddk.nih.gov/research/alphafaculty.asp. The submission of information is voluntary.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) All NIDDK Web pages display a link called "Privacy" which directs users to our Institute's privacy policy. This page can be seen at http://www.niddk.nih.gov/tools/privacy.htm.

This page explains that NIDDK does not capture personally identifiable information unless provided by the user. This page also offers contact information for NIDDK's Privacy officer, in the event the user has additional questions.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: NIH NIDDK Internet Web site system does not store IIF.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Cyrus Karimian

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Pla

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIDDK Intranet Website PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/11/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-0727-00-110-249

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0216

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): NIH NIDDK Intranet Web site
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Roberta Albert
- **10. Provide an overview of the system:** The NIDDK Intranet Web site system provides and manages information that supports the work of NIDDK employees.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The IIF collected by the Intranet system is only shared/disclosed to NIDDK staff responsible for managing that information. Ref SOR # 09-25-0216
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: NIDDK Intranet uses a web based form to collect staff registration information for Institute retreats. The type of information collected includes staff name, lab address, phone number, email address, whether they are presenting, special dietary requirements, transportation needs and roommate preference. This

information is only used by administrative staff responsible for organizing these retreats. Supplying this personal information through the system is NOT mandatory.

In addition, another form collects Investigator information such as name, lab address, email, education, research statement, publications, research interests, and a photograph. This information is posted on the public facing website located at http://intramural.niddk.nih.gov . Only web staff and owner of the content have direct access to this information within the intranet web system. The submission of this information is voluntary.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Both web forms display language that indicates the intended use of the collected information and provides contact information for the staff handling this collected information. The forms that collect Investigator information (for display on the public website) additionally contain a link titled "Privacy" which leads to a page that posts NIDDK's privacy policy and provides contact information for NIDDK's Privacy Officer. Investigators are required to review and update their own information on a yearly basis. All changes to the system are approved by an Intramural Web Advisory Group and then investigators are notified via email.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The Intranet web system requires user authentication provided by active directory. Further controls are put in place on individual IIF containers. The IIF for staff retreats are contained within a spreadsheet in a restricted folder. This folder can only be accessed by web and administrative staff responsible for retreat. The IIF for the public facing website can only be accessed by web staff and the owner of the content. All IIF are contained on servers that are located behind firewalls, password protected and are physically locked in a server room.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Cyrus Karimian

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIDDK NIDDKnet [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/11/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 09-25-01-05-02-0727-00-110-249

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): None

- 7. System Name (Align with system Item name): NIH NIDDK NIDDKnet General Support System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Chuck Pham
- 10. Provide an overview of the system: The NIH NIDDK NIDDKnet is a series of Local Area Networks (LAN) to form a general support system to facilitate management of network services for data processing and communications needs, providing authorized access to information systems and major applications within the NIH infrastructure. NIDDKnet provides a common network environment under a single authority (NIDDK) and security measures to connect servers, workstations, printers, networks, applications, storage devices, and other IT devices, regardless of physical location, to enable users to share resources and communicate directly with each other over a moderately-sized geographic area for connection to the NIHnet.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Yes, within NIH for clinical research only.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: NIDDKnet supports data and communication needs to share network devices and and functions within NIDDK and to access resources provided by NIH, including appropriate protocols and related services for retrieval of data for research purposes and administrative functions. Applications and databases processing, storing and transmitting clinical research information that contain PII, are transmitted using network services supported by NIDDKnet. The information that NIDDK collects from patients, outside medical entities, and the NIH Clinical Center are used as an aid for clinical personnel as well as the basis for research in diabetes, digestive, and kidney diseases. The data, dependent on major application collecting and storing the data, consists of basic demographics, laboratory test results, medications, diagnostic images and other medical data. This data is the minimum necessary to present a clinical description of a patient and to allow retrostrective research on clinical outcomes. Data submission is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Collection and use: Prior to any treatment and collection of medical data, the patient signs a protocol consent form. Via consent to medical treatment, the patient is implicitly acknowledging the collection of medical data. The protocol consent form explicitly addresses the use and distribution of that data with respect to confidentiality and the Federal Privacy Act.

System changes: There is a mechanism to amend the consent based on protocol changes. Patients are required to sign any new approved amendments. This mechanism could be used to cover changes in data policy and/or usage.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** Technical, physical and administrative controls selected from NIST SP 800-53 and the NIH Enterprise Information Security Plan (EISP) are in place to ensure the security of the information. The general support system and component applications operating within a defense-in-depth approach for managing the resources of people, technology, and operations provide a mechanism to enforce assigned

authorizations for controlling role-based access to records at the application-level using user identification and password consistent with the assigned privilege level for their individual access accountability. Role-based access is limited to the nurses and doctors conducting patient data collection and research. Restricted access to privileged functions additionally uses the enforcement mechanism of two-factor authentication using RSA tokens. Privileged access is limited to the system administrators, programmers, and database administrators supporting specific applications or those assigned to support network devices and operations at the general support system level.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Cyrus Karimian

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIDDK Research Data Storage and Analysis [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/11/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-8412-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): NIH NIDDK Patient Information System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Tahir Rameez
- **10. Provide an overview of the system:** Medical data storage and analysis system involving the study of diabetes, obesity and related diseases among American Indian tribes, in particular the Pima of Arizona.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): IIF is made available to designated administrative personnel for data collection and maintenance. IIF is made available to designated NIH research scientists for analysis in the context of diabetes and obesity research and treatment. Data is shared with Indian Health Service and the Gila River Indian Community through the Gila River Health Care Corporation, both as research findings and as records affecting patient care.

Also see Privacy Act System of Records (SOR) Number 09-25-0200.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Medical data is collected under IRB approved protocols at periodic examinations in support of various research studies among native Americans principally involving diabetes and obesity. The data contains IIF. Participation in the research as well as submission of the IIF is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Subjects are required to sign a consent form before any information can be collected. The form describes what is to be collected, the reasons therefor, and the destination of that data.

In the event of a major system change subjects still living will be asked to re-consent to such changes. Ongoing demographic data is maintained by the system to facilitate contacting of subjects.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** Computerized copies of the data collected are physically maintained on a computer server. Paper records are maintained in a designated records room. Both the server and paper records are protected by key entry doors and further protected 24/7 by security guards in the context of overall campus security. Access to both systems is restricted to personnel determined administratively on a need to know basis. Access to computerized data is password restricted to authorized personnel.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Cyrus Karimian

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIDDK Status of Funds Internet Edition (SoFIE)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-0727-00-110-249

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0099

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): None

- 7. System Name (Align with system Item name): Status of Funds Internet Edition (SOFie)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Gwenoldyn Proctor
- **10. Provide an overview of the system:** SOFie is a web-based application supports several offices within NIH for authorized users for financial reporting and analysis functionality, including tracking expenditures within a fiscal year (FY).
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Not applicable
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: SOFie provides NIDDK with distributed budgeting and planning tools for detailed spending analysis of data within the

NIH financial reporting system as an enhanced version of the Visual Status of Funds (VSOF) that it replaces and is not a source database for other information systems.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) System does not process PII to obtain consent. Data consists of IC financial expeditures.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** PII is not used. The SOFie application is used by multiple Institutes within NIH to track NIDDK budget and other financial expediture information. Access to information through SOFie is restricted to specific users to perform their assigned functions and access privileges are enforced through authentication through the NIH Active Directory access controls for authorized access.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Cyrus Karimian

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 12/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIDDK Technology Transfer (TTTS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/11/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-0727-110-249

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0168

5. OMB Information Collection Approval Number: NO

6. Other Identifying Number(s): 09-25-0168

- **7. System Name (Align with system Item name):** Technology Transfer Tracking System Health Service by its Employees, Grantees, Fellowship Recipients, and Contractors, HHS/NIH/OD
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Patricia Lake
- 10. Provide an overview of the system: The Technology Transfer Tracking System (TTTS) is a commercial off-the-shelf (COTS) product developed by Knowledge Sharing Systems that is a customizable database application for managing and tracking data and processes related to protecting and transferring technologies including patenting and agreements negotiations and pre-issuance and post-execution monitoring. The TTTS system enables the Office of Technology Transfer Development to identify legal deadlines, store agreements and technologies, provide information access to technology managers and investigators, track events, and automate processes. The system automatically generates documents, logs events, and logs due dates when certain criteria are met or triggers are hit.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes

- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Only employees of NIDDK and contractors working on the NIDDK domain can access the names, work addresses and phone numbers in the system provided for the purpose of contacting or tracking contacts of the persons who provided their information for that person. Reference SOR #:09-25-0168
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system contains PII in the form of cell phone numbers and also contacts information, including name, work address, work e-mail address, work phone numbers and in a few instances, for persons who are involved in collaborations or negotiations for collaborations with NIDDK or for transfer of scientific materials, including NIDDK employees. The information is used to contact persons for communications involving the relevant collaboration or request. No particular information is mandatory.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No processes are in place to notify individuals whose information is in the system.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The system is accessible only through a username and password. The policy for passwords is that they include at least one number and at least one capital letter. Only the administrative access permits permissions of users to be provided or removed. The system is operated and accessed only on government-owned computer systems, behind a firewall. The user must be accessing the system from a recognized and previously-identified static IP address from within the NIDDK.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Cyrus Karimian

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIDDK Teleresults PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/11/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-0727-00-110-249

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0099

5. OMB Information Collection Approval Number: NO

6. Other Identifying Number(s): NIDDK P.O. number 263-MK-015345 for Teleresults

7. System Name (Align with system Item name): Teleresults

- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Dr. Michael Ring
- **10. Provide an overview of the system:** The Teleresults/Lab Grabber system manages the clinical and research data for patients of the Transplant Lab (Kidney Disease Branch) and the Diabetes Branch. The system was installed specifically for the needs of the solid organ transplant floor, but its use now includes other patients as well.

The driving factors for the installation of the system were:

- Provide a means to handle the specialized requirements of transplant processes
- Provide a location to save the large volume of outside clinical data
- Allow retrieval of data for research purposes.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes

- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Walter Reed Army Medical Center for medical evaluation and consults. In addition, please refer to SOR #09-25-0099
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The information is collected from patients, outside medical entities, and the NIH Clinical Center. The collected data is used as an aid for clinical personnel as well as the basis for research in organ transplant and immunology. The data consists of basic demographics, laboratory test results, medications, and other medical data. This data is the minimum necessary to present a clinical description of a patient and to allow retrospective research on clinical outcomes. Data submission is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Collection and use: Prior to any treatment and collection of medical data, the patient signs a protocol consent form. Via consent to medical treatment, the patient is implicitly acknowledging the collection of medical data. The protocol consent form explicitly addresses the use and distribution of that data with respect to confidentality and the Federal Privacy Act.

System changes: There is a mechanism to amend the consent based on protocol changes. Patients are required to sign any new approved amendments. This mechanism could be used to cover changes in data policy and/or usage. Given the nature of the system (clinical/research), we have had no need for such amendments based on data policy nor do we anticipate any.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Technical, Physical and administrative controls are in place to ensure the security of the information. These include an up to date System Security Plan, Contingency Plan, regular offsite backup of the data, and yearly security awareness training for all personnel. The system is certified and accredited.

The information is secured through multiple levels of security and access controls have been established to authenticate the user and to determine if the user has the authorization to perform

actions requested. The access controls are supplemented with a secure network at both NIH and NIDDK.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Cyrus Karimian

Sr. Official for Privacy Approval: Promote **Sr. Official for Privacy Name:** Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIEHS CRU Clinical Management System

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/4/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: NO

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): n/a

- **7. System Name (Align with system Item name):** NIH NIEHS CRU Clinical Management System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Kimberly Burnett-Hoke
- **10. Provide an overview of the system:** The NIEHS Clinical Management System (eSphere software name) is an Oracle based database and work flow mapping system that will serve as the main patient record, scheduling, and data management tool for the new CRU. The system will hold patient records and medical history as approved by the NIEHS IRB, physician educational and credentialing/privileging data, calendar scheduling, and some basic statistical analysis tools. The system is needed because the NIEHS CRU is a new out patient based clinical reserach clinic that will open and begin seeing patients in January of 2009.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The purpose is to track, monitor, and evaluate NIH clinical, basic, and population-based research activities and protocols. The system may share or disclose information to NIH researchers, agency contractors, consultants, etc. who have been engaged by the agency to perform reserach

related activities. Other discolusres may inlude Congress, the Department of Health and Human Services, the Department of Justice, and the Public Health Service. Disclosures and sharing of information will only be for and will be in compliance of SORN 09-25-0200.

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The information is used to document, track, monitor, analyze, and evaluate NIH clinical, basic, and population-based reserach activities and protocols. The exact data collected for each protocol and from each individual will differ based on final approval of the NIEHS IRB but could include name, date of birth, SSN, mailing address, phone numbers, previous medical records and medical history (as well as newly generated medical notes from new procedures), email addresses, educational levels, military service and deployment locations, foreign activities, height, weight, gender, lab values, and other yet to be determined data.

Submission of all data is voluntary, but is a required condition to participate in the research protocol/activity. Failure to provide any or all required data may exclude the participant from reserach activity eligibility.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) All IIF that is being collected is clearly communicated and listed on the consent forms that are required to be read and signed by all reserach protocol/activity participants. These forms clearly let the participant know what is being collected from them, for what purpose, and who al will see it. It also asks permission to recontact the individuals in the future if changes are needed. If participants elect not o be recontacted any changes will result in that person's IIF and dat being destroyed. If re-contact is approved on the original consent forms, any changes will result in re-contact at which time new consent forms will be presented and signed outlining any changes. All consent forms (and all research protocol/activity forms and IIF data) must be reviewed, approved, and cleared by the NIEHS IRB prior to any data being collected.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The system is password protected according to NIH policy. The system is housed in the NIEHS facility with tightly controlled access. Please

refer to the NIEHS General Support System Certification and Accredidation Package for more details.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Kim Minneman

Sr. Official for Privacy Approval: Promote **Sr. Official for Privacy Name:** Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIEHS DERT Extramural Grantee Data Collection (DEGDC)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 2/28/2012

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: Not obtained yet.

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH NIEHS DERT Extramural Grantee Data Collection (DEGDC)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Kristi Pettibone
- **10. Provide an overview of the system:** We are seeking clearance from the Office of Management and Budget to collect data on grantee outcomes and impacts that are not reported in their progress reports. We are also asking to collect information on their satisfaction with the program management process. We will collect the information using a survey that will be available as a paper-based or a web-based survey. The information collected will be stored in an electronic database. This electronic database is the system. We will use a unique identifier for each respondent rather than a name.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) Outcome information to be collected includes measures of agency-funded research resulting in dissemination of findings, investigator career development, grant-funded knowledge and products, commercial products and drugs, laws, regulations and standards, guidelines and recommendations, information on patents and new drug applications and community outreach and public awareness relevant to extramural research funding and emerging areas of research. Satisfaction information to be collected includes measures of satisfaction with the type of funding or program management mechanism used, challenges and benefits with the program support received, and gaps in the research.
- (2) Information gained from this primary data collection will be used in conjunction with data from grantee progress reports and presentations at grantee meetings to inform internal programs and new funding initiatives. The information will be used to inform programmatic improvements within the National Institute of Environmental Health Science's Division of Extramural Research and Training.
- (3) The data collected does not include any PII
- (4) The data collected does not include any PII so it is neither voluntary nor mandatory. Completion of the survey is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No PII will be collected in this survey.

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No PII will be collected on the system.

PIA Approval

PIA Reviewer Approval: Promote
PIA Reviewer Name: Kim Minneman

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 3/7/2012

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIEHS Drugmatrix Database and Analysis Tool (DDAT)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH NIEHS Drugmatric Database and Analysis Tool (DDAT)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Scott Auerbach
- **10. Provide an overview of the system:** The Drugmatrix database and analysis tool is an NIEHS-owned toxicogenomic resource that allows for analysis of gene expression data from rats. This resource is of interest to those that work in the field of toxicology and environmental disease. The core component of Drugmatrix is a collection of gene expression studies derived from tissues/organs of rats exposed to a variety of drugs and well-documented toxicants. The interface allows users to analyze existing Drugmatrix data or to upload their own data for comparison and analysis using a variety of tools.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) The toxicology information collected will be from rats only., (2) NIEHS will use the information for toxicity studies., (3) The information does not contain PII., and (4) N/A
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Kim Minneman

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/9/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIEHS Employee Database Internet Edition

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-90-0018, 09-90-0024, 09-25-0216

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): None

- **7. System Name (Align with system Item name):** NIH NIEHS Employee Database Internet Edition (EDie)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Lisa Rogers
- **10. Provide an overview of the system:** EDie is an intranet-based application primarily used to manage and track personnel information. Authority for maintenance of the system: 5 U.S.C. 1302, 2951, 4118, 4308, 4506, 7501, 7511, 7521 and Executive Order 10561.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Information is intended for internal administrative use only and will not be shared by other entities. Refer to SORN 09-90-0018, SORN 09-90-0024 and SORN 09-25-0216.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: EDie tracks all information

pertinent to a personnel file for the purpose of personnel management activities. Information is collected from employees via the Human Resources Database (HRDB) system, Fellowship Payment System (FPS), nVision Data Warehouse and NIH Enterprise Directory (NED). Uses consist of the following: a) tracking a time-limited appointment to ensure renewals are done in a timely manner, thereby avoiding any break in service; b) ensuring that allocated FTE ceilings are maintained; c) ensuring salary equity for various hiring mechanisms; d) providing reports requested by the NIH Director, the IC Director, and other management staff, as requested; and e) maintaining lists of non-FTEs, special volunteers, contractors, and other hiring appointments. The type of information collected constitutes PII and includes, but is not limited to the following data elements: name, home address, home phone number, social security number and date of birth. The PII collected is mandatory for all employees.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) PII in the system is downloaded from the HRDB, FPS, nVision Data Warehouse and NED. Changes to HRDB or changes in the way information is used is relayed to employees via official notices from the NIH Office of Human Resources (OHR). Individuals are notified of the collection and use of the data as part of the hiring process. This is a mandatory requirement of potential job applicants seeking employment at NIH.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: PII stored in EDie is accessed by a very limited number of administrative staff with a "need-to-know" status. EDie is password protected and sensitive data is encrypted. The system is located at NIEHS, Bldg. 104, Data Center, Research Triangle Park, NC, behind the NIH firewall.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Kim Minneman

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/9/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIEHS GuLF Worker Study System (GWSS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 9/27/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: OMB Control Number: 0925-0626; ICR

Reference Number: 201012-0925-004

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH NIEHS GuLF Worker Study System (GWSS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: David Johndrow
- 10. Provide an overview of the system: The GuLF Worker Study System (GWSS) is a minor application whose purpose is to support the GuLF STUDY's subject recruitment and data collection efforts. This system will collect data pertaining to participant clean-up-related tasks, demographic and socioeconomic factors, occupational and health histories, psychosocial factors, and physical and mental health. A total of approximately 55,000 persons are expected to be enrolled into the cohort. The GWSS is a secure IT system which consists of commercially available research study software from DatStat (http://www.datstat.com), Microsoft SQL Server 2008 databases, and Avaya Dialer telephone software running on Windows 2008 Rel. 2. The DatStat product, Illume, is the tool used to design, build, test, and manage questionnaires (surveys). Illume is also the tool used for importing and exporting data and managing the data. The DatStat product, Discovery, manages the workflow of the trained personnel who administers computer-assisted telephone interviews (CATI) and computer-assisted personal interviews (CAPI).
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass

through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Collection of this information is authorized under 5 U.S.C. 552a. The primary use of this information is for use in a research study entitled GuLF STUDY: GuLF Long-Term Follow Up Study, sponsored by the National Institute of Environmental Health Sciences (NIEHS). The mission of NIEHS is to reduce the burden of human illness and disability by understanding how environment influences the development and progression of disease. NIEHS pursues this mission through multidisciplinary biomedical research and through communication of research results to regulatory agencies, clinicians, the scientific community, and the general public. The GWSS enables this research.

PII collected as part of this study includes name, address, phone numbers, date of birth, race/ethnicity, social security number, demographic and socioeconomic factors, and medical information. Information is not disclosed to persons outside of the study team, as protected by a Certificate of Confidentiality. Submission of this information is required if a participant wishes to participate in the research study.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Individuals whose PII is collected undergo an informed consent process with a trained member of the study team. Participants are told that their information is protected through a Certificate of Confidentiality and that it may be placed, in a coded or de-identified format, in a database to be used by other researchers. There are no major system changes planned for this research study database that would require participant notification.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The GWSS adheres to SRA corporate policies, CO-POL-27 Information Security Governance Policy and IT-POL-14 Information Security Policy, which detail the formal policy and guidelines for the Security Assessment and Authorization of SRA systems. These policies are reviewed annually. The GWSS is a standalone system with no interconnections to other information systems outside of the authorization boundary. The System Security Plan (SSP) documents an initial security control assessment and is provided to the authorizing official (AO) as a part of the NIEHS authorization to operate process. The SSP uses the NIST SP 800-53 security baseline for a moderate impact system to evaluate the security controls in the GWSS in order to document the extent to which the controls are implemented. The SSP requires substantial administrative, technical and physical controls for access to all project data. Specifically: all project data that contains PII is restricted to project folders, SurveyNet and the SAVVIS data center for study outcomes. As such, administrative controls in effect include the SSP, corporate access policies that restrict access to cleared project personnel only, backup plans that restrict the inclusion of PII for offsite storage, and the inprocess system certification and accreditation. Access to PII is physically controlled through the use of two-factor user authentication, a dedicated Firewall and VPN architecture, database encryption methods and forced password reset/change policies. Physical access to systems that contain PII is controlled via required guards, personnel ID badges, cipher locks, biometrics access-control and is subject to regular monitoring via closed circuit television. Physical access to systems is granted to only project IT support staff and is logged. Sensitive PII adheres to the same controls listed above except that it is restricted to only the SAVVIS datacenter which is the system component that contains by far the most controls in terms of access and go well beyond those that are listed here (mantraps, 24x7 monitoring, etc.)

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Kim Minneman

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/28/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIEHS Hazardous Worker Training Data Management System

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: 0925-0348

6. Other Identifying Number(s): none

- 7. System Name (Align with system Item name): NIH NIEHS Hazardous Worker Training Data Management System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Joseph "Chip" Hughes, Jr.
- **10. Provide an overview of the system:** System provides functionality not available via central systems to support the mission of the hazardous worker education and training program.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): N/A, there is no IIF information in the system.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The information collected includes programmatic data from NIEHS Worker Education and Training grantees such as progress reports and training data. The data management system provides a convenient way for

authorized users to input and access their training data including - course curricula, progress report materials, projected and actual training data, student demographic data, and annual reports; while providing quality control for each submission.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) There is no IIF information located in the system.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: There is no IIF information in the system. (Information is stored on a secure Oracle 9i database that is password protected and is behind the NIH and NIEHS firewalls.)

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Kim Minneman

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIEHS Health & Safety Systems (HSS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-6299-00-110-249

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 9250105

5. OMB Information Collection Approval Number: n/a

6. Other Identifying Number(s): none

- 7. System Name (Align with system Item name): NIH NIEHS Health and Safety Systems
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Scott Merkle
- **10. Provide an overview of the system:** Systems relating to monitoring and tracking the NIEHS health and safety program in conjunction with the NIH mission.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): No individual information is shared by this system. However, procedures in SOR #09250105 apply
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Information collected is needed to assure and monitor employee health and safety in the NIEHS workplace and to comply with safety and health recordkeeping regulations. Information is obtained from other NIH

systems or from NIEHS employees in an on-site medical facility or when safety incidents occur. Occupational health evaluations are mandatory for certain laboratory employees. The types of PII maintained in the system include basic demographics (e.g., name, NED employee ID number, date of birth, personal contact information, and employment status) and summary notes on workplace injury incidents and summary results of exposure and occupational health evaluations.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Information is collected only from employees in conjunction with their job responsibilities. Individuals are made aware of the program when they are hired, the Health and Safety Office and their supervisors would inform them of changes in requirements.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Information is maintained on a database with access only by authorized users with a valid password. Facility is locked with limited key card entry.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Kim Minneman

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/30/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIEHS NCI Agricultural Health Study (AHS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 9/22/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

- **4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** 09-25-0200, Clinical, Epidemiologic, and Biometric Studies of the National Institutes of Health (NIH), HHS/NIH/OD
- **5. OMB Information Collection Approval Number:** 0925-0406
- 6. Other Identifying Number(s): AHSW
- 7. System Name (Align with system Item name): NIH NIEHS NCI Agricultural Health Study (AHS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Novie Beth Ragan
- **10. Provide an overview of the system:** The Agricultural Health Study system of records collects clinical and epidemiological data on health volunteer persons who are part of the Agricultural Health Study cohort, for the purpose of scientific analysis and publication of epidemiological research. AHS is a collaborative effort involving the National Cancer Institue (NCI), the National Institute of Environmental Health Sciences (NIEHS), and the U.S. Environmental Protection Agency (EPA).
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Disclosure of AHS PII:

National Death Index (NDI) - Annual match with NDI Plus files.

Internal Revenue Service - to obtain updated address information - now stored at Westat (for NCI); will be stored at coordinating center (TBA) for AHS Phase IV (for NCI).

Information Management Services - IMS - separately contracted by NCI - performs data analyses for NCI using analytic datasets. Analytic Data (including date of birth, but not including other personal information) are shared among members of the AHS research team at NCI, NIEHS, EPA.

<Names, addresses and phone numbers of research subjects are not stored in analytic databases, records or files hosted at NIH, NIEHS, NCI or EPA. IIF information is not shared on research participants, except date of birth, which is used for scientific research analysis purposes only>

Westat – separately contracted by NCI – currently holds the full AHS participant contact database, including date of birth as well as other personal identifying information for all AHS participants – and handles all direct interactions with Iowa and North Carolina participants for NCI studies within the AHS.

Upon award of the AHS Phase IV Coordinating Center Contract, anticipated by September 30, 2011, the successful offeror will take over the AHS participant contact database.

Westat - separately contracted by NIEHS – performs data analyses for NIEHS. Analytic Data (including date of birth, but not including other personal information) are shared among members of the AHS research team at NIEHS.

<Names, addresses and phone numbers of research subjects are not stored in analytic databases, records or files hosted at NIH, NIEHS, NCI or EPA. IIF information is not shared on research participants, except date of birth, which is used for scientific research analysis purposes only> Social and Scientific Systems - SSS – separately contracted by NIEHS – handles all direct interactions with AHS participants in NIEHS substudies only: namely AHS Lung Health Study, GAP Study, AHS Autoimmune Study, GENARM Study, SAFE Study and FAME Study.

Names, addresses and phone numbers of AHS NIEHS add-on research subjects are stored in secure and locked databases, records and / or files hosted at Social and Scientific Systems (SSS).

This system is also covered und the Privacy Act System of Records Notice 09-25-0200.

North Carolina Field Station - Battelle CPRHE, Durham, NC - separately contracted by NCI - handles all direct interactions with NC participants.

National Death Index (NDI) - Annual match with NDI Plus files.

Internal Revenue Service - to obtain updated address information which is stored at the field stations.

<Names, addresses and phone numbers of research subjects are not stored in analytic databases, records or files hosted at NIH, NIEHS, NCI or EPA. IIF information is not shared on research participants, except date of birth, which is used for scientific research analysis purposes only>

Information Management Services - IMS - separately contracted by NCI - performs data analyses for NCI using analytic datasets. Analytic Data (including date of birth, but not including other personal information) are shared among members of the AHS research team at NCI, NIEHS, EPA.

Westat - separately contracted by NIEHS – performs data analyses for NIEHS. Analytic Data (including date of birth, but not including other personal information) are shared among members of the AHS research team at NIEHS

Iowa Field Station - University of Iowa - separately contracted by NCI - handles all direct interactions with Iowa participants.

North Carolina Field Station - Battelle CPRHE, Durham, NC - separately contracted by NCI - handles all direct interactions with NC participants.

National Death Index (NDI) - Annual match with NDI Plus files.

Internal Revenue Service - to obtain updated address information which is stored at the field stations.

<Names, addresses and phone numbers of

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: AHS analytic data do not contain direct identifiers such as name, address, or SSNs.

The NCI shares PII with NDI and the IRS when performing matches to the NDI and IRS files.

Contact information (name, address, phone number) for full cohort is stored at NCI contractor Westat in anticipation of use in future substudies, cohort maintenance purposes (e.g., possible mailings of study update newsletters), and matching with state and national vital statistics and health registries.

Upon award of AHS Phase 4 contract, AHS contact information for full cohort will be stored at the NCI Coordinating Center.

Participation is voluntary; full and open consent is required before information is collected.

The AHS system collects a wide variety of clinical information including pesticide application histories, medical histories, health information, exposure measurements from field instruments, and questionnaire data.

All IIF (except date of birth) on full cohort research subjects is kept at the Westat (NCI contractor) sites and are not available to investigators.

All IIF (except date of birth) on the sub-sets of AHS cohort research subjects who are participants in NIEHS sub-studies (namely AHS Lung Health Study, GAP Study, AHS Autoimmune Study, GENARM Study, SAFE Study and FAME Study) are kept at SSS (NIEHS contractor) sites and are not available to investigators.

PII collected and maintained on all AHS participants includes name, date of birth, social security number, mailing address, phone number, and pesticide application certificate types.

PII collected, maintained, and updated for NIEHS sub-studies (namely AHS Lung Health Study, GAP Study, AHS Autoimmune Study, GENARM Study, SAFE Study and FAME Study) for AHS participants includes name, date of birth, social security number, mailing address, phone number, and pesticide application certificate types.

Monthly updates to AHS addresses, phone numbers and other PII collected by SSS for NIEHS sub-studies (namely AHS Lung Health Study, GAP Study, AHS Autoimmune Study, GENARM Study, SAFE Study and FAME Study) are sent via encrypted transmissions to Westat (NCI contractor) to update the full AHS cohort data on a monthly basis.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) There have been no major changes in the system and none are contemplated. NCI and NIEHS IRBs would review any major changes prior to implementation and provide us with guidance on any needed notification and consent requirements.

As part of the research protocol, all subjects are required to fill out consent documents which describe how their information will be used. If these change, participants will be contacted and informed.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Extensive safeguards are in place to ensure the confidentiality of each subject is protected.

TECHNICAL CONTROLS: Each AHS subject is assigned a six-digit ID number; these AHS IDs are used for any references to subjects on an individual basis. Names and other indentifying information for full AHS cohort are kept in separate databases maintained by Westat, and not comingled with the analytic data. These data files are joined only for performing linkages to the mortality and cancer incidences databases. Several layers of passwords exist to ensure

unauthorized access to electronically stored data is not permitted. The system is protected by firewalls, intrusion detection systems, and passwords. There are comprehensive system security and contingency plans in place. An Incident Response capability is maintained.

Similarly, names and other identifying information for NIEHS AHS sub-studies (namely AHS Lung Health Study, GAP Study, AHS Autoimmune Study, GENARM Study, SAFE Study and FAME Study) are kept in separate databases maintained by SSS, and not comingled with analytic data. Several layers of passwords exist to ensure unauthorized access to electronically stored data. The system is protected by firewalls, intrusion detection systems, and passwords. There are comprehensive system security and continency plans in place and an incident response capability is maintained.

PHYSICAL CONTROLS: For NIEHS sub-studies (namely AHS Lung Health Study, GAP Study, AHS Autoimmune Study, GENARM Study, SAFE Study and FAME Study), hard copies of questionnaires that contain any personal information are stored in locked rooms at SSS (NIEHS contractor). All personnel involved with the project have signed confidentiality agreements. Badged access is required for all server rooms, with badge lockdown policies in line with existing NIH procedures. Physical racks are key-locked. Data center is behind keycard access with 100% identification badge check by 24/7 security guard.

For the full AHS, PII data are stored at Westat (NCI contractor), where these files are stored in a directory accessible only to the project's lead systems manager and one programmer. They are also encrypted when not in use and the encryption key is known only by the same two staff members. The files are never left in unencrypted form over night so that automatic backups contain only encrypted versions. After the field stations confirm receipt of readable files, the copies at Westat are deleted.

MANAGEMENT CONTROLS: All PIs and investigators are approved by an AHS central board before gaining access to analytical data (including date of birth). Personal contact information for cohort is not available to NIH investigators.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Kim Minneman

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIEHS NIEHS General Support System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/4/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-02-00-01-3109-00-109-026

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): n/a

5. OMB Information Collection Approval Number: n/a

6. Other Identifying Number(s): none

- 7. System Name (Align with system Item name): NIEHS General Support System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: John Grovenstein
- **10. Provide an overview of the system:** This is the certified secure infrastructure that supports NIEHS operations. NIEHS applications and database reside on this system. There is no specific data collection system
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Infrastructure only. Individual systems are addressed separately

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Infrastructure only. Individual systems are addressed separately

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: Yes
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No IIF

PIA Approval

PIA Reviewer Approval: Promote
PIA Reviewer Name: Kim Minneman

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIEHS NTP Chemical Tracking System (Chemtrack)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 9/8/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A
- **5. OMB Information Collection Approval Number:** N/A
- 6. Other Identifying Number(s): N/A
- **7. System Name (Align with system Item name):** NIH NIEHS NTP Chemical Tracking System (Chemtrack)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Beth Bowden
- **10. Provide an overview of the system:** The National Toxicology Program Chemical Tracking Database application supports all aspects of the NTP process at a high level. The application collects all aspects of study administration and study milestones. The application generates various reports for project review.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) Chemtrack contains

tracking information for National Toxicology Program (NTP) committees, nominations, studies and test articles. It is used to manage NTP studies, nominations and test articles. It only contains information from Contracts or the Federal government. (2) The NTP uses Chemtrack to manage its research portfolio. (3) The information does not contain PII. (4) Not applicable.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A - no PII.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Kim Minneman

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIEHS NTP Database Search (NTP DBSearch)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 9/8/2011

2. OPDIV Name: NIH

- 3. Unique Project Identifier (UPI) Number:
- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A
- **5. OMB Information Collection Approval Number:** N/A
- 6. Other Identifying Number(s): N/A
- **7. System Name (Align with system Item name):** NIH NIEHS NTP Database Search (NTP DBSearch)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Beth Bowden
- **10. Provide an overview of the system:** The National Toxicology Program Database Search application allows NTP researchers and public users to search for, view, and download data from NTP studies.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\rm N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) The National Toxicology Program (NTP) Database search makes available to the public detailed scientific data on NTP

studies. It only contains information from Contracts or the Federal government. (2) To make NTP scientific data available to the general public. (3) The information contains no PII. (4) Not applicable.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A - no PII.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Kim Minneman

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIEHS NTP Genetic Toxicology (Genetox)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 9/8/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A
- **5. OMB Information Collection Approval Number:** N/A
- 6. Other Identifying Number(s): N/A
- 7. System Name (Align with system Item name): NIH NIEHS NTP Genetic Toxicology (Genetox)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Beth Bowden
- **10. Provide an overview of the system:** The Genetic Toxicology (Genetox) application collects data on Salmonella and Micronucleus assays and generates reports on these assays as well as other Genetic Toxicology assays. The other assays are Drosophilae, Chinese Hamster Ovary, Chromosome Aberration, and Sister Chromatid Exchange.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) Genetox collects detailed

information on Micronculeus and Salmonella assays from Contract Laboratories. It reports on these assays as well as CHO, Chromosome Aberations, Sister Chromatid Exchange, and other Genetic Toxicology assays that were once used. It only contains information from Contracts or the Federal Government. (2) To hold and report on detailed data on the genetic toxicity of verious chemicals and test articles. (3) The information does not contain PII. (4) Not applicable.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A - no PII.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Kim Minneman

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIEHS Pegasys PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/4/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: NO

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0216

5. OMB Information Collection Approval Number: n/a

6. Other Identifying Number(s): n/a

- 7. System Name (Align with system Item name): Pegasys
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: John Grovenstein
- **10. Provide an overview of the system:** System identifies employees and contractors with badges and allows authorized badge holders to access the NIEHS facility. System issues badges to NIH & NIEHS personnel.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The system is used to issue badges and is used only by staff involved with issuing badges. SOR# 09-25-0216
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The information is used to identify badge holders and issue badges that allow employees and contractors access to NIEHS facilities. Information is copied from the NIH directory (NED) or is provided by the badge holder. The only IIF collected in this system is a photo for the badge. Information can be

retrieved by name. The information is mandatory for employees and others who are given NIH badges.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) If changes are made to the badge system, personnel are notified by all-hands e-mail. Information that is not already in the NIH Enterprise Directory is collected from individuals when they request a badge. Only individuals who are in NED are eligible for badges. The information is used by security personnel to issue badges. It is not shared. The photo is required for a badge. Individuals may report any changes in information to security personnel who will change it.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The system is password protected according to NIH policy. System access is limited to those who use or manage the system. The system is housed in the NIEHS facility with tightly controlled access including guards, key cards and badges. The NIH/NIEHS network is protected by firewall and intrusion detection systems. Remote access requires VPN ..

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Kim Minneman

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIEHS Small Program Support Systems (SPSS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/4/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-6299-00-110-249

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): n/a

5. OMB Information Collection Approval Number: n/a

6. Other Identifying Number(s): n/a

- 7. System Name (Align with system Item name): Small Program Support Systems
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Heather Nicholas
- **10. Provide an overview of the system:** Small applications that support NIEHS program areas including systems for: management and evaluation of programs and research areas; local workflow; tracking scientific activities; project management; library services; information dissemination; and managing application and technical standards for local systems.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No IIF
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Data is collected in conjunction with NIEHS business processes or activity. It is used to track, administer or

perform NIEHS activities in conjunction with its programs. Systems that have private information are not included. Examples of data that is collected are ordering information, project status information or information about Institute program activities.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No IIF

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No IIF

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Kim Minneman

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIEHS Status of Funds Internet Edition (SOFie)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 9/20/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH NIEHS Status of Funds Internet Edition (SOFie)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Susan Hart
- 10. Provide an overview of the system: SOFie is a reporting tool that allows an Institute to manipulate and report on financial transactions and general accounting information downloaded from the NIH Central Accounting System (CAS). It tracks budget allocations, open commitments, obligations, invoicing and payments. Transactions are passed through other systems and then downloaded, or linked into the shared data system called nVision Data Warehouse, where it is then uploaded into SOFie and exported to Excel. Downloads are processed on a daily basis, generally in the evening hours to ensure all allocation entries and adjustments are captured in real time. The daily downloads allow administrative and management staff to accurately report on the budgets established within the IC office, laboratory, section or branch. Financial transaction details are charged to a Common Accounting Number (CAN) which is part of a hierarchical accounting structure termed the Management Account Structure (MAS). The MAS groups CANs into summary levels which include the appropriation source, allotment number, budget activity, allowance name, cost center and CAN. The CAN is tied to a Project Number, categorized by Object Class Code (OC), and summarized and itemized by individual Document Numbers assigned for reference purposes. Additional manipulation is possible to track expenses by month or fiscal year, by data range, and through several stages of the acquisition process.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the

character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\rm N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Fiscal year operational information and general accounting data is downloaded from the NIH Central Accounting System (CAS) into a commercial, off-the-shelf (COTS) software product purchased by the Institute/Center (IC) and exported to Excel. The financial information is specific to the IC and is organized by category (Ex. salary, benefit, award, appropriation, central services, etc.). It can be sorted by organizational code, object class code, date or amount of a commitment, expenditure, or obligation, etc. The system contains no personally identifiable information (PII) on any individual
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) $\rm\ N/A$

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Kim Minneman

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIEHS ToxFX Analysis Tool (ToxFX)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 9/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH NIEHS ToxFX Analysis Tool (ToxFX)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Scott Auerbach
- **10. Provide an overview of the system:** The ToxFX analysis tool is an NIEHS-owned toxicogenomic resource that allows for automated analysis of gene expression data. This resource is of interest to those that work in the field of toxicology and environmental disease. The core component of Tox FX is a collection of gene expression studies derived from tissues/organs of rats exposed to a variety of drugs and well-documented toxicants. The data for this resource is derived from the DrugMatrix datbase. The ToxFX interface allows users to upload their own data for automated scoring of toxicity signatures and generates a report (PDF format) that provides a variety of metrics on the uploaded data set including predicted toxicities.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) The toxicology information collected will be from rats only., (2) NIEHS will use the information for toxicity studies., (3) The information does not contain PII., and (4) N/A
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Kim Minneman

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIEHS Toxicogenomics Initiative Database (CEBS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/4/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-6204-00-110-249

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: n/a

6. Other Identifying Number(s): none

- 7. System Name (Align with system Item name): CEBS
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Jennifer Fostel
- **10. Provide an overview of the system:** Development of knowledge base including collection, processing, search and display of data from microarray, proteomics and toxicological assays conducted through a variety of intramural and extramural research partnerships. Goals include creating a public database relating environmental stressors to biological responses, collecting information relating environmental exposures to disease, and developing an improved paradigm for use of computational mathematics for understanding responses to environmental stressors.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): It discloses the name and affiliation of scientists who have contributed data in order to credit their work. SOR 09-25-0200
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Data is from microarray, proteomics and toxicological assays conducted through a variety of intramural and extramural research partnerships. Data is collected in multiple research settings following scientific study protocols. No personal information is collected about experimental subjects. Scientific collaborators may voluntarily register and provide their names and affiliation.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) All registrations are voluntary. Contributors to the database register to be credited with their contribution. Changes to the system are announced on the Web page. The Web site contains a privacy statement. the CEBS adminstrator can be asked at any time to change or remove information.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The name and affiliation of contributors (provided voluntarily be depositors) are stored in a database in NIEHS and posted on the website in order to acknowledge the depositor's contribution. We do not collect any PII about experimental subjects.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Kim Minneman

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIEHS Toxicology Data Management System Enterprise and Laboratory Data Acquisition System (TDMSE/LDAS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

- **3.** Unique Project Identifier (UPI) Number: 009-25-01-05-02-6202-00-110-249 ,009-25-01-05-02-6205-00-110-249
- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): n/a
- 5. OMB Information Collection Approval Number: n/a
- 6. Other Identifying Number(s): none
- **7. System Name (Align with system Item name):** Toxicology Data Management System Enterprise and Laboratory Data Acquisition System (TDMSE/LDAS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Beth Bowden
- **10. Provide an overview of the system:** The Laboratory Data Acquisition System (LDAS) collects in-life and pathology data from rodent studies and transmits data to the Toxicology Data Management System Enterprise (TDMSE) database where it is stored and analyzed. Other systems maintain and make available in relational databases suitable for analysis all the information resulting from the conduct of multiple types of NTP studes. Also includes loading completed study data into the NIEHS Oracle database, developing procedures for the testing labs to electronically download study data directly and enhancing the study tracking system.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): PII is shared between TDMSE and LDAS using secured file transfer protocol (SFTP).

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Data are collected in multiple research laboratories following scientific study protocols. The data comes from the numerous scientific studies conducted by the National Toxicology Program. The testing program is described at http://ntp.niehs.nih.gov/go/about. Accounts listing user name, facility and unique operator number are created in the TDMSE and LDAS systems as requested in order for personnel at the contract labs to collect and/or view data stored in either system. At the time of initial login to TDMSE, users are requrested to select security questions to allow individuals to reset passwords. Answers to the security questions are stored in TDMSE.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.
- (Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) All accounts are created at the user's request. Users provide their name and facility and are informed of their unique operator number after the account has been set up. Once assigned, operator numbers are not changed. Users are provided with a temporary password which they must reset the first time the system is accessed. The new user defined password is stored in the TDMSE database. Users are given a choice of security questions, some requiring PII and some not. Changes to the user name, facility, security questions or answers take place at the request of the user.
- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** Changes to user accounts can only be made by system administrators with the exception of the security questions or answers. These changes to these parameters are controlled by the user. User profiles are maintained through the Maintain User function within the Administrative section of the TDMSE application. Access to this section of the application is restricted to system administrators. User passwords and security questions/answers are stored in the TDMSE database. The server housing the PII is located at the NIEHS secure data center. The systems housing the PII can only be accessed with password protected accounts which have been set up by the system administrators. Administrators also control the level of access users are granted based on their role at the facility. Passwords are known only to the user and must be renewed every 90 days. Once logged in to the system the application times out after 60 minutes of non-use. Only user names are visible to others based on

facility. Only users at the same facility and with the appropriate access can see the names of other users at the facility.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Kim Minneman

Sr. Official for Privacy Approval: Promote **Sr. Official for Privacy Name:** Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIGMS CAGT System PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-09-25-5156-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH NIGMS Community for Advanced Graduate Training (CAGT) System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Lorena Geddes
- **10. Provide an overview of the system:** An interactive web-based system to promote collaboration between T34 and T32 PIs and between T32 PIs and T34 undergraduate minority students seeking graduate training in NIGMS pre-doctoral biomedical programs.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): IIF is disclosed or shared only as described in the SOR. This information is addressed in the NIH Privacy Act Systems of Record Notice 09-25-0036, published in the Federal Register, Volume 67, No. 187, September 26, 2002.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: We do not maintain NIH employees' information in this system.

CAGT has 3 types of system users:

- 1) Current students participating in T34 programs seeking information about T32 pre-doctoral biomedical programs at various institutions.
- 2) T34 and T32 professors who are conducting training research programs supported via an NIH grant within NIGMS.
- 3) T32 assistants of T32 PIs.

For the above users, the following IIF is collected: names, mailing addresses, phone numbers, email addresses, institution names and affiliations, and areas of scientific training interests.

All the information collected is not voluntary.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) There is no standard process to notify and obtain consent from the individuals whose IIF is in the system when major changes occur to the system, however, since contact information is updated regularly, contact in this situation could be performed by correspondance, email, or phone.

For statistical purposes, the data is collected and permanently maintained sorted by academic year in the NIGMS database archives. However, the student data is deleted from the system in July of every year. New participant contact information is collected and maintained from August throught May in the system.

The system has a privacy notice that notifies individuals of their rights regarding privacy act data which is displayed on the website.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Access to certain information with different levels of authorization in CAGT is limited to NIGMS/NIH Program Officials, and Principal Investigators (PIs), T32 assistants and students at institutions who are currently participating in the NIGMS T32 and T34 biomedical programs. NIGMS/NIH Program Officials use their NIH

Single Sign-On username and password to access CAGT. They oversee the training programs and have access to the user contact information. PIs and T32 assistants can gain access to CAGT via their active NIH eRA COMMONS account. PIs and T32 assistants have access to their students' data. Students gain access to CAGT by registering on the website and getting approval from their respective PI at their institution on the annual basis.

Technical Controls, currently in place, are: user identification and passwords (as described above), and NIGMS and NIH firewalls - set to protect all the NIGMS and NIH systems.

Administrative Controls are as follows: the implementation of the NIGMS standard security plan, process and procedure for purging files, required user training, and distribution of CAGT system user's guide that are given to PIs to distribute to students in the T32/T34 training programs.

Physical Access Controls include:

- 1) controlled physical access to the server via a key card access control list indicating administrators allowed to access the LAN Room.
- 2) The database server is maintained by CIT in an access controlled location.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Kimberly Alllen

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIGMS CMR Meeting Support System (CMSS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-5160-00

009-25-01-05-02-5160-00

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036
- **5. OMB Information Collection Approval Number:** No
- 6. Other Identifying Number(s): NIGMS-0027
- 7. System Name (Align with system Item name): CMR Meeting Support System (CMSS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Lorena Geddes
- **10. Provide an overview of the system:** CMSS is a web-based tool in which CMR members can share comments and evaluate the minority/diversity recruitment and retention efforts of training grant (T32) applications submitted each Council round.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): N_0
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: CMSS downloads and stores grant data from the IMPAC 2 database. The data are stored locally for performance reasons, and are refreshed daily to ensure accuracy. Data includes T32 grant applications, committee members and council meetings. The data also includes the assigned program officials email address contact information. The data are used to support local extramural research activities for the NIGMS Committee for Minority Representation; such information is not supported by NIH or HHS enterprise systems.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) None.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The Intranet server on which CMSS is hosted is available only for NIGMS Intranet users, and is protected by AD account and password in a secure room with restricted Card Key access.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Kimberly Allen

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIGMS Employee Directory (GMED)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-09-02-5151-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0216

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NIGMS-0015

- 7. System Name (Align with system Item name): NIGMS Employee Directory (GMED)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Michael Hong
- **10. Provide an overview of the system:** Provides photographs and contact information for NIGMS staff. Photographs are for internal use only.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): SOR 09-25-0216. This information is further addressed in the NIH Privacy Act Systems of Record Notice 09-25-0216, published in the Federal Register, Volume 67, No. 187, September 26, 2002.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The only IIF information collected from the employee by this system is the digital image, for use to familiarize other staff

with new employees. Other information in the system includes work related (work number, room) data and is accessed from the NED system. Other work related information entered includes start and end date and organization unit. Submission/collection of the image is voluntary.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) As part of the new staff orientation procedures, staff are given verbal notice for their consent to display the photograph on the NIGMS intranet and verbally advised on the use of the photograph.

Email notification would be used to notify and obtain consent from individuals when major changes, if any, occur to the system.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The digital image is stored using NTSF file protections. The intranet site that displays the photographs is available only on the NIGMS Intranet, and is protected by AD account and password in a secure room with restricted Card Key access.

PIA Approval

PIA Reviewer Approval: Promote PIA Reviewer Name: Kimberly Allen

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIGMS External Microsoft Office SharePoint Service (NE-MOSS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-5164-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0106

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NIGMS-0028

- **7. System Name (Align with system Item name):** NIGMS External Microsoft Office SharePoint Service (NE-MOSS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Lorena Geddes
- **10. Provide an overview of the system:** NIGMS SharePoint external is a collection of SharePoint sites within external AD component.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): For PGRN only: Members and NIGMS Administrators of PGRN. Purpose to communicate logistical information about PGRN meetings.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: NIGMS External MS Office SharePoint Services (NE-MOSS) is a tool that provides the Institute and its external-to-NIH

users with collaborative web sites. NE-MOSS is smoothly integrated into the MS Office workplace.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) For the PGRN site (a part of the NE-MOSS): anyone in the public sector interested in becoming PGRN members, fills out and submits a form in the PGRN website (outside PICS). PGRN members are informed via the web and written notification that their information will be shared with other members.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: During this FISMA update (2010), there is only one site in NE-MOSS that collects PII data:

Regular access to information is limited to NIGMS PGRN Administrators who collect the contact data. Developers and/or Contractor employees may have access on an as-needed basis for system administration and maintenance. PGRN members are granted access only after verifying employment. Other access is consistent with the restrictions required by the Privacy Act (e.g., when disclosure is required by the Freedom of Information Act), as authorized by the system manager.)

The database is protected within a locked facility with card key and controlled access.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Kimberly Allen

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIGMS Extramural Support System (NESS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-5111-00

009-25-01-05-02-5111-00-109-026

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036
- **5. OMB Information Collection Approval Number:** No
- 6. Other Identifying Number(s): NIGMS-0008
- 7. System Name (Align with system Item name): NIGMS Extramural Support System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Alexander Naneyshvili
- **10. Provide an overview of the system:** Support extramural research activities for NIGMS that are not supported by NIH or HHS enterprise systems. The system uses enterprise (SOR 09-25-0036) IMPAC2 data. The system does not contain IIF data.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s):
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: The system downloads and stores grant data from the IMPAC 2 database. The data are stored locally for performance reasons, and are refreshed daily to ensure accuracy. Data includes application review status (preaward data) and Principal Investigator name, work address and phone number. The data also includes the assigned program official's name and work contact data, and the assigned grants management specialist's name and work contact data. The data are used to support local extramural research activities for NIGMS that are not supported by NIH or HHS enterprise systems. The system uses enterprise (SOR 09-25-0036) IMPAC2 data. The system does not download, collect, maintain, or disseminate any IIF.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The data is stored using NTSF file protections. The intranet site on which system is hosted is available only on the NIGMS Intranet, and is protected by AD account and password in a secure room with restricted Card Key access.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Kimberly Allen

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIGMS Grantee Email System (GEMS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-09-02-5153-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NIGMS-0005

- 7. System Name (Align with system Item name): Grantee Email System (GEMS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Lorena Geddes
- **10. Provide an overview of the system:** The system is used to generate email messages regarding NIGMS Extramural program information to targeted groups of NIGMS grantees.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system allows users to upload Comma Separated Values (CSV) format files containing email addresses, and storing it locally on a temporary basis to improve performance. The system does not collect, manipulate, manage, or disseminate this data.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: There is no IIF.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Kimberly Allen

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIGMS Integrated Software and Equipment Tracking System (ISETS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-09-02-5146-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NIGMS-0016

- **7. System Name (Align with system Item name):** Integrated Software and Equipment Tracking System (ISETS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Lorena Geddes
- **10. Provide an overview of the system:** IT support system that allows detailed tracking of reservations and returns of portable accountable equipment such as laptops and PDAs. Phase II of system provides ability to track software purchases and licensing.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The systems collects equipment information and tracks loaned equipment and software for NIGMS. An internal id is

used to link the equipment to the name of the requestor, as provided by the NED system. The ISETS system does not contain any IIF.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Kimberly Allen

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIGMS Internet PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-02-00-01-3109-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0106

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NIGMS-0007

7. System Name (Align with system Item name): NIGMS Internet

- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Ann Dieffenbach
- **10. Provide an overview of the system:** The NIGMS Internet is a website that provides information about the mission and programs of the NIGMS.

The NIGMS Internet is a web based application hosted by NIH CIT and it serves as main institute tool/source for the public outreach. The contents are manually entered by the NIGMS OCPL and IRMB staff.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{No}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The NIGMS Internet is a

website that provides information about the mission and programs of the NIGMS. The system does not contain any IIF.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) There is a Disclaimer posted on the Internet of how the data collected with be utilized.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The Internet doesn't store or maintain it. It only collects it and passes data through to a secured internal database.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Kimberly Allen

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIGMS Internet Employee Directory (NIED)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-09-02-5152-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0216

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NIGMS-0026

- **7. System Name (Align with system Item name):** NIGMS Internet Employee Directory (NIED)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Michael Hong
- **10. Provide an overview of the system:** The Staff Contacts page facilitates the public's ability to locate and contact members of NIGMS. The system provides the ability to search NIGMS staff contact information based on First Name, Last Name or Division/Branch. Partial searches are supported for any of the possible search terms.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): IIF is disclosed or shared only as described in the SOR. This information is addressed in the NIH Privacy Act Systems of Record Notice 09-25-0036, published in the Federal Register, Volume 67, No. 187, September 26, 2002.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The data disseminated by the system consists of following elements: NIGMS employees first name, last name, position, work phone, work room number and the NIGMS organizational component. The system does not contain any IIF.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Kimberly Allen

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIGMS MDR Supplements System

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-04-09-02-5154-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NIGMS-0003

- 7. System Name (Align with system Item name): Supplements Tracking System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Alexander Naneyshvili
- **10. Provide an overview of the system:** Collect and maintain data used to generate a required report on Research Supplements for Underrepresented Minorities and Individuals with Disabilities
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The information is normally only shared in aggregate form in a report. The data collected is made available to those outside NIH only as specified in the SOR (09-25-0036)
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The information collected is

required for determining the eligability of the requestor for a financial supplement, it is mandatory information and is provided by the applicant as part of the application process. The system also contains data on educational level, gender, citizenship status, and ethnicity. The data are used only for reporting purposes, and is only provided in aggregate form without identifying information.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No information is collected from individuals, so there is no method to notify individuals or obtain consent. There is no process to notify or obtain consent from individuals in the event of a major system change.

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** Regular access to information is limited to NIGMS staff that are collecting the information or generating the report. Contractor employees may have access on an as-needed basis for system administration and maintenance. Other access is granted only on a case-by-case basis, consistent with the restrictions required by the Privacy Act (e.g., when disclosure is required by the Freedom of Information Act), as authorized by the system manager.

Access is controlled by individualized Oracle accounts, providing role based access to the database. NIH AD accounts provide access to the client side application via server ACLs, authenticating and authorizing the appropriate staff to the server housing the client side application.

The Oracle database is protected within a CIT locked lan room facility while the NIGMS server housing the client side application is located within a key card controlled access Lan Room at the NIGMS location.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Kimberly Allen

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIGMS Meeting Registration System (MREGS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-09-02-5143-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0106

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NIGMS-0017

- 7. System Name (Align with system Item name): NIH NIGMS Meeting Registration System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Anjum Dahya
- **10. Provide an overview of the system:** Provides support for various extramural and scientific meetings, including meeting information dissemination and registration.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): IIF is disclosed or shared only as described in the SOR. This information is addressed in the NIH Privacy Act Systems of Record Notice 09-25-0106, published in the Federal Register, Volume 67, No. 187, September 26, 2002.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The systems collects the registrant's name, title, address and e-mail. The meeting registrant can provide either work or

home contact information, but normally the information collected is work related. The purpose is for registering attendees for meetings. All the information collected is voluntary.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) This data is temporary maintained only during the meeting period and shortly thereafter for sending out post meeting materials. Major systems changes do not occur during data collection (registration) period.

The system has a privacy notice that notifies individuals of their rights regarding privacy act data.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** Access to registration data is limited to the meeting sponsor and assistants, and to administrative staff. Meeting registrants may indicate if their information may be displayed on the website for collaboration and networking. Contractor employees may have access on an as-needed basis for system administration and maintenance, and data may be provided to contractors who are facilitating the meeting for developing name tags, determining rooms requirements, etc. Other access is granted only on a case-by-case basis, consistent with the restrictions required by the Privacy Act (e.g., when disclosure is required by the Freedom of Information Act), as authorized by the system manager.

Technical Access control include:

- controlled physical access to the server via a key card access control list indicating administrators allowed to access the Lan Room. The database server is maintained by CIT in an access controlled location.
- Meeting sponsors, assistants and developers have role based access to the Oracle backend database via individualized Oracle accounts.
- -Meeting sponsors and assistants access administrative meeting functions via a web interface located on the NIGMS Intranet rather than via a public web server. The Intranet requires authentication via NIH AD accounts and NIH Enterprise Single Sign On.
- Server admins control access to the server via ACLs and NIH AD accounts.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Kimberly Allen

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIGMS NIGMS General Support System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009 25 0200 01 3109 00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH NIGMS GSS
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Ivan N. Waldman
- **10. Provide an overview of the system:** The system is a General Support System (GSS) and does not directly collect or store information.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system is a General Support System (GSS) and does not directly collect or store information. The applications/systems residing on the GSS collect and store information. Therefore, individual PIAs have been prepared and submitted for the applications/systems residing on this GSS.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Kimberly Allen

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIGMS OCPL Image Gallery (OCPLIG)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-09-02-5157-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NIGMS-0024

- 7. System Name (Align with system Item name): OCPL Image Gallery (OCPLIG)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Michael Hong
- **10. Provide an overview of the system:** OCPLIG is a repository of NIGMS still image and video media that can be accessed by the public for media relations and educational resources. The OCPLIG supports storing, locating and retrieving of visual media by the public.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The systems collects NIGMS still images and video information and consists of the following elements: description type, source, date, size and format. The OCPLIG system does not contain any IIF.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Kimberly Allen

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIGMS OCPL Publications Database (OPDB)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-09-02-5158-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0106

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NIGMS-0004

- 7. System Name (Align with system Item name): OCPL Publications Database (OPDB)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Anjum Dahya
- **10. Provide an overview of the system:** Collect and maintain addresses of people who have requested receipt of NIGMS educational materials and publications. NIGMS and its contractors will use the data to generate mailing labels.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The NIGMS Internet website provides a listing of publications and electronic mailing lists that are available free of charge. Persons wishing to obtain the materials or subscribe to electronic information must

provide their email address or mailing information. Data includes name and mailing address(es), phone number, and email address. This contact information may be for work or home, depending on the preference of the person requesting the materials. No other identifiable information is requested, and the use of personal email and address, if used, would classify the information as IIF. These data are used in sending the requested materials to the requestor. The information being requested is voluntary, however, we can not respond to the request for materials without their name and email or location address.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The website contains a privacy act statement notifying individuals about what IIF is being collected from them and how the information will be used.

The website privacy policy describes the process for removing or correcting this information.

There is no process in place to notify individuals when major changes occur to the system.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Regular access to information is limited to NIGMS staff that are collecting the information or sending materials. Developers and/or Contractor employees may have access on an as-needed basis for system administration and maintenance. Other access is granted only on a case-by-case basis, consistent with the restrictions required by the Privacy Act (e.g., when disclosure is required by the Freedom of Information Act), as authorized by the system manager.)

The database is protected within a locked facility with card key and controlled access.

PIA Approval

PIA Reviewer Approval: Promote
PIA Reviewer Name: Kimberly Allen

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIGMS Pharmacology Research Associate Tracking System (PRAT)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-09-02-5159-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0124

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NIGMS-0006

- 7. System Name (Align with system Item name): PRAT System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Anjum Dahya
- **10. Provide an overview of the system:** The PRAT system is a web-based system that was developed to collect and maintain information on PRAT participants. In particular, this system enables PRAT administrators to track alumni's career progress, and subsequently, use the collected information to report to NIH, the GAO and Congress.NIH, the GAO and Congress.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The data collected is made available to those outside the NIH only described in the SOR (09-25-0124). This information is further addressed in the NIH Privacy Act Systems of Record Notice 09-25-0124, published in the Federal Register, Volume 67, No. 187, September 26, 2002.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: IIF data includes name and addresses for identification purposes, and is entered into the database while the PRAT fellow is an employee of NIGMS. Other data include contact information such as phone number if work contact information is not available. These data are used in maintaining contact with the former fellows for collecting yearly status on progress after the program. Awards, degrees, and other education and employment information are used in aggregate for determining summary outcomes for congressional justification and reporting.

The PRAT program regularly requests the most recent CV's from all former fellows. Standard information from these (title, organization, work address etc) is used to update the PRAT database. Submission of these CV's is voluntary.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) There is no standard process notify and obtain consent from the individuals whose IIF is in the system when major changes occur to the system, however, since contact information is updated regularly, contact in this situation could be performed by correspondance, email, or phone.

Initial entry of IIF (name, address, phone numbers) is required by the program and is not voluntary. When former PRAT fellows are contacted and asked to submit their CV's, they are told that submission is voluntary. No IIF that is outside of the public domain is requested after the initial, mandatory entry.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Regular access to information is limited to NIGMS staff who are collecting the information or sending materials. Developers and/or Contractor employees may have access on an as-needed basis for system administration and maintenance. Other access is granted only on a case-by-case basis, consistent with the restrictions required by the Privacy Act (e.g., when disclosure is required by the Freedom of Information Act), as authorized by the system manager.

The database is protected within a locked facility with key card controlled access.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Kimberly Allen

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIGMS SCORE Institution/Investigator Database (SCORE-ID)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-5161-00

009-25-01-05-02-5161-00

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036
- **5. OMB Information Collection Approval Number:** No
- **6. Other Identifying Number(s):** n/a
- **7. System Name (Align with system Item name):** SCORE Institution/Investigator Database (SCORE-ID)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Michael Hong
- **10. Provide an overview of the system:** SCORE is a developmental program for principal investigators (PIs) at minority serving Institutions. The goal of the program is to have individuals supported by the developmental programs transition out of the program and into regular research grants. The SCORE-ID system will support the SCORE Program Directors with the information-handling needs not currently supported by other enterprise systems, such as automated system for retrieval and presentation of IMPAC II, NSF, and PubMed data on SCORE-participating Institutions, giving program users the ability to track PI and Institutional progress towards the SCORE program goals.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): IIF is disclosed or shared only as described in the SOR. This information is addressed in the NIH Privacy Act Systems of Record Notice 09-25-0036, published in the Federal Register, Volume 67, No. 187, September 26, 2002.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system downloads and stores grant data from the IMPAC II database. The data are stored locally for performance reasons, and are refreshed daily to ensure accuracy. Data includes application review status (preaward data) and Principal Investigator name, work address and phone number. The data are used to support local extramural research activities for NIGMS that are not supported by NIH or HHS enterprise systems. The system uses NIH enterprise IMPACII data.

(SOR 09-25-0036)

- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.
- (Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) For statistical purposes, the data is collected and permanently maintained sorted by academic year in the NIGMS database archives.

The system has a privacy notice that notifies individuals of their rights regarding privacy act data which is displayed on the website.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: NIGMS/NIH Program Officials use their NIH Single Sign-On username and password to access SCORE-ID.

Technical Controls, currently in place, are: user identification and passwords (as described above), and NIGMS and NIH firewalls - set to protect all the NIGMS and NIH systems.

Administrative Controls are as follows: the implementation of the NIGMS standard security plan, process and procedure for purging files, required user training, and distribution of SCORE-ID system user's guide that are provided to the program officials.

Physical Access Controls include:

- 1) controlled physical access to the server via a key card access control list indicating administrators allowed to access the LAN Room.
- 2) The database server is maintained by CIT in an access controlled location.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Kimberly Allen

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIGMS SOFIE PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-09-02-3199-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

- **5. OMB Information Collection Approval Number:** No
- 6. Other Identifying Number(s): NIGMS-0022
- 7. System Name (Align with system Item name): Status of Funds Internet Edition (SOFIE)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Gene Hernandez
- **10. Provide an overview of the system:** The SOFie application is a reporting tool that allows budget offices to track expenditures in appropriated funds in a fiscal year. The application downloads information from the NIH Data Warehouse.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system does not collect Privacy Act Information. The system provides access to accounting data from the NIH Data Warehouse and does not contain any IIF.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Kimbrely Allen

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIGMS System for Application Management (SAM)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-5162-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): NIGMS-0017

- 7. System Name (Align with system Item name): System for Application Management (SAM)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Anjum Dahya
- **10. Provide an overview of the system:** The System for Application Management (SAM) isupports the first stage of scientific peer review for extramural grant programs. The initial prototype was designed to support the NIH Director's Pioneer and New Innovator Award programs. SAM incorporates a database of potential reviewers and provides tools for maintaining the reviewer database; compiling, inviting, and managing panels of outside reviewers; importing and analyzing data on submitted applications; and producing conflict-free mappings of applications to reviewers based on program specified rules.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The information is shared with the NIGMS NDPA or NIA administrator who inputs and updates data, NIGMS IRMB Contract staff for system maintenance and NIGMS scientific staff working on the NDPA who has read access.

The information is shared with the NIGMS NDPA or NIA administrator who inputs and updates data, NIGMS IRMB Contract staff for system maintenance and NIGMS scientific staff working on the NDPA who has read access.

The information is shared with NIGMS NDPA or NIA adminstrator who inputs and updates data, NIGMS IRMB Contract staff for system maintenance and NIGMS scientific staff working on the NDPA who has read access.

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Information collected does contain the IIF data, such as:

The reviewer name, institution information (e.g. institution name, address, phone and email), gender and minority indicator flag, as well as their field of scientific expertise is collected in order to match an outside expert with an NDPA or NIA application to reivew that is within their scientific area for funding consideration.

The personal information requested is mandatory and could be viewed as a prerequisite to participation in the review process.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The information is shared with the NIGMS NDPA or NIA administrator who inputs and updates data, NIGMS IRMB Contract staff for system maintenance and NIGMS scientific staff working on the NDPA who has read access.

In support of the NIH Director's Pioneer Award (NDPA) and the NIH Director's New Innovator Award (NIA); SAM system contains the contact information and the scientific expertise of scientist that volunteer to review the NDPA grant applications for NIH funding.

These scientists are usually NIH grantees that have an eRA Commons account. This information and all relevant communications and consents are obtained electonically as well.

Disclosure may be made to a private contractor or Federal agency for the purpose of collating, analyzing, aggregating or otherwise refining records in this system.

The contractor or Federal agency will be required to maintain Privacy Act safeguards with respect to these records.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:

- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** Regular access to information is limited to NIGMS staff who are collecting the information or sending materials. Developers and/or Contractor employees may have access on an as-needed basis for system administration and maintenance. Other access is granted only on a case-by-case basis, consistent with the restrictions required by the Privacy Act (e.g., when disclosure is required by the Freedom of Information Act), as authorized by the system manager.

The database is protected within a locked facility with key card controlled access.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Kimberly Allen

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIGMS System for CBI Training Grant Analysis (SCBI)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-5165-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- **7. System Name (Align with system Item name):** System for CBI Training Grant Analysis (SCBI)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Michael Hong
- 10. Provide an overview of the system: SCBI provides a secure Oracle database for storage of data pertaining to CBI training grant (T32) applications and a web-based front end for data entry and reporting. It has capability to synchronize training grant data with IMPAC II, to allow for entry and display of supplemental data for each grant, and provide for a detailed report of all stored data for each grant. The system also include summary views and reports as needed. Core application data obtained from IMPAC II includes applicant name, council, grant number, institution, summary statement, applicant image, and scoring information. Supplementary data is entered by NIGMS employees or its contractors and includes faculty, student and department statistics; program requirements in several areas, program mission descriptions, and Program Director notes. The data is used in aggregate for the production of required reports and the database is maintained and accessed only by NIGMS employees or its contractors.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes

- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): IIF is disclosed or shared only as described in the SOR. This information is addressed in the NIH Privacy Act Systems of Record Notice 09-25-0036, published in the Federal Register, Volume 67, No. 187, September 26, 2002.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:

The system downloads and stores grant data from the IMPAC II database.

The data are stored locally for performance reasons, and are refreshed daily to ensure accuracy. Data includes Council, Grant #, PI Name, Institution, Status of Award, PS, SS, FAC, SLOT, SUP...etc. The data are used to support local extramural research activities for NIGMS that are not supported by NIH or HHS enterprise systems.

The system uses NIH enterprise IMPACII data.

(SOR 09-25-0036)

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) For statistical purposes, the data is collected and permanently maintained sorted by academic year in the NIGMS database archives.

The system has a privacy notice that notifies individuals of their rights regarding privacy act data which is displayed on the website.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: NIGMS/NIH Program Officials use their NIH Single Sign-On username and password to access SCBI.

Technical Controls, currently in place, are: user identification and passwords (as described above), and NIGMS and NIH firewalls - set to protect all the NIGMS and NIH systems.

Administrative Controls are as follows: the implementation of the NIGMS standard security plan, process and procedure for purging files, required user training, and distribution of SCBI user's guide that are provided to the program officials.

Physical Access Controls include:

- 1) controlled physical access to the server via a key card access control list indicating administrators allowed to access the LAN Room.
- 2) The database server is maintained by CIT in an access controlled location.

PIA Approval

PIA Reviewer Approval: Promote PIA Reviewer Name: Kimberly Allen

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIGMS Workshop Registration Management System (WRMS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0106

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- **7. System Name (Align with system Item name):** NIH NIGMS Workshop Registration System (WRMS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Anjum Dahya
- **10. Provide an overview of the system:** WRMS is a web based system for all internal/external applicants who may like to attend the upcoming workshop hosted by NIGMS. It also provides support for various scientific workshop, including workshop information dissemination and registration.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The information will be disclosed to NIGMS program managers responsible for coordinating the workshop. IIF is disclosed or shared only as described in the SOR. This information is addressed in the NIH Privacy Act.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The systems collects the applicant's name, address, phone, education background, email and PostDocs advisor information (name, email, title, address, instituation). The contact information will be used to invite applicants to attend the workshop and to process their expense reimbursement. The information will be disclosed to NIGMS program managers responsible for coordinating the workshop. All the information collected is voluntary

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) This data is temporary maintained only during the workshop period and shortly thereafter for sending out post workshop materials. Major systems changes do not occur during data collection (application submission) period.

The system has a privacy notice that notifies individuals of their rights regarding privacy act data.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** Access to applicants data is limited to the workshop sponsor and assistants, and to administrative staff. Contractor employees may have access on an as-needed basis for system administration and maintenance, and data may be provided to contractors who are facilitating the workshop for developing name tags, determining rooms requirements, etc. Other access is granted only on a case-by-case basis, consistent with the restrictions required by the Privacy Act (e.g., when disclosure is required by the Freedom of Information Act), as authorized by the system manager.

Technical Access control include:

- controlled physical access to the server via a key card access control list indicating administrators allowed to access the Lan Room. The database server is maintained by CIT in an access controlled location.
- Workshop project manager, assistants and developers have role based access to the Oracle backend database via individualized Oracle accounts.

- -Workshop sponsors and assistants access administrative workshop functions via a web interface located on the NIGMS Intranet rather than via a public web server. The Intranet requires authentication via NIH AD accounts and NIH Enterprise Single Sign On.
- Server admins control access to the server via ACLs and NIH AD accounts.

PIA Approval

PIA Reviewer Approval: Promote PIA Reviewer Name: Kimberly Allen

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIMH Administrative System (NAS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-9219-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0217

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIMH Administrative System (NAS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: William Hermach, NIMH ISSO
- **10. Provide an overview of the system:** The NIMH Administrative System facilitates all the administrative support services necessary to support the NIMH mission. The system is part of the NIMHnet GSS.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The system store employee data such as name and phone numbers for NIMH Administrative Officer (AO) use. Reference SOR#: 09-25-0217
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system collects

employee IIF data such as name and phone numbers for NIMH internal use in maintaining IT accounts and emergency contact information. Submission personal information is voluntary.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The system follows the NIMH Emergency Contact Procedure and Account Procedures for maintaining individual IIF information. Individuals are notified via email by their respective AO when any major changes to the system or data use occurs. NIMH staff consent to have their IIF stored in the system at the time of employment.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The IIF will be secured on the system using NIMH Administrative Policies, technical access controls that enforce least privilage access, and encryption of sensitive data as well as limited physical access to the system via card key.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: William Hermach Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIMH Clinical Brain Disorders Branch Database (CBDB)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

- **3.** Unique Project Identifier (UPI) Number: Does not map to a UPI, part of the IRPnet C&A (GSS)
- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200
- **5. OMB Information Collection Approval Number:** N/A
- 6. Other Identifying Number(s): N/A
- **7. System Name (Align with system Item name):** Clinical Brain Disorders Branch Clinical Database (CBDB)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Michael F. Egan, MD
- **10. Provide an overview of the system:** This database includes clinical data on research subjects studied at the NIH in the Clinical Brain Disorders Branch. The authorizing authority is NIH Public Health Service Act, Section 301. The Website includes registration and information on CBDB lecture series.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The system does not share or disclose IIF. Reference SOR#: 09-25-0200
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: We collect IIF information (name, phone, email, address and other research info) when subjects apply to volunteer for research protocols approved by our Institutional Review Board. We use the information to study brain function and the biology of mental illness. Personal information collected from subjects who apply for entry into the research studies includes a limited amount of demographics, psychiatric and medical history and related clinical information. Personal information collected from subjects accepted into the research studies includes additional demographics, psychiatric and medical history and related clinical information, as well as developmental history, and a variety of measures of brain function. Submission of IIF is voluntary to participate in research studies. Minimal PII (name, address, and phone number) is collected for CBDB lecture registration.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Information is obtained from subjects who contact our recruitment department and from subjects who participate in our research protocols. Subjects are requested to provide us with this information for the purposes of evaluating their suitability for research and for the actual research itself. Subjects who are accepted into the protocol sign an IRB approved consent form, which describes what information is to be collected. Participants are told that information they provide is confidential and will only be shared with members our research team. Notification is provided to individuals upon application to participate in a research protocol. Notification is provided via email or Web publication when major changes occur to the system.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The information is stored in a password protected computer database, physically located in a locked research ward. The IIF will be secured on the system using NIMH Administrative Policies, technical and encryption access controls and limited personnel physical access to the system via card key.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: William Hermach Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá **Sign-off Date:** 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIMH Employee Database, Internet Edition (EDie)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-09-02-3196-00-403-131

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-90-0018

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- **7. System Name (Align with system Item name):** EDIE (Employee Database, Internet Edition) formally Visual Employment Database System (VEDS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Quang Tran
- **10. Provide an overview of the system:** EDIE/VEDS is a windows and Web based application primarily used to manage and track personnel information. Authority for maintenance of the system is 5 U.S.C. 1302, 2951, 4118, 4308, 4506, 7501, 7511, 7521, and Executive Order 10561.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The system does not share or disclose IIF. Reference SOR#: 09-90-0018. This information is further addressed in the HHS Privacy Act Systems of Record Notice 09-90-0018, published in the Federal Register, Volume 59, November 9, 1994.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: EDIE/VEDS tracks all information pertinent to a personnel file for the purpose of personnel management activities. Information is collected from employees via the NED system. Uses consist of the following: a) tracking a time-limited appointment to ensure renewals are done in a timely manner, thereby avoiding any break in service, b) ensuring that allocated FTE ceilings are maintained, c) ensuring salary equality for various hiring mechanisms, d) providing reports requested by the NIH Director, IC Director and other management staff, as requested), and e) maintaining lists of non FTEs, special volunteers, contractors, and other hiring appointments. The information collected constitutes IIF, and is mandatory for all employees.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) IIF in the system is gathered from the NED system. Changes to the system or changes in the way the information is used is relayed to employees via official notices from the NIMH AO. Individuals are notified of the collection and use of data as part of the hiring process and is mandatory if the potential job applicant wishes to seek employment at NIH.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Authorized users have been trained in the Privacy Act and systems security requirements. To insure security of the data, each individual user's access level is managed by the Administrator to ensure minimum and necessary access. The server is located in a locked room and is accessible only to specified system support personnel and is also protected by a limited access log-on procedure.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: William Hermach Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIMH Extensive Neuroimaging Archiving Toolkit (XNAT)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

- **3.** Unique Project Identifier (UPI) Number: Does not map to a UPI, part of the NIMH IRPnet C&A (GSS)
- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200
- **5. OMB Information Collection Approval Number:** No
- **6. Other Identifying Number(s):** No
- **7. System Name (Align with system Item name):** Extensive Neuro-imaging Archiving Toolkit at NIH (XNAT@NIH)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Thalene T. Mallus
- **10. Provide an overview of the system:** The XNAT application supports neuro-imaging research by archiving and processing information about subjects and neuro-imaging scans in which they have participated. The database maintains information on approximately 1800 subjects and approximately 10,200 scans over the past 6 years.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The system does not share or disclose IIF.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: The system will store personal (IIF) and medical information about subjects and neuro-imaging scans for the purpose of mental health research. The submission of IIF is voluntary.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Subjects of the system will be contacted electronically and/or in person regarding any major system changes.

A protocol consent notice for each subject that has laboratory contact and data use information as well as patient rights and concerns will be used prior to collection of IIF.

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The database system is behind the perimeters of the NIH firewalls. Least privilege password access to the database is utilized to restrict role based access.

Administrative and technical

- Multifactor authentication:
- + originating IP address
- + x.509 client certificates
- + password authentication
- Encrypted file system for fields containing IIF
- Ongoing host and network security processing, including regular software and OS patching
- Appropriate logging for audits

Physical controls

- Restricted access to host computer

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: William Hermach Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIMH Grants Management System (GMS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-04-00-02-9203-00-205-080

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIMH Grants Management System (GMS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: William Hermach
- **10. Provide an overview of the system:** The Grants Management System overall purpose is to support the management and administration of NIMH's grants. The system is part of the NIMHnet GSS.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The system shares and discloses IIF with the NIMH support and Program staff to send information and correspond with the contacts. Reference SOR number: 09-25-0036
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The NIMH collects and maintains researcher names, mailing addresses, phone numbers, professional qualifications and

areas of expertise for NIMH grants management purposes. The information is voluntarily submitted.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The NIMH grants management procedures involve notification and consent to submit IIF to the system during the grant application process. Individuals whose IIF is in the system are notified when major changes occur by email. Individuals are notified and consent to provide IIF collected by the system in order to provide contact information when appling for NIMH grants.

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The IIF will be secured on the system using NIMH Administrative Policies, technical and encryption access controls and limited personnel physical access to the system via card key.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: William Hermach Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIMH Human Subject Research Database (MAP)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

- **3.** Unique Project Identifier (UPI) Number: Does not map to a UPI, part of the NIMH IRPnet C&A (GSS)
- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200
- **5. OMB Information Collection Approval Number:** No
- **6. Other Identifying Number(s):** No
- 7. System Name (Align with system Item name): MAP Human Subject Research Database
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Dr. Daniel Pine, 15K North Dr. Bethesda, MD 20892
- **10. Provide an overview of the system:** The MAP system collects and centralizes research data for human subjects enrolled in studies conducted by MAP. IIF is stored in order to adequately distinguish subjects, and contact subjects, if necessary. Demographic data and results from psychological testing are stored and used for research purposes. Scientific data which is large in size (such as MRI scans, EEG scans, some genetics results) is not likely to be stored, although fields describing their location are sometimes used. The system is part of the IRPnet GSS.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: IIF is collected with the main purpose of recording human subject, classification data for medical research. Certain IIF such as date of birth may be used for scientific purposes (e.g., correlating an observation with age), but never in a manner that could breach confidentiality. The submission of IIF is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Subjects of the system will be contacted electronically and/or in person regarding any major system changes.

A protocol consent notice for each subject that has laboratory contact and data use information as well as patient rights and concerns will be used prior to collection of IIF.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The database system is behind the perimeters of the NIH firewalls. Least privilege password access to the database is utilized to restrict role based access.

Administrative and technical

- Multifactor authentication:
- + originating IP address
- + x.509 client certificates
- + password authentication
- Encrypted file system for fields containing IIF
- Ongoing host and network security processing, including regular software and OS patching
- Appropriate logging for audits

Physical controls

- Restricted access to host computer

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: William Hermach Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIMH InfoCenter PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-03-02-9218-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0106; 09-25-0156

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): NIMH Information Center
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Christine Kaucher
- **10. Provide an overview of the system:** The NIMH Information Center provides services needed to handle information inquiries with appropriate responses and information dissemination regarding Mental Health research and related NIMH data. The NIMH Information Center provides the necessary services, systems, and qualified personnel to develop and implement such a program, including the information technology systems necessary to screen, track, monitor, and respond appropriately to inquiries received by the NIMH. The NIMH Infocenter ensures that vitally needed and appropriate information on the diagnosis, prevention, treatment, and underlying causes of mental disorders is disseminated in a cost-effective manner, to members of the public, mental health and health care professionals. The system is part of the NIMHnet GSS.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): IIF is shared with another NIMH contractor, DCARC, that warehouses and ships printed information. The requested information and shipping information are used to distribute the data.

The requested medical research information and shipping information fall under two different SOR numbers.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The NIMH Information Center collects the first name, last name, degree, title, organization, address, phone number, fax number, and email of persons requesting NIMH publicly available information. The purpose is to provide complete inquiries response and information dissemination of NIMH, Mental Health research publications and other NIMH materials and Mental Health related information used to respond to public and professional inquiries. Congress mandates the NIMH to provide Mental Health information dissemination to reduce the burden of mental illness and behavioral disorders through research on mind, brain, and behavior. IIF submission is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Consent from individuals is obtained via continue, submit and confirm actions required to enter the IIF. The IIF is not and will not be used or shared other than to disseminate the requested NIMH information to the individual or as required by law. Major changes to the system are inconsequential to the collected IIF since the turn-around time to distribute the requested information is immediate or within a couple of days.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The information is housed on a Windows Sequel Server in a physically secured data center with monitored, key-card access. The database system is behind the perimeters of the NIH firewalls. Least-privilege and role-based access to the database is utilized to restrict unnecessary IIF access.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: William Hermach Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIMH Internet and Intranet Web Sites

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-27-02-9218-00-305-108

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIMH Websites
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: William Hermach
- **10. Provide an overview of the system:** To disseminate Institute information to the public in accordance with Public Law 102-321. The system is part of the NIMHnet GSS.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The system shares and discloses IIF with the NIMH staff and research partners in support of the NIMH mission. Reference SOR #: 09-25-0036
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: NIMH Websites maintain and disseminate information about mental health disorders, news, research and funding opportunities as well as institue information. In addition NIMH Websites provide a portal to

access NIMH Web based applications for grants management, research and administrative functions. The NIMH collects and maintains researcher names, mailing addresses, phone numbers, professional qualifications and areas of expertise for NIMH grants management purposes. The information is submitted voluntarily.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The NIMH procedures involve notification and consent to submit IIF to the system during the grant application and administrative processes. Potential grantees must consent to provide IIF to the system in order to apply for NIMH grants. NIMH consent to have IIF stored in the system as a condition of employment during the hiring process. NIMH Web communications staff notify individuals when major system changes or data use changes occur.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The IIF will be secured on the system using NIMH Administrative Policies, technical and encryption access controls and limited personnel physical access to the system via card key.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: William Hermach Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIMH Laboratory of Brain and Cognition Database (LBC)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

- **3.** Unique Project Identifier (UPI) Number: Does not map to a UPI, part of the NIMH IRPnet C&A (GSS)
- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200
- **5. OMB Information Collection Approval Number:** N/A
- 6. Other Identifying Number(s): N/A
- **7. System Name (Align with system Item name):** Laboratory of Brain and Cognition Database (LBC)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Thalene T. Mallus
- **10. Provide an overview of the system:** A central repository of subjects and associated contact, demographic, and medical information necessary for LBC Researchers, Post-Docs and Research Assistants to determine study availability, eligibility, and obtain MIS requests for LBC cognitive/imaging research protocols. The system is part of the IRPnet GSS.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The system does not share or disclose IIF. Reference SOR#: 09-25-0200
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: The database collects names, contact information, demographics, medical, psychiatric, language, eligibility, and availability information for subjects tested under LBC research protocols. This voluntary information is used as a source pool of available testing subjects and the personally identifiable information collected is used for scheduling and eligibility requirements for LBC cognitive/imaging.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The information is obtained from telephone conversations with potential research participants. Subjects are told verbally that the information is being collected into a central repository and will be treated as confidential and used for research purposes only. Subjects may discontinue participation at any time. After an initial screening, subjects are scheduled for a history and physical to determine further eligibility. Consent to participate in the research effort is obtained at the time of the scanning appointment.

Users of the system are contacted electronically and/or in person regarding any major system changes. Signed protocol consent form for each subject has laboratory contact information for study and/or patient rights concerns.

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The information is housed on a Filemaker Pro Macintosh Server in a locked office space. The database system is behind the perimeters of the NIH firewalls. Least privilege password access to the database is utilized to restrict unnecessary access.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: William Hermach Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIMH NIMH Headquarters Network [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-27-02-9218-00-305-108

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIMHnet
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: John Harris
- **10. Provide an overview of the system:** The system is a General Support System (GSS) and does not directly collect or store information.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The system shares and discloses PII with NIMH staff and research partners in support of the NIMH mission. Reference SOR #: 09-25-0036
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system is a General Support System (GSS) and does not directly collect or store information. The

applications/systems residing on the GSS collect and store information. Therefore, individual PIAs have been prepared and submitted for the applications/systems residing on this GSS.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The NIMH procedures involve notification and consent to submit PII to the system during the grant application and administrative processes. Potential grantees must consent to provide PII to the system in order to apply for NIMH grants. NIMH staff consent to have PII stored in the system as a condition of employment during the hiring process. NIMH Web communications staff notifies individuals when major system changes or data use changes occur.

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The PII will be secured on the system using DHHS, NIH and NIMH administrative policies, NIHnet and NIMHnet technical controls, and encryption of sensitive data. The NIMHnet incorporates role based access controls with the principle of least privilege access and limited personnel physical access to the data center systems via card key.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: William Hermach **Sr. Official for Privacy Approval:** Promote

Sr. Official for Privacy Name: Karen Plá Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIMH NIMH Intramural Research Program Network [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-9219-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): IRPnet
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Quang Tran
- **10. Provide an overview of the system:** The system is a General Support System (GSS) and does not directly collect or store information. Information is stored on applications supported by the GSS and listed in the specific application PIA.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The system does not share or disclose PII. Reference SOR#: 09-25-0200
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system is a General Support System (GSS) and does not directly collect or store information. The

applications/systems residing on the GSS collect and store information. Therefore, individual PIAs have been prepared and submitted for the applications/systems residing on this GSS.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The PII will be secured on the system using DHHS, NIH and NIMH administrative policies, NIHnet and IRPnet technical controls, and encryption of sensitive data. The IRPnet incorporates role based access controls with the principle of least privilege access and limited personnel physical access to the data center systems.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: William Hermach Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIMH Pediatric MRI Database (PedsMRI)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: Does not map to a UPI, part of the NIMH IRPnet C&A (GSS)

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200
- **5. OMB Information Collection Approval Number:** N/A
- 6. Other Identifying Number(s): N/A
- 7. System Name (Align with system Item name): Pediatric MRI Data Repository (PedsMRI)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Judith Rumsey
- **10. Provide an overview of the system:** Pediatric MRI Data Repository contains longitudinal MRI images and clinical/behavioral data from over 500 healthy, typically-developing subjects, age newborn to young adult. The data repository is currently located at the Montreal Neurological Institute. The system is part of the IRPnet GSS.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): A record may be disclosed for a research purpose, when the Department: (A) has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; (B) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and

physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record; (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by, these provisions.

Disclosure may be made to agency contractors, grantees, experts, consultants, collaborating researchers, or volunteers who have been engaged by the agency to assist in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity. Recipients shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

Disclosure may be made for the purpose of reporting child, elder or spousal abuse or neglect or any other type of abuse or neglect as required by State or Federal law.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system collected names, birthdates, dates on which data were collected, and MRI images of the head and brain, age, sex, race/ethnicity, other demographic variables, clinical/behavioral data, e.g., test scores, brain measures. The data included in the Pediatric Data Repository for public release has been deidentified, removing any and all of the 18 identifiers specified by HIPAA. Birthdates and dates seen have been converted to ages. MRI images have been de-faced/de-identified. Submission of personal information is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Prior to the collection of the data in the Pediatric MRI Data Repository, participants were consented/assented (through NINDS IC) regarding what IIF is collected and shared for research purposes. A privacy notice was included with the consent forms. Participants will be notified via email when major changes occur to the system.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The database system is behind a firewall. In

addition, the database connection is made through secure http, which is the encrypted authentication method that is being used to restrict data access. Least privilege password access to the database is utilized to restrict role-based access.

Administrative and technical

- Multifactor authentication:
 - + Identity and access validation
- + password authentication
- Ongoing host and network security processing, including regular software and OS patching
- Appropriate logging for audits

Physical controls

- Restricted access to host computer

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: William Hermach Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIMH Status of Funds Internet Edition (SOFie)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-01-02-3198-00-402-125

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 009-25-01-01-01-3104-00

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): Status of Funds Internet Edition (SOFie)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Quang Tran
- **10. Provide an overview of the system:** Status of Funds Internet Edition (SOFie) facilitates viewing and managing an organization's accounts. The database stores the organization's financial transactions and allows the user to view and summarize as needed for different reporting mechanisms. The system is part of the IRPnet GSS.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The system does not share or disclose PII.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: SOFie stores the IC's financial transactions, which are downloaded daily from the NIH Data Warehouse. The IC's use

the information to monitor spending trends, monitor balances in the accounts, also for specialized reporting, such as, travel reports and salary trends. No personal identifying information is collected.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The NIMH specific financial information is downloaded from the NIH data warehouse system. Suppliers of information and staff are aware the data is collected through authorized acquisition transactions and provide consent through the authorized acquisition process and government employment regulations. The information allows budget offices to track expenditures in appropriate funds in a fiscal year. The application contains a tracking mechanism to track prior year funds as well. The notice of consent is handled electronically through the applicable acquisistion process.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** Authorized users have been trained in the Privacy Act and systems security requirements. To insure security of the data, each individual user's access level is managed by the Administrator to ensure minimum and necessary access. The server is located in a locked room and is accessible only to specified system support personnel and is also protected by a limited access log-on procedure.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: William Hermach Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Pla

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NIMH Unit on Integrative Neuroimaging Database (UINDB)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

- **3.** Unique Project Identifier (UPI) Number: Does not map to a UPI, part of the NIMH IRPnet C&A (GSS)
- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200
- **5. OMB Information Collection Approval Number:** N/A
- 6. Other Identifying Number(s): N/A
- **7. System Name (Align with system Item name):** Unit on Integrative Neuroimaging Database (UINDB)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Jonathan Shane Kippenhan
- **10. Provide an overview of the system:** This system collects and maintains information about subjects and neuroimaging scans they have participated in. NIH Public Health Services Act, Sec. 301. The system is part of the IRPnet GSS.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The system does not share or disclose IIF. Reference SOR#: 09-25-0200
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system collects

information on demographics, medical history, medications and neuroimaging scans, all of which is used to facilitate neuroimaging research. Submission is voluntary. Information is collected from subjects, who are told that the information will be kept confidential and used only for purposes of our research projects.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Users of the system are contacted electronically and/or in person regarding any major system changes. Signed protocol consent form for each subject has laboratory contact information for study and/or patient rights concerns.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Data access is restricted to users with passwords known only to the user (passwords are not stored). System security is maintained via a combination of physical security, passwords, and firewalls.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: William Hermach Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINDS Alchemy PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-8610-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): Alchemy

- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Donna Stephenson
- **10. Provide an overview of the system:** The primary purpose of the Alchemy system is to support the NINDS ASP by managing the large volumes of Utah test result data and other ASP files.

Alchemy also provides a way for authorized users to search for legacy Utah test result data through functions for indexing, archival, query, retrieval, and viewing. The ability to perform searches via Alchemy reduces the need to store microfilm and paper copies on NINDS premises. This, in turn, reduces the requirement for ever-increasing storage space.

The Alchemy system supports the mission ASP, which is to encourage and facilitate the discovery and development of therapeutics for treatment of seizure disorders. The success of these efforts translates directly into new drugs to treat patients with these disorders.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes

- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Researchers receive the letters. Data includes contact information for individual researchers IAW SOR# 09-25-0200
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Correspondence Letter which includes name and business address.

Publically available journal articles which possibly contain name and email address. Submission of the information is voluntary.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The letters either come from the person or are sent to the person as a part of the process in entering test results. Consent and notification are assumed when the individual sends or receives the letter containing the information. No other notification is done.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Single sign-on using user name and password, system resides behind a firewall and is in a server room with no external access. All personal not having card key access are escorted.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Peter Soltys/Sue Titman (301) 496-9244

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Pla

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINDS Antieileptic Drug Discovery System II (ADDS II)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-8610-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: NO

6. Other Identifying Number(s): NO

- **7. System Name (Align with system Item name):** Anti-Epileptic Drug Discovery System II (ADDS II)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Donna Stephenson
- **10. Provide an overview of the system:** The purpose of the ADDS II system is to facilitate the establishment of worldwide collaborative relationships among the government, academia, and industry to search for a cure of epilepsies and to provide the necessary incentives for discovery, characterization, and development of novel antiseizure/anticonvulsant agents.

These efforts are undertaken through multi-level testing directed toward the development of safer and more effective therapies for treating the various seizure disorders. To aid in the process, the Anti-Epileptic Drug Discovery System II (ADDS II) application was developed. ADDS II provides a fully integrated system to support the preclinical drug discovery business area. Users can access chemical compound data, order and manage tests, enter test results, and manage inventory using predefined forms and reports.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Data is not shared. The data is used by NIH personnel only to contact researchers who submitted the data. SOR# 09-25-0200
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Collect name, business telephone number, business email address, business address, institution/company/agency name, public web site URL. Information is collected from researchers who submit compounds for testing. It is used to communicate test results back to the researcher. Information is mandatory.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Institutions submit compounds and test results voluntarily. Consent to collect this information is assumed upon submission. There are no other processes in place associated with the ADDS II system to notify or obtain consent.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Role base security, using user name and password for network and Oracle, system resides behind a firewall and is in a server room with no external access. All personal not having card key access are escorted.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Peter Soltys/Sue Titman (301) 496-9244

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Pla

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINDS Bioinformatics Research Information

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/11/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

- 7. System Name (Align with system Item name): EvoPrinter
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: George Buckland
- **10. Provide an overview of the system:** EvoPrinter supports researchers comparing DNA sequences to a library of known sequences. Research sequences can be submitted and EvoPrinter determines the similarities and differences, especially with regard to evolutionary closeness.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\rm N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: EvoPrinter only processes anonymous DNA sequences. It stores no data.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) None

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The system has several administrative controls in place to secure the data. The NIH requires security training for all system users on an annual basis. Also, the security controls and disaster recovery plan are documented as part of the Certification and Accreditation process. The system is also protected by the Institute's firewall and intrusion detection systems. The system also has several physical controls in place to secure any data. The system is protected by guards, ID badge requirements, and key card access.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Joellen Harper Austin, Executive Officer, NINDS 301-496-4697

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINDS Clinical Information Management System (CIMS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/11/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-200

5. OMB Information Collection Approval Number: N/A

- 7. System Name (Align with system Item name): Clinical Information Management System (CIMS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: George Buckland
- **10. Provide an overview of the system:** CIMS supports the Clinical Research program of NINDS. It consists of two subsystems, the Clinical Study Information System (CSIS) and the Protocol Tracking and Management System (PTMS), that store information relevant to the Clinical Research studies of NINDS and patients involved in those research studies.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Does not share or disclose PII.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: CIMS supports the Clinical

Research program of NINDS. It consists of two subsystems, the Clinical Study Information System (CSIS) and the Protocol Tracking and Management System (PTMS), that store information relevant to the Clinical Research studies of NINDS and patients involved in those research studies. Some PII information may be maintained by the CSIS subsystem, but not by PTMS. Submission of a minimal amount of personal information is required for patients who have volunteered to participate in the clinical studies.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Participants in clinical studies volunteer to participate in the studies and give their written consent to provide PII and medical information. They are notified of such study requirements when they volunteer for the studies, and they are given information on how the study information may be used. It is not feasible to obtain further consent for any later changes in the CIMS system.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Role based security, using authorized user name and password for network access to CIMS. System resides behind a firewall and is in a server room with no external access. All personal not having card key access are escorted.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Joellen Harper Austin, Executive Officer, NINDS 301-496-4697

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINDS Coding PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-8610-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

7. System Name (Align with system Item name): Coding

- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Donna Stephenson
- **10. Provide an overview of the system:** The NINDS Coding system is a web-based application enabling NINDS institute personnel, both Intramural and Extramural, to assign codes to grants and contracts. These code values denote the relationship between the Institute's expenditure and an area of science, disease, or disorder. The system also enables Program, Scientific, and Budget Analysts to analyze expenditures by fiscal year and generate reports. Using this system, analysts generate budgetary and scientific year-end reports that are used to respond to internal and external requests for information.

the database is driven by a frozen table of awarded grants and contracts for both Extramural and Intramural research by fiscal year. The data for the frozen table comes from the IRMB database as well as from local NINDS-specific data sources.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): This system does not contain PII.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system stores the following information:
- Principal Investigator Name.
- System User Name.
- Program Director Name.
- Principal Investigator Institution Name.
- System User Email Address.

As a part of the NIH grant application process, Principal Investigators are required to provide their name and institution name. The NINDS Coding system downloads this information that the IMPACII database has already collected.

Grants are assigned to Program Directors (PDs), and the PD names are stored to record these assignments. This data is a mandatory part of the grant submission process. The data is used to track PD assignments in association with grant applications and awards.

All data contained in this system is from awarded grants and is public record. None of the data is considered PII.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) PII is not contained in this system

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The system has several administrative controls in place to secure the data. The NIH requires security training for all system users on an annual basis. Also, the security controls and disaster recovery plan are documented as part of the certification and accreditation process. Finally, the system maintains several user roles, and each system user is given the least privilege needed to perform his or her business function. The system has several technical controls in place to secure the data. A user must first provide a valid username and password to access the NINDS network. The user must also be a system user before he or she can log onto the system. The system is also protected by guards, ID badge requirements, key card access, cipher locks, and closed circuit television.

PIA Reviewer Approval: Promote

PIA Reviewer Name: Peter Soltys/Sue Titman (301) 496-9244

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINDS Daily Refresh Workload FY XXXX NS

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-8610-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: No

- 7. System Name (Align with system Item name): Daily Refresh Workload FY XXXX NS
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Donna Stephenson
- **10. Provide an overview of the system:** The Daily Refresh Workload FY XXXX NS is a system that refreshes a Grant Specialist workload report on a daily basis. This report is stored on a common drive and is viewed by Grants Management Officials and their deputies.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The system generates a report that only authorized personnel can access. The report displays the workload for each Grant Specialist.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system stores the following information.

- * Grant Specialist name and his/her General Schedule (GS) level.
- * Grant number.
- * Cluster name.

The system creates a report detailing the Grant Specialists workload and compares it with his/her GS level. The use of the GS name along with his/her GS Level could be considered PII. The Information contained in this system is required when the individual accepts a position as a Grant Specialist.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The data is collected by the IMPAC II system and NINDS relies on the IMPAC II system to obtain permission via the grant application process and to notify individuals when major changes are made affecting the use of the data, how the data will be used and why it is being collected. The IMPAC II system uses the data to process grant applications and maintain grants. NINDS uses this automailer as a portion of the grant application process to inform the applicant of the status of their application.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The system has several administrative controls in place to secure the data. The NIH requires security training for all system users on an annual basis. Also, the security controls and disaster recovery plan are documented as part of the Certification and Accreditation process.

The system has several technical controls in place to secure the data. A user must first provide a valid username and password to access the NINDS network. The user must also be a system user before he or she can access the system. The Institute's firewall and intrusion detection systems also protect the system.

The system also has several physical controls in place to secure the data. The system is protected by guards, ID badge requirements, key card access, cipher locks, and closed-circuit television.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Joellen Harper Austin, Executive Officer, NINDS 301-496-4697

Sr. Official for Privacy Approval: Promote **Sr. Official for Privacy Name:** Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINDS Employee Database Internet Edition

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 8/11/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-90-0018

5. OMB Information Collection Approval Number: N/A

- **7. System Name (Align with system Item name):** NIH NINDS Employee Database Internet Edition
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Donna Stephenson
- **10. Provide an overview of the system:** The EDie application supports the efforts of NINDS by tracking employee information. The application downloads this information from the Human Resources Database (HRDB) weekly. Information entered into the EDie database is not uploaded into the HRDB. Due to the sensitivity of the personnel data in this system, access to the EDie database is limited to specific users within NINDS. Users are assigned roles that restrict what data they may view and what functions they can perform. Access privileges are enforced through authentication within the database.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $N\!/\!A$

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The information collected is all information pertinent to a personnel file. There are many uses for this information: (a) tracking a time-limited appointment to ensure renewals are done in a timely manner thereby avoiding any break in service; (b) ensuring that allocated FTE ceilings are maintained; (c) ensuring salary equality for various hiring mechanisms; (d) the ability to provide reports requested by the NIH Director; (e) maintaining lists of non FTEs, special volunteers, contractors, etc. Information is

mandatory at time of hire.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Information is collected from documents provided by employees (CV, resumes, etc) at the time of appointment. It is provided in personnel packages submitted through channels in order to affect a hire. This information is put into the Enterprise Human resources and Payroll System (EHRP) and subsequently downloaded into the NIH NINDS Employee Database Internet Edition. Individuals are notifed of the collection and use of data as a part of the hiring process. Changes to the system or use of the information is relayed to employees via official notices from HR and the system owner.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: This information is provided to key staff by the administrator. The system is authorized only with a person who has a proper access rights with user name and password. The system is secured in an office with locks and the building is secured by the security guard.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Joellen Harper Austin, Executive Officer, NINDS 301-496-4697

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINDS eNotification Automailer

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-8610-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0106 and 09-25-0036

5. OMB Information Collection Approval Number: No

- 7. System Name (Align with system Item name): eNotification Automailer
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Donna Stephenson
- **10. Provide an overview of the system:** The eNotification Automailer is a Microsoft Access database system that queries IMPAC II, generates a report, and sends email notifications to grant applicants. The system searches for grant applications that recently have been given a score or percentile. Based on business rules established by the business users, the system will email notifications that indicate the likelihood that the applicant will receive funding. All reports are stored on a secure network drive and a copy of the email is stored in the Microsoft Outlook Public Folders.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The system sends email notifications to grant applicants on the likelihood that their grant application will be funded.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system stores Principal Investigator Name, Work Address, Email, Administrative Office Email, and Institution Name. The information is collected by IMPAC II as a required part of the grant application and is used to process the grant application and, if funded, to maintain the grant. eNotification Automailer uses this information to inform the applicant about the status of his/her grant application.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The data is collected by the IMPAC II system and NINDS relies on the IMPAC II system to obtain permission via the grant application process and to notify individuals when major changes are made affecting the use of the data, how the data will be used and why it is being collected. The IMPAC II system uses the data to process grant applications and maintain grants. NINDS uses this automailer as a portion of the grant application process to inform the applicant of the status of their application.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The system has several administrative controls in place to secure data. The NIH requires security training for all system users on an annual basis. Also, the security controls and disaster recovery plan are documented as part of the Certification and Accreditation process. The system has several technical controls to secure the data. A user must first provide a valid username and password to access the NINDS network. The user must also be a system user before he/she can log onto the system. The Institute's firewall and intrusion detection systems also protect the system. The system also has several physical controls in place to secure the data. The system is protected by guards, ID Badge requirements, key card access, cipher locks, and closed-circuit television.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Joellen Harper Austin, Executive Officer, NINDS 301-496-4697

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINDS Extramural Financial Management Branch

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-8601-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): NINDS FinEx

- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Donna Stephenson
- **10. Provide an overview of the system:** The FINeX application is a centralized, Internet-based relational database environment that stores data and business rules (procedures) required to maintain the Extramural grant budget. The FINeX application includes the tools necessary to estimate, award, obligate, forecast and report on grant budgets in the Extramural program.

In its in-production state, FINeX resides on the NINDSAPPS3 server as a .Net, web-deployed application. Its interdependencies on other resources (or dynamically-linked libraries (DLLs)) are fully compiled into the installed version of FINeX on NINDSAPPS3. NINDSAPPS3 serves as the web application server for NINDS, where FINeX is exclusively used. The databases on which FINeX is dependant reside on NINDS resources, SQLCLUSTER (SQL Server 2000 database server) and IRIS (Oracle 10 database server). FINeX utilizes, but is not dependent on NIH CIT resources for supplemental data (e.g., IRDB—an Oracle database warehouse server and DataWarehouse—an IBM mainframe finance data warehouse).

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): IIF is obtained from the eRA system in the administration of research grants IAW SOR#09-25-0036.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Financial Grant information. The FINeX application is a centralized, Internet-based relational database environment that stores data and business rules (procedures) required to maintain the Extramural grant budget. The FINeX application includes the tools necessary to estimate, award, obligate, forecast and report on grant budgets in the Extramural program. IIF contained in NINDS FinEx is obtained from the eRA system and is a required part of the Grant submission process.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) IIF is submitted as a part of the grant application process. Information used by the NINDS FinEx is taken from the ERA grant application. Notification and consent from the individual is assumed when the grant application is submitted. All notification and consent is taken care of via the Grant application submission process and eRA systems.

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Role base security, single sign-on using user name and password, system resides behind a firewall and is in a server room with no external access. All personal not having card key access are escorted.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Peter Soltys/Sue Titman (301) 496-9244

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Pla

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINDS Fellowship Mailer PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-8610-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: no

- 7. System Name (Align with system Item name): Fellowship Mailer
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Donna Stephenson
- **10. Provide an overview of the system:** The Fellowship mailer sends reminder notifications to fellowship recipients. The system sends activation reminders to recipients who have not yet activated their fellowships. The system sends non-activated reminders to recipients who did not activate their fellowships by the due date. The system also sends termination reminders to recipients about the reports they need to send to NINDS at the end of their fellowships.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The system sends an email to the Principle Investigator (PI) and the PI's Administrator about the activation status of a fellowship.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system stores the following information:

- Grants Specialist Name
- Grants Specialist phone number
- Grants Specialist email
- Grants Management Official name
- Grants Management Official email
- Grant Number
- Principle Investigator name
- Principle Investigator email
- Principle Investigator's Administrator email

The system sends an email to the Principle Investigator (PI) and the PI's Administrator about the activation status of a fellowship. Disclosure may be made to a grantee or contract institution in connection with performance or administration under the conditions of the particular award or contract.

Principle Investigator information is required when an individual applies for a grant.

Grants Specialist information is required when an individual accepts a position as a Grants Specialist.

The information collected for the Principle Investigator contains PII/IIF.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The NIH collects the PII/IIF from the Grant Application, and NINDS relies upon the NIH policy for notifying and obtaining consent from the Grant Applicants and Principle Investigator. See SOR# 09-25-0036

In this system the information is used to send an email to the Principle Investigator (PI) and the PI's Administrator about the activation status of a fellowship.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The system has several administrative controls in place to secure the data. The NIH requires security training for all system users on an annual basis. Also, the security controls and disaster recovery plan are documented as part of the Certification and Accreditation process.

The system has several technical controls in place to secure the data. A user must first provide a valid username and password to access the NINDS network. The user must also be a system user before he or she can access the system. The Institute's firewall and intrusion detection systems also protect the system.

The system also has several physical controls in place to secure the data. The system is protected by guards, ID badge requirements, key card access, cipher locks, and closed-circuit television.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Joellen Harper Austin, Executive Officer, NINDS 301-496-4697

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINDS GM Close Out PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-8610-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

- 7. System Name (Align with system Item name): GM Close Out
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Donna Stephenson
- **10. Provide an overview of the system:** The GM Close Out system runs a report on a quarterly basis and provides the close out status of grants for all Institutes and Centers (ICs).
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): System does not contain IIF/PII
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system stores Grant Number and Grant Close Out Status for generating the quarterly Grant Close Out report and for historical purposes.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g.,

disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) System does not contain IIF/PII

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: System does not contain IIF/PII

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Joellen Harper Austin, Executive Officer, NINDS 301-496-4697

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINDS GMB Workload Automailer

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-8610-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

- 7. System Name (Align with system Item name): GMB Workload Automailer
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Donna Stephenson
- **10. Provide an overview of the system:** The GMB Workload Automailer is a Microsoft Access database system that queries IMPAC II, generates workload reports, and sends links to those reports via email to the GMO. These workload reports a total of five in all provide a weighted workload score for each Grant Specialist based on business rules established by the GMO. All reports are stored on a secure network drive.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): This system does not contain IIF
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: This system does not contain IIF

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) This system does not contain IIF

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: This system does not contain IIF

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Joellen Harper Austin, Executive Officer, NINDS 301-496-4697

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINDS GMO Unsigned Automailer

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-8610-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

- 7. System Name (Align with system Item name): GMO Unsigned Automailer
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Donna Stephenson
- **10. Provide an overview of the system:** The GMO Unsigned Automailer is a Microsoft Access database system that queries IMPAC II, generates a report, and sends a link to that report via email to the GMO. The report displays all grant applications that Program Staff have completed and that are ready for the GMO's signature. All reports are stored on a secure network drive.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): This system does not contain IIF
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: This system does not contain IIF

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) This system does not contain IIF

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: This system does not contain IIF

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Joellen Harper Austin, Executive Officer, NINDS 301-496-4697

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINDS GMS Unsigned PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-8610-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: No

- 7. System Name (Align with system Item name): GMS Unsigned
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Donna Stephenson
- **10. Provide an overview of the system:** The GMS Unsigned system generates a report of all grant applications that have been signed by the Program Official but not signed by the Grants Specialist. All personnel listed on the report are sent a link to the report.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The system generates a report of all grant applications that have been signed by the Program Official but not signed by the Grants Specialist.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system stores the following information:
- Grant Specialist Name.

- Program Official name.
- Grant application number.

This information contains PII when tied to the Grant Application Number. The GS and PO names are required when accepting these positions.

The system emails a report detailing the grant applications that are awaiting the signature of the Grant Specialist.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The data is collected by the IMPAC II system and NINDS relies on the IMPAC II system to obtain permission via the grant application process and to notify individuals when major changes are made affecting the use of the data, how the data will be used and why it is being collected. The IMPAC II system uses the data to process grant applications and maintain grants. NINDS uses this automailer as a portion of the grant application process to inform the applicant of the status of their application.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The system has several controls in place to secure the data. The NIH requires security training for all system users on an annual basis. Also, the security controls and disaster recovery plan are documented as part of the Certification and Accreditation process.

The system has several technical controls in place to secure the data. A user must first provide a valid username and password to access the NINDS network. The user must also be a system user before he or she can access the system. The Institute's firewall and intrusion detection systems also protect the system.

The system also has several physical controls in place to secure the data. The system is protected by guards, ID badge requirements, key card access, cipher locks, and closed-circuit television.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Joellen Harper Austin, Executive Officer, NINDS 301-496-4697

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINDS GS Reassignment Automailer

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-8610-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

- 7. System Name (Align with system Item name): GS Reassignment Automailer
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Donna Stephenson
- **10. Provide an overview of the system:** The GS Reassignment Automailer is a Microsoft Access database system that queries IMPAC II, generates a report, and sends email notifications to Grant Specialists via email. These email notifications indicate the Grant Specialist assigned to a grant application has been changed, and the system sends notifications to both the new and former Grant Specialists. The email notification also provides a link to the report detailing all reassignments. All reports are stored on a secure network drive.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): This system does not contain IIF
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: This system does not contain IIF

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) This system does not contain IIF

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: This system does not contain IIF

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Joellen Harper Austin, Executive Officer, NINDS 301-496-4697

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINDS Initiatives and Workshops in Neuroscience

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-8601-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: No

- 7. System Name (Align with system Item name): iWIN
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Donna Stephenson
- 10. Provide an overview of the system: The NINDS is responsible for supporting all aspects of biomedical research on disorders of the brain and nervous system. Although NINDS relies heavily on investigator –initiated research, it undertakes specific initiatives to focus efforts on particular problems or opportunities when its leadership is warranted. NINDS plans and implements research through the Initiatives and Workshops in Neuroscience (iWIN) process. The iWIN application is a centralized, Internet-based relational database environment that stores data and business rules (procedures) required to maintain initiative and workshop information for reporting and tracking. In its in-production state, iWIN resides on the NINDSAPPS3 server as a .Net, web-deployed application. Its interdependencies on other resources (or dynamically-linked libraries (DLLs)) are fully compiled into the installed version of iWIN on NINDSAPPS3. NINDSAPPS3 serves as the web application server for NINDS, where iWIN is exclusively used. The databases on which iWIN is dependant reside on a NINDS resource named SQLCLUSTER (SQL Server 2000 database server).
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): This system does not store PII
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Initiative and Workshop information. The iWIN application is a centralized, Internet-based relational

database environment that stores data and business rules (procedures) required to maintain initiative

and workshop information for reporting and tracking. This system does not collect or store PII.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) This system does not collect or store PII.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: This system does not contain PII

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Peter Soltys/Sue Titman (301) 496-9244

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINDS Intent to Pay (ITP) Web

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-8610-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: N/A

- 7. System Name (Align with system Item name): Intent 2 Pay (I2P)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Donna Stephenson
- **10. Provide an overview of the system:** Intent to Pay application aids in the administration of grants by providing a single difinitive list of grant application to pay during a council round.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): I2P passess information to other internal systems (FINEX, iWin, Council Web Site)
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Grant Number, PI Name, Financial information are collected, maintianed, disseminated. This system is used to review grant applications and indicate which will be paid. IIF information is mandatory.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) IIF is submitted as a part of the grant application process. Information used by the NINDS FinEx is taken from the ERA grant application. Notification and consent from the individual is assumed when the grant application is submitted. All notification and consent is taken care of via the Grant application submission process and eRA systems.

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Role base security, single sign-on using user name and password, system resides behind a firewall and is in a server room with no external access. All personal not having card key access are escorted.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Peter Soltys/Sue Titman (301) 496-9244

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINDS Intranet PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-8606-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0106

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): NINDS Intranet

- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Donna Stephenson
- **10. Provide an overview of the system:** The NINDSINTRANET server supports the "NINDS Intranet Employee Website" located at http://intranet.ninds.nih.gov/. The server provides advanced symmetric multiprocessing (SMP) support, clustering, and load-balancing technologies to meet the requirements of NINDS Intranet users.

The server resides on the NINDS private network (Intranet) and, thus, the services it supports are not accessible to the general public.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): This system discloses IIF to authorized NIH Staff with logon access through links to other NIH systems such as NED IAW SOR 09-25-0106
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Information is now directly submitted through the NINDS Intranet. All information displayed on the NINDS Intranet is collected and stored by other systems within the NIH. As far as NINDS Intranet is concerned this IIF is voluntary although it may be required by other NIH systems.

- NINDS directory, including employee contact information
- NINDS calendar
- News and alerts
- NINDS policies
- · NINDS forms
- Human resources information
- · Jobs and training information
- · Information about funding opportunities
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The Intranet only accesses and displays data from other systems. Consent is assumed to have been given when the information was collected by those systems. Notification of major changes to the system are disiminated via email to all NINDS personnel. Consent from individuals concerning IIF that may be displayed on the Intranet is the responsibility of the system actually collecting that information. IIF is only displayed to those Staff who have login access to the systems containing the IIF.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Network sign-on using user name and password, system resides behind a firewall and is in a server room with no external access. All personnel not having card key access are escorted.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Peter Soltys/Sue Titman (301) 496-9244

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINDS Large Grant Mailer

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-8610-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): Large Grant Mailer
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Donna Stephenson
- **10. Provide an overview of the system:** The Large Grant Mailer system runs twice a year and sends emails to all NINDS grantees about the procedures for submitting a grant application in excess of \$500,000.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The system sends and email to the Principle Investigator (PI) with information about submitting grant applications over \$500,000. Disclosure may be made to a grantee or contract institution in connection with performance or administration under the conditions of the particular award or contract.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: The system stores the following information:

- * Principle Investigator name.
- * Principal Investigator email.

PII in the form of PI name and email is contained in the email.

This information is required when the PI submits a grant application.

The system sends an email to the Principle Investigator (PI) with information about submitting grant applications over \$500,000.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The data is collected by the IMPAC II system and NINDS relies on the IMPAC II system to obtain permission via the grant application process and to notify individuals when major changes are made affecting the use of the data, how the data will be used and why it is being collected. The IMPAC II system uses the data to process grant applications and maintain grants. NINDS uses this automailer as a portion of the grant application process to inform the applicant of the status of their application.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The system has several administrative controls in place to secure the data. The NIH requires security training for all system users on an annual basis. Also, the security controls and disaster recovery plan are documented as part of the Certification and Accreditation process for the General Support System (GSS).

The system has several technical controls in place to secure the data. A user must first provide a valid username and password to access the NINDS network. The user must also be a system user before he/she can access the system. The Institute's firewall and intrusion detection systems also protect the system.

The system also has several physical controls in place to protect the data. The system is protected by guards, ID badge requirements, key card access, cipher locks, and closed -circuit television.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Joellen Harper Austin, Executive Officer, NINDS 301-496-4697

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINDS MS Access Nightly Download System

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-8610-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): MS Access Nightly Download System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Donna Stephenson
- **10. Provide an overview of the system:** The MS Access Nightly Download System loads the SRPD_Data.mdb database with data from the IRIS Oracle Database. This process runs on a nightly basis.

The SPRD_Data.mdb serves as a repository of grant information for several NINDS systems.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): No PII is shared.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system collects the following information:

- Grants Specialist (GS) and Grants Management Official (GMO) name.
- Program Official (PO) and Health Science Administrator (HSA) name.
- Grant number.
- Principal Investigator (PI) name.
- Organization name.

The MS Access Nightly Download System loads the SRPD_Data.mdb database with data from the IRIS Oracle Database. The SPRD_Data.mdb serves as a repository of grant information for several NINDS systems used to process and maintain grants.

When used together some of this information may be considered PII.

This information is mandatory for processing and maintaining grants.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The NIH collects the information, and NINDS relies upon the NIH policy for notifying and obtaining consent from individuals. Information regarding individual notification procedures is further addressed in the NIH Privacy Act Systems of Record Notice 09-25-0036, published in the Federal register, volume 67, No. 187, September 26, 2002.

This information is collected by the eRA system when grants are applied for and updated as a grant is awarded and maintained. Notification that this data is being collected, what is being collected and what it is used for is explained in detail in the grant application process. As individuals apply for positions as a GS/GMO/PO/HSA/PI this information is collected and the purpose for collecting it is explained and consent obtained at that time either verbally or in writing. This information is mandatory if a person accepts these positions.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The system has several administrative controls in place to secure the data. The NIH requires security training for all system users on an annual basis. Also, the security controls and disaster recovery plan are documented as part of the Certification and Accreditation process for the General Support system (GSS).

The system has several technical controls in place to secure the data. A user must first provide a valid username and password to access the NINDS network. The user must also be a system user before he or she can access the system. The Institute's firewall and intrusion detection systems protect the system.

The system also has several physical controls in place to secure the data. The system is protected by guards. ID badge requirements, key card access, cipher locks, and closed-circuit television.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Joellen Harper Austin, Executive Officer, NINDS 301-496-4697

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINDS Nightly Download Status Automailer

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-8610-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): Nightly Download Status Automailer
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Donna Stephenson
- **10. Provide an overview of the system:** The Nightly Download Status Automailer is a system that queries IMPAC II, IRIS, SQLCLUSTER, and NINDS_LOCAL_APPLS to check the status of the nightly download and prepares a text file record-count report. The report displays the number of records downloaded from IMPAC II and displays the number of records downloaded into each IRMB database following the nightly download. The report is sent to interested IRMB staff.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): This system does not contain IIF
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: This system does not contain IIF

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) This system does not contain IIF

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: This system does not contain IIF

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Joellen Harper Austin, Executive Officer, NINDS 301-496-4697

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINDS NINDS DIR General Support System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/11/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): DIR General Support System (GSS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: George Buckland
- **10. Provide an overview of the system:** The system is a General Support System (GSS) and does not directly collect or store information.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system is a General Support System (GSS) and does not directly collect or store information. The applications/systems residing on the GSS collect and store information. Therefore, individual PIAs have been prepared and submitted for the applications/systems residing on this GSS.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Joellen Harper Austin, Executive Officer, NINDS 301-496-4697

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINDS NINDS OD DER General Support System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-8610-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): OD/DER General Support System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Donna Stephenson
- **10. Provide an overview of the system:** The system is a General Support System (GSS) and does not directly collect or store information.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system is a General Support System (GSS) and does not directly collect or store information. The applications/systems residing on the GSS collect and store information. Therefore, individual PIAs have been prepared and submitted for the applications/systems residing on this GSS.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Joellen Harper Austin, Executive Officer, NINDS 301-496-4697

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINDS Notify Deputy GMO of NEW PCC in IMPACII

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-8610-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** Notify Deputy GMO of New PCC in IMPACII
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Donna Stephenson
- **10. Provide an overview of the system:** The Notify Deputy GMO of New PCC in IMPACII system sends an email to the deputy GMO when a new Program Class Code (PCC) is created in IMPACII.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\rm N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system stores Program Class Codes (PCC)

The system emails a report if a new PCC is created in IMPACII.

No PII is collected or included in this system.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Joellen Harper Austin, Executive Officer, NINDS 301-496-4697

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINDS Patchlink PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-02-00-01-3109-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): Patchlink
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Donna Stephenson
- **10. Provide an overview of the system:** Patchlink (Lumension Security) is our vulnerability remediation tool. Agents on the client machines provide information such as services, applications, and hardware to the Patchlink server. Patchlink uses this information to see if there are any vulneribilities with this information and then supplies the patches needed to remedy the vulnerability.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): This system does not contain, share, or disclose IIF.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Information is collected from client machines for the sole purpose of determining which patches to apply to remediate vulnerabilities. Lumension's Patch Management and Remediation Solution enables us to

automate the collection, analysis, and delivery of software patches and rapidly create and deploy remediation packages that address a wide range of configuration related issues (i.e. closing down vulnerable ports, shutting down dangerous services, etc.) throughout the heterogeneous enterprise.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) None.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No IIF is collected by this system.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Joellen Harper Austin, Executive Officer, NINDS 301-496-4697

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINDS People/Organization Module (POM)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-09-02-8601-00-402-125

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0216

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): People/Organization Module (POM)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Donna Stephenson
- **10. Provide an overview of the system:** The POM provides a centralized repository of all NINDS employees and tracks the following information:
- IRMB applications used by NINDS employees.
- Employment Status.
- User Roles.
- Cluster Assignments.
- Organization Role.
- Program Class code (PCC)

This information is used by other NINDS systems for their user authentication and authorization.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes

- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\rm N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system stores the following information:
- Name
- Email Address
- NT Login name
- IMPACII Person ID
- Employment Status
- Cluster Assignment
- Organizational Role
- Program Class Codes (PCC)

This information is used by other systems for their user authentication and authorization. This information is mandatory and is collected as a part of the Grants Management process.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The NIH collects the PII, and NINDS relies upon the NIH policy for notifying and obtaining consent from individuals. Information regarding individual notification procedures is further addressed in the NIH Privacy Act Systems of Record Notice 09-25-0216, published in the Federal register, volume 67, No. 187, September 26, 2002.

This information is collected as a part of their employment in a position involving the managing of grants. They are advised of the need to collect this information and how it will be used either verbally or in writing at the time they accept the position.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The system has several administrative controls in place to secure the data. The NIH requires security training for all system users on an annual basis. Also, the security controls and disaster recovery plan are part of the Certification

and Accreditation process. Finally, the system maintains several user roles, and each system user is given the least priviledge needed to perform his or her business function.

The system has several technical controls in place to secure the data. A user must first provide a valid username and password to access the NINDS network. The user must also be a system user before he or she can log onto the system. The Institute's firewall and intrusion detection systems also protect the system.

The system has several physical controls in place to secure the data. The system is protected by guards, ID badge requirements, key card access, cipher locks, and closed-circuit television.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Approval: Joellen Harper Austin, Executive Officer, NINDS 301-496-

4697

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINDS PO Reassignment Automailer

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-8610-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): PO Reassignment Automailer
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Donna Stephenson
- **10. Provide an overview of the system:** The PO Reassignment Automailer is a Microsoft Access database system that queries IMPAC II, generates a report, and sends email notifications to Program Officials (POs) via email. These email notifications indicate the PO assigned to a grant application has changed and notifies both the new and former POs. The email notifications also provide a link to the report that details all the reassignments. All reports are stored on a secure network drive.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): This system does not contain IIF.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: This system does not contain IIF.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) This system does not contain IIF.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: This system does not contain IIF.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Joellen Harper Austin, Executive Officer, NINDS 301-496-4697

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINDS PO Unsigned Report

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-8610-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): PO Unsigned Report
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Donna Stephenson
- **10. Provide an overview of the system:** The PO Unsigned Report system creates a report of grant applications with a To Be Paid status that have not been signed by the Program Official. The email contains a link to the report, which is stored on a common drive.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Not Applicable
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The System stores the following information:
- * Grant Specialist (GS) name.

- * Program Official (PO) name.
- * Principle Investigator (PI) name.
- * Grant number.

The system emails a report detailing the grant applications that are awaiting the signature of the Program Official. This information is mandatory as a part of accepting the position of GS,PO, or PI.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The data is collected by the IMPAC II system and NINDS relies on the IMPAC II system to obtain permission via the grant application process and to notify individuals when major changes are made affecting the use of the data, how the data will be used and why it is being collected. The IMPAC II system uses the data to process grant applications and maintain grants. NINDS uses this automailer as a portion of the grant application process to inform the applicant of the status of their application.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The system has several administrative controls in place to secure the data. The NIH requires security training for all system users on an annual basis. Also, the security controls and disaster recovery plan are documented as part of the Certification and Accreditation process for the General Support system (GSS).

The system has several technical controls in place to secure the data. A user must first provide a valid username and password to access the NINDS network. The user must also be a system user before he or she can access the system. The Institute's firewall and intrusion detection systems also protect the system.

The system also has several physical controls in place to secure the data. The system is protected by guards, ID badge requirements, key card access, cipher locks, and closed-circuit television.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Joellen Harper Austin, Executive Officer, NINDS 301-496-4697

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINDS Public Access Data Load

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-8610-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): Public Access Data Load
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Donna Stephenson
- 10. Provide an overview of the system: The National Institutes of Health (NIH) Requires that the general public have access to publications that result from NIH-funded research. To satisfy this responsibility, scientists must submit their peer-reviewed publication to PubMed Central. The National Institute of Neurological Disorders and Stroke (NINDS) developed the NINDS Public Access Compliance System to help staff track compliance with the requirement. The Public Access Data Load system runs twice a day and queries IMPACII for new Type 5 Progress Reports. These Type 5 Progress Reports are used by the NINDS Public Access Compliance System to help track compliance. More information about the Public Access Policy is available at http://publicaccess.nih.gov/.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\rm N\!/\!A$

- **30.** Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: This system collects Type 5 Progress Reports containing public accessable data which are then used by the NINDS Public Access Compliance System to help ensure compliance with the NIH Public Access Policy implements Division G, Title II, Section 218 of PL 110-161 (Consolidated Appropriations Act, 2008). No PII is contained in these reports. Information contained in this system is not available to the public via this system.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Joellen Harper Austin, Executive Officer, NINDS 301-496-4697

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINDS Purchasing Online Tracking System Shared Service Platform [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/11/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-8602-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): none

- 7. System Name (Align with system Item name): Purchasing Online Tracking System (POTS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: George Buckland
- **10. Provide an overview of the system:** Consolidates workflow relating to acquisition—purchase request, approval, ordering, and receiving—into a paperless, auditable system, and provides a central repository for all purchase-related forms. POTS allows requesters, approvers and purchasing agents to use one Web-based system to perform the tasks needed to submit, review and approve purchase requests.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Purchase-related data

(requester, purchaser, vendor, purchase item descriptions). POTS allows requesters, approvers and purchasing agents to use one Web-based system to perform the tasks needed to submit, review and approve purchase requests. No PII data is requested or stored.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) None

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The system has several administrative controls in place to secure the data. The NIH requires security training for all system users on an annual basis. Also, the security controls and disaster recovery plan are documented as part of the Certification and Accreditation process. Finally, the system maintains several user roles, and each system user is given the least privilege needed to perform his or her business function. The system has several technical controls in place to secure the data. A user must first provide a valid username and password to access the NIH network. A user must also be an authorized system user, with a record in the user table. The system is also protected by the Institute's firewall and intrusion detection systems. The system also has several physical controls in place to secure the data. The system is protected by guards, ID badge requirements, and key card access.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Joellen Harper Austin, Executive Officer, NINDS 301-496-4697

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINDS Receipt and Referral System (RRS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-8610-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NINDS Receipt & Referral System (RRS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Donna Stephenson
- **10. Provide an overview of the system:** The RRS is an electronic reading room that allows NINDS DER Program Directors (PDs) and Program Analysts (PAs) to perform the following tasks:

Pre-sort Type 1 grant applications into clusters.

Indicate an interest in being either the primary Program Director assigned to the grant or the secondary Program Director.

The system allows an administrator, normally the Referral Liaison (RL), to approve the grant application assignments and send this information, i.e., the assigned Program Director's program class code (PCC), to the eRA system. The administrator also has the capability to perform certain system utilities.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes

- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): See SOR# 09-25-0036. This information is further addressed in the NIH Privacy Act Systems of Record Notice 09-25-0036, published in the Federal Register, Volume 67, No. 187, September 26, 2002.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: IIF information in the form of PI Name and grant application number are obtained from eRA for use in processing grant applications. The information is mandatory for processing a grant application and is submitted with the grant application to the eRA system.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) IIF is submitted as a part of the grant application process. Information used by RRS is taken from the ERA grant application. Notification and consent from the individual is assumed when the grant application is submitted. All notification and consent is taken care of via the Grant application submission process and eRA systems.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Role base security, user name and password, system resides behind a firewall and is in a server room with no external access. All personal not having card key access are escorted.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Peter Soltys/Sue Titman (301) 496-9244

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINDS Remedy PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-8610-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0216

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): Remedy
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Donna Stephenson
- **10. Provide an overview of the system:** NINDS Remedy is a change management solution where system change requests can be tracked, validated, and reported against. These change requests are requests to add/modify features in the various NINDS software systems and servers. NINDSREMEDY1 serves as the server for NINDS, where Remedy is exclusively used. The database on which Remedy is dependent resides on a NINDS resource named SQLCLUSTER (SQL Server 2000 database server).
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Data is kept in house and used to track, validate and report change requests.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Information identifying the individual submitting a change request is submitted as a part of the change management process.

The information is used to contact the individual for additional information/justification for the change. This system stores name and contact information for the individual submitting the change request. The information is mandatory to ensure the request can be processed in a timely manner.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Notification and consent to collect and store IIF is assumed when the change request is submitted. Individuals are informed of this policy and the use of the information when they are trained in the use of the Remedy system. IIF stored in the system includes name and contact information of the person submitting the change request. Personnel are informed of changes to the system via email.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Role-based security, single sign-on using username and password. The system resides behind a firewall and is in a server room with no external access. All personnel not having card key access are escorted.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Peter Soltys/Sue Titman (301) 496-9244

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINDS SharePoint Document Library

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-90-0018, 09-25-0216

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): SharePoint Document Library
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Donna Stephenson
- **10. Provide an overview of the system:** The SharePoint Document Library is an electronic library maintained in Microsoft Office SharePoint Server. It contains documents pertaining to all NINDS hardware and software systems, Disaster Recovery and Contingency Planning, training, workflows, and other NINDS/OD/IRMB administrative documents.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Home phone numbers are provided in an emergency call list for use by disaster recovery personnel in the event of a disaster.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Employee name, home

phone number, cell phone number, and business number are collected for use in an emergency recall list used in disaster recovery/contingency planning and execution.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) For the Emergency Call/Recall List(s), personnel are contacted in person when information is collected or updated. They are informed at that time the purpose for collecting this information. Consent is given verbally at that time. Also see SORNs 09-90-0018 and 09-25-0216.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Network sign-on using user name and password. SharePoint software also provides the capability to restrict areas based on rules/roles assigned by the data owners. System resides behind a firewall and in a locked server room with no external access. All personnel not haveing key card access are escorted.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Joellen Harper Austin, Executive Officer, NINDS 301-496-4697

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINDS Special Programs in Neuroscience (SPIN)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-8610-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): Special Project in Neuroscience (SPIN)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Donna Stephenson
- **10. Provide an overview of the system:** SPIN allows staff to track PI's, fellow's, trainees' and supporters who have minority supplements. SPIN allows information on people not stored in IMPAC II to be associated with a particular grant application. PHS Act Section 301.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): See SOR# 09-25-0036. This information is further addressed in the NIH Privacy Act Systems of Record Notice 09-25-0036, published in the Federal Register, Volume 67, No. 187, September 26, 2002.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Collected information

includes, grantee's name, race, ethnicity, education level, and gender. The information is collected for grant application reporting purposes used only within the institute. The collected information is the minimum amount of information that is associated with the application. The information is used to monitor research programs, research capacity, building and training, and health disparities among underrepresented groups (e.g. racial/ethnic, gender, etc.). This information is voluntary within the SPIN application.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The data is collected from the grant applications that an individual submits for consideration in obtaining a grant. Consent is assumed when an individual submits his/her grant application. Notification of major changes to the SPIN system is not made to individuals whose IIF was obtained from their grant application submission. Notification of changes to the use of IIF and consent to collect IIF is handled through eRA and the grant application submission process.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: See SOR# 09-25-0036. This information is further addressed in the NIH Privacy Act Systems of Record Notice 09-25-0036, published in the Federal Register, Volume 67, No. 187, September 26, 2002.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Peter Soltys/Sue Titman (301) 496-9244

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINDS Status of Funds Internet Edition (SOFie)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/11/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): None

- 7. System Name (Align with system Item name): Status of Funds Internet Edition (SoFIE)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: George Buckland
- **10. Provide an overview of the system:** Provides real-time budgeting database information for the NINDS/DIR. It Interfaces with and gets data from the NIH financial management system. Replaced the earlier Visual Status of Funds (VSOF) system.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Internal NINDS day-to-day budget information. Does not collect or maintain PII data.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) None

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The system has several administrative controls in place to secure the data. The NIH requires security training for all system users on an annual basis. Also, the security controls and disaster recovery plan are documented as part of the Certification and Accreditation process. The system is also protected by the Institute's firewall and intrusion detection systems. The system also has several physical controls in place to secure any data. The system is protected by guards, ID badge requirements, and key card access.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Joellen Harper Austin, Executive Officer, NINDS 301-496-4697

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINDS Type 5 Received Automailer

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-8610-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): Type 5 Received Automailer
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Donna Stephenson
- **10. Provide an overview of the system:** The Type 5 Received Automailer is a Microsoft Access database system that queries IMPAC II, searches for specific grant applications and sends the search results via email to the system user. A copy of the email is stored in the Microsoft Outlook Public folders
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): This system does not contain IIF
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: This system does not contain IIF

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) This system does not contain IIF

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: This system does not contain IIF

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Joellen Harper Austin, Executive Officer, NINDS 301-496-4697

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/26/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINDS Workload FY XXXX NS Automailer

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-8610-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): Workload FY XXXX NS Automailer
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Donna Stephenson
- **10. Provide an overview of the system:** The Workload FY XXXX NS automailer is a system that emails the Daily Refresh Workload FY XXXX NS report to the Grants Management Branch Chief on a weekly basis.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The system emails a copy of the Daily Refresh Workload FYXXXX NS report to the Grants Management Branch (GMB) Chief. The GMB Chief reviews the workload for each Grants Specialist.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: The system stores the following information:

- The Grant Specialist name and his or her General Schedule (GS) level.
- Grant application number.
- Cluster name.

The email may contain PII. Submission of the information is required when an individual accepts a position as a Grants specialist.

The system emails a report detailing the Grant Specialist's workload and compares it with his or her GS level to the GMB Chief for review. The GMB Chief reviews the GS's workload to spot potential issues which need to be addressed.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The data is collected by the IMPAC II system and NINDS relies on the IMPAC II system to obtain permission via the grant application process and to notify individuals when major changes are made affecting the use of the data, how the data will be used and why it is being collected. The IMPAC II system uses the data to process grant applications and maintain grants. NINDS uses this automailer as a portion of the grant application process to inform the applicant of the status of their application.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The system has several administrative controls in place to secure the data. The NIH requires security training for all system users on an annual basis. Also, the security controls and disaster recovery plan are documented as part of the Certification and Accreditation process for the General Support System (GSS).

The system has several Technical controls in place to secure the data. A user must first provide a valid username and password to access the NINDS network. The user must also be a system user before he or she can access the system. The Institute's firewall and intrusion detection systems also protect the system.

The system also has several physical controls in place to secure the data. The system is protected by guards, ID badge requirements, key card access, cipher locks, and closed-circuit television.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Approval: Joellen Harper Austin, Executive Officer, NINDS 301-496-

4697

Sr. Official for Privacy Approval: Promote **Sr. Official for Privacy Name:** Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINR Developing Nurse Scientists Online Course

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/25/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-02-00-01-3109-00-109-026

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0014

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): Developing Nurse Scientists On-line Course
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Dr. Natalie A. Rasmussen
- **10. Provide an overview of the system:** The NINR web based Developing Nurse Scientist course provides the general profile of NINR and its guidelines for grant submission. The course also discusses the practical skills necessary for developing a successful research program and as well as the key issues in research including research ethics, IRB, disseminating findings, and recruiting research participants.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): First name, Last Name and email addresses of course registrants are collected for credentialing and provided to the Maryland State Nurse Association . These fields are mandatory.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: Names and email addresses of course registrants are collected for credentialing. The information is mandatory for credentialing.

This system collects IIF from users. The required fields are First name, Last name and email address. (email address is then used as username along with a newly created password. The following fields are required for the password challenge questions used to reset or recover password: pets names, favorite city and year graduated college.) Optional fields include City, State, Zip, Affiliation, Discipline, Educational Level, Educational Level other, Research Experience, Research other, and Years in Research. Users first and last name will be passed on to the State of Maryland in order to receive Continuing Education Units (CEU). Users will be given advance notice of this in the sites Privacy Statement. This information will passed using secure email.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) A Privacy notification statement is displayed in the course as well as a Disclaimer. System users can be notified via email of any changes dealing with PII.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: NCI has in place controls to safeguard and restore data in the case of data loss or catastrophe, to protect the data from unauthorized access or use electronically with passwords, and to prevent physical access to the data with a badging system.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Brian Albertini 301.594.6869

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINR EOL PC Evaluation Survey System (EOL PC)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 3/31/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: Being obtained

6. Other Identifying Number(s): N/A

7. System Name (Align with system Item name): NIH NINR End-of-Life and Palliative Care (EOL PC) Evaluation Survey System

- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Amanda Greene
- 10. Provide an overview of the system: This survey system will collect information about endof-life and palliative care (EOL PC) research grant funders (i.e., federal agencies such as National Institutes of Health (NIH), Agency for Healthcare Research and Quality (AHRQ), Veterans Administration (VA), and philanthropic organizations such as Robert Wood Johnson Foundation) and EOL PC research topics that have been funded. This survey system includes three surveys, i.e., the Funding Source Questionnaire, the Survey of Federal Agencies, and the Survey of Non-Governmental Foundations and Organizations. The purpose of the Funding Source Questionnaire is to identify what government or non-government organization, if any, funded EOL PC research that (i) was published between 1997 and 2010 and (ii) did not list a funding source in the publication. This survey is sent to authors of EOL PC research publications who did not list the funding source for their study in their publication. The purpose of the Survey of Federal Agencies, which is sent to staff at federal agencies that fund EOL PC research, is to gather information on funded research topics and trends, knowledge gaps, reasons for change in funding EOL PC research, funding sustainability, and EOL PC research partnerships. The purpose of the Survey of Non-Governmental Foundations and Organizations, which is sent to staff of organizations with a history of funding EOL PC research, is to gather information about the motivators, facilitators, and barriers to EOL PC research and funding. All three surveys in this system will collect information about EOL PC research including the funder (i.e., agency or organization who awarded the grant) of published EOL PC research, research topics funded, length of grant funding, amount of grant funding, reasons for change in funding over time, issues related to funding sustainability, needs and interests of stakeholder, current or future earmarked funding, trends in research theme interests and programmatic scope, and future opportunities for collaborative partnerships. EOL PC research grants that have been funded by federal and non-profit organizations include studies such as research on providing care in terminal conditions that alleviates or decreases symptoms and improves quality of life, advanced

care planning, bereavement/grief care, care models (e.g., hospice), ethics, cost, caregivers, alternative and complementary medicine, and training professionals.

- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) The EOL PC Evaluation Survey System will collect information using three online surveys (description follows). Responses to all online surveys are voluntary.
- (a) The FUNDING SOURCE QUESTIONNAIRE is a 7-item survey that asks what federal agency or non-federal organization, if any, funded a published EOL PC research study. The survey questions do not collect any personally identifiable information. This survey will only be sent to authors of EOL PC published studies who did not list a funding source. Potential survey respondents (i.e., authors) are identified from publicly available databases such as PubMed. Published literature databases such as PubMed include the author's name, organizational affiliation, and address or email address. Once the survey data is collected the publicly available PII information used to identify potential respondents will be destroyed.
- (b) The SURVEY OF FEDERAL AGENCIES will have less than 30 questions that ask about the agency's grant funding of EOL PC research. The survey questions do not collect any personally identifiable information. All collected information is about EOL PC research funded by the Federal Agency. Federal staff invited to complete this survey will be identified through (I) the NIH Information for Management, Planning, Analysis, and Coordination (IMPAC II) database using publicly available applications like the NIH Research Portfolio Online Reporting Tools (RePORT), (ii) participation in federal work groups, panels or committees focused on EOL PC research, and (iii) a nonprobability sampling method using the snowball technique. The name, email, office telephone number (if available), and Federal Agency name will only be collected in order to invite identified staff to complete the survey.

- (c) The SURVEY OF NON-GOVERNMENT FOUNDATIONS AND NON-PROFIT ORGANIZATIONS will have less than 30 questions that ask about the agency's grant funding of EOL PC research. The survey questions do not collect any personally identifiable information. All collected information is about EOL PC research funded by the Foundation/non-profit organization. Foundation/organization staff invited to complete this survey will be identified (i) by querying publicly-available databases (i.e., The Foundation Center and GuideStar), (ii) listed as the funding source for published EOL PC research, (iii) identified by Federal staff involved in EOL PC research collaborations and partnerships, (iv) participation in national or international work groups, panels or committees focused on EOL PC research, and (v) a nonprobability sampling method using the snowball technique. The name, business email, business telephone number (if available), and foundation/organization name will only be collected in order to invite identified staff to complete the survey.
- (2) NINR/NIH will use this information to identify research topics and funding trends in EOL PC research so that future research needs can be identified and planned for.
- (3) The EOL PC Evaluation Survey System will collect the following information which is federal/business information only: name, affiliation, business email address (or business mailing address if no email listed), and office telephone number (if available). This information is only to identify potential survey participants so that an invitation to complete a survey can be sent.
- (4) Information collected to invite potential survey participants is publicly available information. Response to the surveys is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Brian Albertini Privacy Coordinator, NINR

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 5/6/2011

Approved for Web Publishing: Yes

Date Published: May 23, 2012

06.3 HHS PIA Summary for Posting (Form) / NIH NINR Internet Website (Public)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/11/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-02-00-01-3109-00-109-026

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): NINR Internet Website
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Melissa Barrett
- **10. Provide an overview of the system:** It is the public face of NINR on the web to provide information about NINR and the research that it supports.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: N/A
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original

collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: There is none to secure.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Brian Albertini 301-594-6869

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINR NINR LAN GSS [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 8/11/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): Not Applicable

5. OMB Information Collection Approval Number: Not Applicable

6. Other Identifying Number(s): Not Applicable

- 7. System Name (Align with system Item name): NINR LAN GSS
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Mary Murray
- **10. Provide an overview of the system:** The NINR LAN GSS includes a number of supportive "core services" that are provided through the NCI CBIIT GSS to the NINR user community that provide or enhance network and information security, data storage, backup services, help desk support, and shared application environments (e.g., enterprise database, web, application, and storage platforms). The system is a General Support System (GSS) and does not directly collect or store information. The system is a General Support System (GSS) and does not directly collect or store information.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Not Applicable
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system is a General Support System (GSS) and does not directly collect or store information. The applications/systems residing under the GSS may collect and store information. Therefore, individual PIAs have been prepared and submitted for the applications/systems residing on this GSS.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Not Applicable.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Not applicable.

PIA Approval

PIA Reviewer Approval: Promote PIA Reviewer Name: Brian Albertini

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NINR Status of Funds Internet Edition

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/22/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: No

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): Status of Funds Internet Edition
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Kevin Wilson
- **10. Provide an overview of the system:** SOFie is a financial reporting/tracking system which is accessed via the web.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: All accounting transactions are available for viewing in SOFie. The information is used to track and plan fiscal budgets. It is necessary to have access to this data in order to comply with appropriations laws and regulations.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) There is none.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Information is secured using username/passwords, least privilege, separation of duties, an intrusion detection system, firewalls, locks, badge access, background investigations. A comprehensive IRT capability is also maintained.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Brian Albertini 301-594-6869

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NLM Clinical Text De-Identification

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/9/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH NLM Clinical Text De-identification System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Mehmet Kayaalp, MD, PhD
- **10. Provide an overview of the system:** Clinical text documents contain a rich set of clinical knowledge that is invaluable for clinical research. Unfortunately, they largely remain an untapped resource since disseminating such data as-is would jeopardize the privacy of patients and reveal protected health information.

Computational de-identification is a means to overcome this problem. It involves processing clinical text documents using natural language processing (NLP) tools and techniques, recognizing personally identifiable information (e.g., names, addresses, telephone and social security numbers) in the text, and redacting only those identifiers. In this way, patient privacy is protected and clinical knowledge is preserved.

Without computational tools, de-identification places a heavy burden on clinicians' shoulders, but it is a necessary step for protecting patient privacy as mandated by both the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA) and the Privacy Act of 1974.

The National Library of Medicine (NLM) began testing some existing applications designed for this purpose and finally decided on developing a new software tool that is capable of deidentifying all types of clinical text documents with higher accuracy than other available tools on the market. This way NLM will be able to adjust the software parameters as the nature of electronically available clinical text changes over time.

The application software design involves a number of both deterministic and probabilistic pattern recognition algorithms using various computational linguistic methods. It also uses a number of large datasets for names, addresses, and organizations.

The design accepts text documents in plain text or in HL7 format. If documents are provided in an HL7 format, the application makes use of patient related information embedded in various HL7 segments and fields in order to attain near perfect accuracy.

The application software includes an editor for visualization and markup called the Visual Tagging Tool (VTT). Although its original design was for tagging identifiers that contain personally identifiable protected health information, VTT has been made publicly available to the greater NLP community for general purpose lexical tagging and text annotation.

The preliminary results of this study suggest that computational de-identification methods may attain an accuracy at (or higher than) the level of 99% sensitivity and 99% specificity across a large spectrum of identifiers containing personally identifiable information.

- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\rm N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) No new information will be collected. Existing clinical text documents provided by the Clinical Center at NIH are used to test and ensure that the developed system works as intended. The information in the text is not used. Clinical text documents will not be disseminated.
- (2) Clinical text documents are needed to test the quality of the system that is under development. The system will de-identify clinical text records.
- (3) Clinical text documents contain PII.
- (4) N/A (the data exists)

- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.
- (Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) (1–2) N/A. The project is about the quality assurance (QA) of the de-identification system under development. No research is conducted on patient information. In other words, it is an internal NIH QA activity and considered by Office of Human Subject Research (OHSR) "Not Human Subject Research" based on how OHRP reviews quality improvement under the current OHRP guidance.
- (3) The data is needed to test the quality of the software application that is under development. The software application will de-identify clinical text records.
- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** All data is stored on one server and backed up by another server. The servers and the VLAN router are located in NLM's computer room where access is strictly controlled via various physical measures including biometric security checks. The application has been developed on workstations, which are connected to the server to access the data. The workstations reside in locked private offices in Building 38A in NIH campus. The suits where offices are located are accessed via access card keys during off hours.

The data are stored in flat text files on encrypted disks using FIPS 140-2 compliant encryption methods in workstations and servers, which are connected via a private virtual local area network (VLAN) with no Internet connection. The access to the VLAN is allowed to workstations and servers with specific MAC addresses connected to specific physical ports. In other words, if two such workstations are swapped their physical locations (i.e., their ports), they would not be able to access the VLAN. The workstations are accessed via SecurID. The systems are behind several layers of firewalls. An intrusion detection system is run every month.

Accesses to the system and data are audited continuously. Every user of the system is required to complete all security, ethics, and privacy awareness training before receiving access to the system.

The data in its original text format as received from the clinical center is stored for back up purposes on encrypted USB thumb drives, which are FIPS 140-2 compliant devices. These devices are stored in a safe that is located in a locked private office.

The contractors working in this project adhere to the requirements of the privacy act and their agreements are stated in their contracts with FAR clauses 52.204-2 and 52.239-1.

The security measures are checked and approved by the NLM ISSO.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Dar-Ning Kung

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NLM dbGaP (Database of Genotype and Phenotype)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/9/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: New Project

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- **7. System Name (Align with system Item name):** dbGaP Database of Genotype and Phenotype
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Dar-Ning Kung
- 10. Provide an overview of the system: dbGaP, the database of Genotype and Phenotype, is a database designed to archive and distribute data from genome wide association (GWA) studies. GWA studies explore the association between specific genes (genotype information) and observable traits, such as blood pressure and weight, or the presence or absence of a disease or condition (phenotype information). Connecting phenotype and genotype data provides information about the genes that may be involved in a disease process or condition, which can be critical for better understanding the disease and for developing new diagnostic methods and treatments.

The database does not contain names, social security numbers, fingerprints, photographs or anything enabling facial recognition. The data is strictly de-identified patient data and does not fall under the category of IIF.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Data collected includes the researchers name and institutional information, a research abstract (reason for requesting the data) and co-investigator information. This is collected for further contact with the PI and to provide controlled access to the data requested and to provide public access to the research uses of the data.

The information collected from co-investigators is the same as that from Principal Investigators: name, business address, and email address. The submission of personal information is voluntary.

The dbGaP database contains phenotype and genotype data from researchers and from centers who are conducting genome-wide association studies. NLM/NCBI summarizes, reformats, and redistributes these data acting as a central repository for these types of studies.

The information collected is from studies sponsored by an NIH Institute and is sent from the principal investigator or the center conducting the study. All data received is certified as deidentified data. After NIH review of a request from an investigator and his/her sponsoring organization, the genotype and phenotype data is made available for that investigator to access.

Data are categorized by an accession number assigned by NLM/NCBI (not the investigator) to the dataset. Information is retrieved by the name of the study. The capability exists to search the public data for the name of the study, the protocols used, and the dataset summaries but the retrieval is by accession number.

No information in dbGaP is collected directly from patients. Data has not been collected from other NIH databases. If data were to be provided from other NIH databases, e.g., an intramural study, it would be provided under the same conditions as external data, i.e., all data would be deidentified.

There are no names or personal identifiers linked to the phenotype/genotype records. All data are de-identified prior to the time it is delivered to NLM/NCBI.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Dar-Ning Kung

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NLM Genome Assembly and Annotation (GenBank)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/9/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-0733-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- **7. System Name (Align with system Item name):** NIH NLM Genome Assembly and Annotation (GenBank)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Jim Ostell, NCBI; Dennis Benson, NCBI
- **10. Provide an overview of the system:** GenBank is a database of publicly available DNA sequence information. GenBank is an annotated collection of nucleotide sequences from over 200,000 different organisms obtained primarily from individual laboratories as well through batch submissions from large-scale sequencing centers. The data is exchanged with similar databases in the UK and in Japan. The database is accessible via the web and by File Transfer Protocol.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Data collected include nucleotide sequences and the name of the researcher or laboratory contributing the data, his institution, and a publicly available email address, as associated with the journal article. Submission of data is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Dar-Ning Kung

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NLM Lost Person Finder PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/9/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200

5. OMB Information Collection Approval Number: 0925-0612

6. Other Identifying Number(s): No

7. System Name (Align with system Item name): NIH/National Library of Medicine (NLM) Lost Person Finder System (LPF)

- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Michael Gill
- 10. Provide an overview of the system: The National Library of Medicine (NLM) Lost Person Finder (LPF) project includes Web-based components that collect data to facilitate reunification efforts during or after a disaster event. This data is collected as part of NLM's mission to develop and coordinate communication technologies to improve delivery of health services. NLM is a member of the Bethesda Hospitals' Emergency Preparedness Partnership (BHEPP), which was established in 2004 to improve community disaster preparedness and response among hospitals in Bethesda, Maryland that would likely be called upon to absorb mass causalities in a major disaster in the National Capital Region or other areas. The BHEPP hospitals include the National Naval Medical Center (NNMC), the National Institutes of Health Clinic Center (NIH CC), and Suburban Hospital/Johns Hopkins Medicine. With its expertise in communications, information management, and medical informatics, NLM joined BHEPP to coordinate the R&D program, one of which is development of a person locator tool to assist in family reunification after a disaster.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Yes. Information is shared with, disclosed or transferred to: (1) BHEPP participating hospitals' personnel; (2) the general public via an interactive Web-based system that allows individuals to search for missing family members that may have been recovered (or found) post-disaster; (3) other people locator systems endorsed by U.S. government agencies to ensure that comprehensive data is available to users of such systems and to ensure that use of the NLM system in no way interrupts or distracts from the operation or use of other people locator systems.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The primary uses of the Lost Person Finder project components are to facilitate reunification efforts during or after a disaster. Subsequently, the NLM will use the data to evaluate the functioning and utility of the LPF components and similar technologies and guide future enhancements to the system. Collection of this information is authorized pursuant to sections 301, 307, 465, and 478A of the Public Health Service Act [42 U.S.C. 241, 2421, 286, and 286d] which authorizes the HHS Secretary to conduct and support research. The information collected, maintained and disseminated includes personally identifiable information (or PII) and is collected on a voluntary basis. Biographical information physical identifying characteristics will be collected, maintained, and disseminated.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.
- (Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) (1) There is no process for obtaining consent from individuals whose PII is maintained in the system when major system changes occur. (2) Information is collected on a voluntary basis. (3) Information is posted on the LPF Web site notifying users about how their information will be shared.
- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: PII is secured by NLM's controlled access computer room (Technical/Physical), Access to system must be requested in writing from NLM program staff (Administrative).

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Dar-Ning Kung

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NLM Medical Literature Analysis Retrieval System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/9/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-0705-00-110-219

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- **7. System Name (Align with system Item name):** NIH NLM Medical Literature Analysis and Retrieval System (MEDLARS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Dar-Ning Kung
- **10. Provide an overview of the system:** The Medical Literature Analysis and Retrieval System (MEDLARS) is a multi-purpose application system developed, maintained and operated by the National Library of Medicine (NLM) at the National Institutes of Health (NIH) and consists of various application modules to assist the National Library of Medicine in collecting, organizing, managing, and disseminating health related information.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: No

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Dar-Ning Kung

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NLM NLM Data Center [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 7/20/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): NIH NLM Data Center [System]
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Michael Simpson, OCCS
- 10. Provide an overview of the system: The National Library of Medicine Data Center (NLMDC) is a secure and resilient information system facility located at Bldg. 38A/Rm. B1W17, 8600 Rockville Pike, Bethesda, MD 20894. The NLMDC houses information systems that carry out the NLM mission of enabling biomedical research, supporting health care and public health, and promoting healthy behavior. The Data Center is operated 24/7/365 providing secure physical and virtual access to authorized personnel. The NLMDC is configured with redundant power, cooling and network connectivity. The NLMDC systems and personnel play key roles in System Back-up, Incident Response, Critical Infrastructure Monitoring, System Equipment Monitoring, Service Desk Support, DR/COOP processes, and Physical and Environmental Security.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) NLM Data Center is a general support system that does not collect, maintain, or disseminated information.
- (2) N/A
- (3) No data will be collected and there is no PII.
- (4) N/A
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Dar-Ning Kung

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 8/16/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NLM Open Source Independent Review and Interpretation System (OSIRIS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/9/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: No

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- **7. System Name (Align with system Item name):** Open Source Independent Review and Interpretation System (OSIRIS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Stephen Sherry / Dennis Benson
- 10. Provide an overview of the system: The Open Source Independent Review and Interpretation System (OSIRIS) is a software tool for checking and validating DNA profile data for accuracy and quality. It is a data validation tool for use by local forensic laboratories to measure the conformance of raw data to quality control standards. NLM receives a limited number of DNA samples for the purpose of developing and improving the statistical methods used to validate the results; however, they are de-identified samples from state laboratories. NLM does not maintain any public or production database of the de-identified samples nor does NLM have any way of associating the DNA forensic data with a person or with any other identifying information.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The OSIRIS software tool is a data validation tool developed by NCBI/NLM for use by local forensic laboratories to determine how their data samples conform to quality control standards. The tool is distributed to local forensic laboratories for their own internal use. The tool itself does not collect, maintain, or disseminate data. In the process of developing the OSIRIS program, NCBI/NLM received a limited number of DNA samples to test the statistical methods used to validate the results. These samples were obtained solely for the purpose of developing the software algorithms and were deidentified samples, containing no individually identifiable information.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Dar-Ning Kung

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH NLM Toxicology Data Network [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/9/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-0703-00-110-219

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No
- **5. OMB Information Collection Approval Number:** No
- **6. Other Identifying Number(s):** No
- **7. System Name (Align with system Item name):** NIH NLM Toxicology Data Network (TOXNET)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Dar-Ning Kung
- **10. Provide an overview of the system:** TOXNET (Toxicology Data Network) is the National Library of Medicine's extensive collection of online bibliographic information. It is a cluster of databases covering toxicology, hazardous chemicals, and environmental health and related areas.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: No

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Dar-Ning Kung

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Actions, Training and Reports Data (ATRD)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/27/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: not listed

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-90-0018

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- **7. System Name (Align with system Item name):** Actions Training and Reports Database (ATRD)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Donna Easterday
- **10. Provide an overview of the system:** The ATRD is a PeopleSoft relational database consisting of multiple tables containing information about HR transactions and reports for National Institutes of Health (NIH) employees to be used for training and reporting to mitigate risks associated with using the production Capital HR (EHRP) database.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Information in these records may be used:
- (1) By the Office of Personnel Management, Merit Systems Protection Board (including its Office of the Special Counsel), Equal Employment Opportunity Commission, and the Federal Labor Relations Authority (including the General Counsel of the Authority and the Federal Service Impasses Panel) in carrying out their functions.

- (2) In the event an appeal is made outside the Department, records which are relevant may be referred to the appropriate agency charged with rendering a decision on the appeal.
- (3) In the event that this system of records indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the appropriate agency, whether federal, or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation or order issued pursuant thereto.
- (4) In the event the Department deems it desirable or necessary, in determining whether particular records are required to be disclosed under the Freedom of Information Act, disclosure may be made to the Department of Justice for the purpose of obtaining its advice.
- (5) A record from this system of records may be disclosed as a "routine use" to a federal, state or local agency maintaining civil, criminal or other relevant enforcement records or other pertinent records, such as current licenses, if necessary to obtain a record relevant to an agency decision concerning the hiring or retention of an employee, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant or other benefit. A record from this system of records may be disclosed to a federal agency, in response to its request, in connection with the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant or other benefit by the requesting agency, to the extent that the record is relevant and necessary to the requesting agency's decision on the matter.
- (6) In the event that this system of records indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use to the appropriate agency, whether state or local charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation or order issued pursuant thereto.
- (7) Where federal agencies having the power to subpoena other federal agencies' records, such as the Internal Revenue Service or the Civil Rights Commission, issue a subpoena to the Department for records in this system of records, the Department will make such records available.
- (8) Where a contract between a component of the Department and a labor organization recognized under E.O. 11491 or 5 U.S.C. Chapter 71 provides that the agency will disclose personal records relevant to the organization's mission, records in this system of records may be disclosed to such organization.
- (9) The Department contemplates that it will contract with a private firm for the purpose of collating, analyzing, aggregating or otherwise refining records in this system. Relevant records will be disclosed to such a contractor. The contractor shall be required to maintain Privacy Act safeguards with respect to such records.
- (10) Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressio

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Information provided in HR /informati-onal/metric/workload reports, and training. PIA is mandatory to ensure replication of the production system. ATRD collects transactional data on NIH employees (e.g., action type, employee name, Empl ID, SSN, IC). The agency uses the data to provide workload and testing data to HR management. The collection of minimal personal data (PII) is mandatory to mirror the production database.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) ATRD collects personal data that is used to process personnel actions, e.g., name, Empl ID, SSN, organization, etc. It does rely on SSN, but is an NIH instance of the HHS system; therefore, no employee consent is obtained. To date there are no NIH communities that have access to the ATRD system.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: System uses an ID and passwords; passwords are changed every 90 days. In addition, the system is protected by encryption, VPN, a firewall, and intrusion detection system. Access is based upon roles and on a need to know basis. Physical security is provided through security guards, ID badges, and the use of key cards.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Antoine D. Jones

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Administrative Database [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-01-01-3104-00-402-129

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-90-0018

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH Administrative Database System (ADB)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Carol A. Perrone
- 10. Provide an overview of the system: The Administrative Data Base (ADB) is a legacy system project that is over twenty years old. The new NIH Business System (NBS) was designed to replace the ADB by FY06. The system provides support for a broad range of NIH business (financial and administrative) functions including the purchase, receipt, and payment of goods and services (internal and external); the tracking and supplying of inventories; services and supply fund activities; and property management. Development of the ADB began in 1978 to automate the processes related to the procurement of goods and services and to translate the procurement actions into accounting transactons that are processed by the Central Accounting System (CAS). Since then the CAS has been modified to interface with the ADB. Several other systems have been added and modifications/enhancements continue to be made to the ADB to reflect changing policies, requirements and the need for increased functionality. NIH heavily relies on this system for much of its business transactions and management information. The legislation authorizing this activity is found in the Privacy Act System of Record (SOR) Notice #09-90-0018. It is 5 U.S.C. 1302, 2951, 4118, 4308, 4506, 7501, 7511, 7521 and Executive Order 10561.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass

through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The information is shared with the IRS and the Department of the Treasury. SOR 09-90-0018.

The agency collects data pertaining to the procurement of goods and services for the NIH as well as data pertaining to stipend payment to NIH Fellows. Some of the data collected such as the EIN or SSN and ACH Banking information is required in order to effect payments and prepare 1099s and 1042s. Submission of this data is mandatory.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The agency collects data pertaining to the procurement of goods and services for the NIH as well as data pertaining to stipend payment to NIH Fellows. Some of the data collected is IIF such as the EIN or SSN and ACH Banking information and is required in order to effect payments and prepare 1099s and 1042s. Submission of this data is mandatory. The data is maintained on a Vendor file in the Administrative Database (ADB) System.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Notification or consent is not done via the Operations and Maintenance Support group; the system is merely collecting and storing data entered by the users. Any notification will have to be done by the Business Owners and ICs.

Changes to the ADB system software does not affect the data collected and maintained in the ADB Vendor file. However, if changes in uses occur, notification to the individuals are done by the Institute or Center (IC) where the original request was initiated or by the Office of Financial Management (OFM) and follows the processes in place for those organizations.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The system is run under a secure server and access is restricted through RACF as well as security within the system.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michele Mulholland France NIH/CIT/PECO

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Administrative Information System (AIS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN

number is required for Q.4): 09-90-0018

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): Administrative Information System (AIS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Darlene Blocker
- **10. Provide an overview of the system:** The mission of the Administrative and /Information Technology Office is to support the Office of AIDS Research. The Administrative Office is responsible for directing, coordinating, and conducting the OAR administrative management activities in the areas of: personnel/human resources; space planning; equipments and supplies; procurement; travel; budget; and information technology, as well as supporting the OD competencies and the program evaluation and analysis systems. In addition to developing administrative management policies. The Administrative Office serves as the OAR's focal point for the OAR Intranet and the development of a wide range of administrative management reports and documents. The Administrative/Information Technology Office is designed to completely meet the needs of the OAR.

The Administrative Officer (AO) has developed AIS to support a broad range of administrative and information technology processes and functions to assist staff in performing efficiently in their daily assignments.

AIS allows users to access administrative resources by the intranet. Depending on the designated role, a user will be able to:

Establish Performance Plans:

Prepare purchase requests;

Submit requests for building facility, OAR conference rooms, and telecommunication repairs; Request compensatory time for travel;

Submit online supply requests;

Verify telework days per pay period;

Review policy and procedures on the intranet;

Complete online assessments based on their occupational series; and

Submit online vehicle requests;

AIS is comprised of 18 unique Modules.

- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The AIS database will collect and maintain Purchase Requests, Building and Facility Requests, Telecommunication Requests, and Vehicle Requests. The Performance Module will contain IIF such as Name, Office Mailing Address, Office Phone Number, Grade, and Performance Rating. In addition to the information above, the Purchase Request Module collects the Vendor's Name and Address.

The purpose of AIS system is to collect and store information to process several administrative activites and to develop and close out Performance Plans. The OD Competencies system provides users with a web-based tool that allows them to complete a self-assessment based on their occupational series. This module allows employees and their supervisors to identify strengths his/her weaknesses in each employee.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) A plan is being developed to notify staff on how their

names and grades will be used to develop Performance Plans and Ratings. This information will be not be shared outside of the OAR. AIS is an internal system available to OAR users only. In addition, a plan is being developed to notify staff on how their names and grades will be used to track self-assessment. This information will be shared with the OD Executive Office and NIH Training Center.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** AIS is accessible through the NIH Intranet and web browser. The application will rely on Windows Operating System to secure PII and to authenticate users, therefore the users' passwords do not need to be stored in the SQL Server database. The server is located in a secure facility and one needs a NIH ID to access the building and a card key to access the server. The server is housed in Office of Information Technology suites, which is located at 6011 Executive Blvd.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Antoine D. Jones

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD AIDS Budget System PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 6/28/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): Not Applicable

5. OMB Information Collection Approval Number: Not Applicable

6. Other Identifying Number(s): Not Applicable

- 7. System Name (Align with system Item name): NIH OD AIDS Budget System (ABS) PIA
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Donna D. Adderly
- 10. Provide an overview of the system: The OAR develops the trans-NIH AIDS research budget, which is explicitly tied to the objectives of the annual strategic Plan. Each year, the strategic Plan is distributed to all the ICs. The ICs must submit their AIDS-related research budget requests to OAR, presenting their proposals for all new or expanded program initiatives for each scientific area, coded to specific Plan objective(s). OAR reviews the IC initiatives in relation to the Plan, its priorities, and to other IC submissions to eliminate redundancy and/or to assure cross-Institute collaboration. The NIH Director and the OAR Director together determine the total amount to be allocated for AIDS-related research within the overall NIH budget. Within that total, OAR then develops each IC's allocation for AIDS-related research starting from the Commitment Base, and based on the scientific priority of each proposed initiative. This process continues at each step of the budget development process up to the time of the final congressional appropriation.

To effectively present the NIH AIDS Research Budget the Office of AIDS Research Budget Office developed a system to replace a paper-based, manually intensive process used to collect, consolidate, analyze, and report on the National Institutes of Health AIDS Research Budget. The former process consisted of e-mails, faxes, and spreadsheets, was inefficient and no longer effective in responding to the demands for timely information when developing and managing the AIDS budget. This system streamlined the overall budget collection process, and provided more time for analysis and decision-making.

The ABS is web-based and requires the NIH user name and password for access. The Institutes and Centers provide general budget information on projects that will be funded in the future. The system has checks to make certain that all the budget information is consistent throughout the submission.

This project information contained in the system is used for internal decision making purposes only and is not shared outside of the NIH. There are no grant numbers or any NIH financial system data contained in this system.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Not Applicable
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system will contain general budget information obtained from the ICs on potential AIDS projects to be funded for a given fiscal year. The system will be used to collect, consolidate and analyze NIH AIDS budget information from the ICs. The Office of AIDS Research (OAR) is legally mandated to develop an annual comprehensive plan and budget for all NIH AIDS research. The ICs within NIH provide requests for funding for future projects via the system to the central AIDS budget office. The system does not contain any PII and use of the system is mandatory for all ICs that required NIH HIV/AIDS funding in a given fiscal year.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Not Applicable

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Not Applicable

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Antoine D. Jones

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 8/5/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD AIDS Research Information System III (ARIS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): AIDS Research Information System (ARIS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Darlene Blocker
- **10. Provide an overview of the system:** The AIDS Research Information System (ARIS) III is a database that contains information on all NIH-funded AIDS-Related grants, contracts, and intramural projects. The system allows OAR to track and monitor the NIH AIDS research portfolio to fulfill OARS's Congressional mandate. Congress requires NIH to collect and report on NIH-funded AIDS research every year. ARIS was developed in 1989 in response to requests from Congress, Department of Health and Human Services (HHS), and the Office of Management and Budget (OMB)
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Reports are developed from ARIS III data to respond to requests on AIDS related spending.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The ARIS III contains data on all NIH-funded AIDS research including grants, contracts, and intramural project titles and numbers; names of principal investigators and their institutional affiliations; budget amounts for each project and the funding ICs. ARIS III is cross-functional and utilized by all of the ICs that report AIDS funding. ARIS III allows OAR to collect AIDS budget and project information using several coding systems, such as the Strategic Plan and Special Interest Category (SIC) codes. ARIS III allows staff to develop reports for the Department of Health and Human Services, Office of Management and Budget, Congress, and the general public in a timely and efficient manner.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The IIF that is stored in ARIS III is downloaded from IMPAC II and matched with the data submitted by the ICs. There is not any consent process, data collection storage or transmission of personal data involed between ARIS II and individuals.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Authorized users login to ARIS III using windows authentication. The ARIS III servers are in a secure location maintained by the Office of Information Technology (OIT).

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Darlene Blocker/Antoine D. Jones

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Pla

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Application, Registration, Tracking, and Evaluation Database System [System] PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 3/25/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: Not Applicable

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0158

5. OMB Information Collection Approval Number: 09-25-0299

6. Other Identifying Number(s): Contract: HHSN263200700050C; Solicitation: 263-2007-P(GG)-0199; Requisition: 189146

- **7. System Name (Align with system Item name):** ARTiE: Application, Registration, Tracking and Evaluation
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Patricia Wagner, PhD
- **10. Provide an overview of the system:** The system is designed to identify prospective students for dissertation research (application), register investigators looking for trainees (registration), monitor the progress toward degree of current students (tracking), and evaluate applicants for admission consideration.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Application NIH personnel involved in the admission process for Institutional and Individual Partnerships will have access to the applications for review and selection of students for interviews (Intramural Evaluators). University personnel for the partnerships will have access to partnership specific applications for evaluation (Extramural Evaluators).

Current Students - NIH personnel will review records to monitor progress toward degree of trainees, ensuring completion of key elements for degree requirements (select Intramural Evaluators).

Registration of Investigators - NIH investigators wishing to be listed within a searchable database for prospective trainees must register with the OITE. Registration information contains no PII.

Evaluation of Applicants - Both NIH investigators (Intramural Evaluators) and University professors (Extramural Evaluators) have access to applications for specific partnership affiliations.

Symplicity personnel will have access to data to ensure integrity and security of the data contained on the servers. They will not participate in the admission process.

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The Application, Registration, Tracking, and Evaluation Database System (ARTiE) is used by the National Institutes of Health (NIH) Graduate Partnerships Program (GPP) and can be divided into several interfaces:

Application - NIH personnel involved in the admission process for Institutional and Individual Partnerships will have access to the applications for review and selection of students for interviews (Intramural Evaluators). University personnel for the partnerships will have access to this information (Extramural Evaluators). University personnel for the partnerships will have access to this information (Extramural Evaluators). Application contains PII and submission is voluntary though required for admission consideration. PII includes: name, contact information, educational history, and letters of recommendation.

Registration of Investigators - NIH investigators wishing to be listed within a searchable database for prospective trainees must register with the OITE (Registration information contains no PII; voluntary participation).

Tracking - NIH personnel will review records to monitor progress toward degree of trainees, ensuring completion of key elements for degree requirements. PII includes: name, contact information, educational history, and progress towards degree fields.

Evaluation - NIH investigators participating in an admission committee will review submitted applications into the institutional and individual partnership; contains PII on the applicants but not on the admission committee members. NIH investigators participating in an admission committee is voluntary. See above for PII contained in application/registration of prospective students.

Symplicity personnel will have access to data to ensure integrity and security of the servers. They will not participate in the admission process.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Any major changes in the proposed usage of information will be presented in an email message and/or hardcopy letter to the affected population. The following sections of ARTIE contain PII: Applications, Evaluation, and Trackign interfaces.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The data collected and stored in the ARTIE software are hosted on servers located in Equinix, see http://www.equinix.com/home/ for specific details on the hosting environment and security elements.

Administrative access to various elements of ARTIE are governed by position, role, and calendar activities as determined by the GPP staff.

Technical access to the data contained in ARTIE requires a login / password combination which are activated / terminated by NIH/GPP staff members. Session accesses are automatically terminated after a specified period of inactivity.

Physical access to the hosting environment in Equinix requires visit letters, photo badge, biometric screening and pre-authorized. Equinix is certified SAS Type 1 and 2 data center with 24x7x265 security staff, access controls, biometric controls, physically separated data spaces and camera inside/outside the facility.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Patricia Wagner (wagnerpa@od.nih.gov or 240-476-3619)

Sr. Official for Privacy Approval: Promote **Sr. Official for Privacy Name:** Karen Plá

Sign-off Date: 4/1/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Central Accounting System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-01-01-3101-00-402-124

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-90-0024

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH Central Accounting System (CAS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Carol A. Perrone
- **10. Provide an overview of the system:** The NIH CIT Central Accounting System is a legacy system that processes all accounting and financial transactions for the NIH from systems: ADB, Central Payroll, PMS and IMPAC II.

The CAS will be replaced by the new NIH Business System (NBS). Please refer to project # 009-25-01-4601. The CAS project resides in the Division of Enterprise and Custom Applications, Center for Information Technology, NIH. The CAS is a legacy system project that is over twenty years old, and processes accounting and financial transactions for the NIH. It processes data from several sources including: the Administrative Data Base (ADB); Central Payroll; Payment Management System (PMS); and Information for Management, Planning, Analysis and Coordination (IMPAC). The CAS provides data exchange to the ADB, PMS and IMPAC. Data is extracted from the CAS nightly and made available to the NIH through the NIH Data Warehouse. The CAS produces a wide range of reports that detail spending within the Agency. Financial reports are generated for the Department of Health and Human Services, the Treasury Department, the Office of Management and Budget, and the Public Health Service. The legal authority for SOR #09-90-0024 is found in the Budget and Accounting Act of 1950 (P.L. 81-784) and Debt Collection Act of 1982 (P.L. 97-365).

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass

through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Department of Treasury for payments and IRS for 1099 reporting. SOR 09-90-0024

Financial reports are generated for the Department of Health and Human Services, the Treasury Department, the Office of Management and Budget, and the Public Health Service.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The agency collects data pertaining to the procurement of goods and services for the NIH as well as data pertaining to stipend payment to NIH Fellows. Some of the data collected is IIF such as the EIN or SSN and ACH Banking information and is required in order to effect payments and prepare 1099s and 1042s. Submission of this data is mandatory. The data is maintained on a Vendor file in the Administrative Database (ADB) System and is only passed through the CAS.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No processes are in place other than those specified through the ADB, Central Payroll, IMPAC and PMS systems.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The CAS is a mainframe legacy system that operates in a batch environment. The CAS is not accessible to users other than the individuals who maintain it. Those individuals must have proper RACF security in order to access the system.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michele Mulholland France NIH/CIT/PECO

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Commercial Rate Agreement Distribution Services (C-RADS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/12/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: None

6. Other Identifying Number(s): None

- **7. System Name (Align with system Item name):** Commercial Rate Agreement Distribution Services (C-RADS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Anita Kimberling
- **10. Provide an overview of the system:** Secured Web based distribution of Indirect Cost Rate Agreements for commercial organizations
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: C-RADS is a secured webbased system used to disseminate indirect cost rate information from negotiated rate agreements between NIH and commercial companies that receive the preponderance of their Federal awards

from HHS. Access to the system is limited to HHS employees with a bona fide need of the rate information for use in funding and administering HHS contracts and grants. The system does not contain any IIF.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: None

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Anita Kimberling

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/30/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Computer Access to Research on Dietary Supplements (CARDS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/4/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** Computer Access to Research on Dietary Supplements (CARDS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Karen Regan
- **10. Provide an overview of the system:** CARDS is a database of federally funded research projects pertaining to dietary supplements.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: CARDS stands for Computer Access to Research on Dietary Supplements. It is a database of federally funded research projects pertaining to dietary supplements. The ODS was directed by the U.S. Congress

to "compile a database of scientific research on dietary supplements and individual nutrients" as part of the Dietary Supplement Health and Education Act (DSHEA) which was passed by Congress in 1994. The information in CARDS is useful to the U.S. Congress, agencies of the Federal government, and the NIH Institutes for budgetary considerations. In addition, CARDS will provide useful information for researchers, health care providers, industry and the general public. CARDS contains projects funded by the United States Department of Agriculture (USDA), the Department of Defense (DOD) and the Institutes and Centers (ICs) of the National Institutes of Health (NIH) beginning with fiscal year 1999, the first year that NIH ICs began reporting research related to dietary supplements. Projects funded by other Federal agencies will be added to CARDS as they become available. The data contained in CARDS is downloaded from the Human Nutrition Research and Information Management (HNRIM) system maintained by NIDDK. The data contained in HNRIM is downloaded from the NIH IMPAC database. CARDS includes the following information from IMPAC about each project: sponsoring organization, project identifier numbers, project title, principal investigator, organization name, address, project abstract, fiscal year and start date.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Antoine D. Jones

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Karen Pla

Sign-off Date: 9/30/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Correspondence Management and Action Tracking System (CATXpress)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 2/8/2012

2. OPDIV Name: NIH

- **3.** Unique Project Identifier (UPI) Number: UPI number will be generated after CPIC is submitted
- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0106
- **5. OMB Information Collection Approval Number:** No
- **6. Other Identifying Number(s):** No
- **7. System Name (Align with system Item name):** NIH OD Correspondence Management and Action Tracking System (CATXpress)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Zanette Childs, IT Team Leader, NIH/OD/OAR
- **10. Provide an overview of the system:** CATXpress is the industry-leading, correspondence management and action tracking system. CATXpress is a 508 compliant, secured; Web based application that provides complete, automated document and record control for the purposes of capturing, storing, retrieving, processing, tracking correspondences such as, recommendations, meeting requests, meeting minutes, comments and other notes. It has electronic signatures and full security controls.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\rm N\!/\!A$

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) The information being collected, maintained and/or disseminated in the system are names, personal addresses, personal phone numbers and personal email addresses. (2) This information is being used for the purposes of tracking correspondences in the form of hard and electronic copy. (3) The information does contain PII. (4) Submission of this information is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) A notice is provided at the point of entry into the CATXpress Tracking system informing researchers their PII will be collected when their correspondences are submitted.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Administrative Controls: System Security Plan, files are backed up daily and their are manuals and training guides for users.

Technical Controls: User identification and passwords plus a fire wall. Authorized users will login into the CATXpress using windows networking with multi-level security and access controls.

Physical Controls: The server is in a secured location by OIT.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Antoine D. Jones

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 2/25/2012

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Delegations of Authority Database (DOA)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 6/30/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: No

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH OD Delegations of Authority Database (DOA)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Daniel Hernandez, NIH Delegations Officer, (301) 435-3343
- 10. Provide an overview of the system: The DOA Database provides authorized members of NIH with the ability to enter delegations of authority for their respective IC; edit data concerning IC-specific delegations they enter, and run reports, by IC, on authorities delegated to NIH officials. In addition, they can delegate redelegable authorities within NIH delegations, to another member of the NIH community authorized to receive the particular authority. A delegation of authority is the formal assignment or commitment of legal power, usually to a subordinate official, to make certain decisions and take certain actions that have legal significance. The OD/OM/Office of Management Assessment has the responsibility to coordinate and maintain NIH Delegations of Authority from the NIH Director to senior NIH officials. No PII is contained within the DOA Database system.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\rm N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The DOA Database will mirror and track NIH and IC-specific delegations of authority. The database allows authorized IC and OD DOA Coordinators and OHR Subject Matter Experts to enter a copy of the actual DOA for which they are responsible and and manage it. The DOAs are not disseminated further than the IC responsible for the maintenance of its DOAs. The database is not used to redelegate authorities and does not contain the official record of the delegations of authority. A delegation of authority is the formal assignment or commitment of legal power, usually to a subordinate official, to make certain decisions and take certain actions that have legal significance. The DOA Database is accessible to NIH employees only, via the OMA Delegations website but does not host its own website. User permissions are assigned on a need-to-know basis, as determined by the IC Executive Officers, OD Office Heads, and the DOA Database System Administrator. The database does not contain any PII. There is no submission of personal information.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) $\rm\ N/A$

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Daniel Hernandez, NIH Delegations of Authority Officer, (301) 435-

3343

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 7/1/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Director's Document and Records Management System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 1/26/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0106

5. OMB Information Collection Approval Number: None Assigned

6. Other Identifying Number(s): none

- **7. System Name (Align with system Item name):** NIH OD Director's Document and Records Management System (DDRMS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Ann Brewer, Director, Executive Secretariat, NIH
- **10. Provide an overview of the system:** The system provides the processing, tracking, archiving, search and retrieval of all correspondence and response directed to the NIH Director or Deputy Director; documents include email, hardcopy mail, reports from any source including HHS, congress and the public; records are managed for historical purposes and conform to NARA policies
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Correspondence received may be forwarded to an IC subject matter expert, or Office of the Secretary, HHS for comment, review, drafting a response, or information purposes. Such correspondence might contain PII.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system tracks correspondence that is received by the Office of the Director of NIH and serves as a repository of electronic records for internal NIH use. All information provided to NIH is voluntary. The system may contain records with the following PII attributes: name, personal mailing address, personal phone number, personal email address, legal documents and an image of the original correspondence. Original correspondence may have subject matter that contains other personal information in the text of the correspondence. The information is not tracked by the system but is retained within the image of the original correspondence.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.
- (Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The PII is voluntarily provided by the sender and there are no processes in place to notify, obtain additional information or further consent after the correspondence has been received. DDRMS does not solicit or collect information for a database. The originator/correspondent voluntarily sends PII in the correspondence they authored to the NIH Director or Deputy Director. DDRMS contains only an image of the document originally submitted. DDRMS does not manipulate the information for another use.
- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The system is hosted by CIT where annual security audits are conducted for physical, technical and administrative access. The system web site uses Secure Socket Layer (SSL) and Security Logging is activated. The web user interface provides 128-bit encryption and is PKI-enabled. The system keeps an audit trail of all functional areas. The system, in conjunction with its operating environment, uses identification and authentication measures that allow only authorized users to access the system. The system uses multi-level role-based system access controls that are regularly updated by the business owner and system administrator. Each user is required to log on with their user ID, domain and password. Users have access only to information that is pertinent to their IC. The user screen automatically requires new log in after 30 minutes of inactivity. The database containing the document images is encrypted. Physical records are stored in locked cabinets and deleted documents are shredded. The system provides digital signature capability that uses 2-factor authentication. All records that contain PII are marked in red RESTRICTED.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Antoine Jones

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 6/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Document Delivery System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/12/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-3304-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): RELAIS
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Ben Hope
- **10. Provide an overview of the system:** Relais is a document delivery system that allows library customers to request articles that are not readily available on-line. Relais stores user information that is available publicly in NED and tracks what has been requested.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The system does not share or disclose information.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The organization uses the information to correctly deliver documents to individuals who request them.

The system itself does not collect IIF or disperse IIF to other system. The only IIF that is contained in the system is received from NIH Enterprise Database (NED) through nightly updates. Specifically, they receive:

NIH ID

Name

NIH email

Office Location

Mail Stop

Office Phone Number

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) There are none.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The system is protected by a number of different controls that can be viewed in detail in the system C&A package. Some of the major controls that help to secure the IIF are firewalls, IDSs, VPN for remote access, the use of user names and passwords, and role based access. For physical protection, the NIH campus is protected by guards and police, in addition the server itself is kept behind locked door. Administratively procedures are in place to only allow individuals job related necessity to access IIF.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Karen Cook 301-594-4727

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/28/2010

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD DocuShare PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/30/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: no

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0106

5. OMB Information Collection Approval Number: None

6. Other Identifying Number(s): None

- 7. System Name (Align with system Item name): DocuShare
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Kelly Fennington
- 10. Provide an overview of the system: DocuShare is a web-based content management system used by OBA designed to allow users to employ their Web browser to store, view, edit, and share information with other users across the Internet related to some of OBA's activities. Anyone with access to the DocuShare site can download and upload documents, create, and manage repositories called collections, and create calendars, bulleting boards, and other site objects.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): None
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Contained within the docushare system is information pertaining to human gene transfer protocols including

information pertaining to institutional review boards. Oba does not collect personal identifiable information, although such information may occasionally be contained within information submitted. If such information is inadvertently submitted, this data is redacted before downloading into the docushare system. Information of this nature, pertaining to institutional review boards, is only reviewed internally within oba and not shared with other individuals.

Information related to specific detail regarding adverse events associated with these protocols are not disseminated to the public or shared with other investigators and do not contain personal identifiable information. This information is collected in accordance with the NIH Guidelines and is used for in-house analysis of individual trials as well as across trials with similar products or methods. There is no information related to IBC members or rosters.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Antoine D. Jones

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Pla

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Electronic Government Ordering System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 8/12/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH OD Electronic Government Ordering System (e-GOS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Tim Warrington
- **10. Provide an overview of the system:** The e-GOS application is an integrated, Web-based Task Order (TO) processing system that automates NITAAC's CIO-SP2i Government Wide Acquisition Contract (GWAC). The e-GOS application combines e-Business, Customer Relationship Management (CRM), workflow, and document management to streamline the process of GWAC ordering from concept to closeout, providing interfaces for Government Customers, Commercial Contractors, and NITAAC personnel to collaborate on meeting the procurement needs. e-GOS provides NITAAC, its customers, and commercial contractors the capability to process TOs and manage financial data using the Internet. There is no public access of e-GOS.

The security information used in the initialization and implementation of the e-GOS user profiles needs to be protected to avoid compromising the overall integrity and reputation of the agency's website.

The privacy data items used are: First Name, Middle Initial, and Last Name as well as organization(government or contractor) email address.

- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the

character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The name of an individual may be shared across agencies for the purpose of contacting that individual with respect to a contract. This might be the CO, COTR, or other federal employee, or a representative of a contractor company who needs to be contacted by the Federal procurement organization.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) The system only collects Federal Contract Data in the form of organizational data and work contact information for the organization's representative, such as CO's and COTR's. It also collects contractor data organized by corporation and contact information for the corporation to the extent necessary to make an award to the contractor with the winning proposal. (2) e-GOS is a tool similar to GSA e-BUY and FedBizOpps where solicitations are posted for review, competition, and award by contractors. (3) The PII contained in the information includes only the name of individuals, their place of employment, and work phone, address, and email. (4) Submission of personal information is not required and not desired.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Any major changes in eGOS do not require to obtaining consent from users. No notification procedures are required.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Access to the system is based on roles. The system will be protected with intrusion detection, intrusion prevention, vulnerability scans and firewalls.

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Antoine Jones

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Electronic Research Administration [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/1/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-04-00-01-4613-00-110-219

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036, 09-25-0168

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- **7. System Name (Align with system Item name):** NIH OD Electronic Research Administration (eRA) (FISMA)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Carla Flora
- **10. Provide an overview of the system:** The electronic Research Administration (eRA) program is a component of the Office of Research Information Systems (ORIS) in the NIH Office of Extramural Research (OER), headquartered in Bethesda, Maryland. The eRA systems provide information technology solutions and support for the full life cycle of grants administration functions for the NIH as well as the Agency for Healthcare Research and Quality (AHRQ), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Veterans Health Administration (VA). eRA systems align with Grants.gov (the one-stop Web portal for finding and applying for federal grants), allowing for full electronic processing of grant applications from application submission through closeout of the grant award. eRA supports two main subsystems: "eRA Internal Applications" (also known as IMPAC II (Information for Management, Planning, Analysis, and Coordination)), used by NIH staff, and "eRA External Applications" (Commons, iEdison), accessed by the grantee community through the Internet. eRA helps DHHS achieve its missions of medical discovery and science management by: 1) electronically capturing, managing, and protecting research grant-related data, 2) reducing administrative overhead, 3) reporting research grant-related data as information to NIH and extramural communities, and 4) enabling the synthesis of the information into knowledge that can guide the management of the NIH research portfolio and improve the Nation's health.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether

provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The eRA program facilitate grants administration support to NIH Institutes and Centers and to DHHS agencies that fund extramural research. eRA acts as the infrastructure for conducting interactive electronic transactions for the receipt, review, monitoring, administration and closeout of NIH grant awards to biomedical investigators worldwide.

The SORNs listed in response to question #4 cover the eRA systems as a whole. Refer to the PIAs for the individual eRA systems for details on the information collected by the systems, what the information is used for, whether the information contains PII, and whether submission of personal information is voluntary or mandatory.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Carla Flora on behalf of Oliver (Pete) Morton

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Electronic TRP Information Management System (eTIMS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH OD Electronic Technical Refreshment Proposal Information Management System (eTIMS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Tim Warrington, Sanjay Panniken
- **10. Provide an overview of the system:** The eTIMS vendor portal will help vendors upload their proposals in the proposed format and view the status of their proposals. It will provide automated data quality checks and provide the result instantaneously to the vendors if any data validation error occurs so that the vendor can perform the corrective action and upload. This portal will enable the vendor to view the current status of their proposal and perform actions based on their proposal status. The external users for this portal will be the vendors on Electronic Commodities Store III (ECS III) contract who will have limited privileges as Vendor roles.

Another web module eTIMS II Support Team Portal which uses the same database will help the support team at National Institute of Health Information Technology Acquisition and Assessment Center (NITAAC) to review the received proposal and approve/disapprove the individual Contract Line Item Numbers (CLINS) under the proposal. Only NITAAC internal users will have access to this application and will perform the role of Support team reviewer, Quality Control (QC), Contracting Officer (CO) and admin roles.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass

through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\rm N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: This system will have the proposal data which will be submitted by the prime contractors under the ECS III contract. The prime contractors are the approved vendors like DELL, HP etc under the ECS III contract. It will store the list of prime contractors and the users belonging to those prime contractors who will be able to use this system after registration. No personal information is stored except for the name of the user. This system does not store federal contact data.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) We do not expect to store any PII information other than the name of the user but in case if that happens in future then proper notifications (emails, published on vendor portal) with reasons to why the data needs to be captured and how it will be used will be transmitted to all the vendor users and get thier consent over it.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** In terms of administrative controls we have security plan in place and the system administrators, Managers and operators are trained and made aware about their responsibilities in securing the privacy of the PII data. User Manual is available which provides role based details on the tasks which can be accomplished using the system. Apart from this methods are in place to ensure least privilege and only provide the required access to individual users.

In terms of technical controls the system requires a username and password to access. The system is secured within the NIH firewall. Furthermore, Intrusion detection system is in place

which is monitored regularly to proactively identify any intrusion to the system and thus provide a safe environment.

In terms of physical control only the authorised personals can acces the physical location by using the key cards to enter the location which is monitored using the closed circuit TV.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Antoine D. Jones

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 11/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Employee Database Internet Edition (EDie)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/4/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-90-0018, 09-90-0024, 09-25-0216

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): n/A

- **7. System Name (Align with system Item name):** NIH OD Employee Database Internet Edition (EDie)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Pat Porter or Deepak Mathur
- **10. Provide an overview of the system:** EDie is an intranet based application primarily used to manage and track personnel information. Authority for maintenance of the system: 5 U.S.C. 1302, 2951, 4118, 4308, 4506, 7501, 7511, 7521 and Executive Order 10561.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Information is intended for internal administrative use only and will not be shared by other entities. Refer to SORN 09-90-0018, SORN 9-90-0024 and 09-25-0216.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: EDie tracks all information

pertinent to a personnel file for the purpose of personnel management activities. Information is collected from the employees via the Human Resources Database (HRDB) system. Felloship Payment System (FPS), nVision Data Warehouse and NIH Enterprise Directory (NED). Uses consist of the following a) tracka time-limited appointment to ensure renewals are done in a timely manner, thereby avoiding any break in service; b) ensuring that allocated FTE ceilings are maintained; c) ensuring salary equity for various hiring mechanisms; d) providing reports requested by the NIH Director, the IC Director, and the other management staff, as requested; and e) maintaing lists of of non-FTEs, special volunteers, contractors, and other hiring appointments. The following PII data elements are collected, amintained or dideminated on the system is name, date of birth, SSN, Personal Mailing Address, Personal Phone Numbers, Personal Email Address, Employment Status, and foreign Activities. The information collected constitues PII and is mandatory for all employees.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) PII in the system is downloaded from the FRDB, FPS, nVision Data Warehouse and NED. Changes to the HRDB or changes in the way information is used is relayed to employees cia official notices from the NIH Office of Human Resources (OHR). INdividuals are notified of the colection and use of the data as part of the hiring process. This is a mandatory requirement of the potential applicants seeking employment at NIH.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** PIPII stored in EDie is accessed by very limited number of administrative staff with a "need-to-know" status. EDie is password protected and sensitive data is encrypted. The system is located in OD location in building 31, room B1E35 for Production servers and building 6705 Rockledge, room 1179 for Test Servers, behind the NIH firewall.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Antoine D. Jones Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/9/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Enterprise Ethics system (NEES)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-09-02-4678-00

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): OGE/GOVT-1 and OGE/GOVT-2
- **5. OMB Information Collection Approval Number:** SF-278 approval form No. 3209-0001 (Public Financial Disclosure Statement), OGE-450 (Confidential Financial Disclosure Report), HHS-520 (Request for Approval of Outside Activity), HHS-521 (Approval Report of Outside Activity), NIH-2854 (Request for Approval to Accept Gifts Associated with an Award From an Outside Organization)
- **6. Other Identifying Number(s):** None
- **7. System Name (Align with system Item name):** NIH OD Ethics NEES (NIH Enterprise Ethics System)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Holli Beckerman-Jaffe/Genia H. Bohrer
- **10. Provide an overview of the system:** The NIH Enterprise Ethics System (NEES) is a secure web-based workflow management and information technology system in support of the NIH Ethics Program that assists NIH staff with meeting the required statutes and regulations governing the ethical behavior of Executive Branch employees of the Federal Government.

The objective of NEES is the comprehensive automation of the NIH Ethics Program that takes into account various business policies and processes at NIH, through the utilization of numerous related applications and data stores. Specifically, NEES will provide the means to:

- · Electronically submit all ethics-related reports and requests along with supporting documentation
- · Electronically review and approve all ethics-related reports and requests, along with supporting documentation
- · Electronically track and report on all ethics-related reports and requests, submissions, reviews, and approvals as well as other related activities associated with the Ethics Program at NIH
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This

question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): PII contained in NEES is shared with users in HHS Office of General Counsel for the purpose of reviewing forms submitted by the senior staff at NIH. This data is also available to two NEES technical staff contractors for the purpose of connecting the NEES production database with the development database.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system collects and maintains personal financial data for designated employees, including assets, income, liabilities, transactions, gifts, outside positions, and financial agreements. All of this information is considered PII, alhough the system does not collect or store any identifying account numbers.. This information is reviewed by NIH Ethics Officials to ensure no actual or apparent Conflict of Interest (COI) exists that would breech the public trust. The reporting of this information is mandatory, required by several different statutes and regulations at various levels of government Federal, HHS, and NIH.

Section 5301 of Title 5 of the U.S. Code authorizes collection of this information and includes actions to be taken when this information is not provided.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The website publishes release notes to the site to notify users when major changes occur to the system. The website used to collect the data contains a Security and Privacy Notice detailing the authority for collection as well as the purposes and uses of the information.

Consent is not required as reporting of this information is required as a condition of employment and by Federal law.

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes

- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Administrative: Access to financial data is limited to 3 people: the filer who enters and submits the data; the Ethics Coordinator assigned to review the data, and the Deputy Ethics Counselor who reviews the data and certifies the form. Only these 3 people have the ability to let anyone else view the data.

Technical: Access to the system is controlled by NIH log-in which authenticates the user prior to granting access. Access level and permissions are controlled by the system and based on user, role, organizational unit, and status of the report. All servers have been configured to remove all unused applications and system files and all local account access except when necessary to manage the system and maintain integrity of data.

Physical controls: The servers reside in the CIT Computer Room where policies and procedures are in place to restrict access to the machines. This includes guards at the front door and entrance to the machine room as well as an IRIS scan.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Genia Hess Bohrer/Holli Beckerman-Jaffe

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 10/28/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD eRA Commons PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 8/1/2011

2. OPDIV Name: NIH

- 3. Unique Project Identifier (UPI) Number:
- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036
- **5. OMB Information Collection Approval Number:** No
- 6. Other Identifying Number(s): No
- 7. System Name (Align with system Item name): NIH OD eRA-Commons
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Carla Flora
- **10. Provide an overview of the system:** The eRA Commons is one of the "external" subsystems supported by the Electronic Research Administration (eRA), and is accessed by the grantee community through the Internet. The eRA Commons provides an interface where grant applicants, grantees and federal staff at NIH and grantor agencies can access and share administrative information relating to research grants.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The information is only used internally and is controlled via role based access controls.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Information includes name, date of birth (voluntary), last 4 digits of the Social Security Number (voluntary), gender (voluntary), mailing address, phone number, e-mail address, citizenship information, education

record, and employment status. Commons provides grants administration support to the NIH institutes and centers, and to other Department of Health and Human Services (DHHS) agencies that fund extramural research, and the VA. Submission of PII information is mandatory except where stated otherwise and is used to create the database record for the grant application. Date of birth and gender offer a Do Not Wish to Provide option.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No process exists to notify or obtain consent when there is a major change to the system that effects disclosure and/or data uses since the notice is given at the time of the original collection. Applicants are notified data is collected when they enter it into the system or fill in the paper application.

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Administrative controls include certification and accreditation, system security plan, contingency plan, system backups, policies, and procedures. Technical controls include user ID and password to access system, as well as firewalls, VPN, and encryption. Physical Controls include guards, ID badges, key cards, and locked SAS 70 audited server room.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Carla Flora on behalf of Oliver (Pete) Morton

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD eRA Electronic Council Book (ECB)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 8/1/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): eRA-Electronic Council Book (ECB)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Carla Flora
- **10. Provide an overview of the system:** eRA's Electronic Council Book (ECB) is an administrative tool used to provide summary statements, percentiles, priority scores, key identifying information, and supporting documents for grant applications going to council for second level review. ECB is a subsystem of the larger Electronic Research Administration (eRA) information system, which as a whole facilitates grants administration support to NIH institutes and centers and to all DHHS agencies that fund extramural research; eRA acts as the infrastructure for conducting interactive electronic transactions for the receipt, review, monitoring, administration and closeout of NIH grant awards to biomedical investigators worldwide.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{No}}$

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: eRA's Electronic Council Book (ECB) is an administrative tool used to provide summary statements, percentiles, priority scores, key identifying information, and supporting documents for grant applications going to council for second level review. ECB is a subsystem of the larger Electronic Research Administration (eRA) information system. (1) ECB has the ability to conduct on line reviews of grant applications. This is accomplished via a mechanism called "Early Concurrence." Advisory Council members are assigned to panels created by the various NIH institutes. When members log into the ECB, if they are members of these panels, they have the ability to perform two actions with respect to the applications they have been assigned to review: (a) they can cast votes on line to indicate whether they agree with funding or not funding the application(s) and (b) they may write comments and submit them for the purpose of explaining the rationale behind the votes they have cast. No other information is collected from Council Members. ECB data administrators in each NIH institute have the ability to view this data and create report outputs summarizing both votes and comments. (2) The information is collected for the purpose of conducting expedited council reviews ("early concurrence") which enables NIH institutes to fund qualifying applications in advance of the regular council review cycle. This expedited review process serves the purposes of distributing workload for grants specialists, reducing workload at actual council meetings and shortening the funding cycle so that research dollars reach applicants more guickly. (3) No PII is collected, processed, or disseminated. ECB only displays grant summary statements, not full grant applications. Only the Principal Investigator's name is displayed. (4) There is no submission of PII required.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Carla Flora on behalf of Pete Morton

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD eRA Information for Management, Planning, Analysis, and Coordination (IMPAC II)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 8/1/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- **7. System Name (Align with system Item name):** NIH OD eRA-Information for Management, Planning, Analysis, and Coordination (IMPAC II)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Carla Flora
- 10. Provide an overview of the system: IMPAC II (Information for Management, Planning, Analysis, and Coordination) is one of the two main subsystems supported by the Electronic Research Administration (eRA), which as a whole facilitates grants administration support to NIH Institutes and Centers and to DHHS agencies that fund extramural research. eRA acts as the infrastructure for conducting interactive electronic transactions for the receipt, review, monitoring, administration and closeout of NIH grant awards to biomedical investigators worldwide. IMPAC II includes modules and applications for specific business functions as well as cross-cutting modules and query tools and is the main internal subsystem of the eRA program. IMPAC II is used only by authorized NIH staff and authorized users at eRA's Federal agency partners. IMPAC II provides a suite of electronic tools (modules and applications) to support the four primary phases of grants administration: intake, review, award, and post award management.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The information is only used internally and is controlled via role based access controls.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Information includes name, date of birth (voluntary), last 4 digits of the Social Security Number (voluntary), gender (voluntary), mailing address, phone number, e-mail address, citizenship information, education record, and employment status. IMPAC II is used internally at NIH for the processing of grants and awards. Submission of PII information is mandatory except where stated otherwise and is used to create the database record for the grant application. Date of birth and gender offer a Do Not Wish to Provide option.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No process exists to notify or obtain consent when there is a major change to the system that effects disclosure and/or data uses since the notice is given at the time of the original collection. Applicants are notified data is collected when they enter it into the system or fill in the paper application.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Administrative controls include certification and accreditation, system security plan, contingency plan, system backups, policies, and procedures. Technical controls include user ID and password to access system, as well as firewalls, VPN, and encryption. Physical Controls include guards, ID badges, key cards, and locked SAS 70 audited server room.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Carla Flora on behalf of Oliver (Pete) Morton

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD eRA Internal Applications

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 8/1/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): NIH OD eRA Internal Applications
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Carla Flora
- 10. Provide an overview of the system: eRA Internal Applications is one of two main subsystems supported by the Electronic Research Administration (eRA), which as a whole facilitates grants administration support to NIH Institutes and Centers and to DHHS agencies that fund extramural research. eRA acts as the infrastructure for conducting interactive electronic transactions for the receipt, review, monitoring, administration and closeout of NIH grant awards to biomedical investigators worldwide. eRA Internal Applications include modules and applications for specific business functions as well as cross-cutting modules and query tools and is the main internal component of the eRA program. eRA Internal Applications are used only by authorized NIH staff and authorized users at eRA's Federal agency partners. eRA Internal Applications provide a suite of electronic tools (modules and applications) to support the four primary phases of grants administration: intake, review, award, and post award management.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes

- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The information is only used internally and is controlled via role based access controls.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Information includes name, date of birth (voluntary), last 4 digits of the Social Security Number (voluntary), gender (voluntary), mailing address, phone number, e-mail address, citizenship information, education record, and employment status. eRA Internal Applications are used internally at NIH for the processing of grants and awards. Submission of PII information is mandatory except where stated otherwise and is used to create the database record for the grant application. Date of birth and gender offer a Do Not Wish to Provide option. Not all eRA Internal Applications have access to the PII that is collected.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No process exists to notify or obtain consent when there is a major change to the system that effects disclosure and/or data uses since the notice is given at the time of the original collection. Applicants are notified data is collected when they enter it into the system or fill in the paper application.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Administrative controls include certification and accreditation, system security plan, contingency plan, system backups, policies, and procedures. Technical controls include user ID and password to access system, as well as firewalls, VPN, and encryption. Physical Controls include guards, ID badges, key cards, and locked SAS 70 audited server room.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Carla Flora on behalf of Oliver (Pete) Morton

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD eRA Query View Report (QVR)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 8/1/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): eRA-Query View Report (QVR)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Carla Flora
- **10. Provide an overview of the system:** eRA's QVR is an analytical tool used for ad hoc querying and reporting of grants data. QVR is a subsystem of the larger Electronic Research Administration (eRA) information system, which as a whole facilitates grants administration support to NIH institutes and centers and to DHHS agencies that fund extramural research; eRA provides the infrastructure for conducting interactive electronic transactions for the receipt, review, monitoring, administration and closeout of NIH grant awards to biomedical investigators worldwide.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The information is only used internally and is controlled via role based access controls.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: eRA's QVR is an analytical tool used for ad hoc querying and reporting of grants data. QVR is a subsystem of the larger Electronic Research Administration (eRA) information system. (1) QVR is used to search and view detailed information about grant applications and awards. It integrates information from eRA IMPACII (information on extramural applications and awards), NIH Data Warehouse (database of financial obligations), and NLM's PUBMed (database of indexed journals, citations, and abstracts). It does not collect any information - it is only a query, view, and reporting tool. (2) QVR provides NIH and its Federal agency partners integrated access to query, view, and report from multiple systems. The system provides a series of reports for most grants management functions, acts as a portal for viewing a variety of research and research training applications and awards from eRA IMPACII, allows access to broader extramural obligation data from the NIH Data warehouse, and provides a link to the publicly available National Science Foundation system for grant awards by that agency. (3) No PII is collected or processed. The only PII that is disseminated is the Principal Investigator's name, address, and personal email. The SORN listed in response to question #4 covers the eRA information system as a whole, and is not meant to imply that QVR in particular collects, processes, or disseminates PII. (4) There is no submission of PII required. QVR is strictly a reporting tool and does not collect any information.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) QVR does not collect any PII. The PII that QVR disseminates comes from eRA IMPACII. Individuals whose PII may be displayed via QVR are notified data is collected when they apply for a grant via other eRA subsystems.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Administrative controls include certification and accreditation, system security plan, contingency plan, system backups, policies, and procedures. Technical controls include user ID and password to access system, as well as firewalls, VPN, and encryption. Physical Controls include guards, ID badges, key cards, and locked SAS 70 audited server room.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Carla Flora on behalf of Pete Morton

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

Date Published: May 23, 2012

06.3 HHS PIA Summary for Posting (Form) / NIH OD eRA Research, Condition, and Disease Categorization (RCDC)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 8/1/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- **7. System Name (Align with system Item name):** eRA-Research, Condition, and Disease Categorization (RCDC)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Carla Flora
- **10. Provide an overview of the system:** eRA's RCDC is a computerized reporting process NIH uses to sort and report NIH funding in each of 215 historically reported categories of disease, condition, or research. RCDC is a subsystem of the larger Electronic Research Administration (eRA) information system, which as a whole facilitates grants administration support to NIH institutes and centers and to all DHHS agencies that fund extramural research; eRA acts as the infrastructure for conducting interactive electronic transactions for the receipt, review, monitoring, administration and closeout of NIH grant awards to biomedical investigators worldwide.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{No}}$

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: eRA's RCDC is a computerized reporting process NIH uses to sort and report NIH funding in each of 215 historically reported categories of disease, condition, or research. RCDC is a subsystem of the larger Electronic Research Administration (eRA) information system. (1) RCDC reports on three types of NIH funding: research grants (extramural research), research and development (R&D) contracts, and research conducted in NIH's own laboratories and clinics (intramural research). (2) RCDC provides NIH and its Federal agency partners a complete list of funded research projects by category, consistent category definitions applied to all projects each year, and a clear and efficient process for categorizing and reporting on NIH funding. NIH reports funding to the public for the 215 categories, but also provides funding data for categories beyond the 215 public categories that are used for NIH internal planning and analysis. (3) No PII is collected, processed, or disseminated. RCDC only displays grant summary statements, not full grant applications. Only the Principal Investigator's name is displayed. (4) There is no submission of PII required.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Carla Flora on behalf of Pete Morton

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Genetic Modification Clinical Research Information Systems [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/17/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-01-4630-00-110-219

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200 (Clinical, Basic and Population-Based Research Study Records)

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): 009-25-01-26-02-4630-00

- **7. System Name (Align with system Item name):** Genetic Modification Clinical Research Information System (GeMCRIS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Kelly Fennington
- **10. Provide an overview of the system:** To enhance the collection, analysis, and application of safety information related to human gene transfer clinical trials.

NIH is a major focal point within the U.S. Department of Health and Human Services (DHHS) for addressing the scientific, ethical, legal, and societal issues raised by advances in biotechnical research. A critical objective in NIH's mission is to gather, evaluate, and disseminate information regarding developments in biomedical research programs. NIH provides the information to the general public, which includes patients and their families, physicians, advocacy groups, researchers, biosafety experts, and industry representatives. NIH is sponsoring several initiatives aimed at enhancing the systematic collection, analysis, and application of safety information from gene therapy clinical trials. One of these initiatives is the Genetic Modification Clinical Research Information System (GeMCRIS). GeMCRIS is a data system developed by the Office of Biotechnology Activities (OBA) in collaboration with the Food and Drug Administration (FDA) to manage information about the conduct of gene transfer clinical trials. A key contribution of GeMCRIS is that it will permit access to information in a form that enhances the types of review and analyses critical for optimizing patient safety, identifying critical information gaps, and facilitating scientific collaboration and progress.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the

character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): PII may be entered into the system by various stakeholders, including investigators, study coordinator, and sponsors. The system will share or disclose PII to NIH and FDA for the purpose of Government data analysis and research-safety surveillance.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) In general, the system has the capability to include PII relating to:
- General Notification Information (e.g. Provider/Physician Name, reporter name, Manufacturer contact name etc)
- Subject Demographic Information (including Patient Identifier, Patient's age/DOB, gender, race, height, weight)
- Medical and Event Information (including Adverse Event description containing event outcome, symptoms, reactions, diagnosis, lab results, autopsy information, vaccine information, subject medical history, interventions, observations, and may also include attachments of medical records).
- (2) The agency will use the information to support Government data analysis and research-safety surveillance
- (3) As indicated above, data collected may include PII
- (4) The submission of personal information is voluntary
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.
- (Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) (1) Any major changes to the use of PII stored in the system will be communicated to individuals established for providing notices to partipants who are subjects of the research
- (2) Individuals consent to participation in the research, so consent is obtained to use that information before the information is entered into the system.
- (3) PII (such as DOB, Medical Notes) can only be accessed and viewed by the personnel who are associated with the clinical trials and adverse events.
- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes

- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: GeMCRIS servers are protected by two firewalls: GeMCRIS private firewall and NIH firewall. Only authorized users (whose GeMCRIS access requests have been reviewed and approved by OBA) can access GeMCRIS and their associated adverse event reports. The System Security Plan contains a detailed description of all the physical, technical and administrative controls that are in place.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Kelly Fennington Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Pla

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Grantee Financial Conflict of Interest Notifications Database (FCOI)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 8/11/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: 0925-0417

5. ONID Information Conceion Approval Number. 072

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH OD Grantee Financial Conflict of Interest (FCOI) Notifications Database
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Tom Turley
- 10. Provide an overview of the system: The internal OER FCOI Notifications database was initially developed in 2004 to track incoming FCOI report information. These FCOI reports are received from grantee institutions that identify a financial conflict of interest for an individual defined as an "Investigator" under the FCOI regulation. Information from the incoming report, including the Investigator's name, was manually entered into the database by the Office of Policy for Extramural Research Administration. The internal database was revised in 2007 to include use by NIH IC extramural staff so they could monitor the receipt and review of FCOI reports submitted to NIH. In 2009, NIH developed and implemented an electronic research administration (eRA) Commons FCOI Module for the grantee community's use to report identified FCOIs to the NIH for grants and/or cooperative agreements. The information submitted through the Commons is transmitted to IC staff through the FCOI Notifications database. NIH made use of the FCOI Notifications database mandatory for NIH IC extramural staff on 3/1/2008 and the eRA Commons FCOI Module was made mandatory for use by grantees on 7/1/2009.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass

through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The PII information includes the name of the Investigator with the identified conflict that is shared with the NIH staff to monitor the receipt and review of FCOI reports submitted to the NIH by grant and cooperative agreement applicants and/or award recipients.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) The information collected and/or maintained in the FCOI Notifications database will include the following:

Project number

Awarding IC Name;

Grants Management Contact

Date of incoming FCOI report;

Date of acknowledgement letter sent documenting receipt of FCOI report;

Grantee Institution Name and subrecipient name, if applicable;

Grantee Institution Official's name and contact information (not federal contact information);

Name of the Investigator with the conflict;

Name of the entity with which the Investigator has a FCOI;

Name of the financial interest;

Value of the financial interest;

A description of how the financial interest relates to the NIH-funded research and the basis for the Institution's determination that the financial interest conflicts with such research;

A description of the key elements of the Institution's management plan

Any attachments included by the grantee or IC;

Date when the grants management staff notifies the program staff of the incoming report;

Date of any follow-up letter sent to the grantee;

Date when the IC completes its review;

NIH review status (e.g., pending, completed or legacy);

Commons Status (e.g., WIP, Submitted);

FY or Calendar Year FCOI report was submitted.

- (2) This information is used by NIH staff to monitor the receipt and review of FCOI reports submitted to the NIH by grant and cooperative agreement applicants and/or award recipients.
- (3) The database contains the name of the investigator with the identified conflict. The name of the individual is the only PII data collected.
- (4) Mandatory

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) 1- The information from the FCOI database pulls information from the eRA system of records so this element is not applicable..

- 2- The Grantee Institution submits the FCOI report information on the behalf of the Investigator with the noted conflict; NIH does not seek consent from individuals themselves.
- 3- Information within the system is available for viewing by NIH program and grants management staff during the pre award, award, and post award stages to assess information reported by grantee institutions. Information found in the FCOI Notifications database will generally not be shared outside of NIH. However, this information is subject to the Freedom of Information Act (FOIA).
- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** Administrative: Direct access to the database is restricted to a few administrative users with associated permissions stored on the server. The database is housed at the NIH Data Center and is protected with general network firewalls as well as application-specific firewalls and Disaster Recovery protection. Technical: This site is subject to CIT security scans and reviews of physical security, and operating practices and procedures. Certification and Accreditation of hosting systems is done in accordance with NIH policies and procedures. Only users with registered credentials on secured servers have direct access to related databases. Physical: The NIH Data Center provides 24-7 physical security of its server room. Only authorized users that pass through CIT security guards have physical access to the server.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Antoine D. Jones

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/29/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Human Embryonic Stem Cell Registry Application (hESCRegApp)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0106

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** Human Embryonic Stem Cell Registry Application (hESCRegApp)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Tom Turley
- **10. Provide an overview of the system:** The hESC Registration Application Database is a web based application that will allow NIH to collect, manage and approve hESC lines.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Approximately 10 reviewers will be able to access PII contributed by respondents. Reviewers will be both NIH personnel and selected individuals working on behalf of NIH.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Individuals submitting data

on stem cell lines will be asked for for contact information for the purpose of facilitating NIH review of those lines. Submission of all information is voluntary.

- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.
- (Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) 1) Email addresses and other contact information will be collected from individuals that submit data, this contact information will allow NIH to contact them should changes to how PII is used might be used occur.
- 2) The website that collects the data on stem cell lines will contain an easily accessible privacy statement regarding collected PII.
- 3) The website that collects the data on stem cell lines will contain information that notifies respondents that PII will only be shared with reviewers.
- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Physical controls are in place including guards, keycards, and ID badges.

Administrative controls are in place that ensure least privlege for each user group as appropriate. System administrators will have full access, but the general public will only be able to submit and browse survey responses. All system administrators take required training each year to ensure they understand how to secure information systems and PII data properly.

Technical controls are in place to ensure that those with access to sensitive data and systems use industry accepted best practices to secure login credentials. A corporate firewall is in place that only allows web traffic from outside of NIH, all other firewall ports are closed to prevent outside intrusion.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Antoine Jones

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Human Resources Database [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/27/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-26-02-4999-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-90-0018

5. OMB Information Collection Approval Number: n/a

6. Other Identifying Number(s): n/a

- 7. System Name (Align with system Item name): Human Resources Database (HRDB)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Donna Easterday
- **10. Provide an overview of the system:** The data base contains information collected by the Enterprise Human Resources and Payroll System (EHRP) for the purposes of HR reporting. This information includes job-related data as well as PII.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Information in these records may be used:
- (1) By the Office of Personnel Management, Merit Systems Protection Board (including its Office of the Special Counsel), Equal Employment Opportunity Commission, and the Federal Labor Relations Authority (including the General Counsel of the Authority and the Federal Service Impasses Panel) in carrying out their functions.
- (2) In the event an appeal is made outside the Department, records which are relevant may be referred to the appropriate agency charged with rendering a decision on the appeal.

- (3) In the event that this system of records indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the appropriate agency, whether federal, or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation or order issued pursuant thereto.
- (4) In the event the Department deems it desirable or necessary, in determining whether particular records are required to be disclosed under the Freedom of Information Act, disclosure may be made to the Department of Justice for the purpose of obtaining its advice.
- (5) A record from this system of records may be disclosed as a "routine use" to a federal, state or local agency maintaining civil, criminal or other relevant enforcement records or other pertinent records, such as current licenses, if necessary to obtain a record relevant to an agency decision concerning the hiring or retention of an employee, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant or other benefit. A record from this system of records may be disclosed to a federal agency, in response to its request, in connection with the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant or other benefit by the requesting agency, to the extent that the record is relevant and necessary to the requesting agency's decision on the matter.
- (6) In the event that this system of records indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use to the appropriate agency, whether state or local charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation or order issued pursuant thereto.
- (7) Where federal agencies having the power to subpoena other federal agencies' records, such as the Internal Revenue Service or the Civil Rights Commission, issue a subpoena to the Department for records in this system of records, the Department will make such records available.
- (8) Where a contract between a component of the Department and a labor organization recognized under E.O. 11491 or 5 U.S.C. Chapter 71 provides that the agency will disclose personal records relevant to the organization's mission, records in this system of records may be disclosed to such organization.
- (9) The Department contemplates that it will contract with a private firm for the purpose of collating, analyzing, aggregating or otherwise refining records in this system. Relevant records will be disclosed to such a contractor. The contractor shall be required to maintain Privacy Act safeguards with respect to such records.
- (10) Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressio
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: Information provided in HR status/informati-onal/metric/performance reports. PIA is mandatory for metric reporting purposes.

HRDB collects data on NIH employees (e.g., action type, employee name, Empl ID, , IC). The agency uses the data to provide performance metrics to HR and NIH management. The collection of minimal personal data is mandatory for reporting.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) HRDB collects minimal personal data, e.g., name, Empl ID, organization, etc. It does rely on SSN, DOBs; therefore, no employee consent is obtained. Emails are sent to supervisors and users and when changes in profiles/account-s occur. Notices are in the form of electronic emails.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: System uses an ID and passwords; passwords are changed every 90 days. Access is based upon roles and on a need to know basis. Users are locked out after a specified time period and number of login attempts.

PIA Approval

PIA Reviewer Approval: Promote PIA Reviewer Name: Karen Plá

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Information Security and Privacy Awareness Training

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/12/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-02-00-02-3112-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): OPM GOVT-1, General Personnel Records

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- **7. System Name (Align with system Item name):** NIH OD Information Security and Privacy Awareness Training
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Captain Cheryl A. Seaman
- 10. Provide an overview of the system: The NIH security and privacy awareness website contains a variety of courses which pertain to annual information security awareness, privacy awareness, securing remote computers, completing refresher requirements, etc. The security awareness training is mandatory for all NIH employees and contractors within 60 days of employment. All NIH personnel and other persons using IT equipment and information systems, or who access NIH privacy systems of record are required to complete the courses. The system also allows individuals to self-record role-based training. It also allows individuals to accept (agree to adhere to) the NIH IT General Rules of Behavior, and if relevant, the Remote Access User Certification Agreement.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Information about the status of training completion may be shared with supervisors for the

purpose of reporting non-compliance with the mandatory requirement to complete the training within the specified timeframe.

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The training course requires that NIH users log onto the course using their NIH ID Number. Members of the public are not required to provide any PII. Their progress is not tracked but they can receive a certificate of completion.

The tracking system exists to allow recordation of user's training, agreement to follow the NIH IT General Rules of Behavior, and if relevant, agreement to follow remote access requirements. Individual record information is not disseminated. Compliance statistics are reported to HHS and OMB in the aggregate.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Aside from an individual's name and NIH ID number, there is no other PII information in the system. When an NIH employee or contractor logs in with their NIH ID number, this system runs against active NED data to derive the identity of the individual. The individual is then prompted to verify (Yes or No) their identity so they will receive credit for the course.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: From a User's perspective: Any user can log into the website (not the tracking system) and view their Student Record, which provides completion information (including dates modules/courses were completed, i.e., they can see all the information contained in the system relevant to their record). If they have any concerns about the recordation, they can contact the NIH IT Service Desk.

From the Administrator perspective: There are different levels of access depending on the role of the individual accessing the tracking system. These roles include administrator Institute/Center specific access with or without authorization capability, read-only, read-only and authorize capability.

Tracking system users use a password to access the tracking system.

The need for ongoing access to this online tracking system is verified annually. When a person leaves or they are no longer considered to need access, they are made inactive and can no longer access the data.

The type of role assigned to users is derived based on a request by the relevant Institute/Center Information Systems Security Officer and their need for access.

There is a time-out feature for inactivity (15 minutes) requiring the user to log back into the sytem.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Karen Plá

Sr. Official for Privacy Approval: Promote **Sr. Official for Privacy Name:** Karen Plá

Sign-off Date: 8/12/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Integrated Library System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/12/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-3304-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0217

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): Innopac
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Ben Hope
- **10. Provide an overview of the system:** Innopac is the Integrated Library system that runs the Division of Library Services catalog, their web interface to the DLS catalog, the patron file with public NED information, the acquisitions information for book and journal purchases, and the catalogs for 5 other Libraries.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The system does not normally disclose IIF with other groups. However under particular circumstances, the following reasons can cause information to be released (SOR# 09-25-0217):

Records will be routinely disclosed to the Treasury Department in order to effect payment.

Records may be disclosed to Members of Congress concerning a Federal financial assistance program in order for members to make informed opinions on programs and/or activities impacting on legislative decisions. Also, disclosure may be made to a Member of Congress or to

a Congressional staff member in response to an inquiry from the Congressional office made at the written request of the individual.

Disclosure may be made to the Department of Justice for the purpose of obtaining its advice regarding whether particular records are required to be disclosed under the Freedom of Information Act.

A record from this system may be disclosed to a Federal, State or local agency maintaining civil, criminal or other relevant enforcement records or other pertinent records, such as current licenses, if necessary to obtain a record relevant to an agency decision concerning the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract or the issuance of a license, grant or other benefit by the requesting agency, to the extent that the record is relevant and necessary to its decision on the matter.

Where Federal agencies having the power to subpoena other Federal agencies' records, such as the Internal Revenue Service (IRS) or the Civil Rights Commission, issue a subpoena to the NIH for records in this system of records, the NIH will make such records available, provided however, that in each case, the NIH determines that such disclosure is compatible with the purpose for which the records were collected.

Where a contract between a component of HHS and a labor organization recognized under E.O. 11491 provides that the agency will disclose personal records relevant to the organization's mission, records in the system of records may be disclosed to such an organization.

A record may be disclosed to the Department of Justice, to a court, or other tribunal, or to another party before such tribunal, when: (1) HHS, or any component thereof; (2) any HHS employee in his or her official capacity; (3) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (4) the United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to the litigation or has an interest in the litigation, and HHS determines that the use of such records by the Department of Justice, the tribunal, or the other party is relevant and necessary to the litigation and would help in the effective representation of the government party, provided however, that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

A record about a loan applicant or potential contractor or grantee may be disclosed from the system of records to credit reporting agencies to obtain a credit report in order to assess and verify the person's ability to repay debts owed to the Federal Government.

When a person applies for a loan under a loan program as to which the OMB has made a determination under I.R.C. 6103(a)(3), a record about his or her application may be disclosed to the Treasury Department to find out whether he or she has a delinquent tax account, or the sole purpose of determining the person's creditworthiness.

A record from this system may be disclosed to the following entities in order to help collect a debt owed the United States:

- a. To another Federal agency so that agency can effect a salary offset;
- b. To the Treasury Department or another Federal agency in order to effect an ad
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The information system does not collect any IIF from individuals. IIF is contained within the application however, the only IIF that is contained in the system is received from NIH Enterprise Directory (NED) through nightly updates. Specifically, they receive:

NIH ID

Name

NIH email

Office Location

Mail Stop

Office Phone Number

All of this information is public information which can be viewed at ned.nih.gov The information is used to identify the patron list for the Division of Library Services.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Contact the official at the address specified under notification procedure above, identify the record, and specify the information being contested, the corrective action sought, and the reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The system is protected by a number of different controls that can be viewed in detail in the system C&A package. Some of the major controls that help to secure the IIF are firewalls, IDSs, VPN for remote access, the use of user names and passwords, and role based access. For physical protection, the NIH campus is protected by guards and police, in addition the server itself is kept behind locked door. Administratively procedures are in place to only allow individuals job related necessity to access IIF.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Karen Cook 301-594-4727

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/28/2010

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Integrated Time and Attendance System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 6/1/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-01-4605-00-403-132

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-90-0018

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH Integrated Time and Attendance System (ITAS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: James Chung
- 10. Provide an overview of the system: The Integrated Time and Attendance System (ITAS) is an automated federal timekeeping system developed by the National Institutes of Health. It was modeled after a system developed at the National Science Foundation. ITAS provides a way for employees, timekeepers, administrative officers, and supervisors to record, track, and report time for work hours, leave activities and payroll purposes. Institute personnel such as Timekeepers and Administrative Officers edit the employee profile so it includes accurate time, leave, and tour of duty information. Once employee profiles are established, employees can use the system to record and track their time and attendance. The payroll circle is bi-weekly. Therefore, every two weeks, ITAS system processes are run to compute and accrue leave earned, generate timecards for the upcoming pay period, and produce an output file from the system to be transmitted to the Defense Finance and Accounting Services (DFAS) payroll system via the Department of Health and Human Services(DHHS) payroll interface. Besides NIH, ITAS is also used by the OPDIVs under DHHS, with the exception of Centers for Disease Control (CDC). Authority for the maintenance of the system is 5 U.S.C. 1302, 2951, 4118, 4308, 4506, 7501, 7511, 7521 and Executive Order 10561.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass

through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): ITAS shares IIF information with DFAS Payroll System employed by DHHS for the purpose of payroll processing. SOR #: 09-90-0018
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: ITAS contains user's PII information that is not collected from an individual user. The user's PIA information such as username and SSN is gathered by HR and is being entered by an Administrative Officer to ITAS for setting up the employee's profile. The submission of the users' PII (SSN and username) along with their time and attendance information to DFAS (Payroll System) biweekly is mandatory for employees getting paid.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) ITAS does not collect IIF from individual user. Any major changes in ITAS do not require to obtaining consent from users. No notification procedures are required.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** General users access the system based on their roles. Application administrators are restricted to modifying the configuration options that are specific to application/web servers. Database Administrators have (R/W) access to the SQL database. System administrators are responsible for maintaining the hardware and operating system.

ITAS is integrated with NIH Login, SSO. Passwords expire after a set period of time. Accounts are locked after a set period of inactivity. Minimum length of passwords is seven characters. Passwords must be a combination of uppercase, lowercase, and special characters. Accounts are locked after a set number of incorrect attempts.

The servers are located in the CIT Computer Center. Access to the NIH Computer Center Building 12 complex is controlled. A security guard is stationed at the main entrance of the complex, 24 hours a day, seven days a week. Anyone entering the building must display a valid government ID showing a current identification photo, or register with the security guard to acquire a temporary visitor's badge. These badges must be worn at all times. All entrance doors to the Building 12 complex, and the machine rooms are controlled by card-activated locks that restrict access 24 hours a day seven days a week.

PIA Approval

PIA Reviewer Approval: Promote PIA Reviewer Name: Karen Pla

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 6/6/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Interagency Edision (iEdison)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: No

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0168
- **5. OMB Information Collection Approval Number:** 0925-0001 Research and Research Training Grant Applications and Related Forms
- **6. Other Identifying Number(s):** No
- 7. System Name (Align with system Item name): NIH OD eRA-Interagency Edison (iEdison)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: J.P. Kim
- **10. Provide an overview of the system:** Interagency Edison (iEdison) is one of the "external" subsystems supported by the Electronic Research Administration (eRA). iEdison allows government grantees and contractors to report government-funded inventions, patents, and utilization data to the funding agency that made the award, as required by the federal Bayh-Dole Act, its implementing regulations, and any related funding agreement terms and conditions.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The information is only used internally and is controlled via role based access controls.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: iEdison collects information on government-funded inventions, patents, and utilization data that were developed under funding awards from that agency. The information collected is provided for under 37 CFR 401, FAR 52.227-11, FAR 52.227-12, 35 USC 200-212, and for the purpose of tracking, reporting, and compliance activities under those laws and regulations and other pertinent policies, laws and regulations covering these inventions and discoveries.

PII elements such as name, date of birth, Social Security Number, certificates and legal documents, phone numbers, and e-mail address may be uploaded to the system via image files uploaded as grant processing and invention supporting documentation. PII elements are not requested nor in searchable form. The SORN listed in response to question #4 covers invention, patent, and licensing documents as a whole, and is not meant to imply that iEdison in particular collects, processes, or disseminates PII.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No process exists to notify or obtain consent when there is a major change to the system that effects disclosure and/or data uses since the notice is given at the time of the original collection. Applicants are notified data is collected when they enter it into the system or fill in the paper application.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Administrative controls include certification and accreditation, system security plan, contingency plan, system backups, policies, and procedures. Technical controls include user ID and password to access system, as well as firewalls, VPN, and encryption. Physical Controls include guards, ID badges, key cards, and locked SAS 70 audited server room.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Carla Flora on behalf of Oliver (Pete) Morton

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD IP Track System (IPTRACK)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/8/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0106

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): IP Track System (IPTRACK)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Charlie Jones
- **10. Provide an overview of the system:** Database to track IP addresses of computer systems, and locations of the computers, no IIF collected. Only machine names and room numbers are included in the database.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): None
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Database to track IP addresses of computer systems, and locations of the computers, no IIF collected. Only machine names and room numbers are included in the database.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) None

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: None

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Antoine D. Jones

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Pla

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD IRT Portal PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 1/31/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A
- **5. OMB Information Collection Approval Number:** N/A
- 6. Other Identifying Number(s): N/A
- 7. System Name (Align with system Item name): NIH OD IRT Portal
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Christopher Todd
- **10. Provide an overview of the system:** The IRT Portal is a repository for IT security vulnerabilities at NIH. The primary users are the IRT and each individual IC ISSO. The IRT Portal will be used to track security vulnerabilities related to all systems across NIH. The IRT Portal will be able to interface with the HHS CSIRC Database for various datacalls related security vulnerabilities and the status of each incident.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\rm N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: A scalable, and extendable NIH monitoring and reporting system called IRT Portal. Production IRT Portal modules that will allow the NIH CISO to consolidate compliance monitoring and reporting of:

- Password Policy Waivers
- Encryption Policy Waivers
- Federal Desktop Core Configuration (FDCC) Policy Waivers
- Firewall Exceptions and Waivers
- Intrusion Detection System (IDS) Exceptions and Waivers
- Web Content Filtering Exceptions and Waivers
- Other Information Technology Policy Waivers

The IRT Portal loads data from an array of enterprise systems including nVision, NIH Enterprise Database (NED), Active Drectory (AD), Network Security Section (NSS), AppScan and Teneable Security Consel. The IRT Portal is being extended to enable the NIH CISO to correlate security incident data with other incidents as well as with applicable security policy waivers and exceptions. Additionally, in the near term there will be an incorporation of RiskVision (CSIRC) via a NIH Connector, which support implementation of electronic reporting and exchange of NIH security incidents with HHS. Future intergation with NIH Certification and Accreditation Tool (NCAT) and Security and Privacy Online Reporting Tool (SPORT) data is possible for correlation of incident, waiver data, and Interconnection Security Agreement (ISAs)/Memorandum Of Understanding (MOUs) with NCAT and SPORT data.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No PII is collected or stored on the IRT Portal.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Antoine D. Jones

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 11/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Loan Repayment Programs Website [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/12/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-01-4619-00-110-219

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0165

5. OMB Information Collection Approval Number: OMB No. 0925-0361

6. Other Identifying Number(s): NIH/OER/DLR – LRP System6

- 7. System Name (Align with system Item name): National Institutes of Health (NIH) Division of Loan Repayment (DLR) Loan Repayment Program (LRP) System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Steve Boehlert
- 10. Provide an overview of the system: The NIH Loan Repayment Programs (LRPs) are a vital component of our nation's efforts to attract health professionals to careers in clinical, pediatric, health disparity, or contraceptive and infertility research. In exchange for a two-year commitment to a research career, NIH will repay up to \$35,000 per year of qualified educational debt, and covers Federal and state taxes that result from these benefits. The NIH LRP Website and Electronic Application System provides a web-based interface for individuals to obtain information, such as eligibility requirements and conditions for participating in the NIH loan repayment programs. The website also provides an electronic application system. Applicants log in to a secure website and provide all required documents, and can view the status of all forms they have submitted, as well as the status of forms submitted on their behalf by their supervisors, recommenders, and institutional officials. The NIH LRP system support the NIH strategic goal to foster highly skilled and diverse workforce focused on research goals. As this investment allows applicants to apply for loan repayment online and submit forms electronically, therefore it supports the E-Gov initiatives. The program manages and complies with the NIH Privacy Act System of Record # 09-25-0165, entitled "National Institutes of Health Office of Loan Repayment and Scholarship (OLRS) Records System, HHS/NIH/OD."
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or

other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Sallie Mae, AES, Department of Education, to request loan accessing information and Institutional Officials and Non-NIH Scientists.

The LRP system interfaces with IMPAC II (Information for Management, Planning, Analysis and Coordination). IMPAC II is the successor to NIH's original IMPAC information management system. Its firewalls and user access controls ensure the security of confidential grant, contract, and personal data. NIH staff and authorized users from other U.S. Government agencies involved in health research have access to IMPAC II on a need-to-know basis.

The DLR LRP administers the application and disbursement processes for all of the LRPs, which includes information dissemination, conducting the application receipt and referral process, referring qualified applications to the NIH Institutes and Centers (ICs), evaluating educational debt, reviewing basic eligibility, administering individual LRP contracts, establishing repayment The NIH LRP Website and Electronic Application System provides a web-based interface for individuals to obtain information, such as eligibility requirements and conditions for participating in the NIH loan repayment programs (LRPs). The website also provides an electronic application system. Applicants log in to a secure website and provide all required documents, and can view the status of all forms they have submitted, as well as the status of forms submitted on their behalf by their supervisors, recommenders, and institutional officials. The NIH DLR LRP system support the NIH strategic goal to foster highly skilled and diverse workforce focused on research goals. As this investment allows applicants to apply for loan repayment online and submit forms electronically, therefore it supports the E-Gov initiatives. The NIH System of Record # 09-25-0165, entitled "National Institutes of Health Office of Loan Repayment and Scholarship (OLRS) Records System, HHS/NIH/OD." NOTE: We have submitted an update to the SORN – to be renamed NIH Division of Loan Repayment (DLR) Records System

The LRP system interfaces with IMPAC II (Information for Management, Planning, Analysis and Coordination). IMPAC II is the successor to NIH's original IMPAC information management system. Its firewalls and user access controls ensure the security of confidential grant, contract, and personal data. NIH staff and authorized users from other U.S. Government agencies involved in health research have access to IMPAC II on a need-to-know basis.

The NIH DLR administers the application and disbursement processes for all of the LRPs, which includes information dissemination, conducting the application receipt and referral process, referring qualified applications to the NIH Institutes and Centers (ICs), evaluating educational debt, reviewing basic eligibility, administering individual LRP contracts, establishing repayment schedules with lending institutions, and obligating funds. Participating NIH ICs convene panels

consisting of non-NIH scientists to review, score, and rank applications. The ICs make funding decisions and notify NIH DLR of the results of these decisions. Staff within the ICs coordinate with the NIH DLR to ensure funds are available and that they are charged to the appropriate CAN. These NIH staff also help guide applicants and participants who have questions about the research component of their applications or about other aspects of the application process, such as the peer review process.

The NIH DLR maintains and complies with the NIH Privacy Act System of Record # 09-25-0165, entitled "National Institutes of Health Office of Loan Repayment and Scholarship (OLRS) Records System, HHS/NIH/OD."

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The information collected in the application forms is: name, social security number (SSN), grant number, program application and associated forms, service pay-back obligations, employment data, professional performance and credentialing history of licensed health professionals; personal, professional, and (voluntary) demographic background information; financial data including loan balances, deferment, forbearance, and repayment/definq-uent/default status information; educational data including academic program; employment status and salary verification (which includes certifications and verifications of continuing participation in qualified research); credit reports; and Federal, State and county tax related information, including copies of tax returns.

LRP awards are competitive. The information collected during the LRP application process is used to make basic eligibility determinations and to provide the scientific reviewers the information necessary to assess the potential of the applicant to pursue a career in research and to measure the quality of the overall environment to prepare the applicant for a research career.

Major changes are posted in the Federal Register and public comment is requested.

User consent is implicit in the act of providing the information. Providing the information is voluntary; however, in most circumstances failing to provide the information precludes the applicant from qualifying for the program or precludes the participant from receiving benefits of the program.

The information provided is not disclosed without the applicant/partic-ipant's consent to anyone outside of NIH in a manner that identifies the applicant/partic-ipant, except as permitted by the Privacy Act.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) A copy of our Privacy Act Notification is posted on our Web site (http://www.lrp.nih.gov/privacy/index.htm) and is available to all individuals providing IIF. The Privacy Act Notification lists the purposes for collecting the information, as well as the routine uses permitted by the Privacy Act. The system also informs the user when collecting data – during registration - "Note: We collect your Social Security Number [SSN] to verify your identity, to determine your eligibility for loan repayment assistance and to keep track of the federal funds you receive. We also use your SSN for loan repayment and servicing purposes under the Loan Repayment Program. We also use this information to determine whether you are eligible for loan repayment and the amount of that assistance. See Privacy Act information for additional information."

Major changes are posted in the Federal Register and public comment is requested.

User consent is implicit in the act of providing the information. Providing the information is voluntary; however, in most circumstances failing to provide the information precludes the applicant from qualifying for the program or precludes the participant from receiving benefits of the program.

The information provided is not disclosed without the applicant/partic-ipant's consent to anyone outside of HHS in a manner that identifies the applicant/partic-ipant, except as permitted by the Privacy Act.

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The DLR LRP system permits only authorized and authenticated user access. Additionally, there are Federal (NIST, FIPS, OMB, GAO, agency-level HHS/NIH guidelines and directives compliant) and industry-best practices security measures in place to ensure the system utilizes and ensures the effective use of security controls and authentication tools to protect privacy to the extent feasible. Access to the LRP system user's records is restricted to authorized users behind the NIH CIT firewall. Risk of unauthorized access is, therefore, considered low. The DLR LRP system is maintained in strict compliance with the NIH Privacy Act System of Record # 09-25-0165, entitled "National Institutes of Health Office of Loan Repayment and Scholarship (OLRS) Records System, HHS/NIH/OD."

Authorized user access to information is limited to authorized personnel in the performance of their duties. Authorized personnel include system managers and their staffs, financial, fiscal and records management personnel, legal personnel, computer personnel, and NIH contractors and subcontractors, all of whom are responsible for administering the NIH LRPs.

Physical safeguards: Rooms where records are stored are locked when not in use. During regular business hours, rooms are unlocked but all controlled by on-site personnel. Security guards perform random checks on the physical security of the storage locations after duty hours, including weekends and holidays.

Procedural and Technical Safeguards: A password is required to access the terminal and a data set name controls the release of data to only authorized users. All users of personal information in connection with the performance of their jobs protect information from public view and from unauthorized personnel entering an unsupervised office. Data on local area network computer files is accessed by keyword known only to authorized personnel. Codes by which automated files may be accessed are changed periodically. This procedure also includes deletion of access codes when employees or contractors leave. New employees and contractors are briefed and the security department is notified of all staff members and contractors authorized to be in secured areas during working and nonworking hours. Individuals remotely accessing the secured areas of the DLR Internet sites have separate accounts and passwords, and all data transmitted between the server and workstations is encrypted.

NIH requires the completion of a computer-based training (CBT) course entitled 'Computer Security and Awareness' for NIH staff and contractors. This CBT provides an overview of basic IT security practices and the awareness that knowing or willful disclosure of the sensitive information processed in the LRP system can result in criminal penalties associated with the Privacy Act, Computer Security Act, and other federal laws that apply. This CBT can be found at http://irtsectra-ining.nih.gov/. User access may be requested only by personnel authorized by the Executive Officer. Users are not permitted system access until the required system training prerequisites are completed and they demonstrate the competencies required to fulfill their work responsibilities-. Users are certified as having fulfilled the requirements by their Executive Officer or his or her appointed representative who requests access for the user.

It should also be noted that the DLR LRP system runs as a part of the NIH (CIT/OIT) infrastructure, which also supports policy enforcement to validate security requirements and privacy requirements are being satisfied. Incident handling guidelines are detailed in the Office of the Director (OD) standard operating procedures "OD/EO/OIT Standard Operating Procedures for Malicious Code Attacks, Intrusions, and Offensive Emails" (at http://oit.od.ni-h.go-v/pubs/SOP_-ISSO.pdf) and the NIH Incident Handling Guidelines (at http://irm.cit.n-ih.gov/security/-ih guidelines.ht-ml) are consistent with

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Steve Boehlert

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD My Dietary Supplements (MyDS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision: Not Applicable

1. Date of this Submission: 6/21/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0106

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH OD Office of Disease Prevention Office of Dietary Supplements My Dietary Supplements (MyDS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Jody Engel, M.A., R.D.
- **10. Provide an overview of the system:** My Dietary Supplements (MyDS) was designed to give consumers a free, convenient mobile record of the dietary supplements they are taking. Consumers can use their mobile device to keep track of the vitamins, minerals, herbs, and other products they take and easily share the information with their health care providers. This mobile application may help decrease the potential for interactions between dietary supplements and prescription medications. MyDS can also provide science-based, reliable information about dietary supplements as well as general information about the NIH Office of Dietary Supplements.

Features

- · Create personal dietary supplement profiles for yourself and others;
- Record and store on your mobile device, the name and amount of each dietary supplement you take;
- Add additional information about each dietary supplement in the Notes field;
- Email your dietary supplement profile to yourself, health care providers, pharmacists;
- Add up to two photos of each dietary supplement on your list;
- Protect your information with the option to create a personal password; and,
- · Access reliable information about dietary supplements from the Office of Dietary Supplements.

To set up the MyDS application on a mobile device (i.e., iPhone, iPad, etc.), the user will download the application from the Apple iTunes/Application Store, create a username (email address) and personal password to open the application - Download MyDS

In the near future, the user will be able to access an online WebApp version which will run just like a mobile application, but via the Web.

The Office of Dietary Supplements has embedded the website http://www.flurry.com into the MyDS application. It is an analytics application that counts usage data, downloads, and geolocation (e.g., number of people using the device, browser used to download the application, general (continent) location of the user, etc.)

If users have questions about the MyDS application, they can request MyDS support by composing an email with the subject of their inquiry, message and email address and sending it to: http://ods.od.nih.gov/about/mobile/mydssupport.aspx

- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): System does not share or disclose PII
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: System collects the individuals email address only and does not use it for any communications. The email address will only be used to authenticate access to the system and to support the "forgot password" functionality. The agency will not use any of the individuals personal data. Submision of an email address is mandatory to use the system.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The terms of service and the disclaimer to support the application will be available to the individuals. The terms of service and disclaimer will state that ODS does not use the data, nor does it have direct access to it. If any guidance changes the terms of service and disclaimer will be updated.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The database server which stores the users email address will only be accessible via the Web server. The data will only be available to the end user after login using the app. The email address will be encrypted on the server, so any unauthorized access would not allow a connection of PII to the individuals data.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Antoine D. Jones

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD NDPA-NIA IT System PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

- **3.** Unique Project Identifier (UPI) Number: I need to check on UPI Number that is being assigned by OMB
- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0156
- **5. OMB Information Collection Approval Number:** NDPA Outcome Evaluation 0925-0606 expires 11/30/2012
- 6. Other Identifying Number(s): 0925-0606
- **7. System Name (Align with system Item name):** NIH OD NIH Director's Pioneer Award (NDPA) R01 Outcome Evaluation/NIH OBSSR portfolio
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Stephanie Shipp (571-480-1226)
- **10. Provide an overview of the system:** 10. The purpose of the NDPA outcome evaluation is to determine whether (1) NDPA Awardees are conducting pioneering research with NDPA funds and (2) to assess whether the R01 outcomes are equally pioneering. The data will be kept on a secure password protected computer that is only used for this project. The second project is to examine the NIH Office of Behavioral and Social Sciences Research (OBSSR) portfolio.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The PII are only seen by STPI employee who is conducting outcome evaluations and portfolio analysis. The PII is needed to contact the awardees and applicants.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Components of the NDPA Outcome-R01 Evaluation include:

Interviews with all NDPA awardees (pioneers) from FY 2006.

Interviews with NDPA interviewees (finalists from FY 2004- 2006.

Assessment of awardee and interviewee outcomes by focus group panels.

Expert review

Analyses of QVR and RCDC data

Components of the NIH OBSSR portfolio analyses include:

Creation of a database of OBSSR grants with associated information for subsequent analysis. The contractor will recode NIH-provided data for FY 2006 to be consistent with NIH-provided data for FYs 2007-2010. The OBSSR-based project director shall guide the contractor's work to develop and structure the database. PII information will be on the files to conduct bibliometric and other related analyses.

Table #1: Number of NIH PIs (including the investigator and the project) in the Behavioral and Social Sciences, Fiscal Years 2006-2010

Table #2: Distribution of Behavioral and Social Sciences projects by IC, Fiscal Years 2006-2010

Table #3: Percentage of Competing NIH Grant Applications and other Projects Submitted in the area of Behavioral and Social Science and by Applicants in Other Areas That Were Funded, Fiscal Years 2006-2010

Table #4: Amount of NIH Funding for Behavioral and Social Sciences research Grant Recipients and Awardees in Other research areas, by Type of Application and Fiscal Years, 2006-2010

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) For the NDPA -R01 Outcome Evaluation and NIH OBSSR Portfolio Analyses:

- 1) The NDPA-R01 Outcome Evaluation expert protocols, will contain the following general assurance of confidentiality: "...Your responses will be kept strictly confidential: If you choose to participate, respondent confidentiality will be protected to the extent provided by law, and STPI will report only aggregate information concerning overall impressions of the process to the NIH."
- 2) Data used from QVR and RCDC will only be reported in aggregate format
- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No

- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** In order to ensure data security, all employees of the Science and Technology Policy Institute, are required to adhere to strict standards and sign a non-disclosure agreement as a condition of employment. The Science and Technology Policy Institute has extensive experience collecting information and maintaining its confidentiality and security. STPI accesses QVR and RCDC remotely though a NIH VPN protocol. Our offices are accessed only by STPI employees who must have an ID that is wanded for entry. Our building has a full-time guard who only allows entry to employees and guests with an escort.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Promoted by Antoine D. Jones

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD NIH Business System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/25/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-01-01-4601-24-402-125

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0217

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): NIH Business System (NBS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sean Hagan
- **10. Provide an overview of the system:** The overall objective of the NBS is to enable administrative/scientific support that is cost effective, provides more accurate and timely information, modernizes hardware and software components, and facilitates the scientific mission of the NIH. The scope of the NBS includes seven business or "functional" areas currently included in the ADB: Financial Management Property Management Accounts Payable (Commercial Accounts) Acquisition Service and Supply Funds Operations Supply Management Travel Management. Legal authority for maintenance of the NBS may be found in 5 U.S.C. 301 and 302, 44 U.S.C. 3101 and 3102, Executive Order 9397.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Since NBS is an enterprise financial system, there are many use cases where records containing PII will be shared or disclosed with persons or entities. For example, records will be routinely disclosed to the Treasury Department in order to effect payment, and records may be disclosed to

Members of Congress concerning a Federal financial assistance program in order for members to make informed opinions on programs and/or activities impacting on legislative decisions. The Privacy Act System of Records Notice (SORN) 09-25-0217 provides a listing of whom the PII may be shared and for what purpose. The language in the SORN is succinct with regard to whom records are shared and the purpose.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Name, Social Security Number (SSN) or EIN/TID, address, email address, phone number, purpose of payment or request for payment, bank account and routing numbers, accounting classification and the amount paid or billed. Also, in the event of an overpayment and for outstanding charges, fees, loans, grants, or scholarships, the amount of the indebtedness, the repayment status and the amount to be collected. In the event of an administrative wage garnishment, information about the debtor's employment status and disposable pay available for withholding will be maintained. The IIF contained in the system is mandatory to fulfill the requirements of the system.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) If major changes occur to the system a Systems of Records (SOR) will be filed as appropriate.

NOTIFICATION PROCEDURE:

To determine if a record exists, individuals may write to the System Manager listed in SOR 09-25-0217. A written request must contain the name, address and social security number of the requestor and his or her signature that either is notarized to verify his or her identity or contain a written certification that the requestor is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense subject to a five thousand dollar fine.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requestors should also specify the record contents being sought. Individuals may also request an accounting of disclosures of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the official at the address specified under notification procedure in the SOR identified above, identify the record, and specify the information being contested, the corrective action sought, and the reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

All notices will be published in accordance with the Privacy Act System Notices - Systems of Records (SORs) at NIH as required.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The NBS will conform to applicable law and policy governing the privacy and security of Federal automated information systems. These include but are not limited to the Privacy Act of 1974, Computer Security Act of 1987, Paperwork Reduction Act of 1995, Clinger-Cohen Act of 1996, and the Office of Management and Budget (OMB) Circular A-130, Appendix III, "Security of Federal Automated Information Resources." The IIF will be secured in accordance with Privacy Act System of Record 09-25-0217, entitled "NIH Business System (NBS), HHS/NIH."

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Sean Hagan, NBS ISSO Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Pla

Sign-off Date: 9/30/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD NIH Certification and Accreditation Tool (NCAT) [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/11/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: No

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH Certification & Accreditation Tool (NCAT)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Kathleen Coupe
- **10. Provide an overview of the system:** NIH Certification and Accreditation Tool (NCAT) is a COTS product that tracks FISMA information for NIH systems and also collects the necessary data to develop and maintain Certification and Accrediation documentation and POA&M data. It is hosted on the NIH Data Center and covered by the Data Center C&A except for those controls which are application specific. The program also gives Management an overview of the security status at NIH via the reporting tools.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Trusted Agent does not collect, maintain or disseminate IIF. It contains security control information for NIH systems per FISMA requirements. This include C&A dates, FIPS 199 categorizations, security control implementation. etc., that are used to evaluate system security status. There is no submission of personal information.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) IIF is not collected.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No IIF is collected on the system.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Promoted by Antoine D. Jones

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD NIH Enterprise Architecture Repository (NEAR)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision: Not Applicable

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH OD Enterprise Architecture Repository
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Steven Thornton
- 10. Provide an overview of the system: The NIH EA Repository addresses the need for access to pertinent information in order to make better informed decisions. Specifically, the EA Repository contains information about IT systems and their relationship to NIH Business Processes, Data, Services and other EA Artifacts. This information, which is often tracked in disparate systems, is consolidated in the EA Repository in a way which provides a high level overview of how resources relate are how they are being used within the organization. With this information, ICs can assess effectiveness of their investments, identify duplication and find systems and services for reuse. Furthermore, the EA Repository provides a mechanism by which to quickly identify impacts of a variety of different elements such as policy changes impacting systems, and system retirements.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: 1. The sysem collects employee name, employee business phone number, and employee business email address (federal contact data).
- 2. We collect this information to have a business point of contact for managers of NIH information systems.
- 3. The information is not considered PII, because it is federal employee business contact information.
- 4. The information is currently in an optional field but will be updated to a mandatory feed.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A No PII collected, maintained or disseminated in the system

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Antoine D. Jones

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 10/24/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD NIH Enterprise Architecture Website

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision: Not Applicable

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH OD NIH Enterprise Architecture Website
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Steven Thornton
- **10. Provide an overview of the system:** The NIH EA website is the authoritative source for NIH's enterprise architecture principles, standards, best practices, business process models, data models, integration standards, and other types of enterprise level specifications and communications.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The NIH EA website

collects name, email address, title (optional), organization (optional), and phone number (optional) via a Contact Us form to enable the NIH EA team to answer questions from the public about the NIH EA program or website.

The NIH EA website also collects the NIH.gov email address for NIH employees and contractors ONLY who wish to subscribe to receive alerts – based on their subscription preferences – when content changes on the website. This information is then available to the NIH EA website administrators, who can unsubscribe users manually, if necessary. These subscribers may also unsubscribe themselves at anytime.

The NIH EA website also collects the email address for users who wish to share NIH EA content links with other users and those users' email addresses. This information is not stored.

The NIH EA website uses WebTrends and Google Analytics for analytics. This CIT managed service and Google Analytics collect referring domains for users who navigate to the NIH EA website in support of the NIH EA team's site analytics effort.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The NIH Enterprise Architecture website discloses its use of PII via the site's Privacy Statement:

http://enterprisearchitecture.nih.gov/About/About/Privacy.htm and via its P3P machine readable policy. The current privacy statement - which is being updated to include references to Google Analytics and AddThis share widget states:

Of the information we learn about you from your visit to the NIH Enterprise Architecture website, we store only the following: The domain name from which you access the Internet The date and time you access our site, The Internet address of the website from which you direct-linked to our site. This information is used to measure the number of visitors to the various sections of our site and to help us make our site more useful to visitors. Unless it is specifically stated otherwise, no additional information will be collected about you. When inquiries are emailed to us, we store the question and the email address information so that we can respond electronically. Unless otherwise required by statute, we do not identify publicly who sends questions or comments to our website. We will not obtain information that will allow us to identify you personally when you visit our site, unless you chose to provide such information to us. Questions about NIH privacy policies should be sent to the NIH Privacy Act Officer at NIHPrivacyActOfficer@od.nih.gov.

The new privacy policy will include the following language:

Group "Website Measurement"

At the user's option, we will collect the following data:

URI of requested resource

Request timestamp

User's interaction with a page or resource

Search terms

Client's IP address or hostname

Data bytes in response

Response status code

Client's Browser Type

Client's Operating System

Client's Platform Type

HTTP cookies

This data will be used for the following purposes:

Anonymous user analysis. The user is allowed to opt-out of this usage.

This data will be used by ourselves and our agents. In addition, the following types of entities will receive this information:

Unrelated third parties. The user is allowed to opt-out of this data sharing.

The data in this group has been marked as non-identifiable. This means that there is no reasonable way for the site to identify the individual person this data was collected from.

The following explanation is provided for why this data is collected:

enterprisearchitecture.nih.gov uses Webtrends and Google Analytics measurement software to collect the information described in the bulleted list above. Webtrends and Google Analytics collect information automatically and continuously. No personally identifiable information is collected. The NIH staff conducts analyses and reports on the aggregated data from Webtrends and Google Analytics. The reports are only available to enterprisearchitecture.nih.gov managers, members of the NIH Office of the Chief Information Officer (OCIO), and other designated staff who require this information to perform their duties.

Group "Cookies"

At the user's option, we will collect the following data:

HTTP cookies

This data will be used for the following purposes:

Anonymous user analysis. The user is allowed to opt-out of this usage.

This data will be used by ourselves and our agents. In addition, the following types of entities will receive this information:

Unrelated third parties. The user is allowed to opt-out of this data sharing.

The data in this group has been marked as non-identifiable. This means that there is no reasonable way for the site to identify the individual person this data was collected from.

The following explanation is provided for why this data is collected:

The Office of Management and Budget Memo M-10-22, Guidance for Online Use of Web Measurement and Customization Technologies allows Federal agencies to use session and persistent cookies. When you visit any Web site, its server may generate a piece of text known as a "cookie"

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Because the only PII that is stored are the nih.gov email address of employees and contractors who subscribe to be notified of changes, there are no security controls required to protect it. This feature is not available to public users. A much larger set of the same information can be found publically on ned.nih.gov. Nevertheless, the information is protected, such that only site managers can access it using NIH Login, and by being assigned to the site manager security group. The information sits within the NIH firewall. Only the system owner can grant permission for someone to be added to this security group. Upon her request, the SharePoint administrators grant this permission in the system.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Helen Schmitz

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD NIH Integrated Training System II (NIHITS II)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/27/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-09-02--4610-00-403-224

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0216

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- **7. System Name (Align with system Item name):** NIH Integrated Training System II (NIHITS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Kimberly Hill
- **10. Provide an overview of the system:** The NIH Integrated Training System II (NIHITS II) is a Web-based training nomination system used at the National Institutes of Health (NIH). NIHITS II allows for the creation, approval and tracking of employee training nominations.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): NIH Business System (NBS) for purposes of funds obligation for training nominations. SOR# 09-25-0216
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The NIHITS system will

collect IIF through the Name (First, Last, Middle Initial) of employees within NIH, as well as contractors and other assignments as deemed appropriate by IC authorities at NIH. NIHITS will also collect SSNs for NIH employees, contractors, and other assignments as deemed appropriate. The information collected is required to be able to procure and track training for employees.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The NIHITS system imports Name and SSN information from the NIH Employee Database for purposes of updating list of employees and keeping information up-to-date. Users are notified by email when changes are to occur in the system. Employees don't get directly notified when collecting information from HRDB because they should have been notified when the information was collected in HRDB.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: IIF date is secured by using user identifiers, passwords, firewalls, IDS, backups, ID badges and physical security (guards) in location. Users are restricted to viewing only the data needed to fulfill their duties.

PIA Approval

PIA Reviewer Approval: Promote PIA Reviewer Name: Karen Plá

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD NIH Intramural Database [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/8/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-01-4615-00-110-219

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-90-0018

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): NIH Intramural DataBase (NIDB)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Dale Graham
- **10. Provide an overview of the system:** The NIH Intramural DataBase (NIDB) system collects data relating to oversight and evaluation of the NIH's Intramural Research Program. These data include names of researchers involved in particular projects and the publications they author, as well as which NIH organizations they are affiliated with. In addition, the names and organizational affiliations of extramural collaborators are also collected. For NIH researchers, the NIDB collects NIH email addresses and other data relating to their research position (e.g., their Intramural Professional Designation). All data collected directly relates to the NIH intramural research process. We collect no unique personal information.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Searches of Annual Reports show names of the people participating in the research. NIH contact information is passed to PubMed Central via webservices and to NEES via a database view.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: NIDB collects names, advanced degrees and NIH email addresses for NIH researchers. It also collects from NIH researchers the names and organizational affiliations of non-NIH researchers with whom they collaborate. No personal information (other than names) are collected. Most names for NIH staff are now collected directly from the NIH Enterprise Directory, rather than being entered by NIH staff. These data are used for oversight and evaluation of the NIH Intramural Research Program. The Annual Reports (after approval by Lab/Branch Chiefs and Scientific Directors) is available for searching by members of the public. This contains names, degrees, organizational affiliations for those shown as collaborating on the Reports. There is no submission of personal information.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Not applicable to NIDB. However, NIDB downloads data from NED. Changes to this system and their process notifications are outside of NIDB's scope. What NED indicates is as follows: The following notice is displayed to users following authentication to NED.

"Collection of this information is authorized under 5 U.S.C. 301 and 302, 44 U.S.C. 3101 and 3102 and Executive Order 9397. The primary use of this information is to establish a centrally coordinated electronic directory to conduct administrative business processes at the National Institutes of Health. Information from this system may be disclosed to personnel with a valid need for access to the information in order to conduct agency business. To the extent that they are relevant and necessary, additional disclosures of the information may be made for the following purposes: to contractors or consultants engaged by the agency to assist in the performance of a service; to respond to another Federal agency's request made in connection with the hiring, clearance or retention of an employee or letting of a contract; or to the Department of Justice, or to a court or other adjudicative body for litigation. Failure to provide all or part of the information requested may limit your ability to perform official duties, impact your ability to qualify for an NIH contract or limit your access to NIH services and facilities."

There are no other processes currently in place to obtain additional consent from the individual whose IIF is stored in NED regarding what IIF is being collected for them or how the information will be used or shared. There are also no processes in place at this time to obtain consent from the individuals whose IIF is in the system when major changes occur to the system.

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes

- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** NIDB collects names (public record), and NIH contact information (also public record) via NED. NIDB has access solely to NED's public view and therefore has no access to anything other than that. NIDB also collects information about advanced degrees (when granted, where). Contact information and when and where degrees are granted are NOT made public. This is utilized within the NIH only. Access to NIDB data requires authorization by role for any of this information.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Marie Lagana NIH/CIT/OPEC

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD OCIO IRT Lab [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): NIH OCIO IRT Lab
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Christopher Todd
- **10. Provide an overview of the system:** The system is a General Support System (GSS) and does not directly collect or store information.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system is a General Support System (GSS) and does not directly collect or store information. The applications/systems residing on the GSS collect and store information. Therefore, individual PIAs have been prepared and submitted for the applications/systems residing on this GSS.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Antoine D. Jones

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/29/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD OD Static Websites [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision: Not Applicable

1. Date of this Submission: 8/5/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): n/a

5. OMB Information Collection Approval Number: n/a

6. Other Identifying Number(s): n/a

- 7. System Name (Align with system Item name): NIH OD Static Websites
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Minh Chau, Steve Olsen
- **10. Provide an overview of the system:** This is a "blanket" PIA for all low-security static websites hosted by OIT
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{n/a}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: 1) The systems covered by this PIA will not collect any information. The only information disseminated by these systems is limited to federal contact data for the programs and offices to which the sites pertain.

- 2) No PI information is to be collected by these sites. Any sites which collect PII will be covered by their own PIA and will not fall under the scope of this PIA
- 3) "Information disseminated does not constitute PII (federal contact data only)"
- 4) N/A
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) n/a

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: n/a

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Antoine D. Jones

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 1/20/2012

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD OD General Support System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/8/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): General Support System (GSS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Antoine Jones
- 10. Provide an overview of the system: Office of Information Technology LAN
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): none
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: There is no information collected, maintained, or disseminated from this system.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original

collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) None

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: None

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Antoine D. Jones

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD OER Protecting Human Research Participants Training Courses (PHRP and PPHI)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 11/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

- **7. System Name (Align with system Item name):** NIH OD OER Protecting Human Research Participants Training Course (PHRP and PPHI)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Maria Stagnitto
- **10. Provide an overview of the system:** The training course is for NIH extramural grantees, Associate Investigators and other key research personnel. NIH requires these individuals to take a training course on protecting human research participants but they are not limited to this program, i.e. other training courses are available outside of NIH. This system captures limited information that is only used should it be necessary to verify that an individual has completed the (Human Subjects) training via this course.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The infomation is only used internally and is controlled via role based access controls
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) The name of the individual, their presumed business e-mail address, state and country of residency is required (2) this information is used to create the database of record for participant verification in this method of training (3) The information requested is intended to only collect business-related information as proof of participation for this method of training (4) PII is voluntary because business-related information is anticipated since the information is related to NIH grants involving the use of human subject research. On February 29, 2008 the Office of Extramural Research published in the Guide to Grants and Contract a Notice (NOT-OD-08-054) regarding the on-line tutorial Protecting Human Research Participants. It states "It satisfies the NIH human subjects training requirement for obtaining NIH awards, but it is not the only way to satisfy this requirement. Information on satisfying the requirement and answer to commonly asked questions about the education requirement may be found on OER's FAQs on the Requirement for educa5tion on the Protection of Human Subjects http://grants.nih.gov/grants/policy/hs educ faq.htm)."

Additionally OER has a Privacy Notice published at its website http://grants.nih.gov/grants/privacy.htm

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) (1) On February 29, 2008 the Office of Extramural Research published in the Guide to Grants and Contract a Notice (NOT-OD-08-054) regarding the on-line tutorial Protecting Human Research Participants. It states "It satisfies the NIH human subjects training requirement for obtaining NIH awards, but it is not the only way to satisfy this requirement. Information on satisfying the requirement and answer to commonly asked questions about the education requirement may be found on OER's FAQs on the Requirement for education on the Protection of Human Subjects At the registration site the following statement is provided: "The collection, maintenance and use of the personal information you submit via this website is protected under provisions of the Privacy Act of 1974. As such, all personally identifiable information you provide shall be treated as confidential, shall be used only for the purposes for which it was intended and shall be protected from unauthorized disclosure to the full extent permitted by the Act."

- (2) Registration form is limited to name and e-mail (presumed business-related) state and Country
- (3) The information is requested only to validate participation in this method of training and is not share beyond the need to validate this training.

OER has a Privacy Notice published at its website http://grants.nih.gov/grants/privacy.htm

32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes

- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The system is password protected, and access is limited to role based access controls.

PIA Approval

PIA Reviewer Approval: Promote
PIA Reviewer Name: Margaret Snyder
Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 10/24/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD OOCCR OMTrends Database

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 10/31/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

- 7. System Name (Align with system Item name): NIH OD OOCCR OMTrends Database
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Lisa Witzler
- **10. Provide an overview of the system:** OMTrends is a secure, encrypted database used by the Office of the Ombudsman, Center for Cooperative Resolution to record, track, analyze and report conflict management and resolution of workplace issues, as well as non-identifiable demographics of constituents who use the office, and other important, non-confidential information. It is a customized, password-protected Microsoft Access Database hosted on a NIH/OD server.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\rm N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: (1) We collect the quarter of the year the case is opened (January to March; April to June; July to September; October to December), the current position of the employee, how the employee was referred to the office, bargaining unit status, Institute/Center, and a range (in 5 year increments) of how long they have been at NIH, the general issues that are presented (i.e. communication, performance), the ombudsman activity (i.e. coaching, mediation, referral), where we refer an employee if applicable (i.e. Employee Assistance Program, Employee Relations, OEODM). We are occasionally contacted by non-NIH employees and thus collect this information as well.

- (2) We collect this information for the purposes of providing a service to further scientific research through efficient, effective, and innovative conflict management and resolution methods; improve the work environment, preserve workplace relationships and enhance the quality of work.
- (3) There is no PII collected.
- (4) Usage of the OD/CCR services is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Antoine D. Jones Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 11/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD OSE LifeWorks Ementoring

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: Alteration in Character of Data

1. Date of this Submission: 3/28/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: No; included in existing mentoring project by OBSSR

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0014

5. OMB Information Collection Approval Number: 0925-0475

6. Other Identifying Number(s): None

7. System Name (Align with system Item name): LifeWorks E-mentoring

- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Lisa Strauss, Raymond Liu
- **10. Provide an overview of the system:** LifeWorks E-mentoring is an NIH e-mentoring program that extends existing efforts by the NIH Office of Behavioral and Social Science Research (OBSSR) to provide high school students with information about careers in biomedical research, behavioral research, social science research, and healthcare-related fields. Development and maintenance of the supporting database is administered by the NIH Office of Science Education in partnership with OBSSR. High school students age 16 and older are linked via email to e-mentors who provide them with relevant information, guidance and support. E-mentoring takes place via the Internet.

Mentor Registration--Mentors complete the registration and Conditions of Service agreement online. Failure to abide by the terms results in removal from the program. Mentor registration involves multiple background checks including, the U.S. Department of Justice Dru Sjodin National Sex Offender Public Web site (http://www.nsopr.gov/) and a personal reference check.

Student Registration--The parent/guardian and student must complete the registration form online. Failure to abide by these terms will result in student removal from the LifeWorks Ementoring program.

Security--All student and mentor communications take place behind a firewall and are password protected on a server that is managed by the NIH Center for Information Technology.

Privacy and Internet Safety--Participants are instructed that all communications between mentors and students are restricted to online tool. No contact between students and mentors is allowed

outside of the online tool. To minimize alternative communication channels, email addresses are automatically deleted from messages.

Training--To promote safe internet practices, mentors and students receive separate guidelines that provide information and Web site links about internet safety and e-mentoring rules.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Personal information collected by LifeWorks E-Mentoring will be shared with NIH administrator at the Office of Science Education, and with IT support administrators of same, to archive in database for the direct purpose of matching protegees with mentors. This information will not be shared with third parties unless specifically authorized by legal authorities under existing statutes. IF data will be retained on the system for the projected life cycle (12 months) of proposed activity (e-mentoring). These files will be deleted from the database upon direct request
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: LifeWorks E-mentoring is a free e-mentoring program that helps high school and college students who are interested in behavioral and social science, biomedical science, dental, and healthcare careers find a mentor. Mentors are carefully screened science, healthcare, and education professionals who volunteer to provide information, guidance, and support as students develop their careers. Internet-based communication occurs between high school students and pre-screened postdoctoral fellows, scientists and healthcare personnel who are determined to be well-suited to serve as e-mentors. Submission of all PII is strictly voluntary; however, in order to participate in the LifeWorks E-mentoring program, users must provide PII in response to questions. NIH Office of Science Education administrators assigned to manage LifeWorks E-mentoring will have access to all PII collected.

The form we use to collect student and parent/guardian information is: https://science.education.nih.gov/LifeWorksEmentoring.nsf/Student%20Registration?OpenForm

Required student information includes: first name, last name, school grade, school name, email address, home address, city, state, zip code, phone number, age and gender.

Required parent/guardian information includes: first name and last name.

The form we use to collect mentor information is:

https://science.education.nih.gov/LifeWorksEmentoring.nsf/Mentor%20Registration?OpenForm

Required mentor information includes: first name, last name, title, degree/grade, employer/school, email address, work address, city, state, zip code, phone number, profession and gender.

Required mentor reference information includes: first name, last name, job title, employer/school, phone number and email address.

The data is kept in our Domino database system.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) LifeWorks E-mentoring participants will be notified by regular mail or electronic communication of any changes to the system that are covered by provisions of the privacy act. Consent for collecting and releasing PII that fall outside the scope of the original notice will be made through similar channels.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Access to the LifeWorks E-mentoring users database will be restricted to the designated NIH administrators at OSE. Unauthorized access will be restricted as indicated below.

There will be two completely different databases to this application. The first database will be available to the general public. It is where general information about the program is available. It is also where individuals can go to register as participants. The other database is where the

actual communication resides. It will only be available to eligible participants. This is security at the database level.

Individuals will be required to complete an application, by which they will be given access authority. This is the point at which matches will occur. When a match is formed, mentor and student will be provided ID and password access to the second database. This is security by ID and password authentication.

Although all participants will have access to a common communication database, each person will only have access to his/her own relevant documents. Each document will have limited access characteristics that (a) limit readability to mentor, student and NIH administration, (b) prohibit modification after it is created, and (c) internally/invisibly track who created the document.

In adfdition, all e-communication is firewalled and password protected on a server that is managed by the NIH Center for Information Technology.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Antoine D. Jones

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 4/1/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD PastPerfect Online PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/3/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A
- **5. OMB Information Collection Approval Number:** N/A
- 6. Other Identifying Number(s): N/A
- 7. System Name (Align with system Item name): NIH OD PastPerfect Online Database
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Barbara Harkins
- **10. Provide an overview of the system:** PastPerfect online database contains museum object collection records, photograph collection records and archival material that is in the public domain. These records are accessed by collection name and the information retrieved is description, date of creation, title of collection, number of images. Archival collections will have scope and content information of the collection, dates, number of boxes and folders.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Not applicable
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) The PastPerfect system collections historical and archival information from the NIH community, speficially,

microscopes used in research, photographs of buildings, events and NIH directors (federal employees).

- (2) The purpose of this collection is to preserve the visual and physical history of science at the NIH. These materials are used for historical research only.
- (3) Information contains no PII
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) (1) Consent is not necessary as there is no PII in the PastPerfect database

- (2) Government employees have used these government objects and photographs and donated them to the History Office. PII is not collected from the individuals when the items are cataloged.
- (3) The information is shared by users searching the PastPerfect database
- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The administrator, Barbara Harkins, creates and manages all of the data that is placed in the database. Harkins provides the passwords to individuals using the system (two other individuals, both employees of the Office of History), performs the backups and the software company, PastPerfect Software, performs regular security checks, back-ups and technical support.

PIA Approval

PIA Reviewer Approval: Promote
PIA Reviewer Name: Barbara Harkins

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/2/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Project Performance Monitoring System (PPMS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/12/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-09-02-4694-00-301-092

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): None

5. OMB Information Collection Approval Number: None

- **7. System Name (Align with system Item name):** NIH Program Performance Monitoring System (PPMS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Rosanna Ng
- 10. Provide an overview of the system: The NIH Program Performance Monitoring System (PPMS) is a web-enabled centralized secure reporting system used for gathering, managing, analyzing and disseminating program performance and budget data. The system consist of two (2) major components, the NIH Performance Webpage (http://nihperformance.nih.gov) and an online budget and performance reporting system known as Visual Performance Suite (VPS). The Website component of PPMS links to VPS, historic reports, and relevant performance reporting resources. The VPS component of PPMS provides a web-enabled centralized performance reporting database used to collect, store, and report budget and performance data to support NIH's compliance with the Government Performance and Results Act (GPRA) and related NIH-level performance reporting. The PPMS system was deployed to the development server and went "Live" in July 2007.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Not applicable
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The VPS component of PPMS provides a web-enabled centralized performance reporting database used to collect, store, and report budget and performance data to assist NIH in meeting the requirements of the Government Performance and Results Act (GPRA) and related NIH-level performance reporting. The system does not contain PII. There is no need to submit personal information.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Not applicable. The system does not collect, maintain, or disseminate PII.

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Not applicable. System does not collect, maintain, or transmit PII.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Roanna Ng

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Pla

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Purchase Card System PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/4/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0216

5. OMB Information Collection Approval Number: N/A

- 7. System Name (Align with system Item name): NIH OD Purchase Card System (PCS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Vanessa Palacios (primary), Michelle Foster (backup)
- **10. Provide an overview of the system:** The Purchase Card System tracks NIH employee Purchase Card information. The PCS application will provide authorized staff members of the Purchase Card Program Office with the ability to view, edit, track, and add NIH cardholder/card approval official (CAO) purchase card information. Information includes names, work addresses, work phone numbers, work email addresses, GS Level, employee title, NED ID Number, cardholder/CAO purchase card account, and purchase card training/HHS required purchasing training completion dates.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The system does not share or disclose the NED ID Number (PII) to others or other systems (the system does not connect to other systems). Only the Purchase Card Program Office has access to the system.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system maintains card user's identification information that is related to their account. The information is used to identify cardholders and manage cardholders' account.
- 1. The Purchase Card System (PCS) is a collection of administrative information of Cardholders(CH)/Card Approving Officials (CAO) held within a website for ease of use for the Purchase Card Office. Information collected includes: Purchase Card Account Information (specifically name of CH/CAO, single/monthly purchase limit of that individual, and purchase card account number), NED ID Number, the dates of purchase card required training as well as when the person has to retake training, and work contact information (work address and work phone/fax number). All information collected is work related.
- 2. The purpose of such information is so the office knows which accounts are active/inactive, which has been cancelled and when. It also lets the office know which individuals are up for annual refresher training. In essence, this system acts as an electronic file folder of individuals that have or had government issued purchase cards.
- 3. The NED ID Number is PII and therefore the website contains PII.
- 4. The submission of the NED ID (PII) is mandatory.
- 5. Only federal employee information is collected.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) 1. No major changes has occurred in the system since it is internal use only to the NIH Purchase Card Program Office.

- 2. The NED ID Number is a required field in the purchase cardholder/CAO application form.
- 3. The NED ID Number is not shared (disclosed) outside of the NIH Purchase Card Program Office. Consent of the NED ID Number is given via the purchase cardholder/CAO application form.
- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes

- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Access to information is role based. The PCS application is monitored with intrusion detection, intrusion prevention, vulnerable assessments and firewalls.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Zedekiah J. Worsham Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Research and Training Opportunities System (RTO)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/8/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-4688-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0014, 09-25-0158, and 09-25-0108

5. OMB Information Collection Approval Number: 0925-0299

- **7. System Name (Align with system Item name):** NIH OD Research and Training Opportunities System (RTO)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Steve Alves
- **10. Provide an overview of the system:** The Office of Intramural Training & Education (OITE) administers a variety of programs and initiatives to recruit and develop individuals who participate in research training activities on the NIH's main campus in Bethesda, Maryland, as well as other NIH facilities around the country. These activities range from internships at the high school level through postdoctoral and clinical fellowships. To facilitate its recruitment function, the OITE maintains the NIH Research and Training Opportunities (RTO) Web site, http://www2.training.nih.gov, which includes applications and related forms for a range of intramural research training programs. The application system includes a back-end database that functions as a centralized repository of information regarding program applicants. Collection of the information in this system is authorized under 42 USC 282(b)(10), 282(b)(13), 241, 2421, 284(b)(1)(C), 284(b)(1)(K), 42 CFR Part 63, and 42 CFR Part 61, Subpart A. The primary use of this information is to evaluate applicants' qualifications for research training at the NIH.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): FDA investigators and administrators involved in the recruitment/selection of trainees may be given access to the applicant databases. Access is otherwise restricted to authorized NIH investigators and administrators.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The electronic application system collects information, including PII, necessary to evaluate the qualifications of individuals who seek intramural research training opportunities at the NIH. These fields include the following: name, month and day of birth, e-mail address, mailing address, telephone numbers, citizenship status, visa status, TOEFL score, institutional affiliations, courses completed and grades earned, grade point average (GPA), academic major, publications, a resume or curriculum vitae, contact information for up to 3 references, cover letter/personal statement, scientific research interests. Applicants whose citizenship status is Permanent resident are required to provide their Country of Citizenship and Alien Registration Number. Candidates also have the option of voluntarily responding to questions regarding gender, race/national origin, and disability (RNO). RNO data are made available to authorized NIH users in aggregate form only.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Information is collected through a web-based electronic application system. Applicants are presented with a link to the following Privacy Act Notification Act Statement:

"Collection of this information is authorized under 42 U.S.C. 282(b)(13), 284(b)(1)(C), 241, 2421, 282(b)(10), 284(b)(1)(K), 42 CFR Part 63, and 42 CFR Part 61, Subpart A. The primary use of this information is to evaluate your qualifications for research training at the National Institutes of Health. Additional disclosures may be made to law enforcement agencies concerning violations of law or regulation. Application for this program is voluntary; however, in order for us to process your application, you must complete the required fields." (Electronic Notice)

Applicants who choose to respond to the separate survey regarding gender, race/national origin, age, and disability are presented with a link to the following instructions:

"This survey is used to collect and analyze data involving race, sex, age, disability, and national origin from applicants for employment. The information you provide will be used for statistical purposes only and will not in any way affect you individually. While completion of this form is voluntary, your cooperation is important to help ensure accurate information regarding employment practices. We ask you to answer each of the questions to the best of your ability. Read each item thoroughly before selecting the appropriate response." (Electronic Notice)

There is no process in place currently to notify and obtain consent from the individuals whose IIF is in the system when major changes occur to the system.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Methods are in place to ensure least privilege (i.e., "need to know" and accountability). Accounts to access application data are issued by authorized representatives from the individual ICs. Access to accounts that give the user greater access (to create "read only" accounts and to accept applicants electronically) is controlled by OITE staff. Also, OITE's Web contractors do not have full administrative rights on development and production servers, and only access specific folders on these servers. Technical Controls in place to minimize the possibility of unauthorized access, use, or dissemination of the data in the system include User Identification, Passwords, Firewall, Virtual Private Network (VPN), Encryption, and Intrusion Detection System (IDS). In December 2010, OITE moved RTO behind Federated Identity Login service (NIH Login). Regarding physical access controls that are currently on the system, the Web, e-mail, and database servers that are maintained in secure NIH buildings at which security guards are posted. Access to the servers is restricted to authorized CIT/OIT individuals with valid Identification Badges.

In addition, the IT contractors are required to adhere to the security guidelines contained in the DHHS Automated Information Systems Security Program (AISSP) Handbook. Software development is performed on servers maintained by the contractor. Staging is on a shared NIH server residing inside the NIH firewall. Development will occur on specific servers maintained by the NIH Office of Information Technology. All contract employees are subject to a National Agency Check and Inquiry Investigation plus a Credit Check (NACIC).

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Steve Alves

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Research Condition and Disease Categorization Budget Estimating Tool (R-BET)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/5/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-09-02-4620-00-110-219

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

- 7. System Name (Align with system Item name): Disease Funding Tracking System (DFTS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Sylvia Bennett
- 10. Provide an overview of the system: The NIH will implement the Management Planning and Control (MPC) software from Geac to replace the existing DFTS to enhance the system's capabilities. The MPC implementation will provide the Office of Budget with an application to consolidate all data related to diseases, conditions and research areas for the NIH; use .NET technology instead of JAVA; save history more efficiently than the existing system; and provide better reporting capabilities both ad-hoc and production. The main MPC database will be in a Microsoft (MS) SQL Server that houses the web interface. The existing DFTS will be the main source of historic data. Approximately 18 years of history will be loaded: 1987-2004 with verification being the responsibility of NIH. The NIH will supply extracted and cleansed data in a format compatible with the Geac Data Loader Utility. DFTS data is available to the public.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $N\!/\!A$

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system contains disease fund tracking. The information can be sorted into reports based on.

Disease By Year By IC
Disease By IC By FY
Disease Actual vs. Estimate
Disease Comparison By FY
Percentage Change By IC

Other reports/view may be created by NIH staff. DFTS contains no IIF.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Sylvia Bennett

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Pla

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Research Portfolio Online Reporting Tools (RePORT)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/29/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

- **7. System Name (Align with system Item name):** NIH Research Portfolio Online Reporting Tools: Expenditures and Results (RePORTER)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: James Onken
- **10. Provide an overview of the system:** NIH RePORTER is an online interface that provides access to NIH-funded research projects and the results (publications and patents) citing this support. Only public information available through other existing websites—NIH grant awards, intramural projects, PubMed references, and patent ID numbers from the US Patent and Trademark Office—is available through RePORTER. Users are able to query the database by entering terms or making fielded selections, and the results of the query are returned in a project listing that includes the project number, subproject identifier (if applicable), project title, contact principal investigator, performing organization, fiscal year of funding, NIH administering and funding Institutes and Centers (IC), and the fiscal year total costs provided by each funding IC.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No

- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Information on NIH-funded research is shared with the public for transparency and so they can benefit from the results of that research
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: NIH RePORTER provides public access to NIH-funded research projects and the publications and awarded patents that have cited this support. These data are in the public domain and accessible to members of the public from several sources, including the DHHS TAGGS database, Medline, PubMed Central, the NIH Intramural Database, and the US Patent and Trademark Office database. The only PII disseminated is the Principal Investigator name.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Notification to and consent of Principal Investigators is provided when they apply for a grant through NIH eRA systems.

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: All information in the system is public information. No PII is collected, stored or disseminated.

PIA Approval

PIA Reviewer Approval: Promote PIA Reviewer Name: James Onken

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Research Training Programs Web Site [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/17/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-014, 09-25-0108, 09-25-0140, 09-25-0158

5. OMB Information Collection Approval Number: 0925-0299

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH OD Research Training Programs Web Site (RTP)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Patricia M. Sokolove, PhD
- **10. Provide an overview of the system:** The purpose of the NIH Research Training Programs Web Site (RTP), https://www.training.nih.gov, is to provide access to information regarding NIH intramural training programs and OITE services for prospective and current trainees, staff in the NIH Intramural Research Program, trainees and faculty in the extramural community, and other site visitors.

The RTP site enables OITE to:

- Increase ease of access to the services provided by OITE for trainees in the NIH IRP
- Deliver high-quality, timely information on NIH intramural training programs to OITE's internal and external constituencies
- Streamline internal user community functions in OITE such as registration for and evaluation of events, lectures, and workshops
- Provide network opportunities for current NIH trainees, program alumni, and NIH staff

The Alumni Database is designed to (1) track where the NIH-IRP trainees go once they leave the NIH; and (2) use the alumni population to further enhance the training experience of the program matriculates; a service already performed by many university alumni databases.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system.

This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Authorized OITE staff have access to system data via a CMS on the back end. Registered Trainees, NIH/FDA Staff, and Alumni have access to the public profile data of Alumni who indicated their willingness to serve as Networking Contacts. Public profile data are shared to provide networking opportunities for current trainees and other registered users.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: (1) The type of information collected when a user registers for an account on the RTP site varies by user type, as follows (fields marked with an asterisk are required):

```
{ All users }
```

- User Type* [Current NIH Trainee/Fellow, Current NIH Staff, Guest, or Alumni]

{ Current NIH Trainee/Fellow account fields }

- NIH ID/Badge Number*
- Institute/Center (IC)*
- Campus
- Trainee Type*
- Current NIH Training Program*
- Honorary Title
- First Name*
- Middle Name
- Last Name*
- E-mail* (must be a valid, working NIH or FDA e-mail address)
- Permanent E-mail*
- Preferred E-mail Address
- Password*

{ Current NIH Staff account fields }

- NIH ID/Badge Number*
- Institute/Center (IC)*
- Campus
- Current NIH Position*
- Honorary Title
- First Name*
- Middle Name
- Last Name*
- E-mail* (must be a valid, working NIH or FDA e-mail address)
- Password*

{ Guest account fields }

- Highest Education Level*
- Current Institution
- Honorary Title (Mr., Ms., Dr., etc)
- First Name*
- Middle Name
- Last Name*
- E-mail*
- Password*

{ Alumni account fields }

- Honorary Title
- First Name*
- Middle Name
- Last Name*
- Suffix
- Street
- City
- State
- Zip
- Country
- Phone Number
- Fax Number
- Permanent E-mail*
- Password*

NIH History

- Institute/Center (IC)*
- NIH Training Program*
- When were you at the NIH for this program*
- NIH PI
- Current Status* [Continuing high school, Entering a bachelor's degree program, etc.]

Education

- School*
- City*
- State*
- Country
- Degree(s)*
- Date of Degree Receipt
- Major/Option/Program (If applicable)
- Current Institution ("I am currently enrolled at this institution") [Yes/No]

Employment

- Organization*
- Department
- City*
- State*
- Country
- Job Title/Function*
- Annual Salary
- Description of Bonus/Benefits
- Additional Comments
- Employment Sector (Academic Research University, Academic University, primarily teaching, etc.)
- Current Institution ("I am currently employed by this institution") [Yes/No]
- Dates of Employment*
- Networking Contact* [Yes/No]

("Are you willing to serve as a networking contact for NIH trainees? We anticipate that they might seek your advice on career planning, the graduate/professional school application process, the job search process, or your particular position? Please note that only your name, place of employment/education, your NIH trainee status, and your preferred method of contact will be displayed if you choose to volunteer as a networking contact. Note: By clicking yes, you are

authorizing OITE to include you in the searchable database. By clicking no, you will not be included in any search results provided to the public.")

- Career Counselor Contact* [Yes/No]

("Would you be willing to be a contact for career counselors in the Office of Intramural Training & Education at the NIH or OITE staff organizing training events?")

- Contact Method [E-mail/Phone]
- (2) The purpose of the RTP system is to provide access to training information and OITE services for prospective and current trainees, staff in the NIH Intramural Research Program, trainees and faculty in the extramural community, and other site visitors. Access to some information is restricted to certain user groups. The purpose of the Alumni Database is (1) to welcome current NIH Intramural scientists and trainees, alumni of the NIH Intramural community, and scientists in the broader community interested in learning more about the NIH intramural community, and (2) to promote networking in, and across disciplines, in the sciences.
- (3) The information collected contains PII.
- (4) Submission of personal information is voluntary; however, in order to access certain information (e.g.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) (1) At present, there is no process in place to notify and obtain consent from individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection).

(2) The following text appears at the top of the Alumni Database registration form (https://www.training.nih.gov/alumni/register):

Thank you for taking the time to create an entry for yourself in the NIH Alumni Database. This is a new venture for the NIH Office of Intramural Training & Education (OITE) and we have big plans.

You may be wondering why you should take the time to complete the brief form below today and keep your entry up to date in the future. Here are several reasons:

- First, what's in it for YOU? Networking! You will be helping to create a searchable database of potential colleagues that you can mine to meet your own needs and those of your students and friends. But, in addition
- The OITE invites former NIH trainees to speak at events like the Career Symposium and the National Graduate Student Research Festival. The success of those ventures depends on our keeping in contact with a diverse group of NIH alumni that could include you.
- Applicants to NIH training programs often want to know where program participants go next. Where do NIH postbacs go to graduate or professional school? Where do NIH postdocs find jobs? You can help us provide those data.
- If you wish, you can become part of a worldwide network of NIH alumni who are willing to answer current trainees' questions about schools and jobs.

Database Rules:

- Information that you enter into the database will be made public e.g., to applicants to NIH programs or in publications describing NIH programs, only in the aggregate; no personally identifiable information will be published.
- Your personally identifiable information (see below) will be included in the searchable database only if you authorize the OITE to include it. You can change your mind at any time.
- Only former NIH trainees with entries in the Alumni/ae Database, current NIH trainees, and NIH staff will be able to search the Database.
- You can update your educational and/or employment history and preferences at any time.
- (3) Authorized OITE staff have access to system data via a CMS on the back end. Registered Trainees, NIH/FDA Staff, and Alumni have access to the public profile data of Alumni who indicated their willingness to serve as Networking Contacts. Authorized users must log in in order to access the Alumni Database. Public profile data include the following fields:
 - First Name
 - Middle Name
 - Last Name
 - Suffix
 - Preferred method of contact (Phone Number or Permanent E-mail)
 - Institute/Center (IC)
 - NIH Training Program
 - When were you at the NIH for this program
 - NIH PI

- Organization
- Department
- City
- State
- Country
- Job Title/Function
- Employment Sector
- Current Institution
- Dates of Employment
- School
- City
- State
- Country
- Degree(s)
- Date of Degree Receipt
- Major/Option/Program
- Current Institution
- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: An individual who creates an account must provide a valid, working e-mail address as part of the registration process. Upon submitting his account information, the user receives an e-mail message containing an account activation link. A user wishing to create a Trainee or NIH/FDA Staff account must provide an e-mail address ending in nih.gov or fda.hhs.gov. The account activation message is sent to this e-mail address (even if the user's preferred e-mail address is his permanent e-mail address).

Once a user activates her account, she can modify her profile whenever desired by logging on to the system. User passwords are not visible to any users, including OITE staff.

Access to the Alumni Database is restricted to holders of registered Trainees, NIH/FDA Staff, and Alumni. Guest users are not authorized to access this part of the system.

The data collected and stored in the RTP system are hosted on servers located in Equinix, see http://www.equinix.com/ for specific details on the hosting environment and security elements.

Physical access to the hosting environment in Equinix requires visit letters, photo badge, biometric screening and pre-authorized. Equinix is certified SAS Type 1 and 2 data center with 24x7x365 security staff, access controls, biometric controls, physically separated data spaces and camera inside/outside the facility.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Antoine D. Jones

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 10/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Safety Reporting Portal

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision: Not Applicable

1. Date of this Submission: 8/9/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0200 (Clinical, Basic and Population-Based Research Study Records)

5. OMB Information Collection Approval Number: 0910-0645

- 7. System Name (Align with system Item name): NIH OD Safety Reporting Portal (SRP)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Kelly Fennington
- 10. Provide an overview of the system: The Safety Reporting Portal Project (SRP) was initiated in order to develop a single portal for the electronic submission and analysis of adverse event data in a standardized format to accommodate existing Federal requirements. The SRP will result in a Web-based method for consumers, health professionals, investigators, sponsors, and other parties to electronically submit adverse event reports and other safety information (e.g., consumer complaint and product problem reports) utilizing applicable data sets. The portal will employ an interactive help system that will help reporters determine what specific data need to be submitted and to whom. The system will utilize electronic data exchange standards to make this resource available to anyone needing to report either post- or pre-market adverse event information to FDA or NIH. This collaborative project is expected to create tools that will allow any user to submit adverse event information that corresponds to a wide range of forms already in use by many agencies.
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): PII may be entered into the system by various stakeholders, including consumers, health professionals, investigators, and sponsors. The system will share or disclose PII to NIH and FDA for the purpose of electronically submitting adverse event reports and other safety information (e.g., consumer complaint and product problem reports).
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The portal will employ an interactive help system that will help reporters determine what specific data needs to be submitted and to whom. The system will be available to anyone needing to report either post- or pre-market adverse event information to FDA or NIH. This collaborative project is expected to create tools that will allow any user to submit adverse event information that corresponds to a wide range of forms already in use by many agencies, i.e., FDA Form 1005,1002, VICH GL42 and GeMCRIS.

In each case, the Government Authorization for collecting PII is the same as it is per the corresponding form currently in use today (e.g. section 519 of the Federal Food, Drug, and Cosmetic Act for post-market medical device reporting). The information described on the existing and corresponding forms will be requested through the SRP. The type of PII included in these reports and whether submission of personal information is voluntary or mandatory depends on the type of report and whether it is an initial report or a follow-up report.

In general, the system has the capability to include PII relating to:

- q General Notification Information (e.g. Provider/Physician Name, reporter name, Manufacturer contact name etc)
- q Subject Demographic Information (including Patient Identifier, Patient/Owner Name and address, Patient's age/DOB, gender, race, height, weight, family information, phone number, email etc)
- q Medical and Event Information (including Adverse Event description containing event outcome, symptoms, reactions, diagnosis, lab results, autopsy information, vaccine information, subject medical history, interventions, observations, and may also include attachments of medical records).

A more detailed analysis of the types of information to be contained in the system, including PII, has been documented in the System Security Plan under "System Security Categorization".

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) A Notice of Privacy Practices (NPP) will be posted on the Portal

Consent from users is not required: Law mandates what PII must be collected in mandatory reports.

In voluntary reports, the entering of PII is not mandatory.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Physical: Guards, identification badges, key cards, cipher locks and closed circuit TV.

Administrative: System security plan, contingency (or backup) plan, user manuals for the system and methods are in place to ensure least privilege.

Technical: User Identification, passwords, and encryption.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Antoine D. Jones

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 1/20/2012

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Science and Technology for America's Reinvestment (STAR) Measuring the Effect of Research on Innovation, Competitiveness and Science (METRICS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/12/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH OD Science and Technology for America's Reinvestment: Measuring the EffecTs of Research on Innovation, Competitiveness and Science
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Jack Vinner
- 10. Provide an overview of the system: STAR METRICS is being created in direct response to OMB and OSTP's request that Federal agencies "develop outcome-oriented goals for their science and technology activities, establish procedures and timelines for evaluating the performance of these activities, and target investments toward high-performing programs. Agencies should develop 'science of science policy' tools that can improve management of their research and development portfolios and better assess the impact of their science and technology investments. Sound science should inform policy decisions, and agencies should invest in relevant science and technology as appropriate."[1]

Although the importance of public investments in science, technology, and innovation is understood, the rationale for specific scientific investment decisions lacks a strong theoretical and empirical basis. Accordingly, given the magnitude of the Federal investment and the importance of that investment to our Nation, science policy decision makers must have at their disposal the most rigorous tools, methods and data that will enable them to develop sound and cost-effective investment strategies.

The Office of Management and Budget (OMB) and the Office of Science and Technology Policy (OSTP) asked federal agencies to respond to questions about the impact of federal investments in science, particularly with respect to job creation and economic growth. It is important to collect and analyze data so that such questions can be credibly answered. Currently, the tools available for generating empirical data that would reflect this collective value of the government's grant-based investments in science and technology are inadequate. Additionally, there is currently no

data infrastructure that identifies the universe of individuals funded by federal science agencies (PIs, coPIs, graduate and undergraduate students, lab technicians, science administrators, etc.) and that systematically couples science funding with the outcomes generated by those individuals.

STAR METRICS is a web based application that allows authorized users to upload and manage reporting for federal grants in science and technology. Many pages of the STAR METRICS site are available to users without authentication and authorization. These pages will contain content embedded in the HTML, with no reliance on databases or other software. These pages describe items such a:

- Program overview
- · Upcoming events
- Participation guidance
- · Data field description
- · Frequently Asked Questions

In order to gain access to restricted content and functionality of the STAR METRICS site, users must have an account supported by NIH Federated Login (i.e. NIH, NIH-External, InCommon, etc.) and must be authorized for access. STAR METRICS administrators can authorize users by assigning one or more roles to the user account for one or more organizations (research institutes and/or federal agencies). Access requests are approved and the proper permissions assigned based on the roles a user will perform for his/her affiliated organization. Once a user has an account in NIH-External or another NIH-supported user repository, STAR METRICS project administrators grant access to the site and its functionality by creating a user record associating a user's username to a unique identifier. The administrator then manually assigns one or more roles to the user account. This process is accomplished by using tools available to project administrators only, such as SQL scripts.

Access to the STAR METRICS website is enforced using a role-based permission scheme. Authorized users may be assigned one or more roles depending on the level of access required. The following table summarizes the roles.

RolePermissions Granted

Guest · View public content

This is the default role if no other roles are assigned.

Consumer View data processing status for the organization(s) for which the role is as

13. Indicate if the system is new or an existing one being modified: Existing

17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or

other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: General Overview: Anonymized administrative records are expected to be received from universities. These records will be used to develop measurable outcomes such as jobs and FTEs funded by federal and stimulus science research grant programs. In addition, the data will be matched at the PI level, from publicly available data, with external data bases such as the patents registry[1] and information about citations and publications for the PIs. This, however, will only be performed by participating universities, not the NIH.
- (1) The information the agency will collect, maintain, or disseminate:
- a. Awards Compensation People & Payroll Records
- · Anonymized unique Employee ID's (not Social Security number) of grant funded personnel
- · Occupational Classification
- Federal Award ID number (as provided by the federal grant provider)
- Hours/time charged against the grant account(s) by individual
- Proportion of wages paid to this person for this award at designated pay periods.
- · Universities will provide an additional column for FTEs (allocation)
- b. Overhead Charges
- Approved overhead rate (this is a complex number, because the overhead rate is different from the actual overhead in many cases).
- · Provide the most recent detailed justification of overhead costs approved by your cognizant agency.
- c. Non-Payroll Charges
- · Actual non-payroll charges
- For the non-payroll charges against Awards, information regarding nature of the charge (contract, purchase, invoice, etc), recipient and amount would be useful
- d. Subcontract/Sub-awards

Universities will provide a column for sub-award/subcontract costs budgeted under that award that month

- (2) Why and for what purpose the agency will use the information:
- a. To respond to the ARRA requirement to produce estimates of job creation and retention associated with the Stimulus funds
- b. To respond to the OMB and OSTP requirement that federal agencies manage their portfolios by using sound science, developing datasets, measuring outcomes and evaluating performance.[2]
- c. The 2008 Advisory Committee for the Government Performance Reinvestment Act GPRA recommended that NSF "consider ways to convey the long view of NSF investments in science and engineering" and "track future outcomes from people trained and supported by the Foundation." The committee noted that it takes time¿up to 20 years¿to move from a scientific discovery to a societal impact or market innovation, and it similarly takes time for human capital to develop after the educational investment has been made. If allowed to take a longer perspective, NSF could make the dynamic relationships between strategic goals and outcomes more clear. A performance assessment framework must use a diverse set of measures, timescales, and types of evidence. An annual reporting schedule limits discussion of long-term outcomes, which are the most meaningful for evaluating basic research and education.
- d. To respond to the call from the Science of Science Policy Working Group established by the Office of Science and Technology Policy NSTC Committee on Science That group was charged with developing an evidence-based framework for making policy investments in research and development. Its December 2008 Science of Science Policy Roadmap, articulates the need for and absence of a data infrastructure on which science policy decisions can be based. Such an infrastructure requires information on the universe of individuals funded by federal science agencies (PIs, coPIs, graduate and undergraduate students, lab technicians, science administrators, etc.) and systematically couples science funding with the short term and long term outcomes generated by those individuals.
- (3) Explicitly indicate whether the information contains PII:
- a. No
- (4) Whether submission of personal information is volunt
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:

- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No PII is collected or maintained on the system.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Promoted by Antoine D. Jones

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD SciLife PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 8/9/2011

2. OPDIV Name: NIH

- **3.** Unique Project Identifier (UPI) Number: No:included in the existing mentoring project by OBSSR
- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0014
- **5. OMB Information Collection Approval Number:** 0925-0475
- 6. Other Identifying Number(s): None
- 7. System Name (Align with system Item name): SciLife
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Dr. Bruce Fuchs
- **10. Provide an overview of the system:** To engage high school students in underserved communities through a series of practical workshops on career exploration and college planning. One of the leading occupational choices for both males and females is health care. This is encouraging because 9 of the 20 occupations projected to grow the fastest over the next 10 years are in health care (Bureau of Labor Statistics, 2002, 2003; Thompson and Chao, 2003). However, students who choose this field more often than not state that they plan to be doctors, and few can name other kinds of medical careers (CIEWD, 2002). The National Institutes of Health (NIH) Office of Science Education (OSE) provides the LifeWorksTM Web site as a tool for students to use to raise their awareness about the broad range of health and medical science career pathways and to help them make career decisions.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No.09-25-0014

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: 1 & 2. OSE will collect names, addressess and emails for the pupose of registration for SciLife program.
- 3. Yes, we collect names, addresses and emails.
- 4. The submission is voluntary if they want to register for the program.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) 1. The information is used for contacting the customers only. We notify them via email for changes if any.

- 2. We collect PII information for our internal registration use only. We don't not give out their information.
- 3. We do not give out PII information other than required by law.
- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Administrative: Regular access to information is limited to National Institutes of Health, Office of Science Education (OSE) contractors and employees who are conducting, reviewing or contributing to the SciLife 2008 program. Other access is granted only on a case-by-case basis, consistent with the restrictions required by the Privacy Act (e.g., when disclosure is required by the Freedom of Information Act), as authorized by the system manager or designated responsible official.

Physical Safeguards: Severs where documents are stored are in closed, restricted buildings, in areas which are not accessible to unauthorized users, and in facilities which are locked when not in use. Records collected for this project are maintained separately from those of other projects. Sensitive records are not left exposed to unauthorized persons at any time. Sensitive data in machine-readable form may be encrypted. Faxed permission forms are received in secure, electronic form

Technical Controls: Access to records is controlled by responsible employees and is granted only to authorized individuals whose identities are properly verified. Data stored in computers is accessed only through authentication by authorized personnel. When personal computers are used, magnetic media (e.g. diskettes, CD-ROMs, etc.) are protected as under Physical Safeguards. When data is stored within a personal computer (i.e., on a "hard disk"), the machine itself is treated as though it were a record, or records, under Physical Safeguards. Contracts for operation of this system of records require protection of the records in accordance with these safeguards; OSE project and contracting officers monitor contractor compliance.

http://oma.od.nih.gov/ms/privacy/pa-files/0156.htm

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1 - "Keeping and Destroying Records" (HHS Records Management Manual, Appendix B-361), item 1100-C-2. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER(S) AND ADDRESS(ES):

See Appendix I.

Policy coordination for this system is provided by: Acting Director, Office of Reports and Analysis, Office of Extramural Research, Office of the Director (OD), Building 1, Room 252, 1 Center Drive, Bethesda, MD 20892.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Antoine D. Jones

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Status of Funds Internet Edition (SOFie)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/4/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH OD Status of Funds, Internet Edition (SOFie)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Pat Porter or Deepak Mathur
- 10. Provide an overview of the system: SOFie is a reporting ttool that allows an Institute/Center (IC) to manipulate and report on financial transactions and general accounting information download fron the NIH Central Accounting System (CAS). It tracks budget allocations, open commitments, obligations, invoicing and payments. Transactions are passed through other systems and then downloaded, or linked int the shared data system nVision Data Warehoise, where it is then uploaded into SOFie and eported to Excel. Downloads are processed on a daily basis, generally in the evening hours to ensure all allocation entries and adjustments have been captured in real time. The daily downloads allow administrative and management staff to accourately report on the budgets established within the IC office, laboratory, section or branch. Financial Transaction Accounting Structure (MAS). The MAS groups the CANS into summary levels which include the appropriation source, allotment number, budget activity, allowance name, cost cener, and CAN is tied to a project Number, categorized by the Object Class Code (OC), and summarized and itemized by individual Document Numbers assigned for reference purposes. Additional manipulation is possible to track expenses by month of fiscal year, by data range, and through several stages of the acquisition process.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass

through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\rm N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Fiscal year operational information and general accounting data is downloaded from the NIH Central Accounting System (CAS) into a commercial, Off-the-shelf (COTS) software product purchased by the Institute/Center (IC) and exported to Excel. The financial infirantion is specific to the IC and is organized by category (Ex. Salary, benefit, aaward, appropriation, cental services, etc). It can be stored by organizational code, object class code, date or amount of a commitment, expenditure, or obligation, etc. The system contains no personally identifiable information (PII) on any individual.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Antoine D. Jones Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 10/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Stem Cell Survey Database

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/7/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: N/A

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0106

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH Human Stem Cell Guidelines Comments Database
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Tom Turley
- **10. Provide an overview of the system:** A web based form is provided that asks the public to comment on the "Draft NIH Human Stem Cell Guidelines" policy (URL http://nihoerextra.nih.gov). Three data items are asked for:

Name, Affiliation and Comments. The name is the only piece of data that is PII and it is optional. The web server will insert the comments in an MS SQL 2005 database. The comments will all be publically available.

- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Respondents are notified that the data items listed in answer 10 will all be publically available.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this

description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Question 10 lists the data that will be voluntarily collected. PII data submission is voluntary (first and last name is the only PII collected).

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Respondents are notified while they are filling out the comment form that the only PII data item asked for is optional. The comments provided will be considered by the Federal Government while shaping Human Stem Cell Usage policies.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Physical controls are in place including guards, keycards, and ID badges.

Administrative controls are in place that ensure least privlege for each user group as appropriate. System administrators will have full access, but the general public will only be able to submit and browse survey responses. All system administrators take required training each year to ensure they understand how to secure information systems and PII data properly.

Technical controls are in place to ensure that those with access to sensitive data and systems use industry accepted best practices to secure login credentials. A corporate firewall is in place that only allows web traffic from outside of NIH, all other firewall ports are closed to prevent outside intrusion.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Promoted by Antoine D. Jones

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Strategic Initiatives Database [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/20/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-09-02-8610-00-402-125

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0036

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): OD Strategic Initiatives Database (SID)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Scott Jackson
- 10. Provide an overview of the system: The new Strategic Initiatives Database (SID) provides a robust, scalable, and relational database environment that will store the data and business rules (procedures) required to maintain the strategic initiative budgetary information for forecasting and extensive reporting. It also includes a graphical user interface (GUI) that will be highly deployable by reducing the points of deployment to a single location the Internet. The SID will allow the OD Office of Portfolio Analysis and Strategic Initiatives (OPASI) to access their workloads and will provide them with the tools to print standard and ad hoc reports that meet their daily requirements for financial grant information. The SID will allow budget officers across the enterprise to acquire data (via a secure GUI) for their own budgetary processes. Similarly, the SID controls user access to allow specific data to be viewed only by relevant Users by use of Active Directory (AD) and database security controls.

As a result, the OD OPASI can expedite budgetary changes by applying the changes to the SID data, making forecasting and reporting data immediately reflect accurate, real-time modifications to grant financial information before the effects take place in the IMPACII or DataWarehouse databases. This step circumvents the time-costly need to wait for updates to IMPACII or DataWarehouse data, which often take several days or weeks to reconcile if the results there are incorrect. With the SID, the numbers are made available immediately (and later reconciled with the IMPACII and DataWarehouse databases) or immediately rectified when problems become apparent.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the

individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): IIF is obtained from the eRA system and shared with NIH Budget and Program staff to assist with tracking the funding of research grants IAW SOR# 09-25-0036.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The new SID will store business data include name, phone number, and e-mail addresses, which are required to maintain the strategic initiative budgetary information for forecasting and extensive reporting. It also includes a graphical user interface (GUI) that will be highly deployable by reducing the points of deployment to a single location the Internet. The system contains IIF that is a required part of the grant application.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) IIF is submitted as a part of the grant application process. Information used by the OD Strategic Initiatives Database (SID) is taken from the ERA grant application. Notification and consent from the individual is assumed when the grant application is submitted. All notification and consent is taken care of via the Grant application submission process.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls: IIF in the system will be secured using administrative controls such as least privilege access, which allows for role-based security measure to be in place. Technical controls include single sign-on using user name and password, housing the system behind a firewall in a server room with no external access, and

implementing an intrusion detection system. Physical access controls include guards, identification badges, and key cards. All personnel not having card key access are escorted.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Peter Soltys/Sue Titman (301) 496-9244

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Pla

Sign-off Date: 9/30/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Technology Tracking System (TechTracs)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/2/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-09-02-4621-00-110-219

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0168

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): TechTracS
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Stephen Finley
- **10. Provide an overview of the system:** NIH TechTracS is a relational database management system that manages and monitors all aspects of the technology transfer process; i.e., CRADAs, invention disclosures, U.S. and foreign patent prosecution, license applications and agreements, technology, marketing, royalties' collection, technology abstracts, statistics, and financial management.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s):
- 1) Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.
- 2) Disclosure may be made to the Department of Justice or to a court or other tribunal from this system of records, when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the

Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has an interest in such litigation, and HHS determines that the use of such records by the Department of Justice, court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however, that in each case HHS determines that such disclosure is compatible with the purpose for which the records were collected. Disclosure may also be made to the Department of Justice to obtain legal advice concerning issues raised by the records in this system.

- 3) NIH may disclose records to Department contractors and subcontractors for the purpose of collecting, compiling, aggregating, analyzing, or refining records in the system. Contractors maintain, and are also required to ensure that subcontractors maintain, Privacy Act safeguards with respect to such records.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: 1)The OTT will collect and store inventor name, address, NED Unique Identifier(SSN required if inventor is receiving royalties and non-NIH employee), title and description of the invention, Employee Invention Report (EIR) number, Case/Serial Number, prior art related to the invention, evaluation of the commercial potential of the invention, prospective licensees intended development of the invention, associated patent prosecution and licensing documents and royalty payment information.
- 2) The OTT will collect this information to obtain patent protection for PHS inventions and licenses for these patents to: (a) scientific personnel, both in this agency and other Government agencies, and in non-Governmental organizations such as universities, who possess the expertise to understand the invention and evaluate its importance as a scientific advance; (b) contract patent counsel and their employees and foreign contract personnel retained by the Department for patent searching and prosecution in both the United States and foreign patent offices; (c) all other Government agencies whom PHS contacts regarding the possible use, interest in, or ownership rights in PHS inventions; (d) prospective licensees or technology finders who may further make the invention available to the public through sale or use; (e) the United States and foreign patent offices involved in the filing of PHS patent applications.
- 3) The information collected contains PII (Social Security Numbers) for non-NIH inventors who are to receive royalty payments.
- 4) The submission of the SSN by non-NIH inventors is mandatory only if they are to receive royalties.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Any changes that are made to the information collected would be provided via our website and on any updated EIR. We also have the capability to send

e-mails directly to individuals from TechTracS. We have not had any significant changes to this data since TechTracS was launched and have not had to do this.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** Through the use of limited field access to the system administrator, and user id, passwords, the NIH firewall, and intrusion detection systems. The SSN field is viewable only by the system administrator. The front doors to OTT require a key card to access as does the server storage room. New security safeguards for the protection of SSNs and other personally identifiable information are being made to the system in that the NED ID Badge Number is being used as a substitute for the SSN in some cases. The OTT will work with its ISSO to address additional security measures with the new Tech Tracs system and look for possible solutions at the earliest opportunity.

PIA Approval

PIA Reviewer Approval: Promote **PIA Reviewer Name:** Susan Bruff

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Transfer Agreements Dashboard [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 7/12/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

- 4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): Not Applicable
- **5. OMB Information Collection Approval Number:** No The system does not maintain data as part of an approved OMB information collection survey.
- **6. Other Identifying Number(s):** No
- **7. System Name (Align with system Item name):** NIH OD Transfer Agreement Dashboard (TAD). Old name: Material Transfer Agreement Management System (MTA)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Chitra Dhayalan
- 10. Provide an overview of the system: This is an effort being driven by the National Center for Research Resources (NCRR) with support from the Office of Technology Transfer (OTT) and the technology transfer offices through each NIH Institute and Center (IC). A Material Transfer Agreement (MTA) generally is utilized when any proprietary material is exchanged, and when the receiving party intends to use it for his/her own research purposes. Neither rights in intellectual property nor rights for commercial purposes may be granted under this type of agreement. MTAs define the terms and conditions under which the recipients of materials, provided by either the NIH scientist or the other party, may use the materials. Included in the MTA are the requirements that the materials be used for research purposes only and that the materials cannot be used in human subjects. The NIH also requires that all materials received by their scientists originating from humans be collected under 45 CFR 46, Protection of Human Subjects. The goal of the MTA Management System is to facilitate the rapid exchange of research materials for intramural and extramural investigators (scientists). The current process is heavily manual and often results in delays as investigators await materials to continue their research. A web-based workflow management database system (with four work streams) is expected to facilitate the rapid location of research materials and allow for near instantaneous MTA turn-around time. The system should also provide institutional technology transfer offices with capabilities that increase efficiency and overall management of MTAs, as well as, automation of MTA negotiation and processing. As an example, users can review MTAs, check the status of a work flow, initiate a work flow and take action. The work streams include: Simple Letter Agreement, MTA – TO (Transfer of Organisms to non-profit organization and academia), UMTA (Transfer of Human Material to non-profit organization) and UBMTA (Transfer of Uniform Biologics).

The system is not designed for the storage or collection of any information outside of what is required for the associated MTA. The only data element related to PII required by the MTA is the business name of the recipient scientist and any authorized signatories. During the first phase, users will be able to log in to search for executed MTAs in the system based on the organization that the MTA is filed under as well as the Investigator who provided the material. During the second phase, the system will likely include two-factor authentication. The goal is to allow users the option to provide an electronic digital signature verified by a trusted source.

- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The system does not share or disclose PII.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: 1. The MTA management system will collect, maintain and store the name and the contact data (organization) of the Recipient (external individuals as well as federal employees in NIH) and Provider Scientists (federal employees in NIH). It will also store the name of the Authorized Official for the recipient and the NIH IC who can sign the agreement on behalf of their respective organizations.
- 2. This information is required only if it is needed by the associated MTA form. No other information is collected.
- 3. None of the information collected is PII.
- 4. The submission of contact information is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) 1. No PII is collected and hence a notification to obtain consent from the individuals in the system is required whenever major changes occur to the system and/or data uses have changed since the notice at the time of the original collection, is not

required. A process is in place to request the organization to notify us if any changes occur in the roles assigned to individuals within the system or if contact information changes.

- 2. No PII is collected from the individuals accessing the system but for the contact information which is voluntary. Hence process to notify and obtain consent does not exist.
- 3. The notice to provide contact information and periodically provide modifications to the contact information and roles of the individuals within the system is obtained by a written notice called the 'Participation Agreement' that the external organization signs when initially agreeing to use the system. All NIH users and Federal Agencies sign a written notice called 'E-Signature Agreement' whose purpose is to outline the terms and conditions regarding the use of electronic signatures as a means of ensuring accountability, data integrity and non-repudiation of technology transfer agreements.
- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: No PII is collected or maintained in the system.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name:

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 8/29/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Woman of Color Research Network

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 8/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0156

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** NIH OD Women of Color Research Network (WoCRn)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: J Taylor Harden, PhD taylor_harden@nih.gov or cerise_elliott@nih.gov
- **10. Provide an overview of the system:** The NIH OD Women of Color Research Network (WoCRn) is a web-based application to engage and build a community of scholars and women of color in biomedical research. Members of the WoCRn are volunteers who self-identify as women of color or who are interested in issues of women of color in biomedical research. The network will be a key component of the NIH and OD Office of Research on Women's Health (ORWH) outreach efforts to provide technical and capacity-building assistance to communities of color, constituencies of NIH staff, and other relevant community-based organizations and institutions serving racial and ethnic minority and women's populations
- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The system shares or discloses PII with NIH, the wider scientific community and any member of

the public, through closed membership, for the purpose of providing opportunities for women of color to network and receive mentoring and contribute to expanding the diversity of the scientific workforce

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: 1) The National Institutes of Health (NIH), through the efforts of the NIH Working Group on Women in Biomedical Careers, is pursuing innovative actions to enhance the inclusion of Women of Color (WOC) in biomedical research careers. WOC face challenges related to both sex/gender and race/ethnicity, the combination of which warrants specific attention. The Women of Color Research Network (WOCRN) is one way that NIH hopes to ensure that the unique career challenges faced by WOC are addressed, including recruitment, retention, promotion, and mentoring. It is intended to open doors to new collaborations, career development opportunities, and to provide new avenues for those interested in diversity to connect and interact.

The WOCRN includes career resources, a forum for the exchange of ideas, and a registry where participants can identify themselves, their expertise, and their interests, and can seek out a mentor, a mentee, or both. It provides a platform and source of information for those interested in supporting WOC in biomedical and behavioral research.

The WOCRN is intended to provide opportunities for networking and mentoring for WOC with each other, the NIH, the wider scientific community, and any member who would like to contribute to expanding the diversity of the scientific workforce. Periodically, members may receive email alerts from the NIH and the Office of Research on Women's Health noting upcoming events, invitations to participate in review, and notice of relevant advances in science. This network was designed with the hopes that active participation will help prepare and promote the participation of talented women and men of all backgrounds in the scientific workforce.

- 2) The information in the system will be used for outreach and to aid in diversification of the NIH workforce.
- 3) The information in the system includes PII.
- 4) Submission of PII is voluntary.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) (1) Voluntary submission of PII onto the system will represent the voluntary consent of the individual. A statement attesting to the same is included on the web entry page. Following NIH best practices, when changes to the system are made an electronic announcement will be placed prominently on the system homepage. (2) see preceding paragraph (3) Information will be shared in an electronic format with other registered members and staff of the NIH that also register on the system.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: PII will be secured by user-selected passwords with strong password complexity and expiration policies enforced. Web and database servers are dedicated machines maintained in a secure data center with strong physical access controls and continuous monitoring implemented.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Antoine Jones and/or Karen Pla

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 11/14/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD Workflow information Tracking System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 7/27/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-09-02-4698-00-403-232

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-90-0018

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- **7. System Name (Align with system Item name):** Workflow information Tracking System (WiTS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Terrye Verge
- 10. Provide an overview of the system: WiTS is a workflow management system that will provide corporate consistency through business process management and automated workflows. This automated workflow system enables HR to monitor and track the status of a vast array of actions, correspondence and approvals. It enables the HR to track the location, responsible person/body, action status, action effective/due date, etc., of personnel and other HR actions (i.e., awards, employee relations, correspondence, FOIA requests, etc.); with system access, WiTS can communicate status of actions to administrative staff and management officials through its monitoring views; allow for the measuring of performance of HR staff (trend analysis); identify improvement areas; identify staff skill and competency in HR areas; provide a variety of reports (i.e. workload, gain/loss); and promote/facilitate the provision of customer service through improved communication and timeliness in completing actions. WiTS is secure and webenabled, and with appropriate remote privileges, can be accessed over the Internet from anywhere.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): HR management & staff and IC management officials. SOR#09-90-0018. This information is further addressed in the HHS Privacy Act Systems of Record Notice 09-90-0018, published in the Federal Register, Volume 59, November 9, 1994.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Information provided in HR status/informati-onal/metric/performance reports. PIA is mandatory for metric reporting purposes. No personal information (other than name) is captured in the reports only metrics associated with the HR action.

WiTS collects data on personnel actions processed within HR (e.g., action type, employee name, Empl ID, DOB, Address, effective date, IC). The agency uses the data to provide performance metrics to HR and NIH management. The collection of minimal personal data is mandatory for reporting.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) WiTS collects minimal personal data, e.g., name, DOB, Addresses, Empl ID, organization, etc. It does not collect SSN; therefore, no employee consent is obtained. WiTS sends emails to supervisors and users and when changes in profiles/account-s are requested by supervisors and made in WITS. Send all users notice via LiSTSERV when changes in system occur. Notices are in the form of electronic mail.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: WiTS uses NIH Single Sign On to manage access and remaining security via the GSS.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Antoine D. Jones Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Pla

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD/ORF EDMS PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-3344-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

7. System Name (Align with system Item name): EDMS

- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Samna Ali
- 10. Provide an overview of the system: The NIH EDMS As-Built Drawing Repository is a central, secure, web-based system that authorized users can browse / search for engineering and architectural drawings of NIH facilities. EDMS is an application that supports the management of as-built and final A&E drawings of NIH facilities.. EDMS allows individuals with appropriate permission levels access to the drawings without allowing access to the entire database. It provides an easy-to-use drawing repository. Users with appropriate permission levels are able to import drawings into the repository for easy access via NIH-specific search criteria. EDMS eliminates the problem of terminology inaccuracies and inconsistencies by providing a central repository with index information controlled through user selection lists. It provides for the browsing and categorization of drawings based on building, floor, room, and discipline.

Above description is true for SharePoint based EDMS system.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{N/A}}$

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The EDMS stores information about NIH facilities. The majority of the information is in the form of architectural and engineering drawings; in TIF, PDF, and DWG formats. Some information is in the form of Excel worksheets and Word documents. NIH uses this information to support facility operations including operation and maintenance and renovations.

EDMS users must have access to the NIH Domain to view the EDMS homepage. From the homepage, they must supply a valid username and password to gain access. Access is controlled so users access only the facilities they need to see. Information required for a user account is the username and password (which is stored in an encrypted format). If a user requests to be notified when information in the EDMS changes, an email address can be stored with their user account. Please note, an email address is not mandatory information; It is voluntary information that individuals can provide if they choose to do so – the majority of users don't though. The collected information does not contain any personal information in identifiable form.

The SharePoint-based EDMS system allows users to login using credentials that are used to login to their desktop computer. No additional information is requested from end users. Users can choose to edit their profile, which is voluntary.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) $\rm\,N/A$

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Karen Cook 301-594-4727

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD/ORF Facilties Information Management System(FIMS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-3331-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): Facilities Information Management System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Benjamin Ikwueme
- **10. Provide an overview of the system:** FIMS is comprised of a cluster of applications for storing modifying and disseminating facility information, the core component of which is ARCHIBUS. ARCHIBUS is an integrated suite of applications that addresses all aspects of facilities and infrastructure management. It stores, maintains and reports on NIH owned and leased space. The tracking and reporting of the portfolio is not associated with any personal identifiers.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: The information the agency will collect is the location and square footage of all owned and leased space and the IC/organization occupying the space. This information is used to calculate rent, provide information to ICs/organizations on the space they occupy and to plan moves and renovations. This information will be used to report on Federal Real Property Performance Measures to HHS. The agency will also collect information to provide a centralized repository of available animal facility resources, such as cages, feed, autoclaves, veterinary medical supplies in the event of a campus emergency. The collected information does not contain any personal information in identifiable form.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The system is protected by a number of different controls that can be viewed in detail in the system C&A package. Some of the major controls that help to secure the IIF are firewalls, IDSs, VPN for remote access, the use of user names and passwords, and role based access. For physical protection, the NIH campus is protected by guards and police, in addition the server itself is kept behind locked door. Administratively procedures are in place to only allow individuals job related necessity to access IIF.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Karen Cook 301-594-4727

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD/ORS Clinical Access Manager (CAM)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-3314-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0105

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): OMS Record System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Herb Jacobi or Deborah Wilson
- **10. Provide an overview of the system:** The OMS computer system is a clinic management software application. It integrates an administrative database with an appointment system and allows for limited data collection. These features permit OMS staff to document work-related medical injuries and illnesses and manage several medical surveillance programs.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Disclosure of any information would be in strict accordance with SOR # 09-25-0105 as described under "Routine Uses of Records in the System, Including Categories of Users and the Purposes of Such Uses" This information is further addressed in the NIH Privacy Act Systems of Record Notice 09-25-0105, published in the Federal Register, Volume 67, No. 187, September 26, 2002.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system maintains employee identification and medical records information so that preventive measures can be taken and work-related injuries/illnesses can be managed. Accident and injury information is maintained in compliance with Department of Labor regulations. Submission of the information is voluntary but required to secure treatment. The information contains IIF; submission of this information by patients is mandatory to receive medical care and consultation, maintaining medical accurate records and submitting accident and injury (workers compensation) claims to the DOL.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) There currently are none

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The system is protected by a number of different controls that can be viewed in detail in the system C&A package. In addition, some of the major controls that help to secure the IIF are firewalls, IDSs, VPN for remote access, the use of user names and passwords, and role based access. For physical protection, the NIH campus is protected by guards and police, in addition the server itself is kept behind locked door. Administratively procedures are in place to only allow individuals job related necessity to access IIF.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Karen Cook 301-594-4727

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD/ORS Computerized Maintenance Management System(CMMS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-3348-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): Computerized Maintenance Management System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Matthew T. Harty
- **10. Provide an overview of the system:** CMMS is used to track trouble calls for maintenance; and creates prescribed maintenance work orders.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: CMMS is used to track trouble calls for maintenance; and creates prescribed maintenance work orders. The system specifically collects Name, telephone, building, room all work-related iformation and not PII.

The purpose of collecting this information is to identify where a maintenance issue is. All of the information is voluntarily entered by the individual making the request.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: IIF is not contained in this system. Only work-related contact information is collected.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Karen Cook 301-594-4727 Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD/ORS GRANITE PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-02-01-02-3301-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): Granite Enterprise
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Robert A. DeBellis
- **10. Provide an overview of the system:** This system is used to collect information on the animal resources provided by DVR.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The Granite Enterprise System collects Full Name, NIH contact telephone number and NIH e-mail address. The Full Name is required for both users and Study Protocols. The NIH contact telephone number and or the NIH e-mail address is used for emergency contact information only.

The Full name is the only mandatory information collected.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) There are none.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The system is protected by a number of different controls that can be viewed in detail in the system C&A package. Some of the major controls that help to secure the IIF are firewalls, IDSs, VPN for remote access, the use of user names and passwords, and role based access. For physical protection, the NIH campus is protected by guards and police; in addition the server itself is kept behind locked door. Administratively procedures are in place to only allow individual's job related necessity to access IIF.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Karen Cook 301-594-4727

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD/ORS MAXIMO PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-05-02-3305-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: no

6. Other Identifying Number(s): no

- 7. System Name (Align with system Item name): Maximo
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Ken Deng
- **10. Provide an overview of the system:** The MAXIMO system tracks work orders, equipment information, stock room items, purchase/rental equipment and billing information.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The systems collects contact information for individuals that requests a work order(s). We collect only the requesters name, phone, building, room and email address. All are public information and the information is used only to identify the requester; the technician needs the information to locate the customer and the equipment. The name and office phone number are mandatory.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) There are none.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The system is protected by a number of different controls that can be viewed in detail in the system C&A package. Some of the major controls that help to secure the IIF are firewalls, IDSs, VPN for remote access, the use of user names and passwords, and role based access. For physical protection, the NIH campus is protected by guards and police, in addition the server itself is kept behind locked door. Administratively procedures are in place to only allow individuals job related necessity to access IIF.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Karen Cook 301-594-4727

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/27/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD/ORS Parking and Transhare System (PARTS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-3328-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): SOR# 09-25-0167

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): Parking and Transhare System(PARTS)
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Thomas Hayden
- **10. Provide an overview of the system:** PARTS is the system that manages enrollment in NIH Transportation programs, including the parking enrollment system and the public transportation subsidy distribution system.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): The system shares information with individuals within the Division of Amenities and Transportation Services, Division of Police, and the Division of Employee Services for the purpose of providing transportation services to NIH. Per SOR #09-25-0167,

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

The Department of Health and Human Services (HHS) may disclose information from this system of records to the Department of Justice, or to a court or other tribunal, when (a) HHS, or

any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation, and HHS determines that the use of such records by the Department of Justice, court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however, that in each case HHS determines that such disclosure is compatible with the purpose for which the records were collected.

NIH may disclose applicant's name, unique computer identification number, NIH TRANSHARE commuter card number, and type of participant's fare media to be disbursed to cashiers of the Recreation and Welfare Association of the National Institutes of Health, Inc. (R&W Association) who are responsible for distribution of fare media. Cashiers are required to maintain Privacy Act safeguards with respect to such records.

Disclosure may be made to organizations deemed qualified by the Secretary to carry out quality assessments or utilization review.

NIH may disclose statistical reports containing information from this system of records to city, county, State, and Federal Government

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system shares information with individuals within the Division Amenities and Transportation Services, Division of Police, and the Division of Employee Services for the purpose of providing transportation services to NIH. PARTS collects, maintains, or disseminates the following information: name, NIH identifier, and work location information (from the NIH Directory); and vehicle, parking permit, facial image, and commuting information. The information contains the NIH UID (identifier) from the NIH Enterprise Directory (NED). Personal NED and vehicle information is mandatory if Transportation privileges are requested by the individual.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) There currently are none.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The system is protected by a number of different controls that can be viewed in detail in the system C&A package. Some of the major controls that help to secure the IIF are firewalls, IDSs, VPN for remote access, the use of user names and passwords, and role based access. For physical protection, the NIH campus is protected by guards and police, in addition the server itself is kept behind locked door. Administratively procedures are in place to only allow individuals with job related necessity to access IIF.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Karen Cook 301-594-4727

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/28/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD/ORS Point of Sale System (POS)

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/12/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-3323-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): Point of Sale System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: John Crawford
- **10. Provide an overview of the system:** The POS system provides the functionality for maintaining records of cashier functions and cafeteria purchases. The system handles cash exchanges, but does not deal with any credit card transactions.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): This system does not deal with any IIF
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The agency processes purchase information to complete the sale of items on the NIH campus. The Division of Employee Services will view individual transactions made in the retail and food service

operations not transactions by individuals. There is no specific personal data on individuals that will be collected. These transactions are simple cash/credit card transactions handled at typical retail and food service operations. Howeve the credit card portion is done externally to this system. The quantitative measure of these transactions will be used for analysis and gathering of trends to better give us a snap shot of what our customers are purchasing, how much is being purchased, and what services we can provide to maximize customer satisfaction. Submission of personal information by customers is not required to gather transaction data.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) None; since we are only using this as an automated cash register system. There would be no circumstances where personal information about anyone would be required for use of the system and to make transactions on the system. No individual would have to consent to provide personal data. The data that would be collected would be financial transactions and are not tied to any one individual.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The system is protected by a number of different controls that can be viewed in detail in the system C&A package. Some of the major controls that help to secure the IIF are firewalls, IDSs, VPN for remote access, the use of user names and passwords, and role based access. For physical protection, the NIH campus is protected by guards and police, in addition the server itself is kept behind locked door. Administratively procedures are in place to only allow individuals job related necessity to access IIF

Administration of this system is currently be researched by ORS IT to relocate server to building 13 under the umbrella of the ORS server team. System access is password protected and can only be accessed via specific passwords. Once again the server does not store any personal data on individuals and only certain individuals will have access to the server.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Karen Cook 301-594-4727

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/28/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD/ORS ScheduAll PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-3334-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): #09-25-0106

- **5. OMB Information Collection Approval Number:** No
- 6. Other Identifying Number(s): No
- 7. System Name (Align with system Item name): ScheduALL
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Shauna Everett
- **10. Provide an overview of the system:** Resource scheduling and business management software designed to handle the conference services, multimedia services, and medical arts services needs of the NIH/ORS/Division of Medical Arts.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Information is not shared outside the Division of Medical Arts (DMA). Reference SOR #09-25-0106. This information is further addressed in the NIH Privacy Act Systems of Record Notice 09-25-0106, published in the Federal Register, Volume 67, No. 187, September 26, 2002
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: This system records contact information for those individuals that request services managed by DMA. The IIF information

will be used to reserve services and for correspondence to confirm bookings. The limited IIF that is captured is mandatory for booking and reservation services.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) There are none

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The system is protected by a number of different controls that can be viewed in detail in the system C&A package. Some of the major controls that help to secure the IIF are firewalls, IDSs, VPN for remote access, the use of user names and passwords, and role based access. For physical protection, guards and police protect the NIH campus; in addition, the server itself is behind a locked door. Administratively procedures are in place to only allow individuals job related necessity to access IIF.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Karen Cook 301-594-4727

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/28/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD/ORS Send Word Now PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-3352-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0216

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): Send Word Now
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: James Stringfellow
- **10. Provide an overview of the system:** Send Word Now is a two-way messaging system used to notify various contact points during an emergency or event, it is web based/ hosted with the master account maintained by DEPC.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): This is a system that will be utilized by the NIH and not by our division alone.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: First, last name, Building, IC, Room, Gov't and personal Mobile, land, blackberry devices, email, SMS, pager, and all personal information is voluntarily given. Gov't information (email, telephone) will automatically be passed to system from NED.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Individual ICs who utilize this system are responsible to notify and obtain consent from individuals when changes occur. The ICs are notified when changes do occur to the system.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** The Send Word Now service is architected, designed, and implemented to be highly secure. Send Word Now utilizes a "defense in depth" strategy that provides, where feasible, multiple levels of defense. All traffic to and from the Web interfaces to the SWN Application is encrypted using 128-bit SSL encryption. Additionally, the redundant Cisco firewalls block all but the necessary categories of traffic entering a service complex. These firewalls also provide basic intrusion detection, cutting off suspicious traffic and providing real-time alerts to SWN service Operations personnel. As discussed in Q49, role-based access to sensitive data is provided only-as-needed to the appropriate employees.

Send Word Now SWN's service complexes provide extensive physical security. Onsite security guards are present 24/7, supplementing both indoor and outdoor security monitoring. Access to a facility requires a Hosting Facility photo ID badge and inclusion on the list of authorized personnel for that facility. Biometric hand scans and pulse detection are required for entry to a facility; they limit hosting customers from moving from one co-location area to another within the facility. Hosting customers are escorted to their areas. Closed circuit cameras monitor and record every area within the facilities. Customer equipment resides in locked cages and/or locked cabinets. The hosting provider keeps all keys to cages and cabinets; customers do not have copies of the keys. As a result, only SWN personnel have either physical or logical access to Send Word Now resources.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Karen Cook 301-594-4727

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/28/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD/ORS Verdiem Surveyor

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-3358-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): Verdium Surveyor
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Jennifer White
- 10. Provide an overview of the system: The Surveyor application is comprised of a
- Server
- •Client module
- •SQL database management system
- •Report generator

The system provides remote, network-level control over the PC's and monitor's power settings; manages communications with the Surveyor Clients; and, collects and stores energy-consumption data. The client module resides on each PC to collect and transmit power-state and energy-consumption data to the server, and "check in" with the server for updates to power-setting profiles.

The collected data is transmitted across the network to the server, where it is stored in the SQL database. (If the server is down, the client will continue to collect and store the data until the data can be transmitted to the server.) Reports are then generated to summarize energy usage.

For the initial implementation phase, data is collected for two weeks and sent to the vendor for analysis. In return, the vendor provides the optimal energy saving policies. These policies are reviewed, then implemented. Once implemented, data is captured for another two weeks to determine the baseline energy savings.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether

provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): No

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\rm N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system collects data regarding energy usage of information technology (IT) components used at ORS and ORF. The data is analyzed and profiles are created to optimize energy usage. The energy usage information collected from IT components is mandatory, and does not contain PII.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) There is no PII in this system, only username and login time is captured.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Karen Cook 301-594-4727

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/28/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH OD/ORS WSS - Sharepoint

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/12/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-3358-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): No

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): no

- 7. System Name (Align with system Item name): Sharepoint 2007
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Christine Winchester
- **10. Provide an overview of the system:** The WSS SharePoint system acts as a data repository and collaboration tool for ORS staff. It's primary use is to create working areas where teams/business owners can share documents amongst the team members. Individual SharePoint sites are managed by a member of the team/business owner for whom the site was created. The information that is placed in the SharePoint site is to the discretion of team/business owner.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): No
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The agency does not collect

any information through the use of this system. The Sharepoint application is used as a work area/tool for teams. No PII is requested to be submitted. Any information placed within the Sharepoint system is done so by the individuals using the system. The agency does not review this information.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) PII is not contained in this system therefor it is not applicable to "notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system" or "notify and obtain consent from individuals regarding what PII is being collected from them and how the information will be used or shared."

- **32.** Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: None

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Karen Cook 301-594-4727

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/28/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH ORS Application Hosting Environment [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 5/10/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-3358-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): n/a

- 7. System Name (Align with system Item name): ORS/ORF Application Hosting Environment
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Ben Ashtiani
- 10. Provide an overview of the system: The ORS/ORF Application Hosting Environment is the underlying server and security infrastructure that provides the hosting capability for ORS/ORF applications. AHE is mainly a Microsoft Windows- based environment running on multiple versions of windows to support different business processes. The majority of the equipment is located in Building 12, while the rest of the equipment is located in a server room in Building 10. In addition to the Widows Operating System, AHE consists of the following products: MS SQL, Oracle, EMC and SATA SAN storage devices and management tools such the Symantec NetBackup and virtual tape library which administer the AHE environment. Information stored by AHE is considered generic IT information and does not contain Personally Identifiable Information (PII) as well as clinical data. Most applications hosted in this environment are hosted on VMWare ESX virtual servers; a small number of applications reside on dedicated servers. ORS major applications and supporting data are beyond the accreditation boundary of AHE C&A effort.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $\ensuremath{\mathrm{n/a}}$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: AHE does not collect, maintain or dissiminate PII information.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) n/a

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: n/a

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Karen Cook 301-594-4727

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/28/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH ORS Background Investigation Tracking System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/12/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-3357-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-90-0020

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): Background Investigation Tracking System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Theresa Minter
- **10. Provide an overview of the system:** BITS tracks the background investigation status of potential employees of NIH.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The system shares the investigation status (pending, ongoing, complete).

Investigation status information is shared with HSPD-12 Issuers and Adjudicators who are designated in writing and personnel security staff who must interface with Applicants. Information is shared as part of the PIV card issuing process, e.g. investigation status must be verified prior to PIV card issue or revoking PIV card.

This information is further addressed in the NIH Privacy Act Systems of Record Notice 09-90-0020, published in the Federal Register, Volume 60, January 20, 1995.

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Yes the information contains IIF. Submission of the personal information is voluntary. However, the absence of required information may impact position selection decisions. The agency collects information needed to track the background investigation status of potential NIH employees. Additionally, the system can be used by FTEs to pre-register visitors to the NIH Bethesda campus.

Categories of PII:

Name; Date of Birth; SSN; Photographic Identifiers; Mother's Maiden Name; Vehicle Identifiers; Personal Mailing Address; Personal Phone Numbers; Medical Records Numbers; Medical Notes; Financial Account Information; certificates; Legal Documents; Device Identifiers; Web URLs; Personal E-mail Address; Education Records; Military Status; Employment Status; Foreign Activities; Other

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) The information collected is obtained from the actual individuals. Information is not obtained through observation.

Processes are being put into place, to notify and obtain consent from individuals whose IIF is in the system, with the HHS HSPD-12 System of Records for the HSPD-12 systems. Name, SSN are being collected and this information is shared only with officially designated HSPD-12 Sponsors, Adjudicators and Issuers.

Processes are being put into place, to notify and obtain consent from individuals whose IFF is in the system, with the HHS HSPD-12 System of Records for the HSPD-12 systems when major system changes have occured.

Name, SSAN are being collected and this information is shared only with officially designated HSPD-12 Sponsors, Adjudicators and Issuers.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The system is protected by a number of

different controls that can be viewed in detail in the system C&A package; some of the major controls that help to secure the IIF are firewalls, IDSs, VPN for remote access, the use of user names and passwords, and role based access. For physical protection, the NIH campus is protected by guards and police, in addition the server itself is kept behind locked door. Administratively procedures are in place to only allow individuals job related necessity to access IIF.

Hard copy of IIF data is stored in locked file cabinets inside key card controlled spaces. File cabinet key control is maintained through a key control locker with written log out records. Access is controlled based on officially designated Role assignments which are in writing. System data is protected by dual authentication log on while data base systems are maintained in the NIH CIT security controlled computer facility which has special key card entry controls, guards, and CCTV security cameras. In addition the system network includes an intrusion detection system and firewalls to detect and limit access respectively.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Karen Cook 301-594-4727 Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 4/22/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH ORS Constructware PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/5/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-3344-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): Constructware
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Jon Sweeney
- **10. Provide an overview of the system:** Constructware is the Construction Project Management System for ORF.

Constructware provides tools for project management in the area of capital facilities programs.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Collects information regarding ongoing construction projects within NIH.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) No

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): No
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Colleen Guay Broder 301-594-1713

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/28/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH ORS CPR Training Registration System

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/12/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-3314-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0166

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): CPR/AED Training System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Michael Dunn, PO/ Larry Johnson, CHB Chief
- **10. Provide an overview of the system:** The Division of Occupational Health and Safety CPR/AED Training System maintains records of participant completion.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): The system does not share or disclose IIF.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Name, e-mail address; work address. Mandatory for class registration purposes.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) None

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Administrative: limited access

Technical: password protected and limited user authorization; ITB security protocols

Physical: NIH is a secure facility with fence, guards, and requires ID cards and card key or biometric access to sensitive, controlled areas. See ITB for specifics.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Colleen Guay Broder 301-594-1713

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/28/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH ORS Enviroware PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-3343-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): Enviroware
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: David Mohammadi & Kenny Floyd
- **10. Provide an overview of the system:** Enviroware is a waste management tracking software application which electronically tracks the management of hazardous waste generated at the NIH main campus and off-site facilities. Enviroware also provides various management reports and regulatory required documents to the Maryland Department of Environment and Environmental Protection Agency.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $N\!/\!A$
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: Some of the reports generated by Enviroware list the name, work phone number, building, and room number of

NIH waste generators. These reports are used to performed service requests, provide cradle to grave waste tracking and provide data to assist with waste reduction initiatives. These reports are shared with NIH chemical waste contractors and other NIH component as appropriate. The submission such information, i.e. name, work phone number, building, and room number, is required to create and complete waste service requests.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A. Contact information is collected from waste generators when they call to request waste management services.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Karen Cook 301-594-4727

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/28/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH ORS Lab Safety Training System

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-3314-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0166

5. OMB Information Collection Approval Number: TBD

6. Other Identifying Number(s): No

7. System Name (Align with system Item name): Lab Safety Training System

- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Dr. Deborah E. Wilson/Herb Jacobi
- **10. Provide an overview of the system:** The Division of Occupational Health and Safety (DOHS) training database tracks registration for safety training in-person classes entitled "Laboratory Safety at the NIH," "Working Safety with HIV and Other Bloodborne Pathogens for Non-Hospital Personnel," "Biological Safety Level 3 Training," "Biological Safety Level 3 (Hands-On) Training" and "Shipping Biological Materials Training." Additionally the site allows users to access and take the following on-line classes: "Introduction to Laboratory Safety," "Laboratory Safety Annual Refresher Training," and "Bloodborne Pathogens Annual Refresher Training."

Scores are maintained in relationship to the in-person classes. Completion status is maintained for on-line training programs.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Yes, Supervisors request information regarding training received by subordinates.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The Division of Occupational Health and Safety (DOHS) training database tracks registration for safety training in-person classes entitled "Laboratory Safety at the NIH" and "Working Safely with HIV and Other Bloodborne Pathogens". Additionally the site allows users to access and take the following on-line classes: "Introduction to Laboratory Safety," "Laboratory Safety Annual Refresher Training," and "Bloodborne Pathogens Annual Refresher Training."

Scores are maintained in relationship to the in-person classes. Completion status is maintained for on-line training programs.

Agency may use info in accident or injury investigations, accreditation purposes; and in compliance activities. Mandatory.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) None. Unique purpose.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Administrative: limited access

Technical: password protected and limited user authorization; ITB security protocols

Physical: Database is hosted on a separate machine from the website, secured via a firewall from outside access. The web and database servers are hosted at a datacenter with cameras, ID cards, and entry/egress logs.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Karen Cook 301-594-4727

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/28/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH ORS Radiation Safety Comprehensive Database [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-3314-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0166

5. OMB Information Collection Approval Number: No

6. Other Identifying Number(s): No

- 7. System Name (Align with system Item name): Radiation Safety Comprehensive Database
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Bob Zoon
- **10. Provide an overview of the system:** The Radiation Safety Comprehensive Database System (RSCDS) supports the NIH Radiation Safety Program and its information and record keeping needs. As a multiple licensee of the U.S. Nuclear Regulatory Commission, the NIH Program is required to maintain extensive detailed records on the use of licensed radioactive materials and on the training, performance and radiation exposure of employees, as well as radiation exposure of research patients, visitors and the public. The RSCDS is an essential tool for efficiently facilitating these information collection, storage and retrieval needs.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?): Yes
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): Per SOR# 09-25-0166, Routine uses of Record:

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

Disclosure may be made to the Department of Justice or to a court or other tribunal from this system of records, when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States of any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has an interest in such litigation, and HHS determines that the use of such records by the Department of Justice, court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however, that in each case HHS determines that such disclosure is compatible with the purpose for which the records were collected.

Disclosure may be made to contractors for the purpose of processing or refining the records. Contracted services may include monitoring, testing, sampling, surveying, evaluating, transcription, collation, computer input, and other records processing. The contractor shall be required to maintain Privacy Act safeguards with respect to such records.

Disclosure may be made to: a) officials of the United States Nuclear Regulatory Commission which, by Federal regulation, licenses, inspects and enforces the regulations governing the use of radioactive materials; and b) OSHA, which provides oversight to ensure that safe and healthful work conditions are maintained for employees. Disclosure will also be permitted to other Federal and/or State agencies which may establish health and safety requirements or standards.

Radiation exposure and/or training and experience history may be transferred to new employer.

A record may be disclosed for a research purpose, when the Department: (A) has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; (B) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law; (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

from the congressional office made at the request of that individual.

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether

submission of personal information is voluntary or mandatory: The Radiation Safety Database System tracks exposure badges, compliance surveys, radioactive isotopes, radiation sources, radioactive waste disposal, and radioactive waste discharges (WSSC). In addition the Radiation Safety System tracks the location of radioactive materials and the personnel who are permitted to work with those materials. Personal information collected are Name, NIH Employee ID number, Date of Birth, SSN, work location(s), work mailing address, IC affiliation, work phone number and work email address.

This information is collected for employees, researchers, contractors and any other appointment types that could use or have exposure to radioactive materials. This information is mandatory to operate a Radiation Safety Program which is in compliance with U.S. Nuclear Regulatory Commission licenses, regulations and the regulations of the Occupational Safety and Health Administration, DOL and to protect the health and safety of NIH personnel, patients, visitors and the general public.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) None

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes
- **54.** Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: Database server is kept in secured video monitored room in a secured building. Database network-wise is kept behind 3 firewalls (NIH firewall, Building 21 firewall and database firewall). Access to data in the database is through database accounts which are password protected. Depending on the type of IIF and users job duties users are given database roles to manage access. Only DBA and Developers are given direct access to database from designated clients in the network. Data transmitted between clients and database is encrypted using FIPS —level 2 standards. PI data is encrypted using Oracle's Advance Security Transparent Data Encryption.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Karen Cook 301-594-4727

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/28/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH ORS Sentinel Patriot [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? Yes

If this is an existing PIA, please provide a reason for revision:

1. Date of this Submission: 8/4/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number:

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): Not applicable

5. OMB Information Collection Approval Number: Not applicable

6. Other Identifying Number(s): Not applicable

- 7. System Name (Align with system Item name): NIH CIT Sentinel Patriot System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Renita Anderson
- **10. Provide an overview of the system:** Sentinel Patriot is a Windows based intelligent telephone console designed to provide expanded functionality necessary in critical call processing environments. Sentinel Patriot presents an enhanced user interface to the call taker by: automating key functions, coordinating the delivery of information crucial to first responders and by broadening the range of communications.

Sentinel Patriot utilizes the First Party Call Control method of Computer Telephony Integration (CTI) to integrate the console application to the soft IP PBX in the Patriot Telephony Server (PTS). Patriot receives and transmits signaling data along with the voice path via an IP connection terminating to the Patriot Communication Server (PCS) and to the PTS via one or both of the managed 24 port switches installed in the Patriot cabinet. This data includes the calling party number in the form of Automatic Number Identification (ANI) or Calling Line Identification (CLID) and feature interaction signals between Patriot and the soft PBX installed in the PTS.

- 13. Indicate if the system is new or an existing one being modified: New
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):

- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): There is no PII.
- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: 1. The information that the system collects is record data that stores telephone numbers and building locations used by NIH Staff to include both Federal and Contract Personnel. It only represents Federal contact data.
- 2. This data is used by the NIH Police Department in response to 911 Emergency Situations in which a staff member contacts the Emergency Communications Center.
- 3. The system does not contain any PII information on specific individuals.

The only information provided by an individual is the details of their emergency situation prior to first responders rendering emergency assistance. Information provided is voluntary.

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A - There is no PII.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: There is no PII.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Michele Mulholand France, NIH/CIT/PECO

Sr. Official for Privacy Approval: Promote Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 8/24/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH ORS Troux PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: PIA Validation

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-3358-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): N/A

5. OMB Information Collection Approval Number: N/A

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): ORS Troux
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Ricardo Rodriguez
- **10. Provide an overview of the system:** The ORS/F EA Troux System is used to provide Enterprise Architecture solutions. It supports the modeling of the architectural components that represent individual elements of the ORS/F business; for example, goals, objects, service groups, applications, servers, databases, etc. that together describe the what, where and why of the ORS/F organizations.

The ORS/F EA System uses The Troux Technology (METIS) / The Troux Suite of Tools and Applications to provide EA Solutions, Business Intelligence, Visual Modeling, Metamodeling and data repository.

- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): No
- 23. If the system shares or discloses IIF please specify with whom and for what purpose(s): $N\!/\!A$

30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The ORS/F EA Troux System is intended to provide current, accurate, and reliable enterprise data in a single repository that will allow ORS and ORF stakeholders of varying interests to quickly obtain information about the business, providing answers to business questions, helping to guide business and technology decisions, and promoting the development, use and sharing of business and technical standards.

The ORS/F EA Troux System data includes:

Service Groups and Discrete Services descriptive information,

Goals, Objectives, Measures

Technology information about:

o Applications, Software, Servers, Databases,

o Projects, Vendor Companies and Federal Points of Contacts using Federal Contact Data Only

Relationships among technical and business components

Employee name or business contact information including mailing address and email address may be displayed to ORS managers to identify points of contacts for particular systems, applications, or projects as part of our Enterprise Architecture reporting

31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) N/A - There is no PII in the system.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): No
- 37. Does the website have any information or pages directed at children under the age of thirteen?:
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):
- 54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: N/A

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Karen Cook 301-594-4727

Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/28/2011

Approved for Web Publishing: Yes

06.3 HHS PIA Summary for Posting (Form) / NIH ORS Visitor Badging System [System]

PIA SUMMARY AND APPROVAL COMBINED

PIA Summary

Is this a new PIA 2011? No

If this is an existing PIA, please provide a reason for revision: Commercial Sources

1. Date of this Submission: 8/15/2011

2. OPDIV Name: NIH

3. Unique Project Identifier (UPI) Number: 009-25-01-06-02-3354-00

4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4): 09-25-0054

5. OMB Information Collection Approval Number: n/a

6. Other Identifying Number(s): N/A

- 7. System Name (Align with system Item name): Visitor Badging System
- 9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed: Major Patricia Haynes
- **10. Provide an overview of the system:** The Visitor Badging System application acts as a badge issuance system for visitors to the NIH Bethesda campus. When a visitor arrives on campus, their IDs are scanned into the system as an image file; the image along with other Information in Identifiable Form (IIF) are stored in a back-end Oracle database; identity of the individual is validated through a photo on ID; name and photo of the visitor is checked against a "Do Not Admit/No Entry" list; once approved, the visitor is issued a temporary badge.
- 13. Indicate if the system is new or an existing one being modified: Existing
- 17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):
- 21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4): Yes
- **23.** If the system shares or discloses IIF please specify with whom and for what purpose(s): Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

In the event that a system of records maintained by this agency to carry out its functions indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature,

and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the appropriate agency, whether Federal, or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation or order issued pursuant thereto

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

- 30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory: The system collects information that is stored on a normal form of identification. That could include Name, address, place of birth, birthdate, passport number, license number, photo identification, as well as other identification type info. Collection of personal information is mandatory based on NIH ORS SER DP Policy and Procedures.
- 31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) Write to the System Manager to determine if a record exists. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine. The system records visitors to the NIH; there is no mechanism in place to notify these people when a major upgrade to the system occurs; in this case, due to the purpose of this application, it should be exempt from the aforementioned requirement; individuals are providing the IIF, at the time of visitor registration - therefore, they do not need to be informed as to the information that is being collected.

- 32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII): Yes
- 37. Does the website have any information or pages directed at children under the age of thirteen?: No
- 50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN): Yes

54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.: The system is located on a separate VLAN of a secure NIH network. The network is protected by firewall and IDS devices. Only authorized individuals are allowed access to the system both physically and remotely.

PIA Approval

PIA Reviewer Approval: Promote

PIA Reviewer Name: Karen Cook 301-594-4727 Sr. Official for Privacy Approval: Promote

Sr. Official for Privacy Name: Karen Plá

Sign-off Date: 9/28/2011

Approved for Web Publishing: Yes