NIH eRA Commons Working Group (CWG)

Date/Time: Wednesday, April 30, 2003, 11 a.m.–5:30 p.m.
Location: National Academy of Sciences, Washington, D.C.
Chair: George Stone
Next Meeting: TBD

Action Items

1. (Dan Hall) Make the PI and SO fields on the eSNAP business face-page screen required prior to submission.
2. (George Stone) Investigate the feasibility of appointing a CWG representative to the Grants.gov (formerly E-Grants) group.
3. (JJ Maurer) Publish the choices that were made for format and specifications.
4. (JJ Maurer, Scarlett Gibb) Send the specifications to the listserv when they are published.
5. (Scarlett Gibb, David Wright) Prepare a list of bug fixes and enhancements that have been submitted and distribute them to the CWG through a new Web page so that the CWG can track issues that they have submitted. Also, prioritize the listing of the items.
6. (David Wright) Follow up on how retrospective protocol reviews will be implemented.
7. (Tim Twomey) Get status of citation/publications Help Desk ticket.
8. (David Wright) Take the issue of listing a total subcontract amount awarded instead of separate figures for indirect and direct costs back to the policy office for consideration.
9. (David Wright) Investigate which administrative email address should be used for the Type 5 notifications.
10. (Policy Office) Investigate creating a new personnel type for important personnel who may not be key personnel (e.g., Collegial Collaborator).

Documents

The following documents were discussed in the meeting:

- Agenda and Presentations: http://era.nih.gov/Docs/CWG_Agenda_Presentations_4-30-03.pdf
- The NIH Roadmap: http://era.nih.gov/Docs/Roadmap_SCCRI_slides_CWG_04-30-03.pdf
- Competitive Grant Application Process (CGAP) Re-engineering Issues: http://era.nih.gov/Docs/CGAP_Issues_as_of_4-03.pdf
- Clinical Research Administration Data from the Extramural Community: http://era.nih.gov/Docs/SCRRI_Combined_proposal_draft2CWG.pdf

- eSNAP Certs and Issues: http://era.nih.gov/Docs/eSNAP_04-30-03.pdf

Introduction

George welcomed the group to the CWG meeting and noted that, in response to the last meeting, the hours have been extended to provide ample discussion time. He and David Wright would be co-facilitators of the meeting.

Deployment Update

Dan Hall, NIH eRA Commons Lead Analyst, Z-Tech

(See p. 3 in Agenda and Presentations attachment)

Dan provided a general overview of the NIH eRA Commons. To date, 266 organizations have registered in the eRA Commons and there were 10,000 logins in April, up from 1,600 in January. Currently, there are 6,500 accounts, with a consistent 900 added per month since January. Dan noted that there were 1,700 accounts in Commons 1.

The breakdown of the 6,500 accounts is as follows:

PI	52%	SO	12%	ASST	5%	AA	2%
AO	14%	FSR	10%	IAR	3%		

It was noted that the ASST role is being used a lot. Dan clarified that if a person already is assigned to another role, that person does not need to be assigned the ASST role also.

IAR—The Internet Assisted Review (IAR) module is in pilot but will be deployed in July, at which time the number of accounts should increase. Sixteen meetings with 230 users have gone through IAR and 17 more are scheduled in June. In response to a question, Dan explained that Reviewers can be designated to participate in a review but only the institution can affiliate the Reviewer with the institution. Also, when a grantee moves to a new university, today you can see their grants from the new university. In July, their grants from the current university as well as all awarded grants from former universities will be available.

SNAP—Institutions have submitted 84 SNAPs and NIH would like to see 500 submitted by the end of the summer.

FSR—This module went into full production in March. There are 1,900 FSRs by institutions, with many submitted by paper.

Presentations and Demos—Staff has made a number of eRA Commons presentations this year. Additionally, the new Demo Facility was introduced with much success at the NIH Western Regional Conference in Palo Alto, Calif., in late April. The VirtualSchool (RoboDemo) for FSR was deployed last week and those for the eRA Commons, eSNAP and IAR are being developed (see http://era.nih.gov/virtualschool/).

March Release Highlights—The databases for the NIH eRA Commons and IMPAC II were merged (data goes back to 1996); code was optimized; a demo facility was established for Admin, Status, FSR, and eSNAP; SuperUser access for the Help Desk was completed; scanned applications or eSNAP submissions, abstracts and scanned FSRs were added; and Maintain Accounts, which allows account creation, was released. Suzanne Fisher noted that the scanned applications are done upon receipt by CSR and, therefore, do not contain later budget changes or additions to the application.

Profiles—There continues to be approximately 25 percent duplicate profiles in the system. NIH staff is whittling these down. Most records are matched by social security number (65 percent of records) or, lacking this, other fields such as email address, affiliation, street address, etc. Dan showed a new strategy for user account creation and registration that should speed up the profile verification process for PI accounts. Currently, only five percent of PIs who have profiles in the IMPAC II system have created eRA Commons accounts.

Action: (Dan Hall) Make the PI and SO fields on the eSNAP business face-page screen required prior to submission.

File Upload—The eRA Commons accepts file uploads in PDF, MS Word 97 and above, and text file formats. The eRA Commons Demo facility only accepts attached files in the PDF format due to resource and licensing issues.

CGAP/Grants.gov Update

JJ Maurer, eRA CGAP Project Manager, Ekagra Software Technologies

(See p. 10 in Agenda and Presentation attachment)

CGAP Objectives—Initially, objectives for the CGAP project at the NIH are to receive electronic grant applications (R01) as an XML data stream (XML for structured data and PDF for text and graphics) and process them through receipt and referral. Another objective is to define the requirements for the processing of these e-grants from receipt, through referral and assignment, to award and beyond (e.g., Review, Program, Grants Management). Changes must be made to all modules in the long run, but those changes will not occur this year.

Completed Activities—JJ reported that he developed a detailed project plan, received funding approvals for the project team and hired staff; developed iterations 1 and 2 requirements, released the design document and prototypes, presented at the Receipt and Referral Steering Group meeting, and participated in coordination meetings with Grants.gov.

Current Activities—JJ and his team are preparing message specifications for publications, completing the design for iterations 1, 2, and 3, defining validation rules and the new receipt business process, and continuing to coordinate with Grants.gov.

Business Rule Changes—It was expressed by CWG members that many institutions require a six-month to a year lead time to make changes in IT business rules. Consequently, it is important for them to receive the new business rules as soon as possible.

CGAP Team Meetings—George said the development team met often to address each CWG suggestion and determine its feasibility. He distributed copies of this extensive list, which is a "living document" and will change over time. The team also includes representatives of CSR to ensure discussion of what effect changes in business rules for the new system will have on receipt and referral, assignment and other peer review-related processes.

Deliverables—JJ reported that the CGAP team has published a description of processes and technologies, an XML for 398 document, SOAP packaging instructions and format, major milestones and project plan, and internal design documents ("use" cases, supplemental specifications, design documents and validation rules). All are available at http://era.nih.gov/Projectmgmt/SBIR/ except for internal design documents.

Coordination with Grants.gov—The Grants.gov (formerly called E-Grants, see http://grants.gov) project is proceeding on schedule, now that the development contractors have been hired (Northrop Grumman, AT&T, Ekagra). For its first deadline release in October, submission of applications, including the e-grants-defined "core" data—the data from the Standard Form 424—will be accepted in a pilot. This will not provide the data required for the NIH 398. It was noted that XML data streams will be accepted along with the old forms (which data streams make obsolete) because many agencies do not have systems equipped to accept XML data streams at this time. To ensure that recommendations being made by the CWG to the NIH are vetted to Grants.gov, it was suggested that there be a Grants.gov representative at the CWG meeting and/or conversely a CWG representative at the Grants.gov meetings.

Action: (George Stone) Investigate the feasibility of appointing a CWG representative to the Grants.gov group.

Paul Markowitz said that the focus for the Grants.gov team is the October deadline. Once that deadline is met, the team can turn its attention to research grants outside the 424 core.

Target Time Table—The team is running two weeks behind its targeted timetable but intends to reduce the gap now that the full team is in place. The current, short-term schedule is as follows:

Date	Action
May 2	Publish application packaging specification (SOAP with attachments.
May 12	Publish specifications for tickets, status, error messages.
May 26	Gather feedback. This is a critical date for project planning.
June 6	Complete Release 1 prototype and make available for test.
June 27	Complete Release 1 and make available for test.

JJ said that he didn't receive much feedback on the February schema. Feedback is critical and he asked that the CWG review all documentation and send comments to him.

Action: (JJ Maurer) Publish the choices that were made for format and specifications.

Action: (JJ Maurer, Scarlett Gibb) Send the specifications to the listserv when they are published.

SBIRs—The SBIRs receive the specifications. They then build their products and services on these specifications and make the products available to institutions so that the institutions don't have to develop them.

Clinical Research/Clinical Trials/IRB Data Standards

George Stone, eRA Commons Advocate

(See presentation, The NIH Roadmap)

The NIH Roadmap is a metaphor of Dr. Zerhouni's vision for NIH's realizing major goals. The acceleration in the pace of discoveries in the life sciences, more rapid translational processes and an urgent need for novel approaches led to the development of the NIH Roadmap. Dr. Zerhouni has

visualized three major themes for the NIH as a result of a meeting with extramural scientists, NIH IC directors and NIH program and intramural staff:

- New pathways to discovery
- Multidisciplinary research teams of the future
- Reengineering the clinical research enterprise

There are short- and long-term goals for reengineering the clinical research enterprise. In the short term (1 to 3 years out), he calls for plans to streamline, harmonize and establish clinical research data and process standards with OHRP, FDA and the NIH in regard to adverse event reporting, human subjects protections and GCRC-IRBs. He also wants to establish NIH criteria for minimum standards of consistent phenotypic and historic data required of all patients participating in NIH-funded studies.

The long-term goals (4–7 years out) include shared data standards across NIH institutes and the extramural community; public-private partnership mechanisms in place; a funding mechanism in place to sustain a national system through consensus of all constituents; and a simplified regulatory system in place for networks.

He defined objectives for the Informatics element, including: developing/reiterating data standards; implementing software solutions for information exchange within and between agencies, and between extramural organizations and the NIH; streamlining interagency coordination and data sharing; developing networks to share common data; and developing ways to conduct outreach and education of clinical research investigators and administrators.

The Steering Committee on Clinical Research Informatics (SCCRI) has established four working groups: Data Standards and Core Elements; Toolbox—Smart Tools and Applications; Model Systems and Practices; and Interagency Coordination.

Dr. McGowan, David and George met with Amy Patterson, the OD staff member heading up the SCCRI informatics initiative, to reiterate how important it is that the CWG be involved in the working groups and in this process. Toward this end, Amy agreed to appoint Ken Forstmeier and Steve Dowdy as members of the Toolbox and Data Standards working groups, respectively.

Steve Dowdy reported that ten schools are working together to assist in the requirements, design, testing and implementation of an using the IRB module within MIT's COEUS grants administration software system. Steve suggested that once this module is tested (within the next several months), it will be used as a "strawman" for a common system. An eIRB Task Force has been established within the FDP. Steve is co-chair of the Task Force. As such, the CWG will have excellent continuity with the FDP and other agencies.

eRA Update

John (JJ) McGowan, eRA Project Manager

JJ McGowan reiterated that the vision for the NIH is being defined in the Roadmap. The clinical information will affect NIH research applications. With the success of the eRA project, we've been asked to host other HHS agencies on the IMPAC II system. NIOSH and AHRQ have been using the IMPAC II database for some time. The CDC is currently going through the migration process in IMPAC II and the FDA also is looking at moving to the IMPAC II system.

JJ reported that the project received the added $6M it requested so that the budget is now at $40M. Progress continues on the migration to the new J2EE architecture and a load-balancing system is being installed. This latter is a crucial ingredient in accommodating changes and upgrades without overloading the system. It also is a necessary factor for incorporating other agencies into the system. Load balancing and the shift to J2EE were not in the original project plans so budget accommodations have been made. The overall schedule may slip because of the load-balancing project. Should the schedule slip a week or two, the July–August release will continue on course. However, if the schedule delays push the deployment into mid-August or later—no deployments can be made in late August or September—the next release will fold into the already planned October release.

A factor affecting the October release is the contractor re-compete, which takes place near the end of the summer. Should new companies win the contracts, the ramp-up time for these new players would take place during the development period before the October release. This could adversely affect a successful deployment. JJ said that the contract is being rewritten. There will be contracts for specialized functions, rather than one large contract. This means that there may be many smaller contractors working directly on the eRA project. He said that this new strategy should prove more effective in the overall management and direction of the project.

It was noted that, while the new releases fix bugs and add enhancements, they usually also change the interface and how it's used. This is frustrating for users who want to get their work done as expeditiously as possible. A solution might be to provide a demo site where users can learn the new system before they go "live." This also might be a way to gather input from the system before it is released.

Another suggestion was that there be three sites: development, training and production, available to the CWG members. David Wright responded that, while this is the ideal solution, there currently are not enough resources for three sites.

Grants.gov—eRA and E-Grants officials are working closely on the grants project. JJ noted that Grants.gov is for all agencies while the eRA project is for the NIH.

Staffing—The eRA project is 80 percent staffed by contractors.

Bug Fixes—Most bug fixes and new enhancements are designed into a specific release, and they must be included on the requirements list three months prior to the release. Changes after the requirements are approved must be submitted to the Configuration Change Board (CCB) for approval. However, appointed people in each module can address bugs that need immediate attention. They determine if the bug is an emergency and can authorize fixing it outside the release cycle. They must report the bug fix to the CCB.

eSNAP Pilot Discussion

David Wright

David asked the group for input regarding the eSNAP pilot. Some of the responses included:

- Once we were up to speed, it was an improvement.
- We've had good response from the Help Desk.
- This version is much better than the last version.
- Now that we are using the system, there are several items we'd like investigated. What is the mechanism to get this done? David said, in response, to send bugs to the Help Desk with a copy to him. Enhancement suggestions should be sent to him. The group agreed that they should

receive some type of communication in response to their bug fix and enhancement submissions so they know the status of those requests. Steve Dowdy suggested using an application called Perfect Tracker for this purpose.

Action: (Scarlett Gibb, David Wright) Prepare a list of bug fixes and enhancements that have been submitted and distribute them to the CWG through a new Web page so that the CWG can track issues that they have submitted. Also, prioritize the listing of the items.

- ***Human and Animal Subject Protocol Review***—It was brought to NIH attention that a retrospective review at the institutional level of human and animal subject protocols was to be implemented to meet reporting requirements since eSNAP progress reports no longer contain this information.

Action: (David Wright) Follow up on how retrospective protocol reviews will be implemented.

- ***Broken Code***—Broken code often is not noticed until production. Steve Dowdy expressed the opinion that broken code should be fixed immediately and not have to wait until the next official release. Immediate code fixing is an industry standard. David agreed that if the code must be fixed immediately, it would be.
- ***Publications***—Citations and publications are showing up erratically. Incorrect listings change the way people do business. This was reported to the Help Desk.

Action: (Tim Twomey) Get status of citation/publications Help Desk ticket.

- ***Policy/Regulations***—There should be a means to determine whether or not the system complies with Federal and Agency regulations and policies. A case in point is the "zero percent effort" issue. Currently, zero percent effort is being reported incorrectly according to policy. This is an internal policy issue that has not been communicated adequately throughout the NIH or the extramural community. Also, it was pointed out that the system does not allow fractions of effort, e.g., 7.5%.
- ***Pop-Up Certifications***—Currently, there is no part in the eSNAP process for the PI or SO to certify that the information being provided is accurate to the best of their knowledge and that the institution accepts the responsibilities of administering the grant. Three pop-up messages will be added to the system to accommodate this. One will be displayed when the SO submits the application; another will be displayed when the SO delegates submit authority to the PI; and the third will be displayed when the PI routes or submits the progress report. This will be added either in the July or October releases. While delegated authorities may enter information, there must be a level of responsibility for the acceptance and verification of data—a strict approval system. The PI or SO role currently owns this responsibility. It was suggested that there be a blanket attestation for the SO as opposed to delegation to the PI, to which the group agreed. The PI does not want to take responsibility for the institution. The SO must take the institutional responsibility.

David asked the group what major barriers must be breached to roll out the system to their campuses. Responses included the following:

- Limited file size for uploaded files.
- Most of the messages boxes are not big enough.
- Can't include all publications.

- Need to break the AO role into different components.
- Change type "Order Support" to "Other Support."
- Inability for SOs to delegate the PPF edit authority for PIs.
- The difference between a submitted proposal and a finalized proposal is the timeframe between when you submit the grant, make subsequent changes, and then finalize it. The time for this in the system has been turned to zero, but can be activated to provide this timeframe.
- Suggest including different types of institutions in the pilot, e.g., hospitals.

FSR Module Discussion

David Wright

There are 6,000 FSRs in the system. David asked the group for their comments as well as what functionality they would like to see.

- There are data consistency issues—data showing up in one and not in another.
- There is a long-form/short-form issue. The long-term goal is to eliminate forms altogether and enter data.
- There will be a certification pop-up for the person doing the FSR. This will be done in the July release.
- There were relatively few institutions registered in the old system. Now with the capability to do electronic revisions, many more are using it. The old FSR system was turned off last week.

NIH Vision on Institutional System Integration

Dan Hall

(See p. 23 in Agenda and Presentation.)

Dan reviewed the July release and provided a long-range view of the direction of the NIH eRA Commons in regard to the NIH and beyond. He asked for feedback from the group.

July Initiatives, Tactical Improvements—For July, they are fixing minor role issues, adding an improved workflow and the Human Subjects Inclusion Report in eSNAP, adding a rejection notification and operation fixes to FSR; and adding improvements to the IAR. Dan pointed out that the Human Subjects Inclusion Report includes an old form and a new form for race and gender. When users fill out the new form, the data is posted directly into the system and becomes part of the eSNAP submission.

Dan reviewed what must be in place for the NIH to accept transactions: data quality issues must be minimized, the physical architecture must be in place, and the operational processes must be in place. Each of these is being addressed.

July Initiatives in Support of Strategic Goals—For July, significant infrastructure enhancements are being put into place, specifically load balancing at the middle tier and clustering at the data tier. In addition, the Create Account function is being reworked to increase speed and accuracy of account creation. To improve data quality, degrees are being consolidated and improvements made to the address fields.

Dan explained that when a user creates an account and enters their name, all profiles and information in the system that match the key data appear for the person to verify. This means that if there are duplicate profiles, the user can verify the correct one or collapse multiple profiles with relevant information into one profile. Once the information is verified, it still will go to the data-quality group for final verification, but the process should be much quicker because they will not have to do as much research. The information can be updated at any time through the eRA Commons under Verify Support. The purpose of this exercise is to provide a means to get the most accurate data in the Profile in the shortest time.

Role Types—Dan presented a new way to structure access rights within the institution for the eRA Commons. Today, rights are determined by Roles. Dan suggested that this be changed to maintain instead an organizational hierarchy (user interface and XML transactions to define applications to organizational hierarchies) with defined rights associated within it (user interface and XML transactions). CWG members welcomed this point of view as a reflection of discussions that had taken place in earlier CWG meetings.

Miscellaneous Items

Zero-percent effort for key personnel—When defining key personnel on a research project, it is common practice to include mentors and other people involved in the project, but to list them as contributing zero effort. This is done to acknowledge the input of those colleagues who contributed in some way that was considered mentoring or volunteering rather than paid work time. Often, collaborators are associated with another institution, so that key personnel information is not available.

The NIH has defined key personnel as anyone who is essential to the project and contributes substantive effort. A designation of zero-percent effort is not consistent with this definition.

The group agreed that the researcher has a need to acknowledge all contributors to the project, whether they can be listed with a percent of effort or not. Consequently, the group suggested the following:

- Redefine the requirements for Key Personnel.
- Create a new category, perhaps "Collegial Collaborator," that could be used for acknowledgment of project contributors who do not qualify for the key personnel designation requiring measurable effort.

Action: (Policy Office) Investigate creating a new personnel type for important personnel who may not be key personnel (e.g., Collegial Collaborator).

Direct/Indirect Costs—In eSNAPs, indirect and costs are listed separately, but they are not done so as part of the TS194 data standard. It was suggested that cost reporting be consistent across all grants. Total amount awarded is acceptable and it was suggested that this be used instead of a separation of direct and indirect. The PHS form 398 is coming up soon for revision and this change could be made.

Action: (David Wright) Take the issue of listing a total subcontract amount awarded instead of separate figures for indirect and direct costs back to the policy office for consideration.

Type 5 Notification—A new module, eNotification, is scheduled to be released in January 2004, which will incorporate many different types of notifications. In the meantime, one institute at the NIH has an interim notification system for Type 5s only. It was suggested that this system be promoted within the NIH until eNotification is released.

Part of this solution is, in addition to the PI email address, to use one of two administrative email addresses located in the IPF: the Notice of Grant Award email address (NGA, 600 on list) or the Policy Announcements and Notifications email address (100 on list). Tim Twomey noted that some institutions expect that only Notices of Grant Award be sent to the NGA email address. He suggested that we populate the Policy Announcements email address with the address in the NGA email address field and contact these institutions to let them know what we are doing and how to update their information if they don't want to receive these notifications in that emailbox.

Action: (David Wright) Find out who is registered on the NGA distribution list.

Training—Tim Twomey said that he and his team had conducted eight training sessions using the new training demo site. The response was excellent.

SO Delegation of PPF Edit Authority for a PI—Although in reality it may be easier to allow the SO to delegate responsibility to change a Personal Profile for a PI, this would be contrary to the entire concept of single ownership of the PPF and nullify any accountability on the part of the PI. Accordingly, this constraint in the system will remain.

It was suggested that the delegation options for eSNAP and the PPF be on one page.

Institutional Implementation

A discussion followed concerning how individual institutions were implementing the eRA Commons across their campuses. Many were teaching classes to researchers and administrators on how to navigate and use the eRA Commons. Some were selecting specific people and groups on their campuses as pilot users before rolling out to the rest of the campus. David Wright shared that his former institution, UTMB, paid for 1,000 Adobe Acrobat licenses and taught classes to researchers and administrators how to use the application. It was also noted that Ellen Beck had developed some materials that she would share with the group via the listserv.

Administrative Items

Travel Reimbursement—George reminded the group that eRA would reimburse expenses for this meeting. Send requests for lodging reimbursements to George Stone.

Next Meeting—Although the next CWG meeting wasn't discussed, it most likely will be held in conjunction with the Federal Demonstration Partnership meeting scheduled for September 22–23 at the National Academy of Sciences in Washington, D.C. George and David will canvas the group for the specific date and time of the CWG meeting.

Attendees

CWG Members

Arias, Lynette (Oregon Health and Science Univ.)
Beck, Ellen (UCLA)
Clark, Denise (Cornell Univ.)
Dowdy, Steve (MIT)
Fant, Jane, (Univ. of Medicine and Dentistry of N.J.)
Kirk, Graydon (Emory Univ.)
McKinney, Tolliver (St. Jude Children's Research Hospital)
Randolph, Jim (Univ. of Mich.)
Robins, Sandi (Univ. of Wisc.)
Ross, Susan (Northwestern Univ.)
Sweet, Mark (Univ. of Wisc.)
Webb, Pamela A. (Stanford Univ.)
Wray, Nancy (Dartmouth Coll.)

Others Institutional Representatives

Beattie, Bob (Univ. of Mich.)
Custer, Tammy (Cornell Univ.)
Dwyer, Dan (Cornell Univ.)
Fay, Robert (Univ. of Maryland, College Park)
Hamilton, David (Univ. of Minnesota)
Keogh, Richard (Rhode Island College)
Ludington, Andrew (Northwestern Univ.)
Marcussen, Tom (Oregon Health and Science Univ.)
McCahill, Mark (Univ. of Minnesota)
Page, Melody (MD Anderson Cancer Center)
Robinson, David (Oregon Health and Science Univ.)
Stewart, Darin (Oregon Health and Science Univ.)
Thompson, Kathleen (Stanford Univ.)
Truesdail, Brenda (Cornell Univ.)
Valenzuela, Richard (UCLA)
Williams, Jim (Oregon Health and Science Univ.)
Wilson, Tom (MD Anderson Cancer Center)

Vendors

Johnson, Ed (InfoEd International)
Priest, Ben (Cayuse Software)
Rodman, John (Rams Company)

NIH Staff

Fisher, Suzanne (CSR)
Gibb, Scarlett (eRA COB)
Hahn, Marcia (OPERA)
Panniers, Richard (CSR)
Siegert, Mark (OD)
Stone, George (OPERA)
Twomey, Tim (eRA)
Walker, Cathy (OER)
White, Regina (OPERA)
Wright, David (OPERA)

NIH Contractors

Hall, Dan (Z-Tech)
Maurer, JJ (Ekagra)
Seppala, Sandy (LTS)
Weiser, Mark (RN Solutions)