

NATIONAL HUMAN GENOME RESEARCH  
INSTITUTE/NIH/DHHS

*SUMMARY*



***FOURTH WORKSHOP***  
***OF THE***  
***MAP TRAINING COORDINATORS***

18 FEBRUARY 2010

The Legacy Hotel and Meeting Centre, Rockville Maryland 20852

19 FEBRUARY 2010

Terrace Level Floor Conference Room

5635 Fishers Lane

Rockville, MD 20852

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OF THE  
MAP TRAINING COORDINATORS***

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# SUMMARY

## ***FOURTH WORKSHOP OF THE MAP TRAINING COORDINATORS***

### **I. INTRODUCTION**

In September 2009, the NHGRI made an award to Washington University, St. Louis to develop a data analysis and coordinating center (DACC) which would be a comprehensive system to track and evaluate its MAP and research training programs and to provide reports that would demonstrate NHGRI's progress in meeting its goal of increasing the number of underrepresented minorities participating in genomics research. Over the past several years, the training coordinators had developed a list of common data elements (CDEs) that they would like to see gathered on each trainee. Because our programs are varied and small, more useful data could be obtained by consolidating information across like programs. At the Fall 2009 meeting, the group developed a list of questions they felt would address how progress can be assessed. The DACC mapped the CDEs against the questions to develop the questionnaire for participants. The DACC needs IRB approval from participating centers before it can collect and analyze data from the various programs. The other activities that were part of the meeting were: (1) a discussion with Eric D. Green, the newly appointed Director, NHGRI; (2) a panel discussion by MAP trainee (Anne Marie Noronha) and her mentor (Sarven Sabunciyar); and (3) several discussion topics of interest to the Training Coordinators, focusing on recruitment. The Agenda (Appendix I) and Roster (Appendix II) are attached.

### **II. DIRECTOR'S PRESENTATION**

Eric D. Green, the recently appointed Director, National Human Genome Research Institute, discussed his vision for NHGRI. He started off by describing his path to NHGRI and genomics, starting with a postdoctoral fellowship with Maynard Olson, one of the genome pioneers, a faculty member at Washington University, a Branch Chief and then the Scientific Director of NHGRI's Division of Intramural Research. His appointment as Director, NHGRI was official 1 December 2009.

Eric gave a brief history of the Institute's planning activities which started in 1991 and have continued throughout the program. He noted that the past planning activities have put NHGRI in a good position to spearhead new technologies and resources for genomics. The community has recognized the importance of the Human Genome Project (HGP) by including it in the top ten medical advances in the first decade of the 21<sup>st</sup> century. These discoveries have resulted in a plethora of data and resources that have the potential to provide brand new opportunities, if we are able to analyze and use these data to improve the health of the American people. The next phase of genomics will be to fill in the gaps that will get us from the HGP to the realization of genomic medicine. NHGRI is now beginning a new planning process which will culminate in a

publication by the end of the year. Research has already been started on this path forward. Some of the progress along the path includes: (1) Interpreting the Human Genome Sequence (comparative sequencing, the Encyclopedia of DNA Elements (ENCODE) and the model organism ENCODE; (2) Implicating Genetic Variants with Human Disease (HapMap, Genome Wide Association Studies (GWAS), and Genes and Environment Initiative (GEI); and (3) Interpreting the Human Genome Sequence (\$1000 Genome, 1,000 Genomes and The Cancer Genome Atlas). Computational and information bottlenecks must be addressed, which will require getting the balance right between DNA sequence production and bioinformatics analyses. The Director was optimistic that NHGRI and the community, together, will be able to solve these problems.

Whatever NHGRI does in the future will mesh with the new NIH research agenda, which was discussed by Francis Collins, Director, National Institutes of Health, in an article published in *Science*. 2010 Jan 1; 327(5961):36-37. The five themes are: (1) High –Throughput Technologies; (2) Translational Medicine; (3) Benefiting Health Care Reform; (4) Focusing More on Global Health; and (5) Reinvigorating and Empowering the Biomedical Research Community.

### III. CAREER TRANSITION PANEL

Vicky Schneider, Training Coordinator for the Johns Hopkins University (JHU) CEGS, arranged for Anne Marie Noronha, a former participant of their MAP program and currently a freshman at Johns Hopkins University majoring in Cellular and Molecular Biology, and Sarven Sabunciyani, her mentor and a Research Associate in the Stanley Division of Developmental Neurovirology at JHU to discuss their experiences as trainee and mentor, respectively.

Anne Marie described her first laboratory research experience which was on Muscular Dystrophy where she learned laboratory protocol and critical laboratory techniques. From that experience she was able to prepare a poster at the end of the six-week session. Her second project was on schizophrenia, where she learned additional laboratory techniques. As a freshman, she continues to devote 11 to 12 hours per week on her research project. Sarven mentored Anne Marie on her second project and in her current research experience. Other program activities that Anne Marie found useful were her ability to do lab rotations, talk with other principal investigators about their research, and take a course in biology. She said that without the MAP experience she would have pursued science, but would not be involved in research to the extent that she is now, and that she would not have the confidence to do research. She also stated that the genetics/genomics perspective helped her focus on what she wanted to do in the future, since the Center for Talented Youth, which partners with the MAP program, is focused on producing scholars in all fields. Her goal is to get a Ph.D. and her parents are okay with that choice. Anne Marie would like to have had a 12 week experience while she was in high school, but this was not possible because the way her academic high school year was structured. She also mentioned that adjusting to life as a freshman was easy, given her experience in the MAP program.

Sarven conducts his research in a clinical laboratory. Students are an essential part of a research laboratory so it is important that he has access to students at all levels to participate in his research projects. He views training and mentoring students as an essential part of his "job description." His goal is to get students to work unsupervised. His ideal trainee is one who is interested in science and has some research experience. His method of recruiting students is by word of mouth. Currently he has a "pipeline" of students from Towson University and the University of Utah. He ensures that students have a successful experience by training them in laboratory safety, giving students projects according to their experiences and capabilities, letting them know that if something goes wrong, it is not a disaster, explaining to students why each step in a procedure is important which reduces the number of mistakes they make, giving students more difficult tasks as their laboratory skills and acumen increase, etc. For summer students, he encourages them to return for a second summer because he and they can capitalize on the research experiences from the past year. Sarven found out about the program from a colleague and feels that the programs could be more widely advertised. The fact that the MAP provides

some funding for the research is a plus in his participation. As is true for most universities, scientists do not get recognition for mentoring, but students are very appreciative of the opportunity.

#### IV. TRAINING COORDINATORS' TOPICS OF INTEREST

- What program activities make the biggest impact on transitions?
  - Provide professional development activities that focus on getting students into graduate school.
  - Facilitate a round table discussion with a panel of postdoctoral fellows who will share their professional and social experiences.
  - Enrich students' experience in the sciences, such as scientific seminars featuring emerging issues in science.
  - Expose students to scientists, especially URMs.
  - Provide networking experiences with scientists pursuing alternative careers in addition to academicians; encourage students to approach scientists and talk with them about their interests.
  - Invite URMs from biotechnology and start-up companies to give seminars.
  - Provide opportunities for URMs who are scattered through the university community an opportunity to get together for science or social activities.
  - Encourage students to read, [The Only Black Student](http://dailyuw.com/2009/12/8/only-black-student) by Lull Mengesha, a road map for social and academic success (<http://dailyuw.com/2009/12/8/only-black-student>).
  - Role play to encourage students to ask for help from a professor.
  - Help students avoid the "Imposter Syndrome" where an individual remains convinced internally s/he does not deserve the success s/he has achieved and is actually a fraud. Proof of success is dismissed as luck, timing, or as a result of deceiving others into thinking s/he is more intelligent and competent than s/he believes. It is typically associated with academics and is widely found amongst graduate students.
  - Provide prep courses around standardized tests.
  - Teach students to "speak the language of science" by participating in journal clubs and giving them critical thinking skills.
  - Have students present posters of their research.
- How do you measure the success of your recruitment strategies?

Success was defined as getting the type of student you are targeting; the ratio of the applicant pool to those who accepted; is a dynamic measure, multifaceted, and can be changed.

  - Marketing is important. As the number of applications increase, the larger the pool of applicants you have to select from and the more likely you will get the students you wish to target. Send thank you notes to professors who sent students to your program, include copies of the students' poster sessions as an indication of what they did during their time with you. Ask participants to act as recruiters on their campuses for your program.
  - Meeting demographic needs of the program, having a large ratio of number of applicants versus number of applicants selected and a small ratio of number of participants selected versus number of participants that completed the program and successfully transitioned to the next level in a STEM field.
  - Utilizing various types of communication such as e-mail, snail mail, phone calls, social networking, and face-to-face meetings.
  - Attending national meetings are only productive when you are active participants: judging posters; presenting a platform or plenary talk; talking with students, their

- mentors and department chairs; following up on contacts at the meeting. Handing out cards or sitting at booths do not increase your applicant pool.
  - Identifying students who have a real interest in becoming researchers versus enhancing their CV. Some way of assessing the students' interest in research as a career is looking at their extracurricular activities, determining their interest in and passion for research, reviewing their personal statements, assessing the student's order of intent for MD, MD/Ph.D. and Ph.D. studies, etc to see if these align with the students' stated interests.
  - Helping students understand what a Ph.D. researcher does is important, since so few role models are readily available to most URMs.
- How to increase the number of students interested in genomics?
    - Convey the idea that there are many complex diseases, such as diabetes, cardiovascular diseases, etc. that are difficult to prevent or treat and that genomics has the potential to solve these problems and to help us understand what makes us healthy.
    - Market genomics through social networking, such as Face Book, blogs, web pages, etc.
    - Teach a course or seminar on genomics.
    - Start biotech or journal clubs that focus on genomics; bring in researchers involved in genomics research.
    - Post flyers around the campus alerting a larger group of students about seminars, courses, etc.
    - Create a "pre-genomics track," similar to a "pre-Med" track to establish a genomics pipeline.
    - Aggressively recruit students from community colleges by bringing students and faculty to campus for lectures or going to their institutions to give lectures to their students.
    - Many young students many not really know what career path to take; training coordinators should embrace them as long as they want to do research.

## V. WORKSHOP ON THE IRB PROCESS

The goals of the workshop were to: (1) provide information about IRB approvals of research education programs and (2) develop key working documents for IRB package. Participants were asked to come to the meeting with knowledge about their own institution's IRB requirements for submission of an IRB package. The expertise of the DACC Team was complemented by Caroline Szymeczek and Dawayne Whittington, two experts in evaluating NIH research training programs and submitting IRB packages to institutions in order to perform data analyses.

**Generating a Profile on Each Participant.** The first session was led by Treva Rice who discussed the questionnaire and the importance of collecting accurate data on trainees. There are 60 programs in 24 institutions and most of the programs have small numbers of participants. One of the reasons for collecting data centrally is to allow participants to be tracked once funding for the original institution ends. It was decided that grantees should develop a tracking profile on past, current and future participants. The data to be collected are those CDEs that were mapped against the questionnaires from the Fall meeting. The CDEs are arranged in domains: participant's personal identifiers and background information; test scores and GPA; current degree(s); current MAP program information; participation in other enrichment programs; and accomplishments. The grantees will decide who inputs the data (e.g. training coordinator or trainee), but grantees are expected to check the data for accuracy before sending to the DACC.

The DACC has implemented the Research Electronic Data Capture (REDCap) program for data storage. The database is a secure, web-based application designed exclusively to support data capture for research studies. It has an intuitive data entry interface with data validation and audit

trails for tracking and manipulating data, export procedures for seamless data downloads to common statistical packages (SPSS, SAS, Stata, R, Excel), procedures for importing data from external sources, and advanced features, such as branching logic and calculation fields. This system was developed at Vanderbilt University and was set up for use in clinical research by more than 80 active institutional partners in an international consortium of CTSA (and other) funded institutions. REDCap will provide services through Washington University in St. Louis, to MAP grantees using “Side-door” accounts, and access is through internet connection and a web-browser. The DACC will work closely with the grantees to ensure that the data entry runs as smoothly as possible. The online data entry system is user friendly: point and click, very convenient / intuitive, allows data to be entered in an excel spreadsheet or online; and allows for additional unique questions for individual programs (if requested). It is anticipated that data entry will start in the summer of 2010.

Karen Clark Laseter of the DACC gave a demonstration of REDCap which can be found in Appendix III.

Donna Jeffe of the DACC gave a presentation on the IRB process. She described the two areas of consent needed: (1) past and present MAP participants and (2) future MAP participants and the basic elements of the informed consent document which are: (1) background; (2) purpose of the research; (3) participants, including working with minors; (4) research procedures, including data entry and remuneration; (5) participant privacy; (6) security of sensitive data; (7) risk involved to research participants; and (8) names of PI and Co-PI and other contacts, as appropriate. A description of Donna’s presentation can be found in Appendix IV.

The DACC has approval for the project, but the University’s IRB will not allow the DACC to receive any information from grantees until they have received IRB approvals from their own institutions. It was suggested that if participants could have a unique ID that would follow them throughout their career, that this would be very helpful to the DACC. One suggestion was to see if participants could get an eRA Commons ID.

Some of the agreed-upon ground rules were: individuals would never be identified in publications or presentations of the data; only aggregate data would be used in publications/presentations; and any publications/presentations of these collective and consolidated data would be co-authored by the DACC team and the grantees.

#### **Action Items:**

- Can participants get eRA Commons ID? NHGRI responsibility.  
NOTE: NHGRI staff did speak with the eRA help desk regarding this issue. eRA accounts are created by the institution, specifically the Signing Official or her/his representative. Trainees can get accounts, but it is up to the institution. The eRA account information follows the individual. If an individual forgets that s/he has an eRA account, when they apply to NIH for funding there is a program to try and eliminate duplicate accounts. Information about how accounts are created are in Appendix V.
- How many trainees are supported at each career level for each program? Grantees’ responsibilities
- Who will provide data on mock (not actual) participants to beta test the questionnaire? (volunteers or drafted by HG)

#### **Preparing for the IRB Process**

Caroline discussed the DHHS policy on human subjects research (<http://www.hhs.gov/ohrp/policy/>). Some of the key points that she made were: DHHS defines “research” (in part) as a systematic investigation designed to contribute to generalizable

knowledge and regards “human subjects” as individuals about whom data is collected with individual or identifiable private information. It was decided that the collection and analyses of data and the potential that grantees would want to publish on their findings would now make this initiative a research project and thus requiring IRB approval.

The DACC team, Caroline, and Dawayne provided significant information about what the IRB packages include, model informed consent documents, etc. This information was placed on a CD and made available to all participants. Training Coordinators were asked to come to the meeting knowledgeable about their own institution’s IRB process. It was reiterated many times over that no two IRBs operate the same. It was also recommended that before starting the IRB process that Training Coordinators visit their IRB office, tell them exactly what they are doing (including, noted Caroline, what they are doing with respect to their own MAP evaluation) and ask the officer what the Training Coordinator needs to do in order to submit an acceptable and complete IRB package. Everyone agreed that it is better to understand up front what is needed, rather than have to continually go back and forth to get the package accepted.

After this general discussion, the participants were divided into two drafting sessions: (1) Informed Consent led by Donna and Caroline and (2) IRB application (purpose, benefits, risks, data analysis, confidentiality of data, data security, etc. led by Dawayne and Treva. Both groups had very lively and interactive discussions and came up with drafts that are now being checked by the DACC for consistency, completeness, etc.

Some of the items that should be included or need to be addressed in the model IRB package are:

- Consent to use pre-existing data or to be able to contact previous participants to collect information;
- Consent to allow the DACC to collect and analyze the data;
- Consent to allow the DACC to have access to personal identifiers for the purpose of long-term tracking;
- Consistency between what is in the draft informed consent document and the draft IRB application.

IRB packages should be complete and comprehensive. Any changes require an amendment to the IRB package. Also, the IRB approvals must be renewed annually. The advisors and the experts all expressed the sentiment that this is not a daunting task, if you know what the requirements are.

The DACC will develop a “model” IRB package that grantees will be able to use as a starting point for their IRB process. After the package is finalized, NHGRI will set up a teleconference with training coordinators, DACC, Caroline, and Dawayne and our Advisors to discuss the final version. The goal is then to put this up on the web for future grantees.

***ACKNOWLEDGEMENT: A special thanks to Jeanne Cashman for her help with note taking during the workshop.***

**#1 NOTE OF CLARIFICATION ON TRACKING RESPONSIBILITIES:**

- Training coordinators are required to track participants for ten years. This has been and will always be their responsibility as long as they receive funding from NHGRI. This is NOT a DACC responsibility until after the ten-year period. The big issue comes when grants are terminated; in this case the expectation is that the DACC will have access to the original records on past participants and will be able to track them.
- Whereas our focus now is to get a profile on current trainees, the expectation is that training coordinators will provide records of past participants. It may not be possible to



have complete information on past participants, but training coordinators have always had a requirement to track trainees, and thus, should have some records.

**#2 NOTE: The date/place for the annual Fall MAP Meeting has been confirmed: October 26-27 in Tempe (Phoenix) AZ ; hosted by Arizona State University.**

## APPENDIX I

### 2010 TRAINING COORDINATORS WORKSHOP

18 February 2010  
6:30 p.m to 10:00 p.m  
The Legacy Hotel and Meeting Centre  
1775 Rockville Pike  
Rockville, MD 20852

19 February 2010  
8:00 a.m. to 4:00 p.m.  
5635 Fishers Lane (Terrace Level Conference Room)  
Rockville, MD 20852

### 18 February

### THE LEGACY HOTEL AND MEETING CENTRE

### Rockville, Maryland

- 6:30 p.m. Meet/Greet/Networking
- 6:45 Welcome and Introductions
- 7:00 Panel Discussion:  
A Successful Transition from High School to College via the MAP
- Vicky Schneider  
Coordinator, Center Scholars Program  
Center for Talented Youth (CTY)  
Johns Hopkins University
- Anne Marie Noronha  
Former Participant in CTY  
Participant in Summer Research Program  
Currently Undergraduate Student at Johns Hopkins University
- Sarven Sabunciyani  
Mentor  
Associate Professor  
Stanley Division of Developmental Neurovirology  
Johns Hopkins University School of Medicine
- 8:00 Break
- 8:30 Training Coordinator Generated Topics (30 minutes per topic)

How to market genomics to undergraduate students: Getting beyond "What is it?" (Jason Thomas and Ken Nelson)

Recruitment: measuring success; determining which strategies are most effective; and sharing information on novel and effective strategies (Boston Area MAP)

What program activities make the biggest impact on transitions? (Boston Area MAP)

10:00

Adjourn

Agenda Continued on Next Page

**19 February**

**Terrace Level Conference Room  
5635 Fishers Lane Rockville, MD**

**Workshop on the IRB Application Process**

**Purpose: (1) To provide information about IRB approvals of research education programs and (2) To develop key working documents for IRB package.**

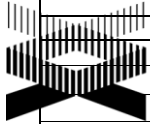
**Prerequisite: Come to the meeting with knowledge about your own institution's IRB requirements for submission of an IRB package.**

**Expected Workshop Outcome: Participants will have information needed to submit IRB packages to their institutions within six weeks of meeting.**

- 7:30 a.m. Network and Continental Breakfast
- 8:00 Mapping the Common Data Elements against Questions related to Success of MAP  
Data Analysis and Coordinating Center (DACC)
- MAP ACTION ITEMS: (1) Use the spreadsheet immediately to develop database of participants. (2) Provide "data on three mock participants" to the DCC by 5<sup>th</sup> March.**
- 9:00 Workshop on Preparing Documents for IRB Approval for Education Research
- Session I: Panel Discussion: Real Live Experiences with IRBs
- Caroline Szymeczek  
Dawayne Whittington  
Donna Jeffe (DACC Team)
- 10:00 Session IIA: Nuts and Bolts of the IRB Package
- Overview by Treva Rice (DACC Team)
- 11:00 Eric Green, M.D., Ph.D.  
Director, National Human Genome Research Institute
- 11:30 Session IIB: Breakout Groups to Develop Core Documents for IRB Package
- Group 1: Informed Consent  
*Documents for Drafting*  
Coordinators: Donna Jeffe and Caroline Szymeczek;
- Group 2: Application Form (e.g., purpose, benefits, risks, data analysis, confidentiality of data, data security, etc.)  
*Documents for Drafting*  
Coordinators: Treva Rice and Dawayne Whittington;

12:00 Lunch  
1:00 Session IIB Continued  
2:00 Break  
2:30 Working Group Reports and Discussion  
**MAP ACTION ITEMS: Submit IRB Package to Institution by April 5.**  
3:30 Help Desk/Time Lines/Next Steps  
4:00 Adjourn

APPENDIX II



<b>National Human Genome Research Institute (NHGRI)</b>
National Institutes of Health
Department of Health and Human Services
<b>NHGRI 2010 Training Coordinators Workshop</b>
<b>18 February 2010</b>
<b>The Legacy Hotel</b>
<b>1775 Rockville Pike</b>
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<b>19 February 2010</b>
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**DATABASES**

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**Data Analysis and Coordinating Center**

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<p><b>Treva Rice</b>  <a href="mailto:treva@wubios.wustl.edu">treva@wubios.wustl.edu</a></p>
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<p><b>Donna Jeffe</b>  <a href="mailto:djeffe@dom.wustl.edu">djeffe@dom.wustl.edu</a></p>
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**NHGRI STAFF**

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## APPENDIX III

### DACC REDCap Demonstration

#### Data Entry System: REDCap [Research Electronic Data Capture]

- **DATABASE**
  - Secure, web-based application designed exclusively to support data capture for research studies.
  - An intuitive data entry interface (data validation)
  - Audit trails for tracking data manipulation and export procedures
  - Automated export procedures for seamless data downloads to common statistical packages (SPSS, SAS, Stata, R, Excel)
  - Procedures for importing data from external sources
  - Advanced features, such as branching logic and calculated fields
- **REDCap**
  - Initiated at Vanderbilt University and
  - Includes more than 80 active institutional partners
    - International consortium of CTSA (and other) funded institutions
  - Services are available for MAP through Washington University in St. Louis
    - “Side-door” and User accounts will need to be requested.
    - Then you need only: Internet connection and web-browser
- REDCap
  - **Will work closely with each training program to ensure things run as smooth as possible**
  - Online data entry system
    - Point and click
    - Very convenient / intuitive
    - Everybody answers these COMMON data elements
    - Another option: Can enter data in excel spreadsheet
    - ***BONUS: REDCap allows for additional unique questions for individual programs (if requested)***
  - Common Data Entry Starts 2010 (Summer)

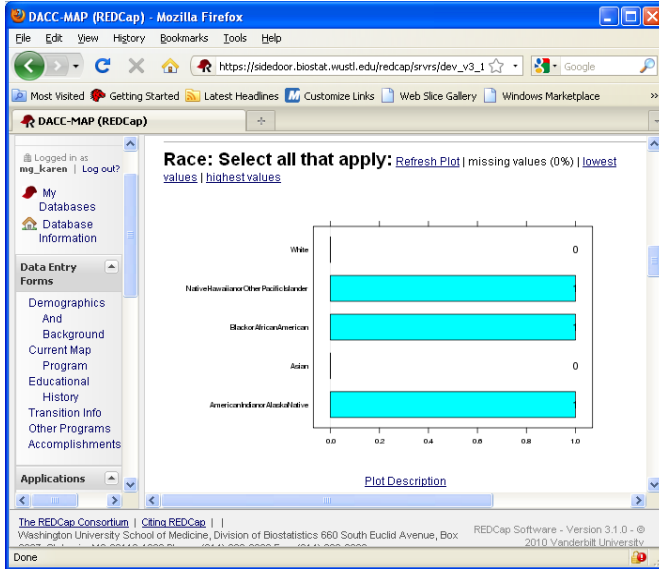
#### DACCMap and REDCap website demo / Karen Clark Laseter

DACCMap Program website created: <http://www.biostat.wustl.edu/daccmap>

- Still under development
- Will have separate links to public and private sections, including a direct link to the REDCap DES

#### REDCap website

- Each user will have unique login and will only be able to see their own institution's data.
- The site can provide descriptive statistics for your own data, such as:



- It will also provide an audit trail of all changes to and exports from the database:

**Logging**

This module lists all changes made to this database, including data exports, data changes, and the creation or deletion of users.

NOTE: Since you have been assigned to a Data Access Group, you are only able to view logging events from your group.

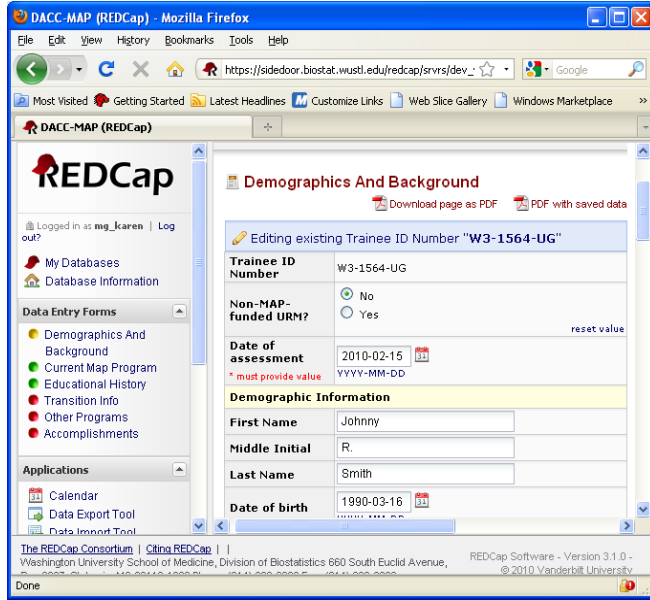
Filter by event: All event types (excluding page views)

Filter by user name: All users

Displaying events (by most recent): 1 - 100

Date / Time	User Name	Action	List of Data Changes OR Fields Exported
02/26/2010 2:36 pm	mg_karen	Manage/Design	Download data import template
02/19/2010 07:56 am	mg_karen	Manage/Design	Download data import template
02/18/2010 9:25 pm	mg_karen	Manage/Design	Delete report
02/18/2010	mg_karen	Manage/Design	Edit report

- Data entry can be completed via direct, online entry or by uploading a completed excel template file.



## APPENDIX IV

### Elements of Informed Consent

There are two areas of consent needed at this time; 1) past and present MAP participants, and 2) future.

Advisable to obtain IRB approval on both, so resubmission to IRB not needed later.  
Basic elements of informed consent

1. Background
2. Purpose of the research
  - a. Benefits to the field [not to the individual]
  - b. Statement that the study involves research
  - c. Part of a national endeavor sponsored by NHGRI to evaluate the effectiveness of MAP training.
3. Participants, including working with minors
  - a. What we are collecting/existing data, but want future contact.
  - b. Description of what they will be doing, asked of them.
  - c. Length of study
4. Research procedures, including data entry and remuneration
  - a. Length of time in study
5. Participant Privacy
6. Security of sensitive data
  - a. Data management
  - b. Destruction of data
7. What are risks as research participant? Minimal risk research
  - a. No alternatives to not participating. Do or don't.
  - b. Want aggregate info and well as individual.
  - c. Ensure confidentiality
    - i. State participant privacy
    - ii. Security of sensitive data, including destruction
8. Name of PI and Co-PI; other contacts

Note: MAP students typically do not have a problem participating in programs such as this.

#### Discussed wording for future permissions....

- Participation in this program is contingent of you participating in this program.

Examples:

#### What is this study and why is it being done?

- You are invited to participate in a research study conducted by (insert name of Principal Investigator or Project Director [PI/PD]) (If PI/PD is a student add the following phrase.) and (insert Faculty Sponsor's name). The purpose of this study is to evaluate the Minority Action Plan (MAP) programs funded by the National Institutes of Health National Human Genome Research Institute (NHGRI) at (your institution's name) and other NHGRI-funded MAP programs nationally. This endeavor is part of NHGRI's strategic plan to evaluate the impact

of short- and long-term training activities to facilitate elimination of health disparities and access to health care in underrepresented populations.

- Institution specific?
- How individual institutions will evaluate programs at their site to improve and refine.

**What I'm I being asked to do [procedures]?**

- As part of this national evaluation, you will be asked to complete surveys and/or interviews to enable us to collect information about short- and long-term educational outcomes of your training in our MAP program. Questions will focus on subsequent training that you might have received as well as educational and career achievements. *If a question makes you uncomfortable, you may skip it (?)*
- We are also asking your consent to allow us to release these newly collected data and previously collected educational data to the Data Analysis and Coordinating Center (DACC) at Washington University School of Medicine in St. Louis, MO, so that data about participants in our program can be used in the national evaluation of all of the MAP programs.

**How long will I be in the study?**

- *(Insert anticipated duration of participation).*
- The amount of time required for your participation will be *(provide specific details e.g., 2 hours with one 15-min. break –OR- approximately 6 hours scheduled in three 2-hour sessions spread over one week).*

**How many other participants will be in the study?**

- About X participants will be involved at Washington University out of a total Y participants. ~~study-wide. (Omit if not known or not meaningful to this research.)~~

Comment [d1]:

→ Note: If we can get an approximation from NHGRI or the programs, we should try to include the number of MAP programs and the total number of past and current MAP program participants nationally, to impress upon the student the national importance of the study.

**Will I be reimbursed for my participation?**

No.

**Are there any costs to me?**

No.

**Are there any risks to participation?**

- There are no known risks associated with this research. The risk of a breach of confidentiality is minimal, since your data will not be stored with your name. We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. The DACC is the data coordinating center responsible for the evaluation of all MAP programs funded by NHGRI. The DACC will create a data entry and evaluation system, maintain the combined data from all MAP programs in a secured, password-protected environment, and perform analyses of the combined data for reports to the NHGRI.

Since NHGRI would like long-term follow-up of all MAP program participants, your consent to participate in this study will allow us to send your contact information to the DACC, so that in future years, they can contact you about your educational and career achievements. Your educational data will be sent to the DACC using an ID number only. This ID number will be linked to you, and the master list will be stored separately from your data. No educational data will be transmitted with names attached.

**Are there benefits to taking part in the study?**

- There may be no direct benefits to you from participating in this study. But the information we learn will contribute new knowledge about the value of the NHGRI-funded MAP programs, such as ours, to help MAP-program trainees advance along the genetics/genomics educational continuum and achieve success and recognition as scholars in this area of research.
- These data will be used to help refine and improve the MAP program at your institution.

**Voluntary Participation [for future participants]**

- Participation in the MAP program indicates your willingness to be a part of this research that will help to define the effectiveness of the MAP program. This research will determine how to best administer the MAP program to assure its continued success and funding of this program.

**What other options are there?**

- If you do not want to be in the study, there are no other choices except not to participate.

**Privacy and Confidentiality**

- We will do everything we can to protect the confidentiality of the information you provide. As part of this effort, your identity will not be revealed in any presentation or publication that may result from this research. In rare instances, a researcher's study must undergo an audit or program evaluation by Washington University or an external oversight agency (such as the Office for Human Research Protection or the Food and Drug Administration). This may result in the disclosure of your data as well as any other information collected by the researcher. If this were to occur, such information would only be used to determine whether the researcher conducted this study properly and adequately protected your rights as a human participant. Importantly, any and all auditors would maintain the confidentiality of any information reviewed by their office(s).

**Contact Information**

- If you have any questions or concerns about this study, or feel that you have been harmed in any way by your participation in this research, please contact (insert PI/PD's name and phone number with area code)



- **(If PI/PD is a student add the following phrase)** or (insert Faculty Sponsor's name and phone number with area code).
- If you wish to talk with someone not associated with the research, or if you have questions about your rights as a research participant, please call \_\_\_\_\_, Executive Chair \_\_\_\_\_ Human Research Protection Office, \_\_\_\_\_.
- 
- Each MAP program should probably include appropriate contact information for their IRB, as well as the HRPO, if the questions pertain to the \_\_\_\_\_

## APPENDIX V

The following information is for use AFTER you are registered with Commons.

### **Procedures for creating a Commons PI account and entering it into your application:**

Below is an example of this process with screenshots and accompanying instructions

The SO must login to his/her Commons account. I have supplied an example with screenshots below for your convenience. Near the top of the page, there is a light blue line (Navigation bar) across the page.

Click on "**Admin**" and then "**Accounts**" and then "**Manage Accounts**" and then "**Create New Account**".

The screenshot displays the 'Account List' page in Internet Explorer. The browser address bar shows the URL: <https://commons.era.nih.gov/commons/account/accountSearch.jsp>. The page header includes the 'eRA Commons' logo and the text 'Sponsored by National Institutes of Health'. A navigation bar at the top contains links: Home, Admin, Accounts, Institution Profile, Personal Profile, Status, eSNAP, xTrain, Links, eRA Partners, and Help. The 'Admin' and 'Accounts' links are highlighted with red boxes. Below the navigation bar, the 'Account List' section is visible, featuring search criteria and a table of account search results. A 'Create New Account' button is highlighted with a red box, and a red text annotation '(Click on this button)' points to it. The footer of the page includes contact information for the National Institutes of Health (NIH) and the Department of Health and Human Services, along with the GRANTS.GOV logo and the text 'FIND. APPLY. SUCCEED.'.

A new page will appear “Create a New Account”. Fill in all of the required fields and click on “Submit”

Electronic Research Administration  
**eRA Commons**  
Sponsored by National Institutes of Health  
Version 2.24.01

Welcome ADMIN\_SO  
Institution: HJWHITE RESEARCH INSTITUTE  
Authority: SO  
[Log-out](#)

Home Admin Accounts Institution Profile Personal Profile Status eSNAP xTrain Links eRA Partners Help

Manage Accounts Delegate Submit Delegate PPF Edit Change Password

## Create a New Account

Do not use spaces or special characters in the User ID.

- To create an Account for an individual at your institution, you must provide the required information, identified by a \*. For Principal Investigators (PI) and Trainees (TRAINEE) with previous NIH support, please provide as much of the optional data as possible to enable the NIH to associate the new account to the existing profile already recorded at the NIH.
- \* indicates required field.

**Account Information**

First Name\*: Joseph

Middle Name\*:

Last Name\*: Green

User Name\*: JBGREEN (CREATE a User Name)

Role\*:  
Hold down Ctrl key to do multiple select or to deselect.  
FCOI  
FSR  
PI  
POSTDOC  
SO  
TRAINEE

E-mail\*: jbgreen@hwhiteresinst.org

Re-Enter E-mail\*: jbgreen@hwhiteresinst.org

Section below is valid for PI, POSTDOC and TRAINEE only (The PI can enter this information later)

Birth Date: / / (mm dd yyyy)

SSN: (123456789)

Prior Support:  
 IC and Serial number required if prior support indicated (Not for new PIs)  
IC: Serial Number

Submit Reset Cancel

Local intranet 100%

The new account information will now be displayed on the screen. If corrections need to be made to the information that was just entered, click **“Return”**. If everything is correct, click on **“Create a New NIH Profile”**.

Identify Account Profile - Windows Internet Explorer  
https://commons.era.nih.gov/commons/account/IdentifyProfile.jsp

Electronic Research Administration  
**eRA Commons**  
Sponsored by National Institutes of Health  
Version 2.24.01

Welcome ADMIN\_SO  
Institution: HJWHITE RESEARCH INSTITUTE  
Authority: SO  
[Log-out](#)

Home Admin Institution Profile Personal Profile Status eSNAP xTrain Links eRA Partners Help  
Accounts  
Manage Accounts Delegate Submit Delegate PPF Edit Change Password

### Identify Account Profile

Account Information

First Name\*: Joseph  
Middle Name:  
Last Name\*: Green  
User Name\*: JBGREEN  
Role\*: PI  
E-mail\*: jbgreen@hjwhiteresinst.org  
Retype E-mail\*: jbgreen@hjwhiteresinst.org  
Birth Date: / / (mm dd yyyy)  
Prior Support:  IC and Serial number required if prior support indicated  
IC: Serial Number:

(Click on this button)

Name	Email Address	Status	Action
			<a href="#">Return</a> <a href="#">Create a New NIH Profile</a>

[ [Contact Us/Help Desk](#) | [Privacy Notice](#) | [Disclaimer](#) | [Accessibility](#) ]

National Institutes of Health (NIH)  
9000 Rockville Pike  
Bethesda, Maryland 20892

Department of Health and Human Services

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Screen Rendered: 10/29/2009 07:09:35 EDT  
Screen Id: ADM1014

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Local intranet 100%



To complete the process, click on “Continue”.

The screenshot shows a web browser window titled "Create a New NIH Profile - Windows Internet Explorer". The address bar shows the URL: <https://commons.era.nih.gov/commons/account/confirmNewProfile.jsp>. The page header includes the "eRA Commons" logo, "Sponsored by National Institutes of Health", and "Version 2.24.01". A navigation menu contains links for Home, Admin, Institution Profile, Personal Profile, Status, eSNAP, xTrain, Links, eRA Partners, and Help. A sub-menu for "Accounts" includes Manage Accounts, Delegate Submit, Delegate PPF Edit, and Change Password. The main heading is "Create a New NIH Profile".

The "Account Information" section contains the following fields:

- First Name\*: Joseph
- Middle Name:
- Last Name\*: Green
- User Name\*: JBGREEN
- Role\*: PI
- E-mail\*: jbgreen@hjwhiteresinst.org
- Retype E-mail\*: jbgreen@hjwhiteresinst.org
- Birth Date: / / (For PI only) (mm dd yyyy)
- Prior Support: (For PI only) IC and Serial number required if prior support indicated.  IC: Serial Number.

Below the form, a message states: "This action will create a new NIH Profile and Account that will not be associated with any NIH support. If you wish to create an account for an individual who already has NIH Support, please select the Create Account link for any matching profiles." At the bottom of the form are two buttons: "Return" and "Continue". A red arrow points to the "Continue" button, with the text "(Click on this button)" above it.

The footer contains links for Contact Us/Help Desk, Privacy Notice, Disclaimer, and Accessibility. It also includes the National Institutes of Health (NIH) logo, Department of Health and Human Services logo, copyright information (© 2009 NIH. All Rights Reserved. Screen Rendered: 10/29/2009 07:16:54 EDT), and the GRANTS.GOV logo. The browser status bar shows "Local intranet" and "100%" zoom.

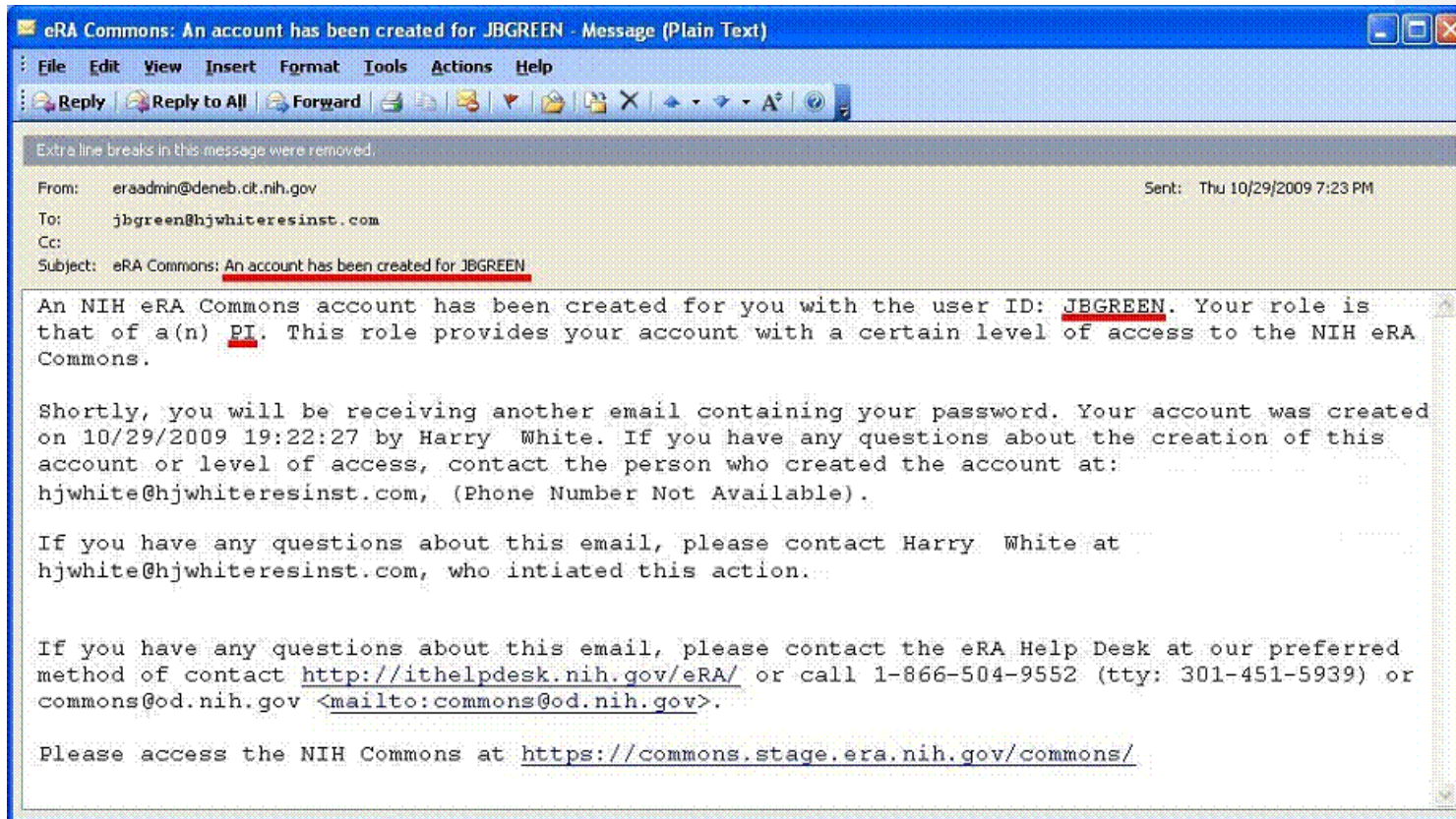
The screen will display a small message that a new PI account has been created.

The screenshot shows a web browser window titled "Account Information - Windows Internet Explorer". The address bar displays "https://commons.era.nih.gov/commons/account/accountView.jsp". The page header includes the "eRA Commons" logo, "Sponsored by National Institutes of Health", and "Version 2.24.01". A navigation menu contains links for Home, Admin, Institution Profile, Personal Profile, Status, eSNAP, xTrain, Links, eRA Partners, and Help. A secondary menu includes Manage Accounts, Delegate Submit, Delegate PPF Edit, and Change Password. The main content area is titled "Account Information" and features a table with columns for Search, View, Edit, Delete, and Create. A red-bordered message box states: "An account has been created for JBGREEN with a new profile." Below this, the account details are listed: First Name: Joseph, Middle Name: (blank), Last Name: Green, User Name: JBGREEN, Date of Birth: (blank), Role: PI, Account Creator: ADMIN\_SO, and E-mail: jbgreen@hwhiteresinst.org. The footer contains contact information for the National Institutes of Health (NIH) and the Department of Health and Human Services, along with copyright information for 2009 NIH and the GRANTS.GOV logo.

Account Information - Windows Internet Explorer  
https://commons.era.nih.gov/commons/account/accountView.jsp  
File Edit View Favorites Tools Help  
Account Information  
Electronic Research Administration  
eRA Commons  
Sponsored by National Institutes of Health  
Version 2.24.01  
Welcome ADMIN\_SO  
Institution: HJWHITE RESEARCH INSTITUTE  
Authority: SO  
Log-out  
Home Admin Institution Profile Personal Profile Status eSNAP xTrain Links eRA Partners Help  
Accounts  
Manage Accounts Delegate Submit Delegate PPF Edit Change Password  
Account Information  
Search View Edit Delete Create  
An account has been created for JBGREEN with a new profile.  
Account Information  
First Name: Joseph  
Middle Name:  
Last Name: Green  
User Name: JBGREEN  
Date of Birth:  
Role: PI  
Account Creator: ADMIN\_SO  
E-mail: jbgreen@hwhiteresinst.org  
[ Contact Us/Help Desk | Privacy Notice | Disclaimer | Accessibility ]  
National Institutes of Health (NIH)  
9000 Rockville Pike  
Bethesda, Maryland 20892  
Department of Health and Human Services  
© 2009 NIH. All Rights Reserved.  
Screen Rendered: 10/29/2009 07:22:31 EDT  
Screen Id: ADM1009  
GRANTS.GOV™  
FIND. APPLY. SUCCEED.™  
http://commons.era.nih.gov/ Local intranet 100%

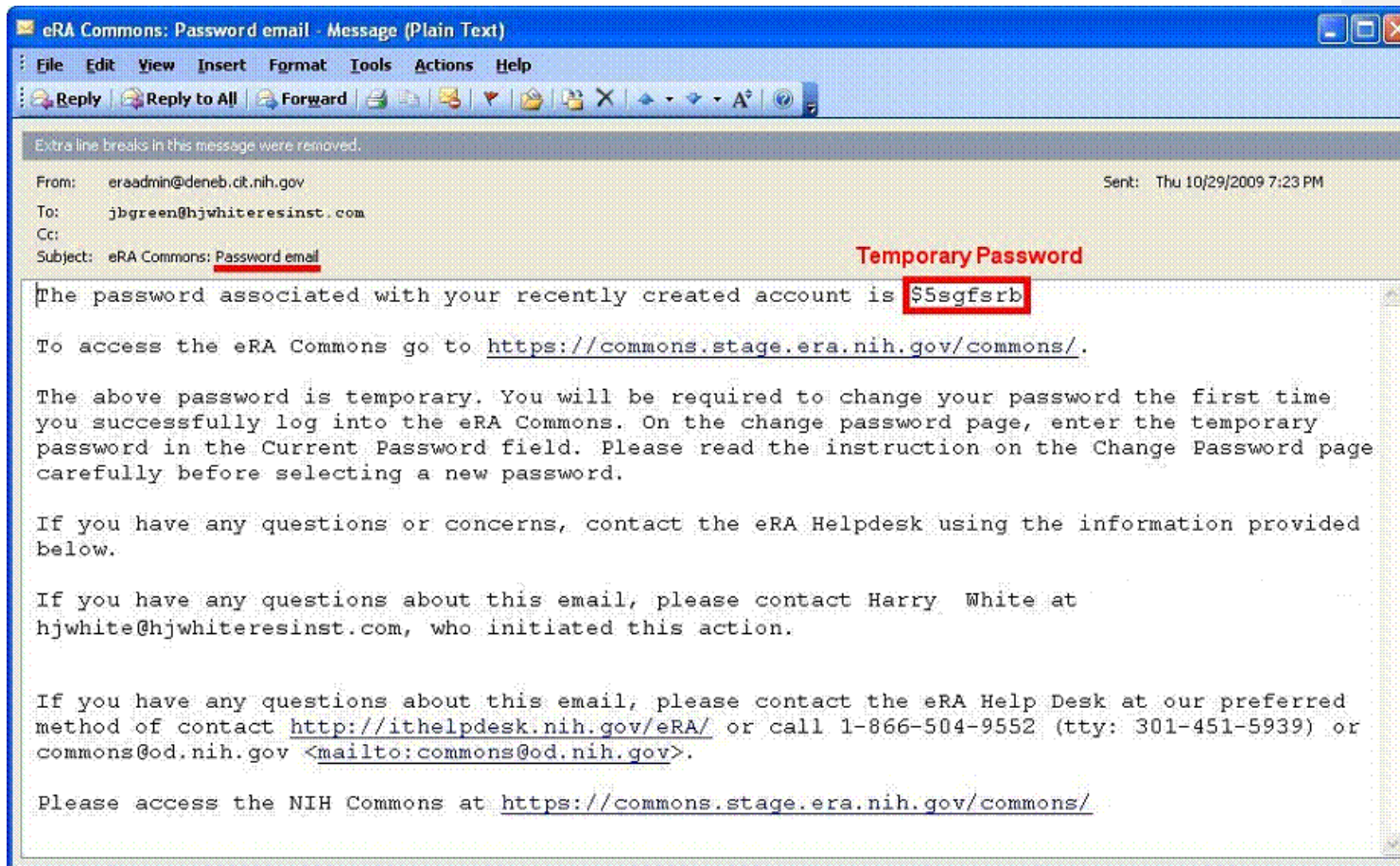
Now the Commons system creates two emails and sends them to the new PI.

One of the emails confirms the PI account was created and displays the PI's Username/User ID





The other email is a temporary password for the PI to use when logging into his/her Commons account for the first time.





**NOTE:** If time is critical, the PI doesn't have to login to his/her Commons account before the application is submitted.

Finally, enter the PI's Username/User ID into the "Credential" field of the Senior/Key Person Profile form.

**NOTE:** You MUST enter the PI Username into the Credential field or NIH will not receive your application!

Adobe Reader

File Edit View Document Tools Window Help

Please fill out the following form. You can save data typed into this form.

Close Form Print Page About

### RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix:  \* First Name:  Middle Name:

\* Last Name:  Suffix:

Position/Title:  Department:

Organization Name:  Division:

\* Street1:

Street2:

\* City:  County:

\* State:  Province:

\* Country:  \* Zip / Postal Code:

\* Phone Number:  Fax Number:

\* E-Mail:

**Credential** e.g., agency login:

\* Project Role:  Other Project Role Category:

\* Attach Biographical Sketch

Attach Current & Pending Support