

NIH Commons Working Group (CWG) Meeting

Date/Time:	Wed., Sept. 18, 2002, 1–5:00 p.m.
Location:	Four Points Sheraton, 1201 K St., NW, Washington, D.C.
Chair:	George Stone
Next Meeting:	Wed., Jan. 8, 2003, 1–5 p.m., Irvine, Calif.

Action Items

- 1. (George Stone) Invite the SBIR awardees to the next meeting to discuss their product and how we can work together as true partners.
- 2. (George Stone) Start a dialog with key organizations to confirm use of the TS194 datastream as a standard for NIH grants administration.
- 3. (Tim Twomey) Add an institutional identifier field in the NIH eRA Commons so that there is always an identifier for use should there be an API developed to transfer data from the institution to the NIH.
- 4. (Tim Twomey) Send the current "bug" list for the NIH eRA Commons 2.0 to all members of the CWG.
- 5. (George Stone) Explore with Belinda Seto the possibility of the NIH working with the CWG in the area of defining a human subjects research protocol data dictionary.

Documents

The following documents were discussed in the meeting:

- Agenda for CWG Meeting (George Stone's presentation): <u>http://era.nih.gov/Docs/CWG_Agenda_Presentation_9-18-02.pdf</u>
- Commons Working Group Update for September (JJ McGowans' presentation): <u>http://era.nih.gov/Docs/eRA_Update_McGowan_CWG.pdf</u>
- NIH eRA Commons 2.0 Screens (Tim Twomey's presentation): http://era.nih.gov/Docs/Commons screens CWG 9-18-02.pdf

Introduction

George Stone welcomed the group, mentioning that it was the seventh meeting of the Commons Working Group. The purpose of the group is to share views and gather the requirements necessary for partner institutions to communicate with NIH through the NIH eRA Commons system.

George introduced to the CWG the fact that David Wright will be joining the NIH as the newest member of the eRA Commons team. He has been selected for an NIH staff position and will start Oct. 1. David will be the Grants Policy Liaison to the eRA project with emphasis on identification of grantee user and functional requirements, validation of those requirements to technical experts, and outreach to the extramural grantee community. In this position, he will report to Regina White, director of OPERA.

eRA Update

Dr. John (JJ) McGowan

Dr. McGowan gave an overview of the eRA project, including the NIH eRA Commons and associated modules. While the NIH eRA Commons is being prepared for deployment, the eRA team also is preparing an outreach plan (<u>http://era.nih.gov/Docs/eRA_Update_McGowan_CWG.pdf</u>). It is important that the NIH eRA Commons provide everything that our partner institutions need to do business with the NIH. In addition, it is important that these partners also get the right support by way of training and helpdesk.

He asked for input regarding two specific areas: what functionality is needed in the institutions—what works for each institution—and what kind of support do they need to ensure a high level of participation in the NIH eRA Commons. With input from the institutions, the Project Team can start to articulate clear requirements for future training and Commons deployment.

Looking at the Health of the Project (see slide 4 of presentation), Dr. McGowan noted that one major project change this year has been the transition from system releases each month to releases three times a year. This ensures better quality control and a longer period between releases to better develop and test the releases.

All future development will be viewed from a slightly different angle in that it must fit into the integrated architectural plan—not be a "stovepipe" view—and it must follow the project management plan. Most of the eRA modules overlap in function and data so that their development and functionality must mesh.

The overall development issues faced by the eRA Project team are how to match adequate resources to each development effort, deliver when promised and provide the functionality requested by users.

Dr. McGowan said that the development resources now are being poured into the migration to J2EE (as opposed to Oracle Forms in client-server) architecture. This has added a strain on the resources available for the project. However, several modules being developed in J2EE will be released in the coming months:

• eSNAP

- Internet Assisted Review
- Financial Status Report
 eNotification
- Committee Management
 Program Portal

Several of these modules that have NIH eRA Commons interfaces will be released in November and January. These releases are dependent upon the successful release of the NIH eRA Commons, which will be tested by members represented here and released to all 185 institutions in November. With J2EE development of the project, IMPAC II is scheduled for shutdown in January 2005, at which time there will be just the eRA.

To better focus resources and make best use of budget allocations, budgets were cut for Northrop Grumman Information Technology (the prime eRA contractor) and RN Solutions (a subcontractor to Northrop Grumman), changes were made in the NGIT management structure and changes were made in the eRA management structure. These necessary cuts have translated into approximately 30 percent reductions in previously developed specifications. At the same time, the NIH is committed to the premise that in the NIH eRA Commons 2.0, no interface will be deployed unless it offers at least the same extent of functionality as was in NIH eRA Commons 1.0.

Dr. McGowan also announced that Tim Twomey has been appointed as the lead for all NIH eRA Commons activities and is responsible for all NIH eRA Commons implementation and deployment activities. He has succeeded Jerry Stuck who has returned to the NSF after a one-year detail.

IMPAC I will be shut down on November 4, according to plan. The most urgent NIH eRA Commonsrelated outcome of this shutdown is that Financial Status Reports (FSRs) no longer will be able to be submitted as they have in the past. Instead, the new FSR interface on the NIH eRA Commons will need to be deployed coincident with the shutdown.

The Project Team will attend a two-day retreat in mid-October to assess the project's progress and develop strategies for moving ahead.

In addition, six awards have been made in response to the eRA Small Business Innovation Research (SBIR) RFA for a total of \$2.5 million. These companies will conduct research to assess various approaches to eRA implementation in the extramural community. The outcome of the research will involve the development of a tool or service that can be purchased by or licensed to NIH grantee organizations. These software applications and services will provide grantee organizations with value-added tools to enhance electronic interaction with the NIH. In the coming month or so, each of the awardees will make a presentation to the eRA Project Team to begin the communication that must exist to allow for optimal conduct of the research and successful product development.

The suggestion was raised that it would be beneficial to the CWG to know more about the products that are being developed through the eRA SBIR initiative. George Stone agreed to oversee, including the SBIR awardees for presentations at future CWG meetings.

Action: (George Stone) Invite the SBIR awardees to future meetings to discuss their products and how we can work together as true partners.

Dr. McGowan next summarized the key features of the initial NIH eRA Commons 2.0. He emphasized the scope that includes single point of ownership for institutional and individual profiles. It provides access to the NIH for the PI and administrative offices through the Status screen for reviewing pending applications, finding contact information for Grants Management and Program Official associated with each application, linking to Study Section rosters, linking to any application whose reviews are pending, viewing Notice of Grant Award (NGA), viewing Summary Statements and scores, and viewing a prepopulated Type-5 face page.

Integration of eRA with other NIH Administrative Systems

The NBRSS and the Loan Repayment Program (LRP) are being developed by other NIH components. There are ongoing discussions at the NIH that could result in these systems becoming integrated into the eRA system. Some consideration has been given to including the Electronic Contract Management System (ECMS) in eRA; however, no decision as yet has been made.

The eRA and the Office of Loan Repayment (OLR) conceptually have agreed upon the integration of the LRP with IMPAC II. However, eRA does not have the resources to pay for this. Consequently, the OLR will pay for the integration and eRA will commit technical resources to make it happen. The LRP is the NIH program that allows doctors to get their medical loans paid by the government if they do certain types of clinical research.

Dr. McGowan suggested that if CWG wants to know more about the LRP that they ask Mark Horowitz, NIH OD, to make a presentation at a future meeting about the LRP and how it affects organizations.

Funding

In FY 1999, \$15 million per year was allocated for eRA. In FY 2000, this funding was increased to \$34 million per year based on the business case and five-year financial plan.

With the new drive to move to the new J2EE technology, the budget has a shortfall this year. A considerable amount of the funds are going to maintain the old Oracle Forms technology so that the NIH business processes are not interrupted. At the same time, and sometimes in parallel, new J2EE modules are being developed that will soon replace the old system. This process is more costly from when the project first began, which was before the decision to move to J2EE. In the long run, however, this leap to J2EE technology will increase productivity, reduce IT costs throughout ICs and intramural institutions, and streamline the grant application process.

Datastream Standards

One issue that remains to be resolved is the datastream standard for submission of data to the NIH. The CWG plays a crucial role in providing the NIH with a strong recommendation as to these standards, while bringing this issue to closure so that future development, especially the SBIR grantees and the extramural community, can work to this standard.

This issue also has a broader implication. It stands to reason that, based on the magnitude of potential electronic business that will be done by the NIH with grantee institutions, any strong recommendations by the CWG will have considerable impact within the larger HHS and the e-Grants initiative.

The CWG can serve as the major force in coordinating the determination of this standard for the NIH and make a recommendation. OMB has to agree to enforce the validated data stream standards, once they are agreed upon.

George Stone recounted the extensive effort that has been put forth toward a common grants administration standard, starting in 1994. From early on in the eRA effort, the NIH has joined with the extramural grantee community to support the 194 data dictionary. George agreed to revisit this topic with the CWG to determine if there is any question as to the use of the 194.

Action: (George) Start a dialog with the CWG to reiterate commitment to a datastream standard.

NIH eRA Commons 2.0 Update

Tim Twomey

Tim showcased the screens for the new eRA Commons 2.0 via a live demo to a staging instance of the system. The group discussed the new Web site and the following comments and suggestions were made:

- *Maintain Organization Hierarchy screen:* If a subcomponent in the institutional hierarchy is deactivated, concern was expressed that there appears to be no way to see the grants that have been linked to that subcomponent. Tim indicated that the facility to handle such situations will not be part of the first release, but will be available in a later version.
- *Contracts*: In response to a question, Tim confirmed that research contracts have not been integrated into the eRA system. There has been some discussion at the NIH as to where contract-

related electronic submissions will ultimately reside. Once this issue is resolved, the CWG will be notified.

- **Data Entry:** The point was raised that much of the data required for entry into the NIH eRA Commons as part of creation of profiles and submission of other types of information has already been entered into university databases. The CWG reiterated the importance of being able to submit via datastream information that relates especially to profiles. Tim confirmed that such a batch submission is one of the important aspects of electronic communication that the SBIR products should help with.
- **Designation of Grantee Institution as "eRA Capable."** A question was raised as to how deployment of the NIH eRA Commons 2.0 will be limited to the CWG or other selected group. Tim indicated that in the earlier version of the NIH eRA Commons, an "FDP flag" was defined to limit deployment to the FDP institutions. For Version 2.0, a similar type of flag has been contemplated to identify an institution that is eligible for registration on the NIH eRA Commons. Tim further confirmed that he will follow up on finalizing this requirement.

Action: (Tim Twomey) Add an identifier field to the IPF to show whether or not that institution can electronically transfer data between the institution and the NIH.

• *Reports:* It would be useful to be able to save a specific report query so that one could use it over again.

CWG Agenda Items

George Stone, Tim Twomey

NIH eRA Commons 2.0 Implementation

George reviewed the implementation schedule for the eRA Commons 2.0 (see slide 4 of presentation <u>http://era.nih.gov/Docs/CWG_Agenda_Presentation_9-18-02.pdf</u>). He acknowledged that the deployment of the NIH eRA Commons 2.0 is behind by several months, but deployment is now imminent. He further noted that once Version 2.0 is deployed, the next major effort will be for the NIH to complete the list of action items that came out of the extensive BPR, in which the CWG participated over the last year. The NIH eRA project team has devoted 100 percent of resources of late toward getting Version 2.0 deployed, and no real progress has been made to move forward with planning implementation of the competitive application as a datastream submission.

George pointed out that X-Train is being used by 23 organizations in its current implementation. It is scheduled for migration to the J2EE infrastructure with deployment in mid-2003.

Consistent with the focus on deployment of NIH eRA Commons 2.0, Tim Twomey presented the deployment details to be accomplished in the next several months. The NIH eRA Commons is being released in stages, as follows:

NIH eRA Commons 2.0 Release Stages

Stage	Date	Activity
1	Aug. 22	Three external organizations to employ V. 2.0 in Staging instance of the system (Northwestern, UCLA, Dartmouth).
2	Sept. 12	All CWG organizations in Staging.
3	Oct. 14	All CWG organizations in Production instance of the system.
4	Nov. 14	185 external organizations in Production. E-Snap may not be available to all organizations.
		When all problems encountered with these stages are resolved, the project will move ahead to Stage 5.
5	No date set	Open Registration.

Those testing the NIH eRA Commons 2.0 should send their input to the eRA helpdesk. So that duplication is minimized, the group suggested that they receive the current "bug" list so see what problems have already been identified.

Action: (Tim Twomey) Send the current "bug" list for the NIH eRA Commons 2.0 to all members of the CWG.

George reviewed the functionality that has been incorporated into this release of the NIH eRA Commons 2.0 (see slide 7 in presentation). There is a new graphical user interface (GUI); however, cascading menus, as requested, are not being used as yet because they are not 508-compliant. In future, as tools become available that allow cascading menus to be 508-compliant, they will be incorporated into the design. This first release focused primarily on content and workflow; therefore, more work will be done on the graphical aspects in future releases.

For Accounts Administration, George said that NIH eRA Commons 1.0 profiles have been validated by NIH staff and migrated to NIH eRA Commons 2.0.

NIH eRA Commons 2.0 functionality includes:

- New GUI.
- Registration with authentication using IPF numbers. The use of DUNS numbers for authentication will not be implemented until a future release.
- Account Administration.
- IPF, including maintenance of information, assurances and certifications, full user-defined organizational hierarchy, assignment of applications to the hierarchy.
- PPF, including ability to create and maintain profile information and user-defined integration of organizational hierarchy within the profile.
- Status, including: view status information, full contact information, links to rosters, link to NGA and the availability of pre-populated forms for renewals.
- Fully functional demo version of the system.

- Single point of ownership for PPF and IPF.
- eNotification in a limited configuration. This functionality will be more fully developed as part of a future release.

NIH eRA Commons Training

Some of the options discussed concerning training for the NIH eRA Commons 2.0 were:

- On-line help and documentation
- Computer-based training
- WebEx training or some other Web-based training tool
- Training sessions at regional seminars and association meetings
- On demand (for fee), on-site training

The CWG agreed that most of the options were consistent with what is available for many other types of computer software packages. Clarification of the last option was sought. Tim indicated that the concept of assembling a team of trainers, whose major role would be to travel the country on a for-fee basis, was possible. Whether it would work would be determined by the level of interest in the extramural community.

eNotification

Marcia Hahn reviewed the status of eNotification for non-competing submissions (so-called T-5s). Phase 1 of eNotification—a public Web site that provides institutions with a list of upcoming deadlines for T-5s—was launched in August 2002. She noted that new records are added to the Web site list around the 30th of the month and she encouraged grantees to run a query once a month to be sure their information is accurate. Currently, she is collecting feedback for improvements to this interface, which will be evaluated and incorporated into the next phase.

The second phase of eNotification will be incorporated into the NIH eRA Commons Status interface. That is, for the eRA Commons 2.0 Status interface, prepopulated face pages will be available. This phase will not include any "push" of information. The grantee AO or SO will be able to query for the availability of the face page on a grant-by-grant basis. A future enhancement will be to allow for the receipt of such face pages as a batch.

The next phase will incorporate a "push" of the information. This will be based on a field for an email address in the IPF. Actual T-5 "push" notifications will be addressed after the eRA Commons Version 2.0 is fully deployed. Finally, as a last phase, each PI as well as AO will receive the notification of pending deadline. As part of this phase, the user will be able to access the information through the Status interfaced or be notified via email.

In an effort to standardize and clean up notification data, the IPF has been modified to include a generic email address. This address should be maintained as separate from the generic email address to which email NGAs are sent. There would likely be a single, generic email address per institution for this purpose. The institution would then take responsibility for monitoring and "pushing" out messages to the appropriate grantee.

X-Train

Twenty-three grantee organizations are using X-Train today. There have been 236 trainee appointments processed since Oct. 1, 2001. The outstanding issue is the PI (PD) delegation and notification to minimize unauthorized submissions. This issue should be resolved with the release of the eRA Commons Version 2.0. The further upgrade of X-Train, the so-called Version 2.0 release, is scheduled for mid-FY 2003.

e-SNAP

The first release of e-SNAP will include the following functionality, which has resulted in part from the reengineering accomplished by the CWG:

- Submission 45 days prior to anniversary (paper submissions are required 60 days prior to anniversary)
- No abstract updating
- Submission of research accomplishments, distinct from progress report narrative
- Delegation of submission to the PI, controlled by the institution's SO
- Improved display of e-SNAP questions, which improves usability
- Presentation of personnel data page, which includes summary information for planning purposes
- PPF, IPF, and routing similar to Version 1.0

For e-SNAP routing, unlike what is shown on the current slide #23, the live deployment will allow for the submission to be routed to any NIH eRA Commons account holder of either the "AO" or "SO" type. It was noted that at the bottom of the screen (see slide 23 of presentation) in the Routing History List, there are two options, "Approve" and "Reject." George queried the group as to whether the word "reject" would be acceptable to the grantee institutions. The question was whether any institutional official or PI would see the word "reject" in an unacceptable light. No reasonable alternative was recommended.

On the mockup for PI Delegation (see slide 24 of presentation), it was pointed out that the Current PI Delegates list should have checkboxes next to each name and not radio buttons. Checkboxes allow more than one selection. George and Tim indicated that this page is being redesigned to better designate PI access.

e-SNAP Deployment

The overall phased deployment plan for e-SNAP follows the same general format as that used for the NIH eRA Commons:

e-SNAP Release Stages

Stage	Activity
1	Three external organizations to employ V. 2.0 in Staging instance of the system.
2	All CWG organizations in Staging.
3	All CWG organizations in Production instance of the system.
4	185 external organizations in Production.When all problems encountered with these stages are resolved, the project will move ahead to Stage 5.
5	Open Registration.

Exact dates for the first release of the e-SNAP have not been finalized. Plans call for phase 1 of the deployment to begin on or around November 1, 2002.

FSR

Mark Weiser lead the discussion of the new Financial Status Report (FSR) interface. The deployment of this interface is time-critical. The current means for submission of FSRs is through an interface with IMPAC I. Since the legacy system will be shut down in November of this year, it becomes crucial to have the NIH eRA Commons-based FSR interface completed.

Mark first presented a simplified view of the workflow associated with preparation and submission by the grantee, and receipt, review and acceptance or rejection by the NIH. Mark noted various aspects and constraints in the workflow, for example, that specific reports are retained in the system for 18 months, and, once the report is "In Review," only the NIH can edit the file although the institution can still view it.

This workflow, as it applies to the NIH eRA Commons user, results in a search screen and hit list displaying each pending FSR and its status. The user with FSR authority then can drill down to process a single-screen, data-entry form for each FSR.

Mark and Tim noted questions regarding specifics on the data entry form. One issue involves a field that identifies whether the FSR was "Previously Reported" (see slide #29). This field provides a reference between the historic data entered through the IMPAC I interface only. It will be deleted once all the data brought over from IMPAC I is validated. Because it is not certain that all the data was brought over, this field alerts users that the data was already entered at one time.

FSR Deployment

A phased deployment plan for FSR, similar to e-SNAP and the NIH eRA Commons 2.0, would be ideal. Such a plan may not be possible because IMPAC I will be taken offline in November. If time permits, a phased approach will be followed. Alternatively, the deployment will be accelerated, with open registration quickly following initial deployment.

Institutions interested in becoming first adopters of the new NIH eRA Commons-based FSR interface should contact Marcia Hahn, 301-435-0932, <u>hahnm@od.nih.gov</u> or David Wright, wrightd@od.nih.gov.

Reengineering the Competitive Application

Meetings of the CWG held in November 2001, January 2002 and May 2002 were dominated by discussions of how to better align and streamline the way business workflow occurs throughout the competitive application process. Out of the discussions came a list of approximately 25 action items to be undertaken by the NIH as we move toward a proposed means for electronic submission of the competitive application. Once the NIH eRA Commons 2.0 has been deployed initially in production, a business process/IT analyst will be devoted 100 percent to this task.

Not only will the analyst address questions of data requirements, but also revisit and seek clarifications of questions that relate to the business process. In communication with Suzanne Fisher and Brent Stanfield of CSR, they offered to involve reviewers in future discussions as a means to further clarify system requirements from their perspectives. George confirmed that the participation of real users of the systems, as would be the case for peer reviewers, is always welcome.

eRA SBIR Initiative Status

The eRA Small Business Innovation Research (SBIR) RFA, as cited by Dr. McGowan, attracted many good applications, and six were awarded. These companies will conduct research to evaluate the basis for providing value-added solutions to eRA for the grantee community. Out of the research, each will develop a tool or service that can be purchased by or licensed to NIH grantee organizations. Throughout the process, the grantees will work closely with the NIH eRA project staff to ensure that their prototype software packages are fully compliant with data standards and formatting requirements. These applications and services will provide grantee organizations with the tools for continued electronic interaction with the NIH; in other words, they will provide tools to augment the functionality of the NIH eRA Commons. Each of the awardees has a different research component.

Jerry Stuck emphasized that the NIH, in coordination with other federal agencies and the user community, must agree upon a data standard so that these companies can write their programs to that standard.

Datastream Standards

As a segue from the discussion of the SBIR initiative and the importance of data standards, George looked to the CWG for a statement concerning whether the 194 or XML-equivalent would continue to be the choice of the extramural community.

After much discussion, the group agreed that, from their perspective, staying with the 194 or XMLequivalent standard would be the most cost-effective choice in light of all the effort that has gone into its definition and implementation over the years. They further agreed to canvass theirs and other grantee institutions, and report back if there were any alternative standards that they felt warranted further discussion or consideration.

Administrative Items

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

The next meeting will be held on Wednesday, January 8, 2003, 1:00–4:00 p.m., in Irvine, California, in conjunction with the FDP meeting.

Attendees

CWG Members

Lynette Arias (Oregon Health Sciences Univ.) Ellen Beck (UCLA) Denise Clark (Cornell Univ.) Steve Dowdy (MIT) Jane Fant, (Univ. of Medicine and Dentistry of N.J.) Ken Forstmeier (Penn State Univ.) Jill Keezer (Cal Poly State Univ.) Graydon Kirk (Emory) Tolliver McKinney (St. Jude Children's Hospital) Jim Randolph (Univ. of Mich.) Sandi Robins (Univ. of Wisc.) Holly Sommers (Emory Univ.) Mark Sweet (Univ. of Wisc.) Pamela Webb (Northwestern Univ.) Tom Wilson (Baylor College of Medicine) **Others Institutional Representatives**

Bob Beattie (Univ. of Mich.) Tammy Custer (Cornell Univ.) Dan Dwyer (Cornell Univ.) Phil Martin (Dartmouth) David Robinson (Oregon Health Sciences Univ.) Jerry Stuck (NSF) Brenda Truesdail (Cornell Univ.) Richard Valenzuela (UCLA) Jim Williams (Oregon Health Sciences Univ.)

Vendors

Archita Bhatt (InfoEd International) Chris Harker (Cayuse Software)

NIH Staff

Jim Cain (OER) Suzanne Fisher (CSR) Marcia Hahn (OPERA) Chris Lambert (OER) Rich McKay (CSR) Richard Panniers (CSR) George Stone (OPERA) Tim Twomey (eRA) Regina White (OD) David Wright (OPERA)

NIH Contractors Sandy Seppala (LTS) Mark Weiser (RN Solutions)