NIH eRA Commons Working Group (CWG)

Date/Time:	Wednesday, May 19, 2004, 9:00 a.m.–4:00 p.m.
Location:	National Academy of Sciences, Washington, D.C.
Chair:	David Wright
Next Meeting:	Wednesday, January 12, 2005, Las Vegas, Nevada

Action

1. (David Wright) Send an invitation to and detailed information about the eRA Symposium to the CWG distribution list.
2. (Dan Hall) Remove the restriction of having unique names for departments in an organization's hierarchy because there may be more than one "department of biology" in an institution.
3. (Dan Hall) Send the Organizational Hierarchy Request for Comments (RFC) to the CWG distribution list.
4. (Dan Hall) Investigate the need for those with admin rights to update, for example, all eSNAPs in a department.
5. (David Wright) Verify that the no cost extension deadline issue resulting from the project end date that is stored in the system as 12:01 AM rather than 11:59 PM has been resolved.
6. (Jennifer Flach) Investigate what requirements should be established regarding the number of attachments that could be sent after the application has been received.
7. (David Wright) Prepare a list of actions that trigger an email, what the emails say and who receives them. Send the list to the CWG.
8. (Dan Hall) Investigate giving permission to submit trainee data to more people than the PI.
9. (Sandy Seppala) Post the two letters of assurance on the eRA website in both Word and PDF format.

Presentations

- eCGAP/Grants.gov Update: http://era.nih.gov/docs/eCGAP_CWG_09-22-04.pdf
- Organizational Hierarchy, Just in Time, X-Train: http://era.nih.gov/docs/Hierarchy_JIT_X-Train_09-22-04.pdf
- Commons Update: http://era.nih.gov/docs/Commons_Update_09-22-04.pdf
- GCRC Progress Reports: http://era.nih.gov/docs/NCRR_GCRC_09-22-04.pdf

Welcome

David Wright welcomed the CWG to the meeting. The group agreed to hold the next meeting on Wednesday, January 12 in Las Vegas in conjunction with the Federal Demonstration Partnership (FDP) (http://thefdp.org/). David will send details later.

CGAP/Grants.gov Update

Jennifer Flach

The electronic Competitive Grant Application Process (eCGAP) received about 45 applications for the completed pilots. They included:

- June 1 receipt date: 17 new, simple, and modular applications
- July1 receipt date: 7 revised, modular competing continuation; 6 modular, competing continuation; and 1 full-budget, competing continuation (first full-budget received)

For the full-budget applications, applicants indicated that they preferred to format the budget justification themselves rather than enter text into a structured format. Consequently, Jennifer said that the full-budget justification was changed to a PDF image.

The current pilot started on September 13 and will act as a dress rehearsal for declaring production in early 2005 for simple modular grant applications. There are an estimated 50 applications for each receipt date for unlimited modular simple grant applications. In Pilot 2, the Service Providers are limited to five full-budget applications.

Six Service Providers will participate in this pilot, which will include improvements from prior pilots and provide the opportunity to refine all the processes.

Future eCGAP Pilot Plans

There are plans for a pilot that will accept simple applications in response to RFAs. RFAs that would be suitable candidates are being identified. There is the possibility for moving the applications directly to the IRG for review, which would reduce processing in CSR. Peer Review redesign focus groups are underway to streamline the Peer Review module and workflow.

The February/March 2005 pilot will include supplements and full-budget applications. It also planned to have the ability to handle some corrections (addenda) after receipt. Jennifer noted that business rules for correcting an application are very complex. The eCGAP team is conducting a business analysis so that making corrections can be incorporated into the system in the future.

Plans for Production

eCGAP will be released to production in January 2005 for the following types of applications:

- Simple (R01, R03, R21)
- Types: New (Type 1), Competing continuations (Type 2)
- Revisions
- Modular Budget

eRA Symposium—To advertise that these types of applications can now be submitted electronically, a number of outreach activities are planned. The eRA Symposium, scheduled for December 2, has as its theme, "Electronic Receipt." Its goal is to educate internal NIH staff about electronic applications and how this process will benefit workflow. Service Providers have been invited to staff a table where they can talk with interested staff members about what they are offering applicants and institutions for electronic submissions. The Service Providers, who now include more than the initial recipients of the SBIR awards, also will meet at that time with the NIH eCGAP team to discuss technical issues.

Dr Israel (Izja) Lederhendler, interim project manager for eRA, invited CWG members to the Symposium on December 2, giving them a chance to see the products and services offered by Service Providers.

Action: (David Wright) Send an invitation to and detailed information about the eRA Symposium to the CWG distribution list.

Application Information—For the grantee community, an applicant orientation package was developed and posted on the website (http://era.nih.gov/Projectmgmt/SBIR/CGAP/Participant_Package_06-21-04a.pdf).

Service Provider Questionnaire—As a result of the discussion about the services and products of Service Providers at the last CWG meeting, a questionnaire was sent to all Service Providers. Its purpose was to provide grantee institutions with some overall information about each Service Provider. The questionnaire asked a number of questions regarding their product or service, customer support, availability and contact information. The questionnaires are posted on the eRA website: http://era.nih.gov/Projectmgmt/SBIR/sbir_grants.htm.

Service Providers—The NIH eCGAP team is refining its support for Service Providers. There is a bi-weekly conference call that addresses technical questions the Service Providers ask. The eRA Partnership website was redesigned to provide better navigation to information. The eRA Helpdesk is taking a greater role in providing support for Service Providers, and there is an expanded facility for monitoring and reporting on eXchange (the eCGAP database) activity. Since new Service Providers are expected, an orientation process is being developed.

The original six recipients of the Small Business Innovation Research (SBIR) awards are now considered "Service Providers" along with a few new institutions and companies who also are developing services and products for electronic grant submission. Referring to this group as "SBIRs" is incorrect nomenclature. A list of all Service Providers with a description of their product is on the eRA website under "Submitting Grants Electronically:" http://era.nih.gov/Projectmgmt/SBIR/sbir_grants.htm.

Certification—Service Provider certification currently is a manual process. The Service Provider submits a certain type of application to the test environment and if it works, the Service Provider is certified to submit that type to production. In the future, this process will be automated and the list of types of applications a Service Provider is certified to submit to production will be posted on the eRA website.

Grants.gov Integration

This summer, eRA worked with Grants.gov for the submission of Pioneer Award applications. The new government form, the SF 424, was part of the submission. However, it was not a true system-to-system data exchange. A test currently planned in the January-February 2005 timeframe, using "dead" data, will be the first system-to-system exchange.

In preparation for working with Grants.gov, an analysis was conducted and the results submitted to Grants.gov regarding the NIH-specific information that would have to accompany the new SF 424 Research and Related (RR) form. Additionally, the SF 424 RR form elements were mapped to the eRA database and the business validations for Grants.gov applications were defined. Using test SF 424 applications, initial system-to-system testing was conducted with Grants.gov, calling Grants.gov Web services with security in place.

In the short term, there will be few changes in the forms, but in the long term there will be some more changes. One of them will be to increase the field for titles allowing them to be longer and not truncated. However, while it seems like a trivial change, it will require changes in every module of the eRA System.

The next steps include integrating Grants.gov Web-service calls with the eRA eXchange and implementing business validations for Grants.gov applications. The team needs to create a mechanism to report warnings and errors back to applicants via the Commons. At this time, Grants.gov is using the "post office" model, i.e., it receives the applications and agencies have to come to Grants.gov to pick them up. No business validation of the grants application is built into the system and agencies are expected to provide their own validations. The eRA Commons, using the Status module, will be NIH's vehicle for communicating application errors to the sender. The eCGAP team currently is developing these validations. Jennifer noted that applications will be counted as on time when they are received by Grant.gov. There will be a grace period for applicants to make corrections.

When Grants.gov finalizes NIH-specific forms and schema, it will generate a 424 RR-based format grant image, which will be posted in an applicant package. The RR part of the form is divided into components, one of which is the budget component. For version 1, a generic budget is being used. This will allow more time for the RR budget form to be vetted through all NIH business areas.

Work on the 424 schema has just begun because the data schema has not been stable. As the work continues, NIH will seek input from the CWG.

Jennifer asked for volunteers to participate in a test pilot with Grants.gov using "dead" data in January. This would be the first time to run data through the workflow with Grants.gov.

Outgoing Transactions

The Notice of Grant Award (NGA) will be the first major outgoing electronic transaction for the eRA eXchange. The requirements analysis is underway and development is expected to begin by the end of the year with a pilot in early 2005.

eRA eXchange

There was an eCGAP refactoring release that decoupled eRA eXchange and the eCGAP process. This was important for stability and scalability.

A new Test environment is being established for Service Providers that integrates eRA eXchange and the Commons demo.

ebXML is being adopted as the standard for trading-partner registry and messaging. An evaluation task order is underway and the construction phase is scheduled for early to mid 2005.

The eCGAP team is collaborating with the National Center for Research Resources (NCRR) for General Clinical Research Centers (GCRC) progress reporting. See the section, *GCRC Progress Reports*, below

For grantee institutions interested in developing their own electronic submission system or wanting to understand the current programming that is in place, there is a multitude of information on the eRA website (http://era.nih.gov/) in the section, *Partnership Information.* This section contains background material, schema and other technical information. This information also can be useful for universities as they prepare to transition to the SF 424 RR form.

There is no set schedule as yet for transitioning to the SF 424 from the 398. However, Marcia Hahn pointed out that the 398 will continue to be used because it is the vehicle for OMB approval and to collect other data.

It also was confirmed that all of the information on the forms is required and necessary for evaluation and award and for reporting to the public. Several people expressed concern that there could be major problems if the new forms differ greatly from the current, familiar ones. PIs already have noted differences in the electronic forms and worry that it will jeopardize their application evaluation. The SF 424, which now is an approved OMB form, represents an even greater change. PIs must be convinced that the use of the electronic format will not bias the evaluation of the application.

Everyone agreed that PIs will need training to help them transition to the new forms. It was suggested that the eRA outreach group communicate these changes to department and institute leaders as well as PIs.

It was mentioned that Reviewers also have expressed preference for having one format for the applications they review.

Marcia Hahn reminded the group that the SF 424 is for pre-awards only while the 2590 is for post-awards and uses a different process.

JJ Maurer clarified that the technology we are developing is the foundation for the transition to the 424—the packaging may change but the basic technology will not.

Future Plans

The eCGAP team expects to accomplish the following in 2005:

- Expand types of grant mechanisms
  - SBIR/STTR
  - Training, fellowships, AREA grants, etc.
  - Complex program grants and subprojects
- Support corrections and addenda to applications post-receipt
- Provide enhancements to the grant image
- Incorporate new transactions, including eSNAP, eNAP, and FSR

Additionally, there will be a new focus group at the NIH for eCGAP. It will provide a forum for addressing problems and vetting new enhancements.

Dan Hall reported that the end-to-end processing for eCGAP soon will be available at the Commons demo site. This will provide PIs and other staff who submit applications to try out the new electronic system and to practice using it before attempting to submit their application.

Organizational Hierarchy

Dan Hall

Dan introduced a new organizational hierarchy by noting that while the previous security scheme worked for small institutions, its basic structure could not accommodate the many roles required by larger institutions and did not reflect the structure school/division/department of many institutions. Consequently, a new scheme needed to be devised that could work in all sizes of institutions and allow a role or *right* hierarchy that also could be accommodated in the eRA System.

Dan presented the new scheme, which should accommodate requirements of both the NIH and grantee institutions. He pointed out that, in deference to university parlance, the term "institutional role" has been changed to "institutional right." Additionally, the number of rights in the hierarchy has increased to six from the three in the past (SO/AO/ASST).

The new scheme allows "rights" to be defined at different levels within a hierarchy. It also allows grantees to define the organizational hierarchy structure, assign rights to any node within the hierarchy, and move grants and projects within the hierarchy structure in support of both reporting and permissions.

The Signing Official (SO), Account Administrator (AA) and Principal Investigator (PI) roles will remain the same but now will be called "institutional rights." The Assistant (ASST) role will be a right and renamed "basic." See the attached presentation for an outline of the new hierarchy rights: http://era.nih.gov/docs/Hierarchy_JIT_X-Train_09-22-04.pdf.

Dan explained the following implementation notes:

- Must define the NIH "school" at the first level of the hierarchy (i.e., School of Medicine).
- Must define the NIH "Department" (i.e. Department of Biology) at the Leaf level (i.e. lowest) node before adding projects). There is a restriction that all department names must be unique in an organization. However, group members pointed out that there may be several "Departments of Biology" within colleges of the same university so that there may have to be a workaround or change to accommodate this.

Action: **(Dan Hall) Remove the restriction of having unique names for departments in an organization's hierarchy because there may be more than one "department of biology" in an institution.**

- Projects are assigned by discrete Activity Code, Serial Number, Institution (i.e., R01CA-12345). A project cannot be divided across departments.
- Will only affect current and future year rankings (i.e., changes through 09/03/04 impact only FY2004 and FY2005 rankings).

Conversion and Next Steps

The following actions will be taken to convert to the new hierarchy scheme:

- AO Role will be given AA Institutional Right and AO Hierarchy Right at Institution (i.e., root) level.
- Financial Status Report (FSR) converted to two Hierarchy Rights at the Institution (i.e., root) level (one for data entry and one for submission).

- Existing Hierarchy will be migrated.
- Request for Comments (with prototype) to be available in October.

Action: (Dan Hall) Send the Organizational Hierarchy Request for Comments (RFC) to the CWG distribution list.

Dan also mentioned that he is investigating the eSign program for signature authority, which may be adopted by the eCGAP project.

Regarding eSNAPs, they must be initiated and updated by the Principal Investigator (PI). However, this does not necessarily mimic reality where an assistant may initiate or update the eSNAPs in a department.

Action: (Dan Hall) Investigate the need for those with admin rights to update, for example, all eSNAPs in a department.

Commons Update

David Wright

After a quiet period, there will be three releases of the Commons in October and another one next April or May. Additionally, a new task order has been given preliminary approval for work on the Commons. For a full listing of the releases, see the attached presentation: http://era.nih.gov/docs/Commons_Update_09-22-04.pdf.

Release 2.6.4—Scheduled for October 1, this release will contain many maintenance fixes that have been reported. A major item is the ability to self-select for eSNAP. In other words, institutions will be able to enable the eSNAP functionality without calling the Helpdesk. This will reduce the burden on the Helpdesk.

Release 2.7.0—Scheduled for October 16, this release will contain content management, Closeout, better error handling and IAR enhancements. This will allow simple editing changes, such as typos, to be corrected without waiting for a release.

Release 2.7.1—Scheduled for October 30, this release will include a few maintenance changes. This also will include the ability for PIs to see eCGAP submission errors using Status.

Release 3.0.0—Scheduled for April/May 2005, this new-development release will include the new organizational hierarchy, Web QT, National Library of Medicine (NLM) integration and the ability to download FSR search results into Excel.

The new task order is the second development task order for the Commons. It will include small- and medium-sized enhancements. The overall list for this task order includes:

- Address the more than 80 enhancements that are in the queue.
- Upload Office of Laboratory Animal Welfare (OLAW) documents.
- Provide an enhanced version of just-in-time (JIT).
- Include several enhancements to eSNAP.
- Expand the data in the demo facility.
- Add new non-XML administrative transactions such as change of PI and request carry over of funds.

- Include more IAR enhancements. More than 113,000 critiques have been uploaded in IAR and the module is widely used.

The question was asked whether or not the project end date and time in the system had been changed from 12:01 AM to 11:59 PM.

Action: (David Wright) Verify that the no cost extension deadline issues resulting from the project end date that is stored in the system as 12:01 AM rather than 11:59 PM has been resolved.

Discussion

NLM—Israel Lederhendler reported that public access data collection of publications resulting from NIH funding is in the hands of the NLM. The eRA wants access to document listings posted in the NLM for inclusion in some sections of the eRA System. The publisher, submitter and author(s) of documents can submit them to the NLM for inclusion in the library.

eSNAP—Only key personnel will be listed in eSNAP. Others will be exempt.

eNotification—The eNotification application is being developed by eRA and appropriate parts of it will be used by eCGAP.

Supplemental Information—eCAGP has built in accommodation for supplemental information but it has not been built into the Commons as yet.

Attachments—eCGAP allows one attachment with the application. However, there may be a need to send more than attachment after the application has been received.

Action: (Jennifer Flach) Investigate what requirements should be established regarding the number of attachments that could be sent after the application has been received.

Appendix Materials—For the eCGAP pilot, PIs should send appendix materials to the SRA on paper or by email.

Email—The issues of necessary and unnecessary emails, what actions trigger them and who is receiving the emails were raised.

Action: (David Wright) Prepare a list of actions that trigger an email, what the emails say and who receives them. Send the list to the CWG.

Subprojects—Dealing with subprojects in the eRA System is quite complex and will be addressed sometime in mid-2005.

GCRC Progress Reports

Peter Highnam

General Clinical Research Centers (GCRC) have been an NIH program for more that 20 years, with about 80 GCRCs across the U.S. With about $280M in FY2004, the GCRCs are attached to a large institution and are a clinical research resource provider (e.g., beds, nurses, labs, IT). GCRC reports (M01) are large and complex.

The annual progress reports monitor the number and areas of disease-related studies; track GCRC utilization and their common and unique resources; collect GCRC scientific accomplishments,

publications and advances for evaluation; provide information for modifications in overall program; and identify new resources.

Currently, the PI and the institution prepare financial and other oversight data and progress reports. The progress data is uploaded to the NCRR databases and then NIH personnel produce key reports from the combined data. NCRR Program Officers review the technical progress reports.

The National Center for Research Resources (NCRR) is developing an XML-based system for uploading GCRC progress reports. The NCRR is working with eRA to take advantage of the eRA eXchange system-to-system capabilities to accomplish this goal. System-to-system transmission of GCRC reports will reduce the administrative load on GCRC administrators, staff, nurses and researchers and prepare secure informatics groundwork to make multi-site collaborative work routine. Working with eRA harmonizes informatics choices with the larger federal government and NIH directions. The eRA eXchange will provide basic schema and virus checking for the NCRR using mechanisms already in place or planned.

David Wright noted that by working with NCRR to upload these complex reports we will have a template for uploading other reports for eRA.

The project team is in place and is working on the overall plan. The XML-based plan for the GCRC interface is scheduled to be released at the end of September.

X-Train Trainee Account Create Process

Dan Hall

The last piece has been done to emulate the paper process for X-Train and keep all data. For it to work in the eRA System, every trainee will be required to have a Commons account. X-Train will be integrated with the Commons and will have its own menu item. The goal is to capture all data about a trainee from the beginning to the end of their career.

Dan noted that submissions will require the signature of a PI. However, the group said that this does not reflect the reality of who submits trainee data and it asked that the submission approval permissions be expanded. Often the PI initiates it but it goes through an institutional review cycle and is submitted by the Signing Official (SO).

Action: (Dan Hall) Investigate giving permission to submit trainee data to more people than the PI.

However, regardless of the institutional workflow, the NIH form only requires approvals of the trainee and PI. The rosters will be accessible to those with the “Basic” access right.

It also was suggested that work should begin to get this trainee data into the database of the university.

There was some discussion regarding the validity of electronic signatures. While the OMB has approved electronic signature, it is not widely known nor used as yet. Many organizations have yet to develop the capability for electronic signatures.

New Commons Initiatives

David Wright

The Commons supports the following business processes at this time:

- Financial Status Reports (FSR)
- Just in Time (JIT)
- No-Cost Extensions
- eSNAP
- eCGAP (in pilot)
- Closeout (due in fall 2004)
- X-Train (in development)

There are three major eRA initiatives underway:

- Grants Management is undergoing a major enhancement, called the Grants Folder, which will affect the Commons.
- Work is being done to define a system for workflow/notification between the Commons and internal systems.
- A second task order to expand the Commons has been issued.

The task order will focus on four areas:

- Consolidate Status reporting (eSubmission, IC/Committee Assignment, Score, Award, Closeout)
- Define integration requirements for Grants Management and Program by defining new requests and submissions
- Enhance existing requests and extend the number of requests supported
- Develop status queries on the state of the transaction

There are a number of requests for changes and David asked the group to review them and give him other suggestions. The current list, which is not in rank order, includes the following:

- Change of PI
- JIT enhancements (separate submissions)
- OLAW assurances
- Change of grantee institution
- Additional project extensions
- Human Subject inclusion and enrollment (outside of eSNAP)
- Carryover
- Re-Budgeting
- Administrative supplements

Regarding the use of eRA for all of HHS, there is no schedule for this. As might be expected, it will take some time to define all elements required by the many operational divisions within HHS before eRA can be used by them. However, a few already are using the system with others showing interest.

Misc. Items

***No-Cost Extension Process*—**There were suggestions to build in a routing system based on the new hierarchical rights. However, after discussion where there was some concern that PIs would be forced to spend more time on electronic administrative duties than on science, the group agreed to leave the system as-is for the time being.

***Virus Checking of Files Uploaded to Commons*—**Up until now, the eRA has relied on back-end systems for virus checking and to clean files. However, this system has proved inadequate so the eRA is in the process of developing a virus-checking system for all uploaded files to the Commons. It will be designed so that if the system finds a virus in a file, it will send a message to the sender to clean the file and resend it. The group asked that, if possible, a reference be made in the message that points to the error itself.

***JIT Approval Date*—**There only is room for one IRB approval date for a project. The last protocol approval date should be entered.

JIT IACUC Date—There is no place to enter the IACUC date even though the system asks for it. This is a known bug and is being fixed.

eCGAP Assurance Letters—There are two letters in PDF format on the eRA website (http://era.nih.gov/Projectmgmt/SBIR/) that provide assurance of the validity and fair consideration of grant applications submitted electronically:
http://era.nih.gov/Projectmgmt/SBIR/CGAP/CSR_Assurance_Ltr_PI_05-28-04.pdf for PIs and http://era.nih.gov/Projectmgmt/SBIR/CGAP/CSR_Assurance_Ltr_SS_05-27-04.pdf for a study section. A few members would like to modify the letters for their specific staff and would like the letters to be posted in Word format along with the PDF format.

Action: (Sandy Seppala) Post the two letters of assurance on the eRA website in both Word and PDF format.

Attendees

CWG Members

Beck, Ellen (UCLA)
Custer, Tammy (Cornell Univ.)
Dowdy, Stephen (Mass. Institute of Technology)
Fant, Jane (Univ. of Medicine and Dentistry of New Jersey)
Forstmeier, Kenneth (Pennsylvania State Univ.)
McKinney, Tolliver (St. Jude Children's Research Hospital)
Randolph, James (Univ. of Mich.)
Robins, Sandi (Univ. of Wisconsin Medical School)
Ross, Susan (Northwestern Univ.)
Sommers, Holly (Emory Univ.)
Wray, Nancy (Dartmouth College)

Other Institutional Representatives

Beattie, Robert (Univ. of Mich.)
Cheng-Chong, Cora (Mass. General Hospital)
Cook, Faye (St. Jude Children's Res. Hospital)
Drinane, Tom (Dartmouth Coll.)
Dwyer, Dan (Cornell Univ.)
Fay, Robert (Univ. of Maryland, College Park)
Kirk, Graydon (Emory Univ.)
Smith, Marcia (Mass. General Hospital)

Swavely, Todd (Univ. of Penna.)
Valenzuela, Richard (UCLA)

Service Providers

Bozler, Dianne (ERA Software Systems)
Burnette, Travis (Clinical Tools)
Harker, Chris (Cayuse)

NIH Staff/Contractors

Butler, Robert (NIH/NCRR)
Fisher, Suzanne (CSR)
Flach, Jennifer (OD)
Gibb, Scarlett (OD/PCOB)
Hahn, Marcia (OPERA)
Hall, Dan (Z-Tech)
Katzper, Linda (OD)
Maurer, JJ (OD/eRA)
Seppala, Sandy (LTS/PCOB)
Siegert, Mark (eRA)
Silver, Sara (IBM/OD)
Tatham, Tom (CSR)
Turner, David (OD)
Twomey, Tim (OD)
Walker, Cathy (OD)
Wright, David (OPERA)
Zucker, Sherry (OD)