



NIH eRA Commons Working Group (CWG)

Date/Time: Sunday, September 21, 2003, 8:30 a.m.–4:30 p.m.
Location: National Academy of Sciences, Washington, D.C.
Chair: David Wright
Next Meeting: TBD

Action Items

1. (CWG) Review HTML prototype of the Status Search Engine and provide feedback to the eRA Help Desk at < commons@od.nih.gov >
2. (Policy Office) Determine policy/regulation for IACUC and IRB date requirement for JIT pre-awards.
3. (Dan Hall) Pursue having the JIT checkboxes for IACUC and IRB dates default to be checked.
4. (David Wright, Marcia Hahn) Provide direction on what date should be entered in the IACUC and IRB fields when multiple protocols are associated with a study.
5. (CWG) Review HTML prototype for Project Extension and provide feedback to the eRA Help Desk at < commons@od.nih.gov >.
6. (David Wright) Provide direction on how to handle publications with eSNAPs.
7. (David Wright) Send Excel spreadsheets to CWG members or SOs participating in pilot specifying the information needed for compliance. First audit will cover a year, but subsequent audits will be done quarterly.
8. (David Wright) Alter agreement letter sent to new eSNAP institutions describing the quarterly audit and its purpose to facilitate long term change.
9. (David Wright) Send email to the CWG group to see if anyone is interested in a small offline session at the NCURA meeting to gather thoughts on the Web QT/Ad Hoc Query.
10. (David Wright) Send list of possible data streams (e.g., NGA, FSR, professional profile) for CWG members to rank.
11. (David Wright) Send email clarifying the intended use of the IPF Policy Email Address.

Introduction

David Wright welcomed the group to the CWG meeting and passed on George Stone's apologies for not being able to attend.

Marcia Hahn introduced Joe Ellis, the new Acting Director of OPERA. He replaced Regina White, who has taken a position at Brown University.

Deployment Update

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

Presentation: http://era.nih.gov/Docs/commons_deployment_status_cwg09212003.pdf

Dan provided a general status of the NIH eRA Commons. He reported a sharp increase in usage since the April meeting:

- Organizations that have registered increased from 260 in April to 525 in August
- Logins per month increased from 10,000 in April to 15,000 in August
- Number of PI/Reviewers doubled from 3,600 in April to 7,300 in August
- Projecting 3,000 new accounts created in September (up from 1,500 in previous months)
- Internet Assisted Review (IAR) accounts now 10 percent of the total (up from 3 percent in April)

Dan reminded the group that although the statistics show a very positive trend, usage is still a fraction of the targeted critical mass of 75,000 users to be ramped in over the next 18 months.

eSNAP—There have been 420 eSNAPs initiated since the start of the pilot (ten with Inclusion) and 305 SNAPs submitted to NIH (three with Inclusion). The pilot has been expanded to 30 institutions and is targeted for full production in November.

FSR—There are 13,700 FSRs of which 60 percent have come from Grantees (i.e., no paper).

IAR—The Internet Assisted Review (IAR) module went into full production in August. Thirty-four meetings for October Council representing 535 users and 79 meetings for January Council representing 1,335 users have been scheduled.

Discussion point: Dan reminded Account Administrators to create needed affiliations for IAR users. The group provided feedback that the manual process of looking up each last name to verify users prior to creating affiliations is tedious. They suggested having an electronic list of pending affiliations that can be verified programmatically would be a great timesaver. Sherry Zucker later demonstrated how the Ad Hoc Query Tool (Web QT) could be used to generate a report with the desired information.

Demo Facility—The demo facility continues to be a great training tool. Dan reminded the group that the demo facility is an excellent place to check out the new eSNAP Inclusion functionality.

August Release Highlights—Performance improvements (load balancing, SSL Acceleration, database scalability); eSNAP enhancements for Tracking and Inclusion; eSNAP complete/no complete wizard; and a reworked PI/Reviewer account creation process were released.

Discussion point: The group appreciates why the Profile information has to be cleaned up. However, they are concerned that they may have to repeat the process for every government agency with which they work. They strongly suggested a government-wide ID that could be shared among all government agencies. eAuthentication does not address the issue since it does not include Profile information. Is there any work being done (perhaps with Grants.gov) that will address this issue in the future?

Fall Release Initiatives—Address eSNAP Inclusion study set-up issues; full production of eSNAP; new password policy; IAR in demo facility; Status search engine; pre-award Just In Time (JIT); and project extensions are targeted initiatives for Fall.

Discussion points:

- Approximately 30 percent of eSNAP progress reports are not set up correctly (study information was not entered by the institute before the progress report was due). Need to go back and provide default study information.
- HTML prototype available for the Status Search Engine.

Action: (CWG) Review HTML prototype of the Status Search Engine and provide feedback to the eRA Help Desk at < commons@od.nih.gov >.

- Why are the Institutional Animal Care and User Committees (IACUC) (for Animal Subjects) and Institutional Review Board (IRB) (for Human Subjects) dates required for JIT pre-awards?

Action: (Policy Office) Determine policy/regulation for IACUC and IRB date requirement for JIT pre-awards.

- The JIT code only displays the IACUC and IRB entry fields when Animal and Human subjects are part of a study. Since the fields are required whenever they are presented to the user, why is there a checkbox in addition to the date field (two-step process)? Can the default be “checked” to remove one step?

Action: (Dan Hall) Pursue having the JIT checkboxes for IACUC and IRB dates default to checked.

- Multiple protocols can be associated with a study, but IACUC and IRB date fields can only handle a single date. What date should be provided?

Action: (David Wright, Marcia Hahn) Provide direction on what date should be entered in the IACUC and IRB fields when multiple protocols are associated with a study.

- As an alternate option to filling out the Human Subject Education text entry field of the JIT screen, it would be nice if you could import the human subject training .pdf document (easier, more consistent entry).
- There are no automated notifications regarding grants that are eligible for project extensions at this time. Analysis is needed to determine the best approach for notification. However, a Status report can be run periodically to gather the information.
- HTML prototype available for Project Extension.

Action: (CWG) Review HTML prototype for Project Extension and provide feedback to the eRA Help Desk at < commons@od.nih.gov >.

- How should publications be handled with eSNAPs (scan to .pdf, hyperlink, separate mailing)?

Action: (David Wright) Provide direction to the institutions regarding how to handle publications with eSNAPs.

CGAP and the eRA Exchange

JJ Maurer, eRA CGAP Project Manager, Ekagra Software Technologies

Presentation: http://era.nih.gov/Docs/cgap_era_exchange_cwg09212003.pdf

JJ presented an update of the CGAP project.

Fall Release—This release will include basic (limited but functional) exchange system that includes: ability to process multiple message types (request for submission, 398 from service provider, 398 from Grants.gov, status requests, status response, error/validation messages, reports and utilities); reference implementation for the “other=submitter side”; validation installation and site; NIH systems to process e-apps up through Review; and manual configuration for exchange partner setups, and security and transaction definitions.

October 2003 “Pilot”—The pilot will include a limited number of applications from pre-recruited applicants. Applications can be submitted through sponsored Service Providers or Grants.gov. Grants.gov is due to release their 398 form support to users by October 31; however, eRA is trying to get access to the test version so a few users can complete the pilot. eRA analysts will individually monitor each application and will use paper applications for backup as needed to ensure there is no risk to the PI.

Since CGAP is due to be released to production November 10 (after applications are due), participants must submit the face page, page 2 and specific aims to David Wright who will ensure the applications are accepted by NIH Receipt and Referral as “on time” for Review. Participating applicants should not submit the same applications through the traditional “paper” path in addition to the electronic pilot. For the pilot, applications will be run through the test system for verification and then re-submitted to the production center after the release.

Grants.gov—Coordination with Grants.gov is ongoing.

eRA Exchange—JJ proposed the use of ebXML (Electronic Business using eXtensible Markup Language) as the standard to conduct business through the exchange of XML messages. The group identified Notices of Grant Award (NGAs) and Financial Status Reports (FSRs) as possible candidates for non-administrative transactions that could use this technology.

Delegation of Authority via Exchange—JJ proposed three models: no delegation to broker, trusted broker, and pass through. The group suggested looking to the Liberty Alliance for possible direction.

eSNAP IRB/IACUC Post Review Discussion

David Wright

In preliminary discussions, NIH agreed not to collect Institutional Review Board (IRB) and Institutional Animal Care and User Committees (IACUC) dates at the time of submission with the understanding that retrospective reviews could be used to verify compliance. The assumption at the time was that random sampling would be used and the burden of the verification would be minimal. However, the policy office has recently determined that a random sample is insufficient. Therefore, institutions must now supply this information for any progress report that has come in via eSNAP.

The group discussed whether to go back to the original method of collecting the dates at grant submission or work through the more burdensome post process to collect data and challenge policy. The group agreed to move forward with the current solution and provide the required data as a post process.

Action: (David Wright) Send Excel spreadsheets to CWG members or SOs participating in pilot specifying the information needed for compliance. First audit will cover a year, but subsequent audits will be done quarterly.

Action: (David Wright) Alter agreement letter sent to new eSNAP institutions describing the quarterly audit and its purpose to facilitate long-term change.

Ad Hoc Query Tool for Internal NIH and Commons Users

Sherry Zucker, eRA Software Analysis & Development Branch Chief

Presentation: http://era.nih.gov/Docs/ad_hoc_query_tool_cwg09212003.pdf

Sherry reviewed a proposal to add an Ad Hoc Search option to eRA Commons Status that would take advantage of Web QT, a new query and retrieval system developed for internal eRA System users. Web QT combines the best features of multiple existing reporting tools into a single, consistent, powerful interface. After a great deal of analysis, a common set of elements used by all existing tools was identified. This element set served as the foundation for Web QT. In a later release, Web QT will provide the ability to customize the hitlist and to save up to three named hitlists for future use. Web QT enables users to quickly manipulate data to suit their needs.

Sherry walked the group through a series of screen snapshots highlighting the many features and flexibility of the Web QT system.

The Web QT engine will be used to implement Status for the Fall release. The Ad Hoc Query option of Web QT will be prioritized with other Commons initiatives for a future release.

The group enthusiastically endorsed the idea of adding the Ad Hoc Query option but with the proviso that the system default to institution-specific data (i.e., not cross-institutional). The suggestion was made to allow a complete scroll through the hitlist. Sherry mentioned the hitlist could be sent to Excel for further manipulation.

Send Ad Hoc Query questions/comments to Patti Gaines at gainesp@mail.nih.gov.

Action: (David Wright) Send email to the CWG group to see if anyone is interested in a small offline session at the NCURA meeting to gather thoughts on the Web QT/Ad-Hoc Query.

Future Initiatives: Organizational Hierarchy/Security Discussion

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

Presentation: http://era.nih.gov/Docs/future%20initiatives_cwg09212003.pdf

Dan reviewed some of the initiatives scheduled for the Spring 2004 release, including:

- X-Train
- Definition of XML transactions
- Fully integrated content management in eRA Commons
- Security
- Organizational hierarchy (basic requirements)

Proposal: OLAW Interface with eRA

David Wright

Presentation: http://era.nih.gov/Docs/olaw_era_interface_cwg09212003.pdf

David presented the attached proposal from the Office of Laboratory Animal Welfare (OLAW) to develop an interface with eRA through the NIH eRA Commons to provide institutions with the option of electronic submissions of annual report data and assurances.

David pointed out that this is an opportunity to circumvent the creation of another extension system.

The group had no objection to the proposal; however, it did not view it as a high priority item.

Re-compete Update

Jim Cain, Director of the Division of Extramural Information Systems

Jim Cain described the evolution of the eRA project.

Date	Description
1994	Pre-eRA; funding tentative; three NIH staff; two contracts; inward focus; development shop
1999	Many base requirements deployed (client/server); production mentality
2000	Recognition that project was underfunded; JJ McGowan appointed Project Manager; NIH commitment
Past 3 years	Many contracts; Operations, User Support and Analytical staff ramped; 230+ NIH and Contractor staff; greater management structure; more mature processes

Jim noted that for the past year, the eRA management team has been reassessing business practices. For some functions (e.g., user support), there are multiple contractors performing the same work. For others (e.g., development), there is a single contractor with no competitive incentives.

The current development contract is due to expire on November 30 (although there is an option to extend). Most other contracts will be terminated. There will be an overlap of contracts to facilitate smooth transition.

Four new contracts have been identified:

- **Integration:** Awarded to IBM Business Consulting Services
- **Operations:** Awarded to RN Solutions
- **User Support:** Request for quotes out
- **Design and Development:** Want more competition to keep cost down and quality up; task orders will be put out for bid among a small group of awardees

Jim noted that the management team is maintaining an extensive risk list with mitigation strategies to provide system stability throughout the transition period. However, despite best effort, the transition

period may still bring adverse effects to users and he asked for patience as the team works through any issues that may surface.

eRA Deployment Strategy

Jim Cain, Director of the Division of Extramural Information Systems

Jim said that the project is moving away from calendar-driven planning to more strategic planning. To date, the eRA team has been selecting a release date and working back from that date to determine schedule milestones. Release dates are often met by sacrificing functionality or compressing key steps in the process. Now that the project is more mature, Jim would like to take a more strategic approach to scheduling. He has instructed his team to take the time necessary to work through the appropriate planning steps (prioritize open requirements, determine cost/time estimates, perform architecture and budget reviews, create a project plan) and then determine a release date. Further, the number of major functional releases will be reduced to 1–2 per year with maintenance releases (bug fixes only) occurring each 4–6 weeks. Separating maintenance and new development activities will allow quicker response to production issues. Automated testing is a key requirement for quick turnaround of maintenance releases. Jim reported that it is the goal of eRA to have automated testing in place by early spring.

Other Items

Delegation Discussion—It is impractical to continue with current strategy of delegations. The group decided the issue cannot be resolved until the rights vs. roles issue is addressed.

Priority Setting

1. Organizational hierarchy and delegation/rights
2. Ad-Hoc Query Tool (Web QT)
3. Data streams

Action: (David Wright) Send list of possible data streams (e.g., NGA, FSR, professional profile) for CWG members to rank.

NOTE: CGAP implementation assumed.

X-Train—Deployment of new version has been postponed several times and may not happen until mid-2004. The current version of X-Train is experiencing system quality issues and the eRA team is evaluating whether to shut it down. There are 18 institutions with access to the current system of which 7 are *regular* users. Although there are political ramifications for shutting down the system, it is hard to justify the expense with only 300 uses in the last year and a half.

New IPF Assurances

IPF Policy Email Address—In the institutional profile there is a field for IPF policy email address. The specified email address was intended for broad notification to Commons users of issues.

Action: (David Wright) Send email clarifying the intended use of the IPF Policy Email Address.

Competing Priorities—David alerted the team that system requirements are driven from many areas, including: mandated policy (e.g., password policy), HHS grant system consolidation, code upgrade activities, and executive roadmap. eRA is continually gathering requirements and prioritizing its limited

resources. It is important for CWG to clearly identify its high priority items so that its representatives can properly represent the team's desires.

Attendees

CWG Members

Beck, Ellen (UCLA)
Clark, Denise (Cornell Univ.)
Dowdy, Steve (MIT)
Fant, Jane, (Univ. of Medicine and Dentistry of N.J.)
Forstmeier, Kenneth (Penn State Univ.)
Kirk, Graydon (Emory Univ.)
McKinney, Tolliver (St. Jude Children's Research Hospital)
Randolph, Jim (Univ. of Mich.)
Robins, Sandi (Univ. of Wisc.)
Webb, Pamela A. (Stanford Univ.)

Other Institutional Representatives

Beattie, Bob (Univ. of Mich.)
Cook, Faye (St. Jude Children's Research Hospital)
Custer, Tammy (Cornell Univ.)
Denson, Don (Emory Healthcare)
Dwyer, Dan (Cornell Univ.)
Elliott, Bruce (Northwestern Univ.)
Ludington, Andrew (Northwestern Univ.)
Marcussen, Tom (Oregon Health and Science Univ.)
Martin, Phil (Dartmouth Univ.)

Valenzuela, Richard (UCLA)
Wilson, Tom (MD Anderson Cancer Center)

Vendors

Harker, Chris (Cayuse Software)
Rodman, John (Rams Company)

NIH Staff

Cain, Jim (eRA)
Ellis, Joe (OER)
Fisher, Suzanne (CSR)
Gaines, Patti (eRA)
Gibb, Scarlett (eRA)
Hahn, Marcia (OPERA)
McKay, Rich (CSR)
Soto, Tracy (eRA)
Twomey, Tim (eRA)
Walker, Cathy (OER)
Wright, David (OPERA)
Zucker, Sherry (eRA)

NIH Contractors

Cummins, Sheri (LTS)
Hall, Dan (Z-Tech)
Maurer, JJ (Ekagra)