eRA Commons Working Group (CWG) Meeting Notes

Meeting Details:

Friday, September 23, 2016
1:00-3:00 p.m.
Room: Lobby Level, Congressional A
Hyatt Regency Washington
400 New Jersey Ave, NW
Washington, DC 20001
Map and Directions
Floor Plan

Agenda Items:

1. **eRA Commons Update**

Facilitator: Scarlett Gibb

- eRA Commons continues to expand its support of other HHS agencies
- SAMHSA
  - Big effort has been made to support their non-research grants
  - 2 FAOs using SF-424 have accepted submissions via ASSIST
  - Now working on SAMHSA Amendment process (very different business rules from what NIH does)
    - Any change needs an amendment, processed through ASSIST
      - Initiation of amendments
      - Status of Amendments
      - Award of Amendments
- Question: How many of you work with both NIH and SAMSHA grants? Quite a few indicate yes.
  - For institutions that work with SAMHSA, please provide advice on procedures, would like to make processes between NIH and SAMHSA as consistent as possible
- New Public Access support
  - Goal is to reduce the applicant/grantee burden
  - Added new notifications/icons
    - Gold lock icon = publication reported on last report, cannot be removed without contacting NLM
    - Silver lock icon = a publication added by a peer in
  - All three Service Desks (eRA, NCBI, and NLM) working more closely, meet monthly
- New PI Status feature
  - Now that applications are grouped by family, needed a way to display current status
  - New field will show color coded/text information of the most recent status
- Coming in January 2017, Final RPPR as part of Closeout
  - Will have a hard cut off: reports due after date (Jan 1?) will have to use the Final RPPR format
  - Guide Notice with details to be published soon
- Genomic Data Sharing coming to RPPR
- Prior Approval
  - Withdrawal Request has been available for some time now
  - Adding Direct Costs of more than $500k requests
    - Release delayed at the request of ICs to meet their needs

        - ICs, through the Program Official, will invite applicants to submit the 500K request, they initiate the process
        - Who gets the invitation?
            - Sent to the contact PI and the Notice of Award (NoA) address
        - Suggestions: For Post Award Prior Approvals include in heading of request, Contact PI, Title of Project, and if it is a multi-PI application
        - Add a Prior Approval $500K contact address on the Institution Profile, default to the NoA address if not updated
        - Would be great to add to the system a way to generate a cover letter for $500K requests from the information provided in the form so work does not have to be duplicated
    - Send additional ideas/suggestions to GibbS@mail.nih.gov
- HSTS Notification- switching all https connections to federal web pages using *HTTP Strict Transport Security* (HSTS)
    - Few years ago we had to update all of the URLs adding "public." to identify publically accessible web pages
    - Old URLs (i.e. commons.era.nih.gov) were redirected to new URLs (i.e. public.era.nih.gov/commons)
    - Under federal mandate OMB-M-15-13, the redirects must be discontinued
    - That means for any guideline, instructions, resources, etc. you have linked using the old URLs will need to be updated
    - Hoping to get a minimum of a 60 day lead time to alert customers
    - This will impact iEdison pages as well

2. eSubmission Update

- Clarification of the announcement made at FDP by Dr. Mike Lauer from NIH and Andrea Brandon from HHS: Plans have been put in place with NIH and HHS leadership to have Grants.gov and NIH work more closely together to have ASSIST be part of Grants.gov's solution for supporting all federal agencies with on-line forms. It is too early to know exactly what this will mean, operationally
    - Concern raised by CWG: Will these conversations include the perspective of S2S users, some who have invested large amounts of time and money in the development of their solutions?
        - NIH will be a major player, and we believe strongly in a cooperative process that involves all stakeholders.
        - One of NIH's roles will be to ensure NIH applicants are not negatively impacted

eSubmission update from Laurie Roman:

- SAM Registration information now available in ASSIST
    - Will appear 14 days before expiration. Thank you for your perspectives on this.
    - Red icon will indicate when registration has expired
- New Summary roll-ups in ASSIST for multi-project applications will happen in the October release
    - Stem-cells
    - Human Subject / Vertebrate animals
- New text generator for generating application image being implemented in eRA's User Acceptance Testing environment in October, ASPOSE for release November 17
    - ASPOSE generates application PDFs, and supports user friendly functions like hyperlinking the table of contents in the application
- Screen widening effort in ASSIST will take advantage of unused/under-utilized boarder area
- Updates to SBIR/STTR forms likely in 2017. We are still in planning phases.
- Discussions begun about how to accept type 3, 6, 7's for multi-project applications electronically. May have some solutions.
- More pre-population of data coming in ASSIST
    - CWG members supported the idea of prepopulate data from Senior/Key Personnel using IPF information, as long as it would still be possible to change the info that got prepopulated in the application.

- Change in Appendices policy
  - CWG members expressed support for including a warning to check the FOA when appendix material is included in the application, given the new appendix policy.
- Other Agencies Validations as they transition to ASSIST
  - Should validations documentation be made available for other (non-NIH) agencies?
    - YES
  - Should it be one big document or broken out by agency?
    - Broken out by agency can be helpful for some folks.
  - eRA has an internal validations look up tool that, once more and a broader internal rollout is done, we hope to make public.
    - The group strongly supported this direction.

3. Optimizing the Just-in-Time Process

Facilitator: Jessie Floura/Stefanie Harris

- Always confusion about JIT there is. When to submit information?
- Would it be better to have the link triggered by the IC when they actually want information
  - YES!!
  - If this change would be particularly helpful, let us know by documenting the burden it would relieve. Emails can go to Scarlett Gibb (email GibbS@mail.nih.gov)
  - Q: When would automated email notifications go out? A: When link is triggered by IC.
    - Look into making automated notifications customizable to the IC staff. Ability to add special language and/or terms.
  - In the interim, considered now is lowering the threshold for automated messages
    - From a score of 40 to 30
    - Reduce the number of false positive notifications

4. Detailed Status Screen Redesign

Facilitators: Scarlett Gibb/Yuri Gorbach

- New design of Details Status Screen (screen you get to by clicking on application ID#)
- Look and function similar to Personal Profile with expandable tiles/categories
  - Status first tile/category
  - Open by default
- Suggestion from members is to show PI name, Title and Application number in header, have a link to the latest NoA
- Text filter will bring you to category with that info, no need to open them all searching
- Comment: IC need to do better at updating contact info for SROs and POs
- Any fields that you would want removed? Send comments and suggestions to Scarlett (email GibbS@mail.nih.gov)

5. Changes to Tracking and Monitoring of Clinical Trials

- New form is in the works to collect information on clinical trials. Help us identify implications and issues we should consider when designing/rolling out new forms.

Facilitator: Megan Columbus/Stefanie Harris

- NIH made a number of announcements last week about new policies, regulation, and tools to help improve oversight and management of clinical trials.
  - All NIH funded clinical trials need to be registered at ClinicalTrials.gov (CT.gov) with penalties for those who do not comply
  - Applicants will need to apply to clinical trial specific FOAs
  - New clinical trial specific forms
    - Replacing data provided in “Other Attachments” section with discrete data fields on forms
    - Capturing info needed for ClinicalTrials.gov to eventually help reduce data entry requirements
    - New clinical trial form will be needed per protocol, and will likely have inclusion tables wrapped into it
    - Question: do folks prefer attachments or short answer data fields? Answer: Attachments. Short answer data fields costly to implement for systems.

FDP Meeting for 2017

Hyatt Regency Capitol Hill
January 8-10, 2017
May 10-12, 2017
September 6-8, 2017

Tentative CWG Meeting for 2017

Hyatt Regency Capitol Hill		
Tuesday, January 10, 2017		1-3PM
Friday, May 12, 2017		1-3PM
Friday, September 8, 2017		1-3PM