Electronic Research Administration
A program of the National Institutes of Health

eRA Commons Working Group (CWG) Meeting Notes

Next Meeting:

Friday, May 11, 2018
12:30-2:00 p.m.
Location: TBD

Follow Up to Discussion of Human Subject and Clinical Trial Management System

- If people have input on the initial concepts presented at the FDP meeting of the new system, let us know.
- It will work much like the Inclusion Management (IMS) system does currently, with human subject and clinical trial information to be populated from the incoming application and then updated periodically through Commons and wrapped up into the RPPR.
- Clinicaltrial.gov registration will be able to be initiated through the Commons, and data from Clinicaltrial.gov will be considered the system of record and can be pulled in to populate the Human Subject and Clinical trial Management System.

eRA Commons Update

- ORCID iD link has been implemented on the Personal Profile
    - Within first 2 days, 244 new accounts created/associated with Commons accounts
- IRAM and FRAM have been enhanced with automatic convert if the award goes from Closeout to Type 2, or from Type 2 Not Funded to Closeout as part of IRPPR/FRPPR.
- Personal Profile, New UI
    - Using new web framework called Spring MVC
        - More secure
        - Cleaner
        - Easier to read
    - No changes in data being requested
    - No changes in location of data field
    - No changes in validations
- Partner Updates
    - Annual RPPR now available to CDC
    - FFR functionality now available to SAMHSA
- What's Coming
    - Delegation for IRPPR and FRPPR coming at the end of January
    - Generalization of Terminology to accommodate other funding mechanisms
    - Will see in many places the word 'grant' changed to 'award'
    - Closeout functionality being worked on for CDC

Providing Systems Support to Other Agencies

- As more partner agencies come to use Commons, we want to be sure we develop documentation that is as helpful as possible
    - Terminology challenges
        - Same terms mean different things across agencies
        - Same processes may be accomplished in the system differently between agencies
- In what ways can documentation be structured to support all variations?
    - Hard to tell yet
- Current model is to have all information in a single help system and ID where things are different for Partner Agencies
- Suggestions:
    - Be clear to which partner agencies the different instructions apply (call them out by name)
    - Consider asking up front which agency they are working with and display only those instructions

How Are Current Transitions Going

- How have the transitions to FORMS-E and clinical trial specific FOA reissuances been for users? We tried to make it as transparent as possible. How did we do? Last forms change, we rolled out new forms in a phased way based on due dates for specific FOAs to avoid having people use the wrong form. There were pros and cons. This time we released the forms all at once, posting them over a few weeks.
    - Transition fairly smooth
    - Difficulty with some specific FOAs
        - Usually a result of waiting on an IC to reissue the FOA so new forms could be made available for that FOA
    - As long as forms are available well ahead of the deadline, that is ok. Putting forms out without enough time is problematic.
- How are early submissions on the wrong forms handed?
    - Dealt with on a case by case scenario by Receipt and Referral
    - In most cases the submission has been early enough, applicants have been able to convert application to correct forms package
    - CWG participants do appreciate the effort made to ease the transition as much as possible
- Clinical Trials FOAs - Has there been a big push back from PIs? We have tried to make help resources with updated case studies, podcasts, etc.
    - CWGers have been training staff and spreading the word on the new CT definition, procedures, etc.
    - They have been pointing staff to the CT info on the grants.nih website
    - Very appreciative of all the resources NIH developed.
    - It is important to note that these changes have a significant impact on institutions
        - Training staff
        - Development of resources
        - Changing workflows within organizations since so much science in the new forms
        - Time & money

2. Help Us Get a Better Understanding of Our Users

- Do the roles we have match what your users do?
  - Not so much
  - Requirements identified at prior CWG meeting for a permissions based rather than role based approach to users still stands.
    - Currently the development cost of that is prohibitive.
- What about Grants vs Contracts? Do the same people work on both?
  - No set model or structure, each institution is differently organized. Sometimes yes and sometimes no.
- What people have we not identified, or do we not understand the behavior of, who interact with our systems?
  - In relationship to the clinical trial data/forms, it may be RNs who are dealing directly with patients, clinical coordinators, study managers
    - These people are not part of the Sponsored Research Office
    - May get their information on NIH changes and systems and such from PI
    - Information flows to these folks from IRB
      - NIH does not interact directly with IRBs
    - We rely on the Sponsored Research Office to act as a liaison between institution and NIH
    - Most IRBs are on top of the info and policies coming from NIH ("they frequently know before we [research admins] know")
- Other Users?
  - It would be helpful to have Commons filter based on user role and/or funding agencies
  - Only tabs and information that is related to that role
  - For people new, do we have enough information
    - We do have New to eRA Commons?
  - A checklist of responsibilities for what each role can do would be helpful
    We do have this Signing Official and Principal Investigator Privileges in eRA Commons
  - Would be good to have more conversations with smaller institutions, more perspective
    - See if NIH can get in on the FDP Emerging Research Institutions lunch.
  - Lots of good info on the NIH websites
  - Need more of roadmap type info on processes
  - Currently lots of time and effort is taken to track down students who worked on a project for a short period of time who do not have Commons accounts and who are not interested in creating an account now that they are no longer doing research just to fulfill RPPR requirements.
    - Need to reduce administrative burden of adding student data when RPPRs are due
    - Might be a two pronged approach:
      - Initially communications from NIH could suggest that institutions may want to have students register in Commons and get an Orcid ID as they are "on-boarding" the student to the grant.
    - Explore if there is anything NIH can do to help
      - Change the system to allow students to self-register, with an approval/institutional affiliation request requiring the institution to just push a button to complete the registration.
      - Could NIH change the system to allow students to get a request to register?
      - Could there be a way to override the system and input information so RPPRs can be completed?
      - Could institutions create some sort of shell record for students who are no longer available?
      - There is he ability in AMS to run a report for incomplete PPFs. It could send reminders to folks who did not complete the registration.

3. Tracking Prior Approvals – Can NIH Approval of a Request Be Displayed?

- Prior Approval screen shows a variety of statuses but not Approved
  - Usually when approved a NoA is generated, and that is the indication of approval, but that notification comes by email to PI
  - No indication in Prior Approval to indicate request has been approved or denied
  - This creates a manual workaround and workflow at grantee institutions to track that information, and makes compliance more difficult
  - Challenge is each IC has a different process for approvals
  - Strong need for S2S administrators to have this info for post award processes

4. Brainstorm Ideas To Make Working with the GONE Act Easier

- Add a Closeout status for S2S in Status web service
  - Want to avoid unilateral closeout process
  - Getting systematic feedback that closeout is due/pending will allow admins to 'encourage' PIs to complete Closeout documentation/process
- Would including a clinical trial indicator be helpful?
- Let Scarlet Gibb know which statuses would be most helpful
  - Does not seem to be a huge development issue
  - Might be NIH awards only

5. General Discussion / Wrap-up

- NSF looking to enforce fonts, headers systematically. Will NIH do the same?
  - We enforce most of those types of validations manually and currently have no plans for systematic enforcement
    - NIH permits graphs with legends which are not restricted to font type/size which make it very difficult to enforce fonts systematically
    - Don't want to invalidate an application because of a graph
- Difficulty with calculating Admin Supplements and new budget date
  - Very difficult to systematically calculate the change in budget dates because of the difference between budget and project dates.
  - This is something NIH recognizes and has tweaked numerous times.
  - Might need to consider making the fields a manual input