Electronic Research Administration
A program of the National Institutes of Health

eRA Commons Working Group (CWG) Meeting Notes

Meeting Details:

Friday, May 12, 2017
12:30-2:00 p.m.
Room: **Congressional B, Lobby Level**
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
   - **RPPR**
     - In December 2016, Final RPPR (FRPPR) became required (with the exception of SBIR)
     - February 2017, Interim RPPR (IRPPR) with T2 submissions became required
     - In coming months, IRPPR will automatically be converted to the FRPPR if the T2 is NOT awarded
     - Likewise, if T2 is awarded, the IRPPR will become an annual RPPR
     - June FRPPR will be implemented for SBIR

   - ? – Can an AO help with the FRPPR as they can with an annual RPPR?
     - A – The requirements at the time of development stated that the FRPPR should work the same as the Final Progress Report (FPR)
     - A – Delegations will be reviewed
       - Have already had many requests to allow delegation for all versions of RPPR
       - Starting May 25, reprints will be available in PubMed NCBI

   - Comment: we like the new detailed Status page
   - ? - are the reference letters available?
     - A – Yes, and you can always use the filter to find specific information
   - ? – We had a discussion about a new admin role… what is the status of the central administrator (SO Lite) role? Power to do everything except submit.
     - A – still a desired feature, but development team deal with many initiatives and development resources are limited
   - ? – Will the same business rules apply to the Final and Interim RPPR?
     - A – Yes

2. Seeking Feedback on New Electronic Prior Approval Processes

Facilitator: Anastasiya Hardison

- **Prior Approval**
  - Now supporting:
    - Change of PD/PI
    - More than $500K in direct cost requests
    - Withdrawal of an application
      - Comment: People love this
    - Carryover (yeah!)
- Comment: Not all Program Officials (POs) are familiar with the electronic option for $500K requests
  - Response: Part of the issue is that IC want different info and different format (PDF), it will take time for them to adopt the electronic process

3. Potential Adjustments to FOA Dates: Help Identify Any Unanticipated Consequences

Facilitators: Sheri Cummins

- Aligning Open Dates and Publishing Dates
- Shifting Close Dates to match AIDS Dates for all FOAs with standard due dates
- **Open dates**
  - Current practice:
    FOA open date set to 30 days prior to first due date
  - Future practice:
    FOA open date = posting date (i.e., FOA immediately available for submission)
    - Comment: No concerns, make them the same
  - Why change?
    There is no longer a business need to delay the open date.
    Originally we set the open date to 30 days prior to the due date to allow NIH to post FOAs in advance of systems being ready to process them. Now, with ASSIST and web services to do pre-submission validations and image generation, systems must be ready to process applications at time of posting.
- **Shifting close dates to match AIDS dates for all FOAs with standard due dates**
  - Current practice:
    - FOA close date is last due date
  - Future practice:
    - FOA close date is last AIDS due date in cycle
      - Comment: Make them all the same, close dates match AIDS dates
      - Note: this will not affect RFAs
  - Why change?
    - R01 FOAs that use standard due dates, but do not accept AIDS applications close on the March/July/November 5 standard due dates for Resubmissions/Renewals/Revisions applications.
    - The cut-off dates for continuous submission applications are April/August/December 16. Even with the current 35 day grace period, FOAs stop accepting applications before the continuous submission cut-offs. Further, many applicants don't understand that NIH FOAs have a grace period where applications will continue to go through the systems.
    - Aligning with the AIDS dates allows FOAs to remain active for all continuous submission applications and reduces reliance on grace period to much smaller subset of applicants (those submitting AIDS applications late or under continuous submission).

4. Human Subjects & Clinical Trails (Forms E) Role Out

Facilitator: Sheri Cummins

- **Forms E Transition**
  - eRA has asked Grants.gov to hide the Forms E packages until the FOAs are open since changes are still coming

- Guide notice issued – NOT-OD-17-062
- Resources:
  - High-level Summary of Form Changes in FORMS-E Application Packages
  - Annotated Form Set for NIH Grant Applications
  - Do I Have the Right Form Version For My Application?
  - Application Forms, Form Updates, and Choosing the Correct Forms FAQs

- Comment: The new Human Subjects forms have lots of appendices. Make validation difficult as we get lots of warnings. ? – Couldn't all that data be part of the form?
  - Response: the challenge is that not all the info is part of the review criteria, so if it made into form fields, it becomes part of the application image, and therefore, reviewers will see it
  - We need to see how IC's will use the new forms and structures

- **High-level timeline**

Date	Action
April 27, 2017	Announce pending FORMS-E form changes – NOT-OD-17-062.
May 12, 2017	Add NOT-OD-17-062 to Related Notices section of all FOAs with due dates on/after January 25, 2018.
May 2017	Begin posting FOAs with initial due dates on/after January 25, 2018 without an application package (FOAs will include note to revisit FOA after November 10 when forms are available).
June 19-21, 2017	Grants.gov to release support for NIH form updates to their training environment.
Late June 2017	Make full suite of test FOAs available in Grants.gov training environment (will not be able to test through to eRA Commons until late summer/early fall).
Early October 2017	Update all FOAs with due dates on/after Jan. 25, 2018 to include new Clinical Trials indicator • Only accepting applications that propose clinical trial(s) • Only accepting applications that do **not** propose clinical trials • Accepting applications that either propose or do not propose clinical trial(s)
Early October 2017	Add Clinical Trials indicator as an NIH guide search parameter.
By October 25, 2017	Post FORMS-E application guides.
October 25, 2017	Begin posting FORMS-E packages with new FOAs with due dates on/after January 25, 2018.
Oct. 25 – Nov. 25, 2017	Add FORMS-E packages to all existing FOAs with due dates on/after January 25, 2018. Set FORMS-D packages to close on Jan. 24, 2018 with 21 day grace period (accommodate late, system-issue and continuous submission policies)
November 10, 2017	Complete posting of FORMS-E packages for any FOAs previously posted without an application package.
By January 24, 2018	Expire all FORMS-D FOAs that plan to continue supporting clinical trials applications for due dates on/after January 25, 2018. All FOAs that will allow Clinical Trials application for due dates on/after Jan. 25 will be reissued with updated FOA instructions and review criteria.
January 25, 2018	First due dates to use FORMS-E.
January 25, 2018	Post non-competing Type 6, Type 7 and Admin Supplement (Type 3) parent FOAs and IC issued Admin Supplement (Type 3) FOAs.
February 7, 2018	Last legitimate competing application submissions using FORMS-D (end of 2-week late window of consideration for Jan. 24 due date and end of continuous submission receipt period for AIDS applications in May Council).
February 25, 2018	Last legitimate non-competing applications to FORMS-D Type 6, Type 7 and Admin Supplement (Type 3) parent FOAs and IC issued Admin Supplement

	(Type 3) FOAs.

- Trying to align implementation of Final Rule which adds two new Human Subjects exemption codes and redefines existing exemptions with FORMS-E changes
    - Would mean additional change to the R&R Other Project Information form and the PHS Human Subjects and Clinical Trials Information form (specifically the addition of the human subjects exemption codes 7 and 8)
    - Grants.gov is doing the development now
        - ready for testing in June in the Test environment
        - Full testing in the fall, 2017, once all development is done
- **Downloadable Forms**
    - Will hide Forms E until they are required
    - Grants.gov is communicating that downloadable forms are going away and that Workspace MUST be used from that point forward – NOT TRUE
        - We will continue to communicate that ASSIST is the other (better) option
    - Updated Application Guide is being worked on with new resources. Feel free to send suggestions
    - Webinar for ASSIST and new Human Subject/Clinical Trials forms (Forms E) is coming

- ? – Will reporting requirements include Clinical Trial information?
    - A – Yes, we are sure it will be
    - A – Instructions will be included in the coversheet of the HS/CT applications

5. Admin Supplements for Single Projects

Facilitator: Megan Columbus

What are the implications of making electronic submission required?

- **Supplements for Single Projects**
    - Currently three methods of submission
        - Grants.gov
        - eRA Commons
        - "Paper"
    - Should process be required to be electronic?
    - Comments:
        - Get rid of the "paper" option
        - Issue with Grants.gov is up to a 2 day delay in processing
        - IC sometimes ask for a start date before they will take the submission
        - Program Officials need training on policy requirements
            - Having to redo work when information is requested from the ICs that conflicts with policy
    - Summation: no issue with getting rid of "paper" option for single projects

6. Training Grant Challenges: What are they and how can they be lessened?

Facilitator: Barbara Inderwiesche

- ? – Can termination notices assigned to a specific SO/BO be routed to another SO/BO?
    - A – a fix is coming that will allow the PI to recall a notice and re-assign it to another SO, May 25
    - Comment: would like to have the option that another SO/BO reassign it
- Concerns about training grants:
- ? - Why is so much data requested for training tables?
    - A – xTRACT created to help with the creation of training tables
    - Data is a result of the BMW initiative (Bio-Medical Workforce)
    - Grantees would like to know what the data is used for, a justification for requiring so much information
    - Megan will discuss with NIH staff and put an article out in the Nexus
        - Driving force is to know what people do long term as a result of NIH support
        - At this phase ICs can see the date, and can use the data if they wish
        - Comment: it is also a burden to maintain and report this information for 15 years

7. General Discussion / Wrap-up

Facilitator: Megan Columbus

- ? - Payback Agreements: can that process be made electronic?
  - A- It is a policy issue, Megan can discuss with them
  - General Council says No
    - Security concerns
- Grants.gov Lock/Unlock feature
  - ? – can ASSIST have something similar?
    - An unlock feature to by-pass the timeout process to release forms
      - Who would be able to use it?
      - Start with SO role and let it be managed through the Manage Access Role
- Grant Support Index
  - (In the time since the meeting, this has been rolled back)