eRA Commons Working Group (CWG) Meeting Agenda

Next Meeting Details:

Date: Tuesday, January 9, 2018
Time: 12:30 PM – 2:00 PM (tentative)
Location: **TBD**

Agenda Items:

1. **Clinical trial changes – seeking advice on getting the word out**
   - NIH working on all fronts to get the word out.
   - Been working with uncertainty – we don't have final confirmation about the timing of the Common Rule, so built in the extra human subject exemptions into the form so we are ready if it does go into effect in January. We will make application instructions clear about their use.
   - The 2014 NIH definition of a clinical trial (CT)
     - Means many studies now meet the definition of the CT that previously would not
     - People just now starting to understand that this will impact them.
     - Current communication focus is on identifying whether your study is a clinical trial, and picking the right FOA.
   - How are institutions preparing for the change?
     - Institutional educational outreach to faculty and PIs
     - Working with Human Subjects division and developing a communication plan
     - Discussing changes with staff and IRB
   - Suggestions:
     - Add context in communication (this is a CT trial because…)
     - Why These Changes PowerPoint available, in addition to other presentations and resources. See NIH clinical trial requirements website, presentation resources available under "training resources" link on right sidebar.
   - OER needs help – Are resources hitting the mark (helping)?
     - Yes, they help.
     - Recent video providing an overview of the new human subject and clinical trial information form is helpful, "People like it."
       - https://www.youtube.com/watch?v=nz9NWFhYOG8&t=97s
     - Need to make sure we continue to push out communications so messages get "pushed it to the top" for people who may have missed it the first time, or have been away for the summer
     - How will future changes be handled? Like RPPR, etc.
       - More communication coming on RPPR changes, need community to focus initially on application submission
     - Add Clinical Trial search function similar in Commons
       - An SO Search function
     - Case Studies and FAQs on the definition have been developed to help provide context / examples

        - "living documents"
        - New cases studies and answers to be added as appropriate
- Commons to be updated to track human subject and clinical trial study data much like the Inclusion Management System (IMS) does
    - Grantees will be able to update study information after award
    - Tentatively May 2018
    - Update group at January CWG
- To help applicants, making clinical trial allow-ability as clear as possible in the FOAs, both in the title and in section II.
    - Clinical Trial required
    - Clinical Trial optional
    - Clinical Trial not allowed
- How to Avoid Confusion for F and T applicants
    - Fellowship and Training grant FOAs will not support independent clinical trials. This means that fellows or trainees are not allowed to be the ones ultimately responsible for a clinical trial. However, they can be involved in a clinical trial that is overseen by their mentor
    - We plan to include indicator in section 2 of FOA that makes it clear that the FOA does not allow independent clinical trials, but does allow clinical research experiences
    - Should we be clear in titile as well, or would that be more confusing than clarifying?
    - Conclusion: leave out of title, keep info to Section 2
    - What about for Ks, where FOAs for some activity codes will not allow independent clinical trials and others will?
    - Conclusion: Be clear in the title of K FOAs whether independent clinical trials allowed or not.
    - Applicants will need to follow instructions carefully to be sure they fill out the correct fields, since for those FOAs that do not accept independent clinical trials, clinical trial information cannot be included in the protocol synopsis part of the form.
        - SF424 Instructions will be clear about how to complete human subject fields for F, T, and K applications.
        - Couldn't the system help showing fields that needed to be completed based on previous info added?
            - ASSIST could be programmed that way in the future.
            - But we don't control the interface for other methods of submission.
            - Application instructions need to be written to meet the needs of all submission methods
- Confusion about terminology: Human Subjects vs Human Participants
    - At NIH, terms are sometimes used interchangeably, including in policy language.
    - "Human subject" references in policy refer to everything, including human specimens
    - At times we use the word "participants" to refer to the actual individuals participating in studies
    - Confusion because terms are mixed across resources for instructions, forms, and policy statements – not consistent
- IMS confusion in Forms E (validations)
    - Forms E permits the submission both Planned and Cumulative (or Actual) for RPPRs and the Inclusion Enrollment Report
    - This may be an error in the .dat file for validations shared with S2S developers
    - This will be investigated
- Suggestions related to clinical trial communications? Send it to megan.columbus@nih.gov.

2. Approach to collecting individual age and ethnicity post submission – implications of requesting CSV file in RPPR?

- Why will NIH be collecting age of participants?
    - 21 Century Cures Act - https://www.nih.gov/research-training/medical-research-initiatives/cures
    - Requires by law the collection of this information, including data on pediatric subgroups
    - NIH has not issued a policy on this yet.
- New fields are already in Forms E
    - Minimum to maximum age of participants

- Applicants will continue to provide a justification for age range
- Collecting age data
    - How to collect with minimal amount of burden to investigators?
    - How to collect without exposing Personally Identifiable Information (PII) (not collecting birthdates)?
- Plan is to allow the upload of .CSV or .XML files versus .PDFs.
    - File would have columns for race, ethnicity, sex/gender and age.
    - Age would be in time increment (hours, days, months, years) depending on need
    - Age would be taken at the time of enrollment in the trial
- No huge concerns expressed
    - Other agencies allow or require file types other than PDF
    - More of challenge for S2S
        - Programming requirement for different scenarios of when it is PDF only or another file type
    - Some concern with regards to investigator burden
        - More data to collect
        - More data to track and report on
        - What about long term studies, 5, 10 years+, age becomes a factor?
        - But, collecting the CSV file would mean that applicant would not have to do all the tallying currently required by inclusion plans and reports.
- What will work best for applicants/grantees?
    - Uploaded file (.csv / .xml)?
    - Electronic form?
    - Share with Dawn Corbett, NIH Inclusion Policy Officer, at inclusion@mail.nih.gov
- Timing of collecting age data is still to be determined.

3. Reducing risk

- Back to communications discussion - How can we best alert people changes such as the elimination of downloadable form package, changes for Forms E, etc, to help ensure successful submission of an application?
    - Human Subjects Forms E has 70 pages of validations
        - New validations and clinical trial specific FOAs make it more critical than ever to submit early to give time to adjust application before the due date if needed
    - S2S system issues do not get the special consideration in NIH's system issue policy that issues with Federal systems get.
        - Applicants need a back-up plan/option for what to do if their s-s does not work
        - Downloadable form packages used to be that option for some
        - Workspace requires some setup with permissions and such
        - Plan ahead!
- Validations for S2S is difficult in part due to limitations to the NIH validation web service
    - Does not allow for partial validation of an application
    - It is all the application or nothing
    - Ideally we would allow for validation of the application form by form.
- In November we will start to communicate the need to apply early for CT applications especially
- One thing to share, new forms shifts some info that used to go into the research strategy to the new human subject form, which frees up space in the research strategy section for other information
- Contact Sheri Cummins with ideas/suggestions on how to reduce risk at cumminss@od.nih.gov

4. Feedback on effectiveness of eRA video tutorials. Suggestions welcome!

- Do they help?
    - Yes
    - Good resource
- How long should they be?
    - 10 minutes max
    - 3 minutes for faculty videos
    - If longer than 10 minutes, use chapters so people can click to desired information
- Learning checks not particularly helpful for system information, better for policy

5. eRA Commons Update

- SBIR RPPR and IRPPR have been released
- IRAM (Interim Request for Additional Materials) to be released soon
- PRAM to be updated with the option to request new Outcomes statement
    - It will not replace the submitted Outcomes in report
    - Requested Outcomes will be used for the publication only
    - Designed so that if the PO thinks initially submitted Outcomes in not appropriate for public consumption
- Going from IRPPR to FRPPR or vice versa is now automatic
- A lot of work has been done for partner agencies, notably for SAMHSA
- Change in language for Personal Profile (PPF)
    - Residency' have been changed to 'Post-Graduate Clinical Training.'
    - Part of the Next Generation Researchers Initiative
    - Information used to determine an investigator's eligibility as an Early Established Investigator (EEI) status
- Work on RPPR for Clinical Trials will be starting
- ORCID number on PPF will be updated to pull directly from the ORCID system
- Can FRPPR be made available for users with the ASST role?
    - That has come up before and is being looked into.
    - No timeline for availability as of yet
- Can EEI/ESI status be made available as part of the persons search for SOs?
    - Excellent idea, it will be brought to management for consideration