

eRA Commons Working Group (CWG) Meeting Notes

Next CWG Meeting
Tuesday, September 24, 201

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Omni Shoreham Hotel 12:30 PM - 2:00 PM

Room: TBD

Agenda Items:

1. Commons Update

Facilitator: Scarlett Gibb

Scarlett discussed recent issues with MyNCBI and progress reports. MyNCBI recently introduced a new system and while eRA and MyNCBi worked to ensure the integration between the two systems went well, there were some un-anticipated issues. It is believed all the primary issues have been addressed, however, if users experience a problem, please report to the <u>eRA Service Desk</u>.

The new Signing Official Status screen continues to be developed. Scarlett is coordinating with the working group on a date when a demo and review can done to show the progress and get additional feedback.

Question: Considering search options, can the ClinicalTrials.gov clinical trial ID number be included as a search variable?

Answer: Scarlett will add the suggestion to the development wish list.

How to Best Get Undergraduates to Complete their Personal Profile Information

Undergraduates are not providing key information on the Personal Profile that is needed for the progress report and aggregate reporting for the Biomedical Research Workforce initiative. This is particularly troublesome for trainees and their termination notices.

Some of the ideas discussed to help get trainees and undergraduates to complete the personal profile were:

- •NIH could create a new report feature that would indicate which users have incomplete personal profiles. In this way, undergraduates could be contacted and encouraged to the complete the missing information.
- •Some institutions withhold the student from the training program until the Personal Profile is complete.
- The Commons could send an automated email to the trainee to remind them to complete the profile when added to the RPPR and/or roster.
 - eRA now annually sends an email to users to remind them to check their profile and update as necessary. See NIH eRA Items of Interest August 2018
- Allow users to self-register to eRA Commons.
 - Institutions could require complete profiles before affiliating the account.
 - Shifts the burden to the trainee to get the information completed so they can be added to a grant.
 - Would need procedures to ensure accounts are not duplicated.
 - o Does this approach reduce burden for administrators?

The challenge is that institutions have different business processes with many different people attempting to manage the trainees and training grants, therefore, lots of variables to consider.

Question: Since these are undergrads, couldn't the profile be completed by someone else?

Answer: This information is considered Personally Identifiable Information (PII), particularly the demographic information that is need for the BMW initiative. The individual is the owner of that information unless they delegate the task to someone else.

Everyone agrees this an issue but a workable solution is difficult. If you have additional ideas, please contact Scarlett Gibb.

Scarlett to carry these ideas forward starting with the updates user report to provide users with incomplete profiles.

Question: Considering search options, can the CT.gov clinical trial ID number be

included as a search variable?

Answer: I don't see why not. (Scarlett to add to development list)

2. eSubmission/ASSIST Update

Facilitator: Laurie Roman

Tweaking validations on various aspects of ASSIST continue.

Rebranding ASSIST to Reduce Potential Confusion

This topic was discussed at the previous CWG meeting.

The team has taken 2 steps to reduce the confusion about being taken from Commons to ASSIST when clicking on the Human Subjects link in the RPPR.

- •Update the banner image for the Human Subjects System (HSS) for pages specific to human subjects reporting. This involved reducing ASSIST to its acronym in the banner and adding a header "Human Subjects" to the screen
- •Remove references to ASSIST in the on screen instructions and other instances of text information. Using "Human Subjects" vs "HSS" to match with terminology on the RPPR.

Is this enough given the context of accessing HSS?

•Make the human subjects header more prominent.

Everyone is in agreement that this is a step in the right direction.

Question: What about the search feature in ASSIST and accessing HSS data from within ASSIST?

Answer: The vast majority of users will access HSS from the RPPR screen. Only if a user took note of the unique application ID for the human subjects report would they get to the information from within ASSIST.

Suggestion from group: Why do Signing Officials (SOs) have to sign off (submit) HS inclusion data, or to create a new study record? There is no need for them to sign off on these items as they have no knowledge to determine if the information is accurate, appropriate, or necessary. PI's should be able to carry out these functions without the need of the engaging the SO.

We will take the suggestion back to see whether it is feasible from a policy perspective to develop an HSS delegation allowing PIs to submit HSS data.

Suggestion: There is one area of ASSIST that could use some evaluation for

changes, and that is identifying expired FOAs and FOA submission packages. A user had a case where it was not caught until the application has been submitted to Grants.gov that the opportunity had expired. ASSIST's pre-validation did not identify this error.

The issue is complicated in part because for any given application due date, there are allowable reasons to submit after the close date under out late application, system issue, and continuous submission policies. These exceptions are accommodated by setting a grace period in Grants.gov which allows applications to continue to flow through systems after the close date leaving acceptance decisions to agency staff. Grants.gov does not expose the grace period externally to ASSIST and S2S solutions making it difficult to identify when applications will no longer be accepted by Grants.gov. Many applications could receive a Warning even when the systems will process them. We need to be aware of the potential of creating more confusion in an attempt to address a less frequent scenario.

Laurie made a note to discuss this internally for a potential solution.

3. Moving Toward Requiring ORCID IDs for Trainees, Fellows and K Awardees and Appointees

Facilitators: Laurie Roman, Jennifer Sutton and Anastasiya Hardison

ORCID ID will be required for appointees to institutional training grants and other awards that make appointments through xTrain, beginning in October 2019.

Applicants for fellowships and individual K awards will be required to have ORCID IDs beginning with applications for due dates on and after January 25, 2020. eRA systems will validate that the ORCID ID is present in the personal profile of the PD/PI Commons ID included in the Credential field of the application. An error will be given if the ORCID ID is not present and the error must be cleared in order to successfully submit. To help raise awareness of this change, a warning will be given starting this fall and will be switched to an error in early January.

Comments to consider...

- Could the ORCID ID be included in the Person Module web service so S2S development could include data calls for it? (Yes)
- Could the ORCID ID be included as a search variable and as part of the data returned when searching for a user via the Account Management System (AMS)? (Yes)
- Need to caution users from accidently creating additional instances of ORCID IDs.
 ORCID folks are aware of this potential issue and are looking at ways to reduce the ability of users to create multiple IDs.
- Since the ID is designed to be a unique identifier, there is some discussion starting about adding new data to the Person Profile. Something along the line of:
 - o Aliases
 - Preferred Name(s)
 - Previous Name(s)
- There is no target date yet set to require the ID for other types of applications, but it is general agreed that that is the direction the process is going.

4. Encouraging Trainees to Complete Demographic Information for Better Aggregate Reporting

Facilitators: Anastasiya Hardison and Jennifer Sutton

Related to the previous discussion on getting trainees to complete their Personal Profile, there is a need for users to complete their demographic information. In particular this information is needed for the Training Diversity Report.

Of the reported undergraduate trainees, about 25% of them are selecting the "Do not wish to provide" option when it comes to demographic information. This creates a negative impact in trying to successfully monitor the diversity of the programs NIH offers. We need ways to encourage and or convince people to complete this information honestly.

Comments to consider...

- Could a pop-up dialog box be presented when completing the profile any time a user selected the "Do not wish to provide" option? The dialog box could be used to provide the rational and importance of the information.
- Why are they not providing it?
 - o Could it be they have the attitude of "None of your business!"?
 - Could they have concerns that the information may be used to track them specifically?
 - o Could they have concerns that the information may create bias in the review of their applications, or applications they are associated with as Key Personnel?
 - Do they have appropriate options? For example sexual identity. Is "male" and "female" enough?
- We have to use the guidelines and policies issue by OMB, so at this point other
 options are not permitted. It is also why we have to give them the "Do not wish
 to provide" option.

5. Alternate Approach to Provision of Sexual Harassment Statement in Institutional Support Letters for Training Grant Applications

Facilitators: Scarlett Gibb, Laurie Roman, Kristin Ta

This topic was discussed at the previous CWG meeting.

eRA will be adding a new section to the Institutional Profile (IPF) page. Here you will upload the Sexual Harassment Letter currently required to be submitted with each institutional training grant application to NIH.

The new process will require that a letter "that describes the institutional commitment to ensuring that proper policies, procedures, and oversight are in place to prevent discriminatory harassment and other discriminatory practices" is updated annually via the IPF.

Validations will be included that will create an error if the letter does not exist or that the annual renewal period has lapsed.

Like the System for Award Management (SAM) expiration, an email notification will be sent to the Institutional Contact as listed on the IPF reminding of the pending expiration of the letter. A new letter, appropriately dated, will need to be uploaded.

This feature is scheduled to be implemented in October 2019.

6. Implications of Moving Away from Commons as Submission Option for Administrative Supplements

Facilitator: Laurie Roman

There are currently five methods for requesting Administrative Supplements:

- 1. Grants.gov Workspace
- 2. eRA Commons Admin Supp option
- 3. System-to-System solutions
- 4. ASSIST
- 5. Paper (actually typically by email and PDF submitted directly to the agency)

The "paper" option will be going away in an effort to make the process more consistent across all NIH agencies. An electronic submission solution will provide more accountability and tracking for such requests.

The question is, "What would the impact be if the eRA Commons solution was also eliminated?"

- To most S2S users, there would be no impact whatsoever. S2S systems have the advantage of pulling more info from the institution to complete the application and pre-fill much of the data.
- ASSIST, workspace and S2S systems can copy applications, and provides the pre-submission validation capability.
- eRA Commons option is not preferable and frequently does not provide the agency with all the information they are seeking.
- Without having to describe paper and eRA Commons submission methods, FOA instructions could be streamlined to a single set of instructions to address submission through Grants.gov via ASSIST, S2S or Workspace.

Admin Supplements via Commons are problematic when responding to a Notice of Special Interest (NOSI). NOSIs highlight areas of interest and then point to active FOAs for the submission of applications. They often include instructions for Research Strategy and other attachments that aren't available for Commons submissions. They also require the NOSI notice number in the Agency Routing Identifier field (SF424 R&R form, item 4b) which is also not currently available for Commons submissions. Without the notice number applications cannot be appropriate tracked.

Some concerns...

- If the paper and eRA Commons options are eliminated, there may be a need to bypass the 2 day viewing period to reduce the time the submissions are available to IC staff who offer a very small window of opportunity to submit the supplement For example, one option would be to:
 - Have a button that permits the application to be pushed forward
 - "I have reviewed the application image, submit to agency immediately."
- We need to improve internal communications, some ICs will only accept the "paper" process because their staff are not aware of all of the available submission method options and confuse the electronic processes not understand the difference between ASSIST and Commons.
- S2S providers have a hard time testing the supplement submission process in UAT because they have little award data to test against in UAT.

General Discussion/Wrap-up

Some general comments and requests:

Get SROs to send additional materials requests to the SO, not just the PI. The PI frequently does not look at the request until the last minute, creating a bit of a panic. And as NIH is fond of saying, we award to an institution, not a person, so the institutional representative should be included in these communications.

Question: Would it be possible to auto-populate UAT with review data, such as bogus review meeting, study section, assigned IC, etc. for more thorough end to end testing of the grant process?

Answer: It should be.

Comment: There seems to be an issue with ClinicalTrials.gov data and the integration with Commons. Correct ClinicalTrials.gov data is not matching with information in Commons.

How does NIH integrate with ClinicalTrials.gov?

Response: In the June release improvements will be made in the integration. Laurie and Scarlett will coordinate a conference call with S2Sers on the integration parameters.

Question: What are OTAs? Financial Assistance?? There seems to be no appropriate federal classification for OTAs. They are not grants, and they are not contracts since they don't follow the policies for either. Are they reported as CFDA (Catalog of Federal Domestic Assistance)?

Answer: OTAs are specific to themselves. They are their own classification.

Changes are coming this fall in the HSCT form to better manage human subjects and human specimen information. Changes are set to go to OMB in June for review.

Question: Can someone help with a Pooled Account issue as related to a corrected overdraft?

Answer: Kristen Ta requested to be emailed about the specifics and try to coordinate with Payment