



eRA Commons Working Group (CWG) Meeting Notes

Agenda Items:

1. Commons Update

Since the last meeting, there has been significant work done with partner agencies and behind the scenes updates. Due to an upcoming security audit, security has been a big focus, so if you find you cannot access something you used to be able to access, it may be a result of these changes. Contact the Service Desk if you have questions or concerns.

Because of the security work and changes for partner agencies, updating the Signing Official Status screen has been delayed. The hope is come back to it next month for another working group meeting. It should be noted that the new features and layout are fantastic in no small part to those of you who have volunteered time and input to the process. So, thank you.

Additional work has been done as eRA has been moving to the cloud environment.

And for partner agencies:

- Closeout is now being used for the VA and FDA
- SAMHSA will soon be transitioning to the Closeout module as well
- CDC now has the ability to process multi-component RPPRs
- The Prior Approval module now supports Change of PD/PI, Carryover, and No-Cost-Extension for the FDA

Another new feature includes the ability to reassign a grant to a new/different department during the pre-award process. Once an application has been assigned to an IC for review, and SO can reassign the application to a different department within the applicant organization.

Life Cycle Certification is now required for SBIR/STTR applications as an upload.

ESI (Early Stage Investigator) extension request is being re-built to take advantage of the Commons' Prior Approval module

2. eSubmission/ASSIST Update

Most recently we have been doing a lot of work on the Human Subjects Clinical Trial Information form validations as they apply to RPPRs and HSS data. Your feedback is requested and appreciated, as always.

A new feature in ASSIST is being rolled out at the end of February that allows an SO or AO or other designated individual to override a locked application before the 45 minute wait period has expired. A new privilege is being added to the manage access screen that will allow the SO to control who can carry out the override activity. [Note: this is a slight change from the CWG discussion. We took into account the comments regarding ASSIST Access Maintainer.

Additional work is being done to integrate HSS and ClinicalTrials.gov data to be able to export data out as XML for easy integration into other systems. This will be done by the person at the institution with access to ClinicalTrials.gov.

Question: Could we have a Commons role for ASSIST to deal with ClinicalTrials.gov registration process?

Back on December 12, 2018, the system that creates the application image in ASSIST was changed to address various technical issues. The decommissioning of the old system will result in application image previews created before December 12 to be lost. To see a preview again, you will have to generate a new preview. If you have any concerns about this, please contact [Laurie Roman](#).

3. User Acceptance Testing Upgrade

This summer, we plan to move from ASPOSE to iTEXT, initially in the UAT environment. Laurie is looking for people to assist with submitting application with technically complex application data. Specifically looking for applications that include complex equation, complex graphs, etc. [Contact Laurie](#) if interested in helping.

[Laurie is also looking at input](#) for bookmarking the HSCT form for easier navigation.

As stated earlier, eRA services are moving to the cloud. One of the systems to be impacted by this move is UAT. When the move is made in Mid February, UAT will be refreshed and you will have access to more recent production data, however:

Old data will be lost

- External (production accounts affiliated with your institution and passwords will be maintained
- Commons Demo accounts will be removed
- Non-production institutions (institutions you created within the system for testing) will be lost
- Production (real) institutions will remain
- Laurie will check to see if old UAT opportunities will still be available. YES THEY WILL

Also looking for input:

- What actions or status changes would help make UAT more helpful?
- Having HSS data available in UAT?
- The ability to get into ASSIST from UAT to practice and play with uploads?
- If there was a way to complete review/study section information to make it look more real and thus set user expectations better
- How much time do you need before the move is made and UAT is refreshed with newer data?

[Contact Laurie](#) if you have additional comments/concerns.

4. Results of Age Inclusion Pilot

We have only received a single piece of feedback on the age inclusion pilot. Feedback is encouraged to help us refine the implementation. First real impact will be seen this spring as the first RPPRs will be due.

There are some concerns about the delegation of submission of HSS data. Currently if a PI is provided the Submit delegation, they can submit both the RPPR and HSS reports. However, some institutions need HSS data to be submitted by the PI, not the SO, but do not want to permit the PI to submit RPPRs.

The challenge is that submitting HSS is more than information concerning Planned vs Actual Enrollment, but could include adding an entirely new study, which needs SO approval. The issue is what happens with mid-cycle submissions and the need for 2 paths for SO approval. The desire would be not to need SO approval for mid-cycle changes.

Couldn't the submission of the RPPR automatically go and fetch the most recent HSS data for that investigation? Regardless of the status?

Currently, SOs are just "rubber stamping" the HSS info since the PIs have the understanding of the impact of the changes, or adding a study. What is it that policy thinks the SO are looking for and what needs their approval?

We will need to get input from policy to understand better what is feasible and required as it relates to the submission of HSS information in the RPPR.

HSS Notifications: Question: Who is supposed to receive HSS submission notification? How is the SO that is notified selected? It is supposed to be the SO that is assigned to the application. Suggestion: It would be nice if any SO can assign the RPPR/HSS report to any other SO. Also an option for a centralized mailbox where staff could route the submission request to the appropriate SO.

Suggestion: Another wish-list item would be how we refer to the “Enrollment” update requirement for existing studies. PI tend view enrollment as adding new subjects. Having a button that would permit them to use pre-existing data would help, and if awarded NIH should remove the reminder for updates.

HSS Branding in ASSIST

Does ASSIST branding (banner) in HSS confuse people?

- People initially think they are brought to the wrong place.
- Yes, to some extent, although most get over it.
- The change in URLs is confusing for those who notice.
- Could the screens have watermark added?
- Could the banners be updated for HSS?

It might be possible to provide some communications, and a video if needed.

5. Inclusion of Sexual Harassment Statement in Institutional Support Letters for Training Grant Applications

Originally NIH issued a policy notice stating that a separate letter of institutional support was required, and then NIH issued a second notice saying that the information should be combined into a single letter.

Suggestion: Since the requirements come from different departments or divisions of an institution, two separate letters was easier than one.

Suggestion: It is significant burden to have to provide the letter(s) with each application. A more streamlined approach would be to provide the letters as a certification or assurance. Possibly this could be done as part of the Institutional Profile and renewed on a yearly basis.

6. Follow Up on Discussion of Inclusion of Central Post-award Email Option in Institutional Profile

Post award notifications:

While the last CWG meeting there was discussion about a potential need for the ability for institutions to designate separate mailboxes for various post award notifications, at this meeting it was agreed that this was not the top of the priority list.

Suggestion: All these notices look very much alike, for example the “Ready for Submission...” for HSS is almost identical in subject line and content as the ASSIST ready to submit. One is easily ignored and the other should not be ignored. So the language and subject lines of all notifications should be reviewed to make sure they are all unique enough to be easily distinguished from each other.

Unfunded application notifications.

Suggestion: NIH could send a batch notification rather than individual notifications of applications that are not funded. It could include a table of:

- Application ID
- PI name
- Title (truncated to fit table)
- Submission date, and
- Status (aka Not Discussed, etc.)

It could state that currently the following applications are not to be funded....

Table could be in message body or attached as a spreadsheet for easier sharing and manipulation. The timing could be possibly after each council round (4x a year) and after 13 months of the original submission date (ensuring the application is not picked up later).

The notification could be sent to the AOR on record, possibly the SO and possibly the NoA address on the Institutional Profile. And extensive discussion and testing on notifications should be done.

For suggestions and comments, please contact [Kaneisha Akinpelumi](#).

7. Redesign of eRA Informational Website

After a yearlong survey of users using Foresee, the eRA (<https://era.nih.gov>) website is in the process of being redesigned. Targeting release in late spring.

- More intuitive navigation
- Main screenshots of systems added to help figure out process at a glance

- Commons/ASSIST log-in buttons moved to prominent location on upper right-hand corner of home page.
- Hover drop-down menus added to menu topics on home page to provide a glimpse of inside content
- Designed for improved accessibility (508 compliant)
- Direct links to system tasks where possible
- Dynamically resizes for mobile, tablet use

Note: URLs changing; please remember to change bookmarks after launch (temporary redirects from frequently used pages will be in place)

Feedback always welcome! Send comments/questions to eRACommunications@mail.nih.gov

8. General Discussion/Wrap-up

xTrain functionality

Question: When a Business Official (BO) leaves, what can be done with Termination Notices (TN) that are awaiting processing by that person?

Answer: The PI can recall the TN and reassign it to another BO.

Could the system be updated so that an SO or BO can access it and reassign it directly without the PI having to take action?

Next Meeting (tentative)

Tuesday, May 21, 2019

12:30-2:00 p.m.

Room: **TBA**

The Omni Shoreham Hotel

2500 Calvert Street, NW

Washington, DC 20008