Transcript - View, Edit & Submit Human Subjects Studies

Welcome to this video tutorial on how to view, edit and submit Human Subject Studies through the Human Subjects System (HSS).

A principal investigator or signing official may need to edit an existing human subjects study record for:

- Post-award for updates to the Research Performance Progress Report (RPPR)
- Pre-award (post review) for just-in-time information or correction of human subjects data
- Off-cycle updates as required in the Funding Opportunity Announcement or terms and conditions of award.

To edit an existing study, log into eRA Commons and access the Human Subjects link via the Status or RPPR tabs.

3-1. From the Status tab search for the desired award and in the Action column you will find the Human Subjects Link. From the RPPR tab, find the desired award. Click Edit, and navigate to tab G. If the award is a human subjects or clinical trials opportunity, the Human Subjects link will appear in section G.4.b. Click the Human subjects link.

The Application Information screen is displayed, showing a summary of your grant. Click on the *Human Subjects Post Submission* tab. This will take you to a summary page *Study Record(s)* screen where all study records and delayed onset studies associated with your grant are displayed.

Click on the **View** button to bring up a particular study.

To update the human subjects information on that study, including inclusion enrollment data, click the **Edit** button at the top of the screen.

Inclusion data is found at the end of Section 2

There are two ways to edit data in the existing Inclusion Enrollment Report (IER) for Cumulative (or Actual) counts:
- By clicking the Edit button, you can update the cells online in the existing report itself, by typing in the fields.
- Or you can download a spreadsheet template for entering participant-level data by clicking on the '*Download Participant Level Data Template*' button.

- Fill the template out with data — race, ethnicity, sex or gender, age at enrollment, and age unit. Age at enrollment may be reported in units ranging from hours to years. Please do not change the template format in any way. Altering the format or category titles will cause an error in uploading.
- Then upload the spreadsheet by clicking on the '*Upload Participant Level Data Attachment*' button. This uploaded data will populate the cells in the report.
- You can click on the '*Download Current Participant Level Data*' button to download the file containing the data for your own records.

Some Notes to consider:
If you plan to upload the data, you must use the template.

Individual-level participant data on sex/gender, race, ethnicity and age at enrollment are required in progress reports for competitive applications submitted for due dates on or after January 25, 2019 (See NIH Guide Notice NOT-OD-18-116). Since NIH will be piloting the process of providing individual level data starting in June, we encourage you to get familiar with the template as we believe it will cut down on duplicate entry and save you time.

For the Planned counts, the data cells must be updated online in the report itself.

The entire study can be previewed before submission by clicking on the **Preview Current Study** button on the left navigational column under Actions.

If the PI is making changes:

- The PI can click the **Save and Release Lock** button to save the changes.
- The submission status then changes to *Work in Progress.*
- PI then updates the status to '*Ready for Submission*.'
- SO logs into the system, clicks the Pending Human Subjects Action link, on the Status page. The search screen in HSS is presented, and allows SOs to search for post submission/human subject submissions that are ready to submit.
- Once the application is found, the SO clicks the Submit button.

If the SO is making changes:

- The SO can click the **Save and Keep Lock** button to save the changes.
- The submission status changes to *Work in Progress.*
- SO changes status to '*Ready for Submission*.'
- The 'Submit' action button becomes active on the Application Information page.
- SO clicks on the Submit button

Only the SO can submit the application to NIH. The submission sends all updated study records associated with the application to NIH at one time.

Program officials and grant specialists are notified automatically of study changes and can review those changes. Some changes may require prior approval.

Several resources are available to assist you with the Human Subjects System (HSS). Please visit the Human Subjects System Overview page at: https://era.nih.gov/hss_overview.cfm

And the HSS Training page at https://era.nih.gov/hss_training.htm

This concludes this tutorial on 'How to Edit, View, and Submit Human Subjects Studies.' Thank you for watching.