Human Subjects System (HSS) for Institution Staff User Guide

May 11, 2023

NOTE: This user guide is an identical PDF version of the online help.

2 Contact Us

Additional Help Needed? Please contact the eRA Service Desk (https://www.era.nih.gov/need-help).

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Hours: Mon-Fri, 7:00 a.m. to 8:00 p.m. Eastern Time

Feedback on the user guide? Please email the eRA Communications Office (era-communications@mail.nih.gov).

Disclaimer STATEMENT

No data shown in illustrations represents any real account, project, or individual. Any resemblance to actual accounts, projects, or individuals is purely coincidental.

2 Latest Updates

May 25, 2022

Updated Roles & Privileges page.

March 17, 2022

Documentation Refresh.

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1 The Human Subjects System (HSS)

Purpose

The HSS system is a shared system that enables grant recipients to electronically update study data on human subjects and clinical trials and report that data to NIH. It also enables agency staff to monitor and manage that data.

The HSS is automatically populated by human subjects and clinical trial data entered by the principal investigator on the Human Subjects and Clinical Trial Information form in applications submitted for due dates of January 25, 2018 and beyond. This data is then made available to PIs and signing officials through a Human Subjects link that is available on the eRA Commons Status screen and the Research Performance Progress Report (RPPR).

Key Changes

1. NIH migrated enrollment records in IMS to HSS. ***Updates to enrollment records must have been submitted to NIH no later than June 8, 2018 or entered in HSS***. Updates not submitted by June 8, 2018 are not available in HSS and must be re-entered.
2. Grant recipients completing an RPPR (Research Progress Performance Report) are prompted to access HSS to update inclusion enrollment reports. Recipients can access the system through the Human Subjects link in the RPPR or the eRA Commons Status page.
3. *Section 6: Clinical Trial Milestone Plan* is intended for use in progress reports for competing applications submitted on or after January 25, 2018 and is required for clinical trials unless otherwise noted in the Funding Opportunity Announcement or terms and conditions of award. Recipients should refer to the RPPR Instruction Guide for guidance.

4. The HSS system includes a new interface and workflow. When submitting studies to the funding agency, Signing Officials (or delegated contact PIs) submit all study records associated with an application at one time rather than separately.
5. Participant-level sex/gender, race, ethnicity and age data may be submitted in a CSV file to populate the Inclusion Enrollment Report. Participant level data is required for applications submitted January 25, 2019 or later. See NOT-OD-116 for additional information.
6. Investigators and signing officials may make study updates or corrections (including just-in-time or off-cycle updates) by accessing HSS through the Human Subjects link in the eRA Commons Status page. Some changes, including those involving increased risk to human participants, may require prior approval by NIH.

How NIH Grantees Use HSS

Depending on their roles and privileges, grantees can use the Human Subjects system to:

- Edit existing studies
- Add studies
- Convert Delayed Onset studies

Resources

Additional resources such as video tutorials, crosswalk, and infographic on the Human Subjects System (HSS) are available at https://era.nih.gov/help-tutorials/hss/era-training-hss.htm?q=help-tutorials/era-training-hss.htm.

Additional information about the HHS Human Subjects and Clinical Trials Information form is available at https://grants.nih.gov/policy/clinical-trials/new-human-subject-clinical-trial-info-form.htm.

2 Access Human Subjects System (HSS)

The *Human Subjects System* can be accessed by Principal Investigators (PIs) or Signing Officials (SOs) through either the RPPR or through the *Status* screen in eRA Commons

Human subjects information might need to be updated in the following scenarios:

- 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
- Corrections to human subject data

Here is a quick summary of the ways HSS can be accessed (more detailed instructions follow):

- SO: Status tab > General Search screen > Specific Award >Action column > Human Subjects Link
- PI: Status tab > Status – PI Search screen > Status Result – List of Applications/Awards screen > Specific Award >Action column > Human Subjects Link
- Both: RPPR tab > Manage RPPR > Specific Grant > RPPR Menu screen > Edit button > Inclusion Section (G.4.b) > Human Subjects Link

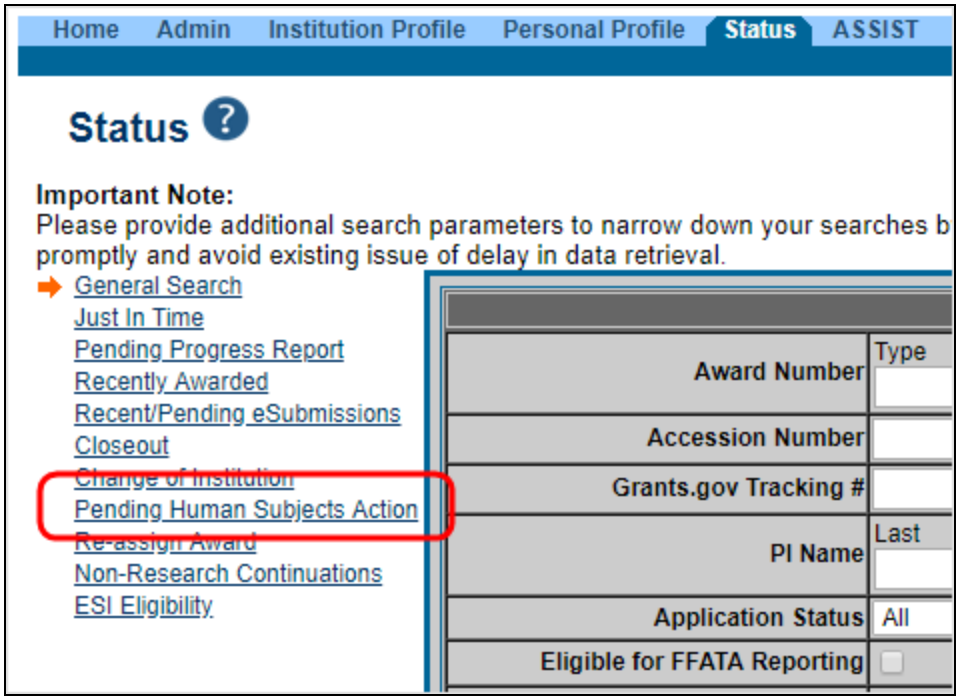
Each method results in access, via HSCT Post Submission, to information in regular study records, such as inclusion enrollment reports. Delayed onset study records are also accessible.

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

Access via Status

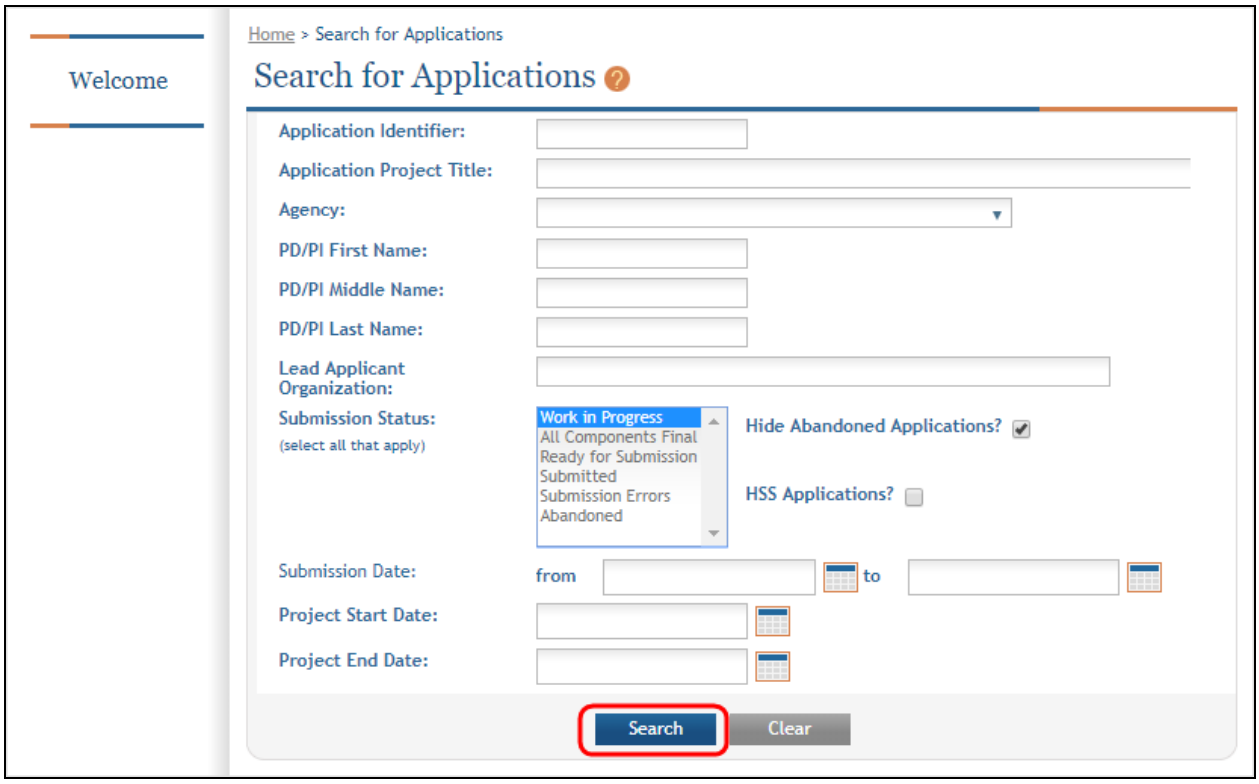
SOs

- SOs see a link on the *Status* page for **Pending Human Subjects Action**. .

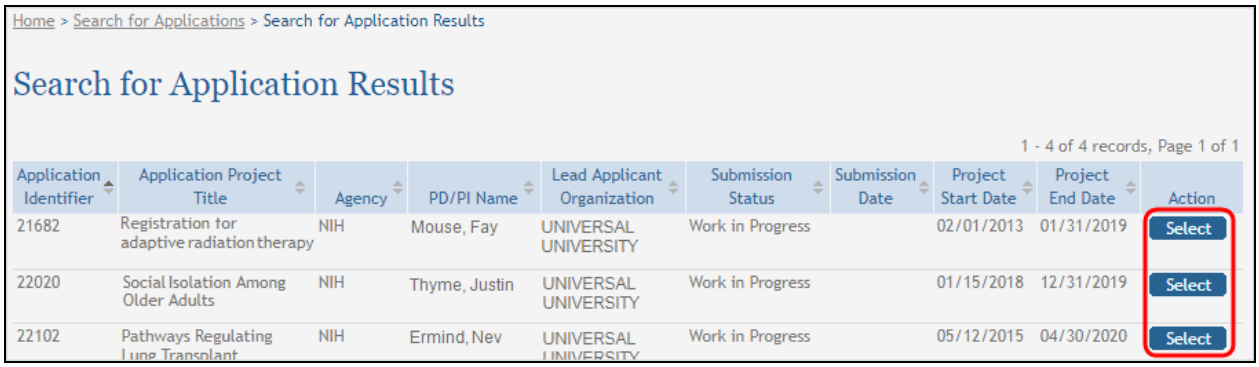


- Select the *Pending Human Subjects Action* link to be taken to the *Search for Applications* screen. On this screen, you can search via a submission status or use additional details

to narrow the search results.

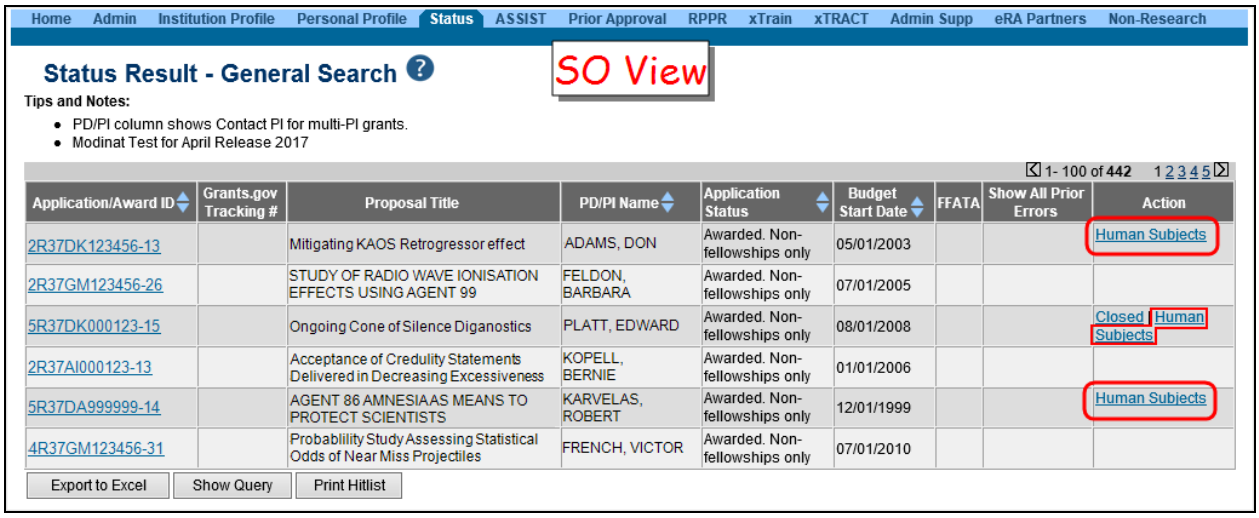


- On the resulting search results, click the **Select** button. The application summary page is displayed.



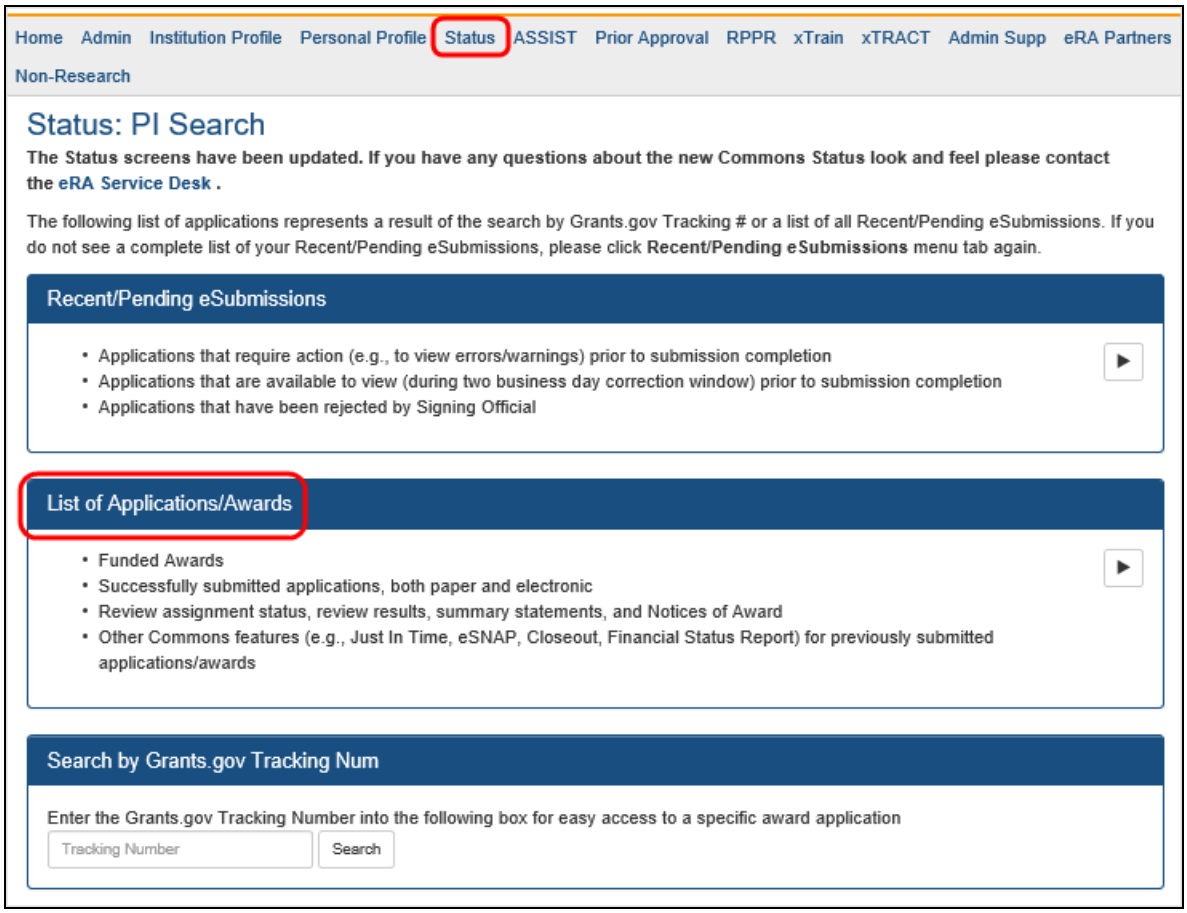
- Additionally, the SO can use the *General Search* on the *Status* screen to find a list of

applications and then select the *Human Subjects* link in the *Action* column.



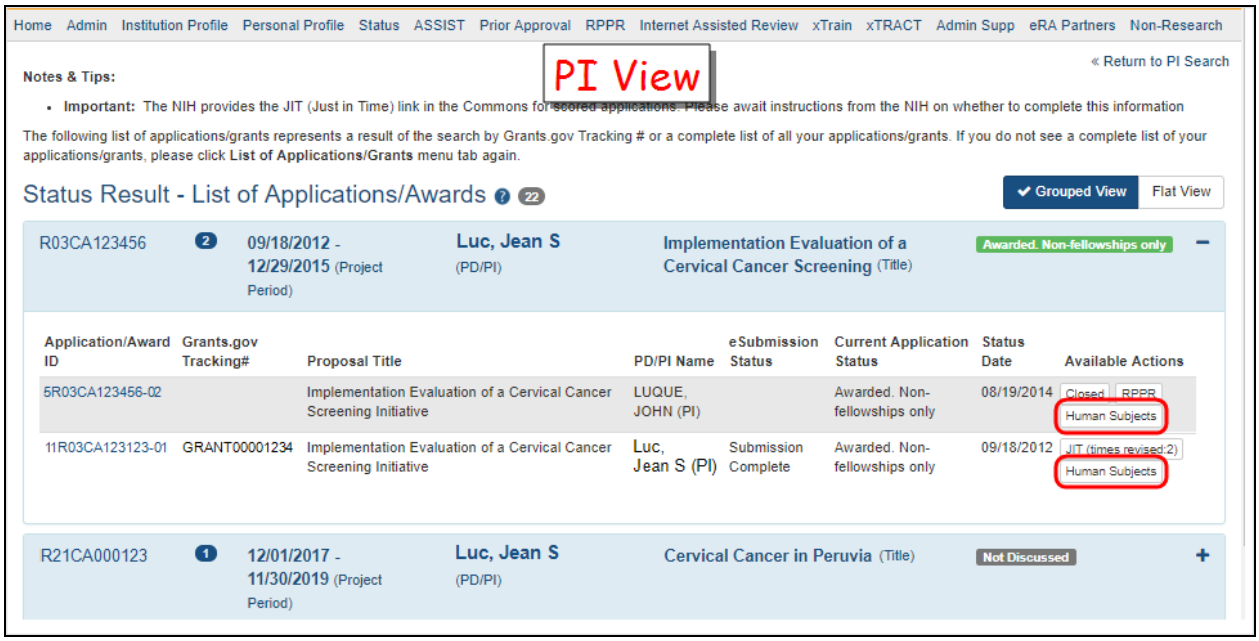
PIs

- A PI can click on the *Status* tab and then on *List of Applications/Awards* to see a list of their applications.



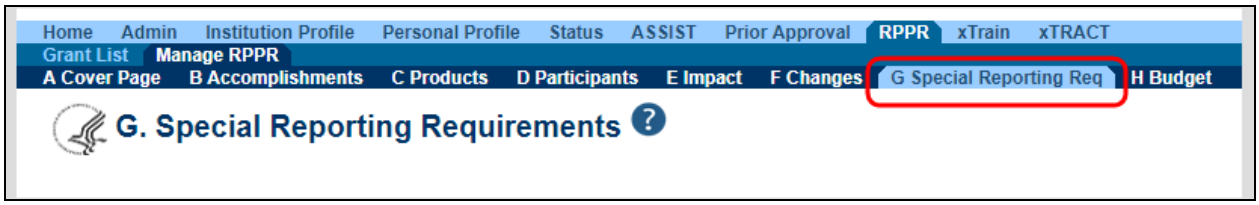
- The resulting search results have a **Human Subjects** button in the **Available Actions** column on those applications with exempt or non-exempt human subjects research. Selecting the **Human Subjects** button opens the Summary page for that application with the HSCT Post Submission tab available to access the human subjects data and make necessary updates, such as updates to Inclusion Enrollment Reports (IERs). IERs replace the Inclusion Data Records (IDRs) used in the prior inclusion management sys-

tem.

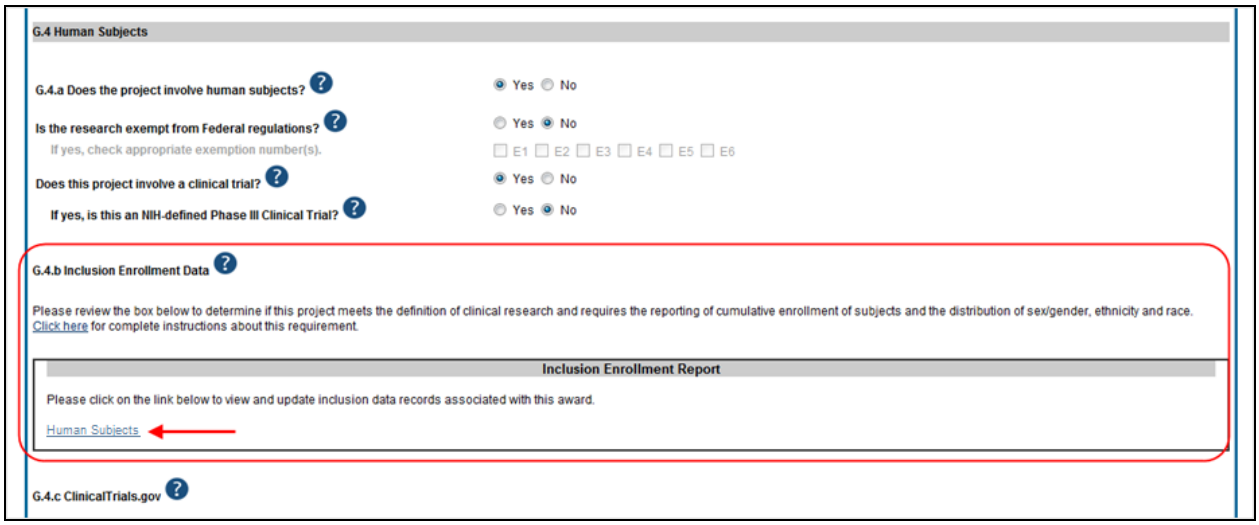


Access via RPPR

To Access HSS via an RPPR, select the *RPPR* tab and then, in the *Edit* view, select the tab labeled, *G Special Reporting Req*.

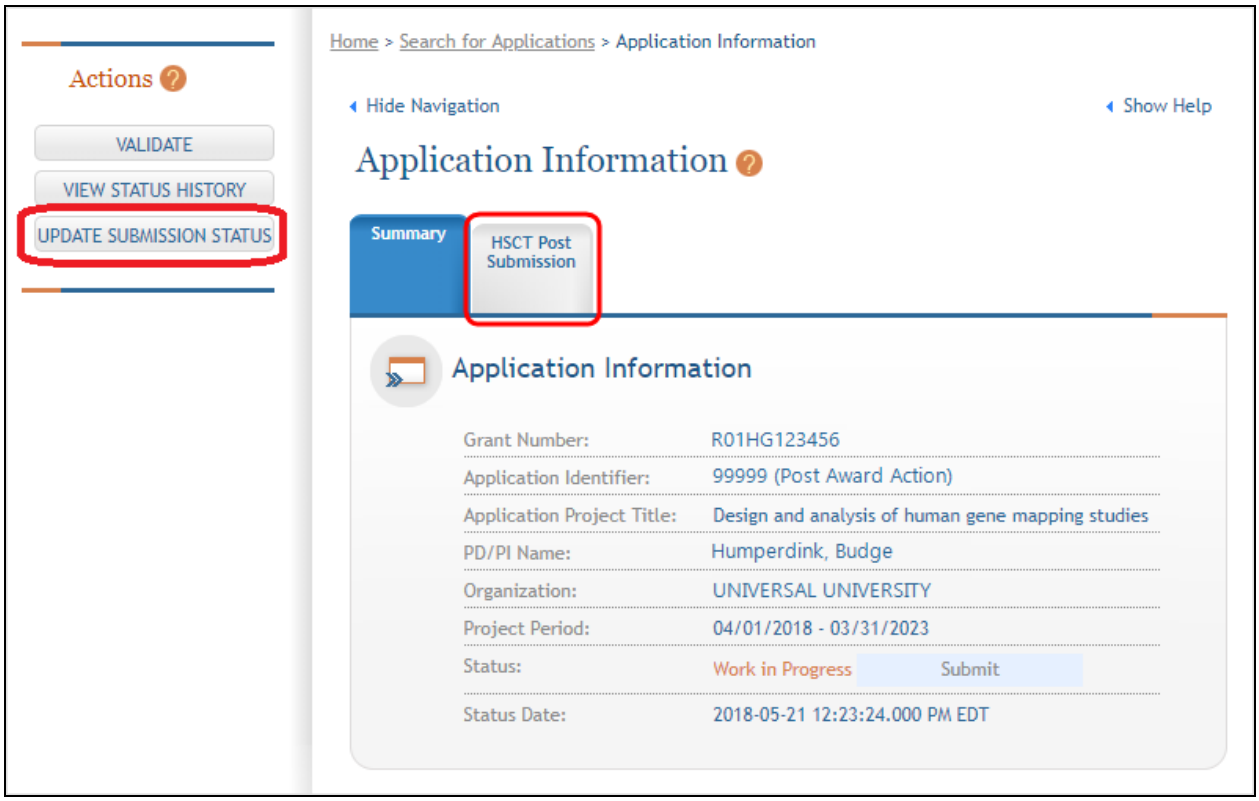


After selecting the GSpecial Reporting Req tab, scroll down to section G.4.b Inclusion Enrollment Data and then select the link for Human Subjects.



The above methods take the user to the *Application Information* screen and provide access to the *HSCT Post Submission* tab.

Click on the *HSCT Post Submission* tab. This takes you to a *Study Record(s)* screen where all study records and delayed onset studies associated with your grant are displayed.



NOTE: Click the **Update Submission Status** button if you want to change the Status to "Work in Progress" in order to edit the application.

3 Crosswalk Between IMS & HSS

There are differences in the way that inclusion data were accessed and managed in the retired IMS module compared to HSS. Please see this handy resource to figure out the differences.

Crosswalk between the Inclusion Management System and HSS - Word; May 16, 2018

4 Editing Studies

In order to edit study information, the principal investigators (PIs) or signing officials (SOs) can access the HSCT form using the *Human Subjects* links in either the RPPR or through the *Status* screen in eRA Commons. Refer to Access Human Subjects System (HSS) for details.

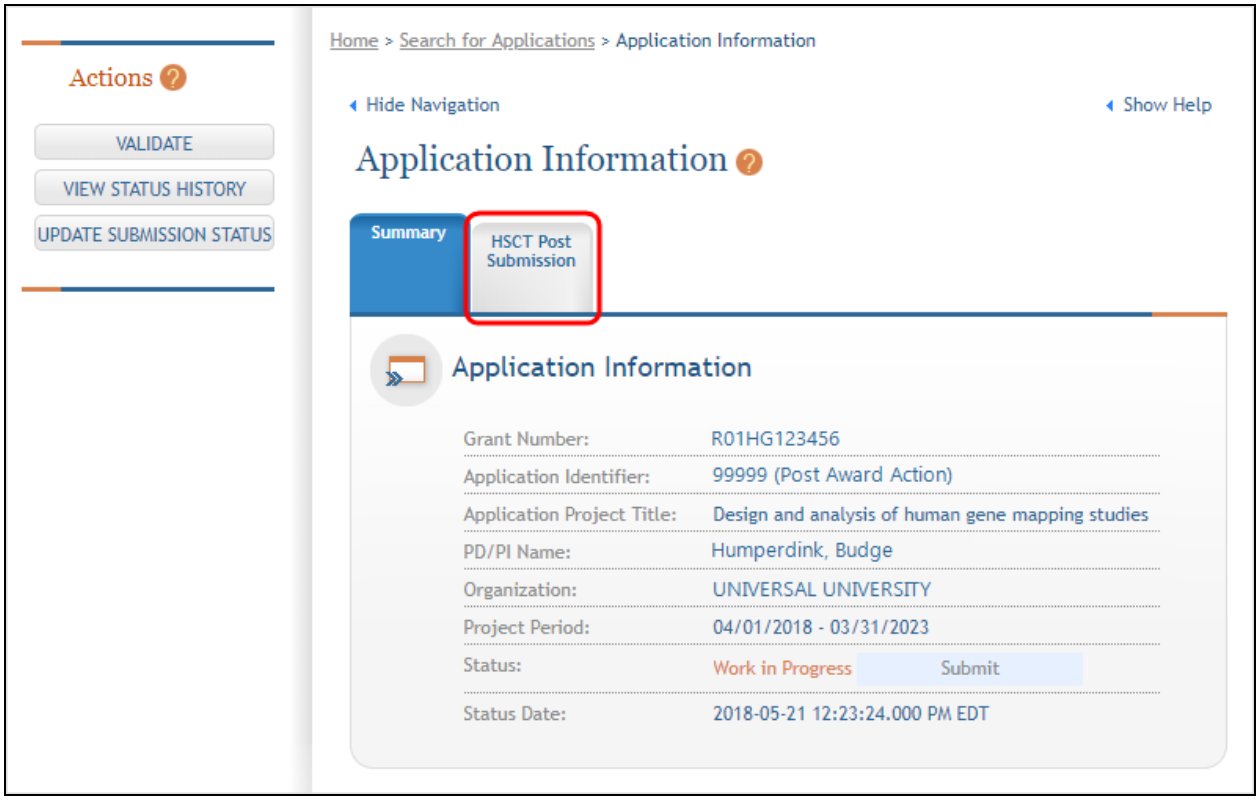
Human subjects information might need to be updated in the following scenarios:

- Post-award for updates to the Research Performance Progress Report (RPPR), *including updates to inclusion enrollment reports and the Clinical Trial Milestone Plan (Section 6)*
- Pre-award (post review) for *Just-in-Time (JIT)* information or correction of human subjects data
- Off-cycle updates as required in the *Funding Opportunity Announcement (FOA)* or terms and conditions of award

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

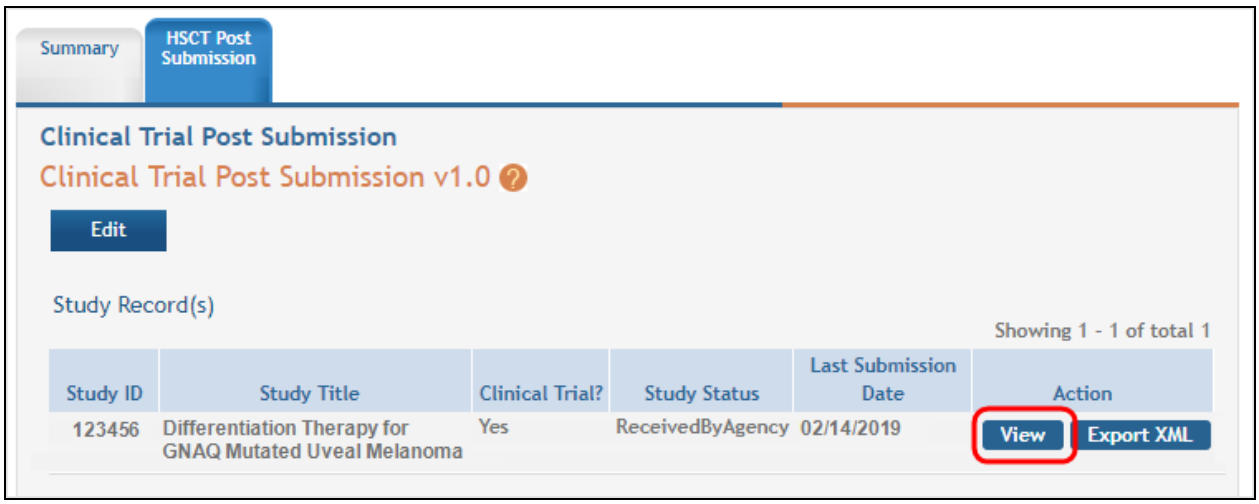
The *Application Information* screen is displayed, showing a summary of your grant. You have two ways of accessing and editing the study data. Both begin by accessing the *HSCT Post Submission* tab.

Click on the *Human Subjects Post Submission* tab. This takes you to a *Study Record(s)* screen where all study records and delayed onset studies associated with your grant are displayed.
Note: In order to edit, the HSS record must be in Work in Progress status. See How To Change the Application Status and Resubmit for instructions on updating the status.

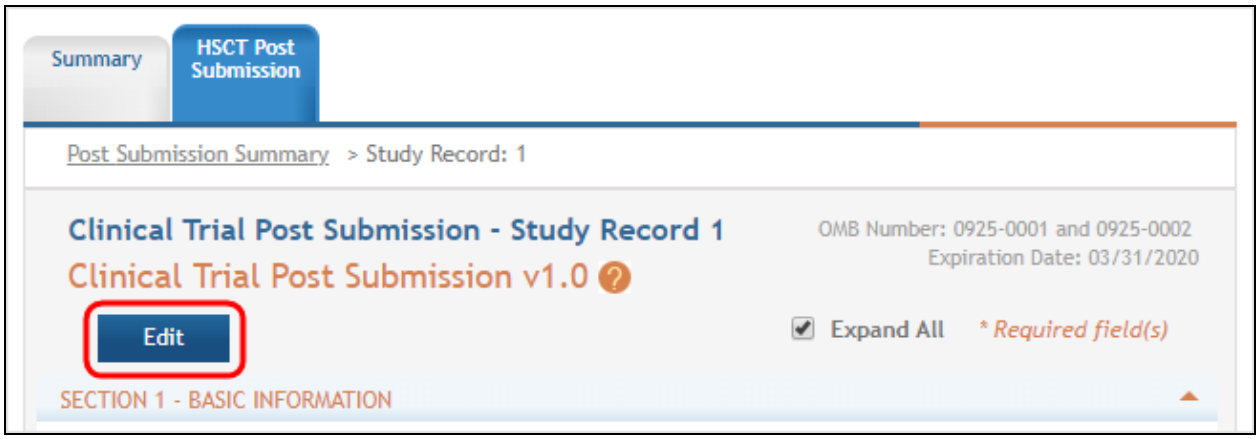

Actions
VALIDATE
VIEW STATUS HISTORY
UPDATE SUBMISSION STATUS
Home > Search for Applications > Application Information
Hide Navigation
Show Help
Application Information
Summary
HSCT Post Submission
Application Information
Grant Number: R01HG123456
Application Identifier: 99999 (Post Award Action)
Application Project Title: Design and analysis of human gene mapping studies
PD/PI Name: Humperdink, Budge
Organization: UNIVERSAL UNIVERSITY
Project Period: 04/01/2018 - 03/31/2023
Status: Work in Progress Submit
Status Date: 2018-05-21 12:23:24.000 PM EDT

Option 1

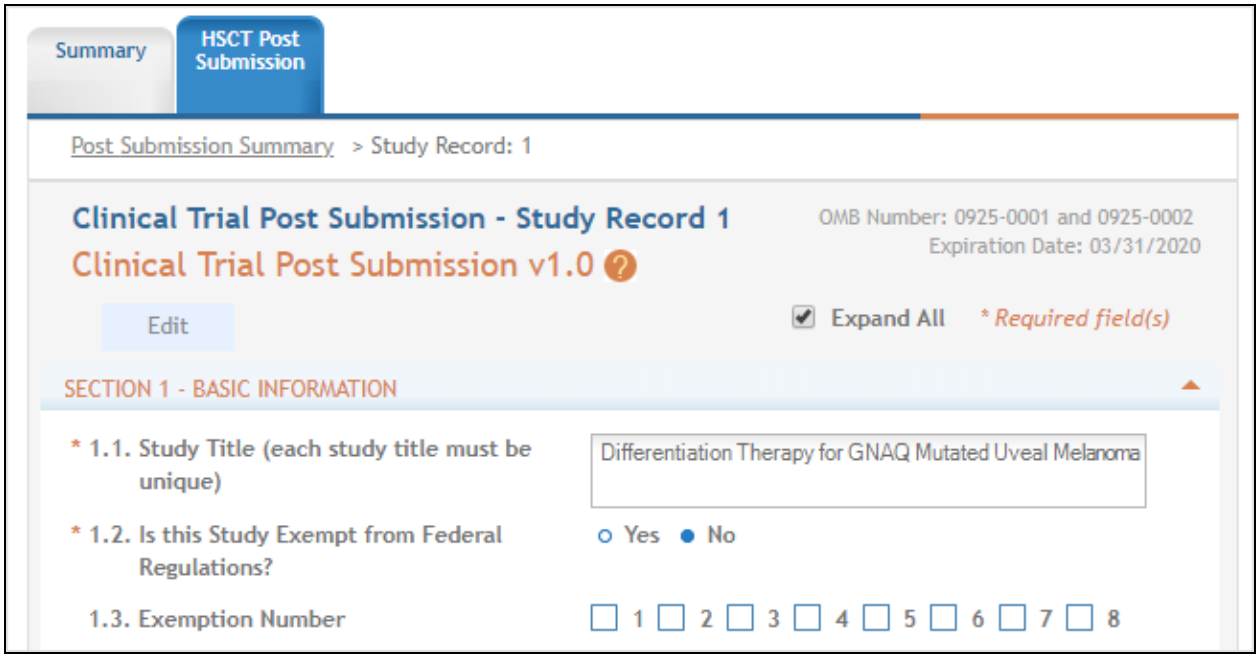
- Click on the **View** button to open the study record data.



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

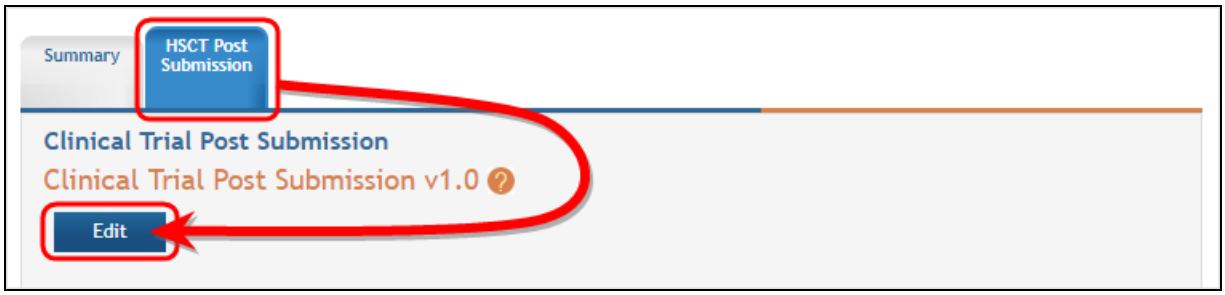


- The study record is opened and the fields can be updated.



Option 2

- Select the *HSCT Post Submission* tab and then click on the **Edit** button. (click to view)



- Now you see that the existing study has an **Edit** button available and there are additional buttons to add regular or delayed onset studies.

Summary | HSCT Post Submission

Clinical Trial Post Submission

Clinical Trial Post Submission v1.0

Edit

Study Record(s) **Add New Study**

Showing 1 - 1 of total 1

Study ID	Study Title	Clinical Trial?	Study Status	Last Submission Date	Action
123123	Research Consortium of HPV-related Cervical Cancer	Yes	WorkInProgress	03/29/2018	Edit View

Delayed Onset Study(ies) **Add New Delayed Onset Study**

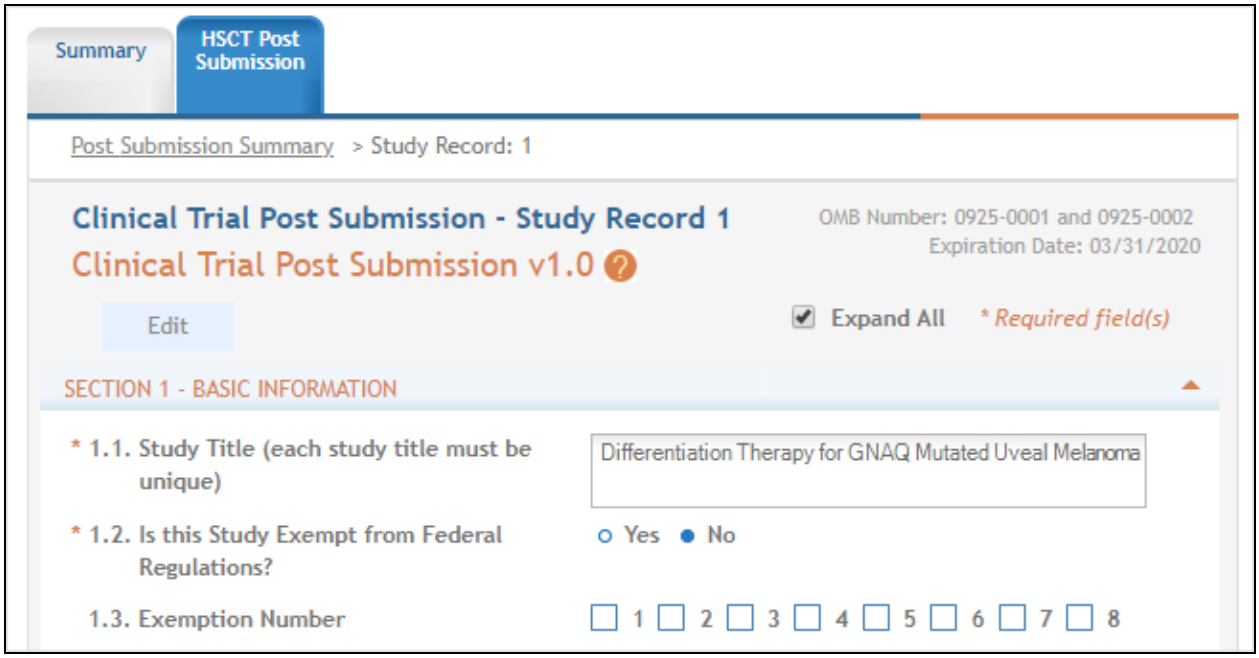
Study ID	Study Title	Anticipated Clinical Trial?	Justification	Last Submission Date	Delete on save	Add/Update Attachment	View Attachment	Action
Nothing found to display								

Associated Studies Reported on Other Projects

Study ID	Study Title	Clinical Trial?	Last Submission Date	Reporting Project	Action
Nothing found to display					

Save and Keep Lock | Save and Release Lock | Cancel and Release Lock

- Select the **Edit** button for the existing study to open the edit screen.



Editing Clinical Trial Information

Several fields in HSS are mapped to ClinicalTrials.gov to support clinical trial registration and reporting compliance. These fields include:

- 2.1 Conditions or Focus of Study
- 2.2 Eligibility Criteria
- 2.3 age Limits
- 2.6 Recruitment Status
- 4.1 Detailed Description
- 4.1.b. Primary Purpose
- 4.1.c. Interventions
- 4.1.d. Study Phase
- 4.1.e. Intervention Model

- 4.1.f. Masking
- 4.1.g. Allocation
- 4.2 Outcome Measures

See the application guide for more information. Generally, it is best to keep ClinicalTrials.gov information up-to-date and update HSS with this information as necessitated by the FOA or the terms and conditions of the award.

Exporting HSS data for ClinicalTrials.gov registration

If HSS data entry occurred before ClinicalTrials.gov registration, the clinical trial data in HSS can be used to initiate registration in ClinicalTrials.gov. See the ASSIST Online Help, Export and Upload Data to ClinicalTrials.gov for instructions.

Using the Populate button to update clinical trial data

After a clinical trial has been registered in ClinicalTrials.gov, HSS fields that map to ClinicalTrials.gov can be updated with the information available in ClinicalTrials.gov.

1. To perform this task, the ClinicalTrials.gov identifier (NCT number) should be entered in the field numbered 1.5.
2. Next, select the **Populate** button as shown below and the system does a best effort copy of form data from the official Clinical Trials records.

SECTION 1 - BASIC INFORMATION

* 1.1. Study Title (each study title must be unique) TEST for Documentation 1

* 1.2. Is this Study Exempt from Federal Regulations? ○ Yes ◉ No

1.3. Exemption Number ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8

* 1.4. Clinical Trial Questionnaire

If the answers to all four questions below are yes, this study meets the definition of a Clinical Trial.

1.4.a. Does the study involve human participants? ◉ Yes ○ No

1.4.b. Are the participants prospectively assigned to an intervention? ◉ Yes ○ No

1.4.c. Is the study designed to evaluate the effect of the intervention on the participants? ◉ Yes ○ No

1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome? ◉ Yes ○ No

1.5. Provide the ClinicalTrials.gov Identifier (e.g., NCT87654321) for this trial, if applicable

Click the Populate button to retrieve data from ClinicalTrials.gov registration once Identifier is entered.

NCT12345678 Populate

Inclusion Enrollment Report

Standalone PHS Inclusion Enrollment Report forms are no longer used. Instead, data collection for up to 20 *Inclusion Enrollment Reports* has been folded into each *Study Record*. Click on the link in *Section 2.8* of the *Study Record* screen to initiate the *Inclusion Enrollment Report*.

SECTION 2 - STUDY POPULATION CHARACTERISTICS

2.1. Conditions or Focus of Study	Action
Nothing found to display	

Add New Condition

2.2. Eligibility Criteria

Enter up to 15000 characters

Characters Remaining: 15000

2.3. Age Limits Minimum Age Maximum Age

2.4. Inclusion of Women, Minorities, and Children Add Attachment Delete Attachment View Attachment

2.5. Recruitment and Retention Plan Add Attachment Delete Attachment View Attachment

2.6. Recruitment Status

2.7. Study Timeline Add Attachment Delete Attachment View Attachment

2.8. Inclusion Enrollment Report(s)

Add New Inclusion Enrollment Report

Entry #	Enrollment Location Type	Enrollment Location	Action
Nothing found to display.			

For each *Inclusion Enrollment Report*, applicants must create a title, and indicate whether an existing dataset or resource will be used and whether the enrollment location type is domestic or foreign.

There are also a few optional fields in the report, including a text entry ***Comments*** section.

Summary | R&R Cover | Cover Page Supplement | Other Project Information | Sites | Sr/Key Person Profile | R&R Budget | Research Plan | Human Subjects and Clinical Trials

Human Subjects Summary > Study Record: 1 > Inclusion Enrollment Report: 1

Inclusion Enrollment Report 1 v1.0

OMB Number: 0925-0770
Expiration Date: 09/30/2024

Edit

* 1. Inclusion Enrollment Report Title — Enter up to 600 characters — Characters Remaining: 600
* 2. Using an Existing Dataset or Resource — ○ Yes ○ No
* 3. Enrollment Location Type — ○ Domestic ○ Foreign
4. Enrollment Country(ies) — None selected
5. Enrollment Location(s) — Enter up to 255 characters — Characters Remaining: 255
6. Comments — Enter up to 500 characters

Top part of the Inclusion Enrollment Report screen

Planned and *Cumulative* enrollment data collection are in separate tables.

Planned

	Ethnic Categories				
	Not Hispanic or Latino		Hispanic or Latino		Total
Racial Categories	Female	Male	Female	Male	
American Indian/Alaska Native	0	0	0	0	0
Asian	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	0	0	0	0	0
White	0	0	0	0	0
More than One Race	0	0	0	0	0
Total	0	0	0	0	0

Cumulative (Actual)

	Ethnic Categories									
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			Total
Racial Categories	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

Save and Keep Lock | Save and Release Lock | Save and Add | Cancel and Release Lock | Remove Report

Bottom part of the Inclusion Enrollment Report screen

Editing Inclusion Counts

Inclusion data is found at the end of Section 2.

SECTION 2 - STUDY POPULATION CHARACTERISTICS

2.1. Conditions or Focus of Study	Action
Nothing found to display	

Add New Condition

2.2. Eligibility Criteria

Enter up to 15000 characters

Characters Remaining: 15000

2.3. Age Limits Minimum Age Maximum Age

2.4. Inclusion of Women, Minorities, and Children Add Attachment Delete Attachment View Attachment

2.5. Recruitment and Retention Plan Add Attachment Delete Attachment View Attachment

2.6. Recruitment Status

2.7. Study Timeline Add Attachment Delete Attachment View Attachment

2.8. Inclusion Enrollment Report(s)

Add New Inclusion Enrollment Report

Entry #	Enrollment Location Type	Enrollment Location	Action
Nothing found to display.			

Planned Enrollment Counts

When creating a new inclusion enrollment report that is not marked as an existing dataset or resource, planned enrollment counts are required. To add Planned counts, edit the cells in the table.

Cumulative Enrollment Counts

There are two ways to edit the existing Inclusion Enrollment Report (IER) data for Cumulative (Actual) counts:

1. You can update the cells online in the existing report itself.
2. You can provide participant-level data in a spreadsheet that populates the cumulative table after upload.

For research from competing applications with due dates prior to January 25, 2019, either method may be used.

For research from competing applications with due dates January 25, 2019 or later, participant-level data are **required** in progress reports (see NIH Guide Notice NOT-OD-116).

- If you plan to upload the data, you **must** use the **Participant Level Data Template**. The template is a spreadsheet file in the proper CSV format to be used by the system.
- You can download the template by selecting the Download **Participant Level Data Template** button. This CSV file can then be updated with new totals.

To use the template:

- Download the spreadsheet template for entering participant -level data by clicking on the **Download Participant Level Data Template** button. Fill the template with data for the study.
- The columns in the template ***should not be altered***: altering the format or category titles results in an error during the uploading process.
- Data can be copied/transferred into the template from another source or entered directly into the template. When copying data be sure to copy values only and ensure your data are free of formulas.
- Once the new totals have been entered into the template and the file has been saved, use the **Upload Participant Level Data Attachment** button to upload the file that will update the Cumulative counts.

  If you need to clear the current records, use the **Remove Current Participant Level Data** button.

Cumulative (Actual)

	Ethnic Categories									
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			Total
Racial Categories	Female	Male	Unknown /Not Reported	Female	Male	Unknown /Not Reported	Female	Male	Unknown /Not Reported	
American Indian/Alaska Native	42	31	0	7	6	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	676	510	0	15	20	0	0	0	0	1221
White	3526	2663	0	300	214	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	240	0	0	0	0	240

Need Help

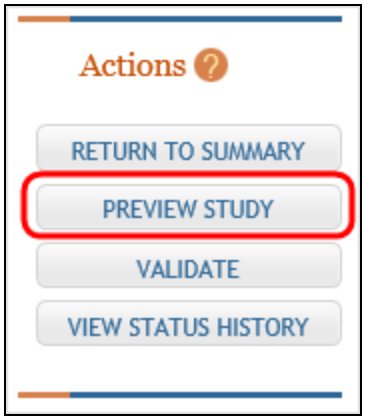
Participant level data file (CSV):

Download Participant Level Data Template | Upload Participant Level Data Attachment

Download Current Participant Level Data | Remove Current Participant Level Data

Save and Keep Lock | Save and Release Lock | Save and Add | Cancel and Release Lock | Remove Report

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



PI and SO Actions

If the PI is making changes:

- The PI changes the submission status to Work in Progress.
- The PI can click the **Save and Release Lock** button to save the changes.
- PI changes status to *Ready for Submission*.
- SO logs into ASSIST, finds the application, and submits it.

NOTE: If the SO has delegated Submit authority to the contact PI, the PI can submit the application.

If the SO is making changes:

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

NOTE: The SO can delegate Submit authority to the contact PI. If this delegation is not done, 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 might require prior approval.

NOTE: If the application has been submitted and needs to be placed back into a work in progress status, refer to these instructions to perform this action; https://era.nih.gov/erahelp/ASSIST/default.htm#ASSIST_Help_Topics/5_Preview_Print_Submit/Revise_Application.htm?Highlight=status

5 Adding Studies

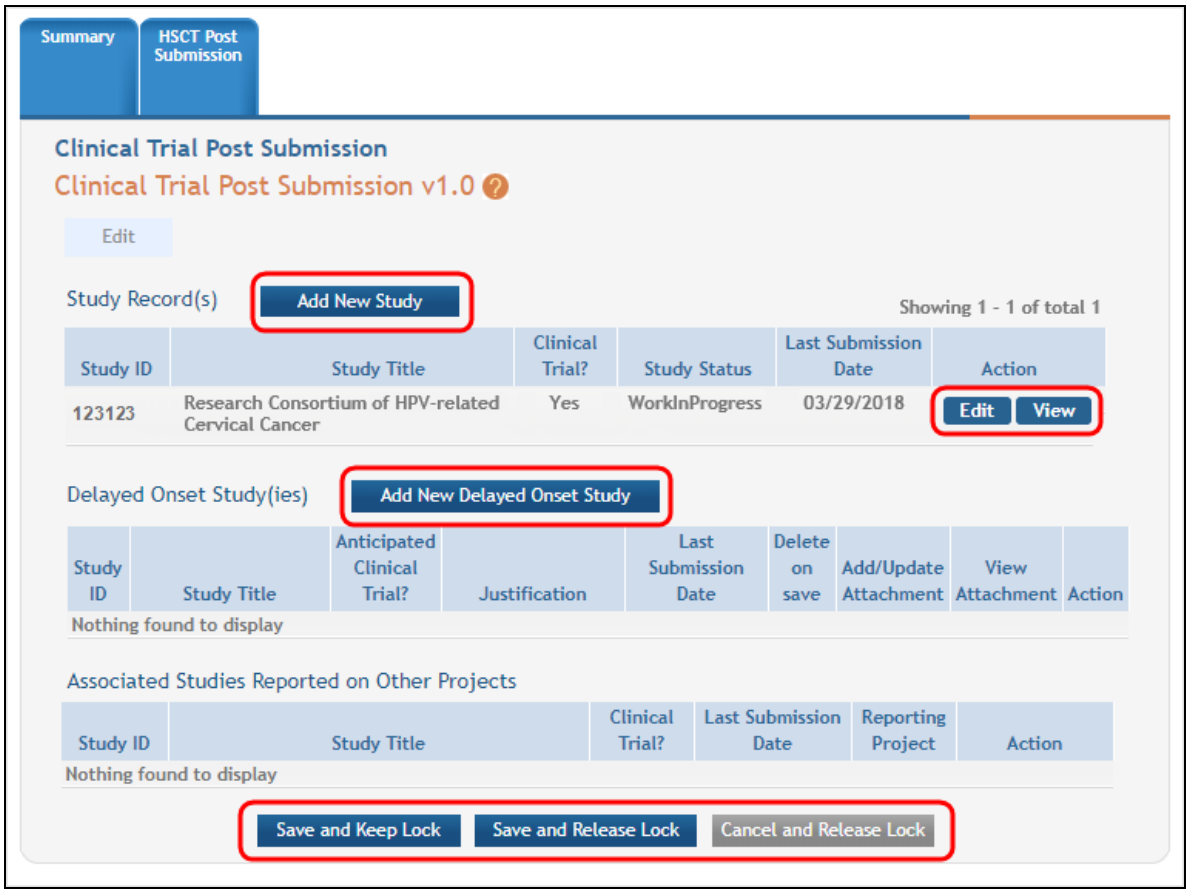
After the initial submission of the application, additional studies can be added once the summary statement is released.

Access HSS via the Human Subjects links in the Action column of Status or the Human Subjects link in section G.4.b in the progress report. To add studies, the HSS record must be in Work in Progress status. See How To Change the Application Status and Resubmit for instructions on changing the submission status.

Access HSS via the *HSCT Post Submission* tab via the *Human Subjects* links in the *Action* column of *Status* or the *Human Subjects* link in section G.4.b in the progress report. To add studies, the HSS record must be in Work in Progress status. See How To Change the Application Status and Resubmit for instructions on changing the submission status.

From the *Application Information* page, click on the **HSCT Post Submission** tab, then click the **Edit** button.

Any study records already submitted are displayed and can be viewed and buttons to **Add New Study** and **Add New Delayed Onset Study** are displayed. Click on the appropriate button to add studies.



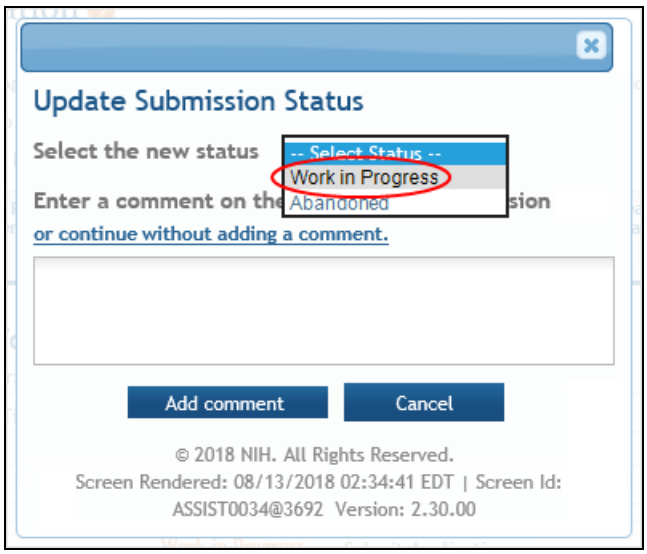
Once the study has been added be sure to use the **Save and Keep Lock** or **Save and Release Lock** buttons to secure your updates.

6 How To Change the Application Status and Resubmit

To revise and resubmit an application:

1. From the *Application Information* page click the **Update Submission Status** button from the **Action** list on the left side of the screen.

   The *Update Status* window displays.
2. Select the *Work in Progress* status from the Select Status drop-down list.

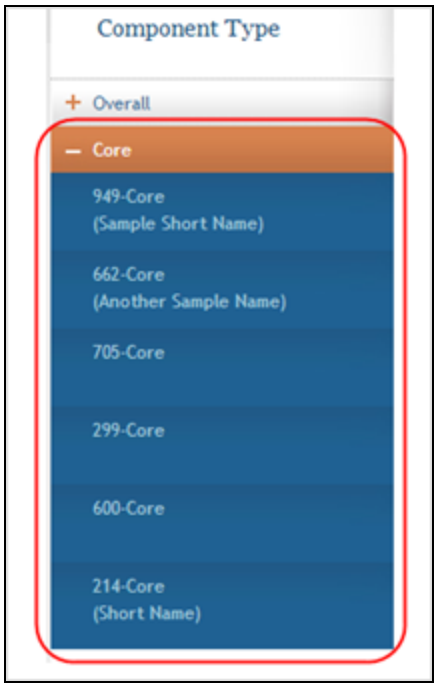


3. Complete the status update:
   a. Enter a comment in the provided text box.
   b. Select the **Add comment** button.

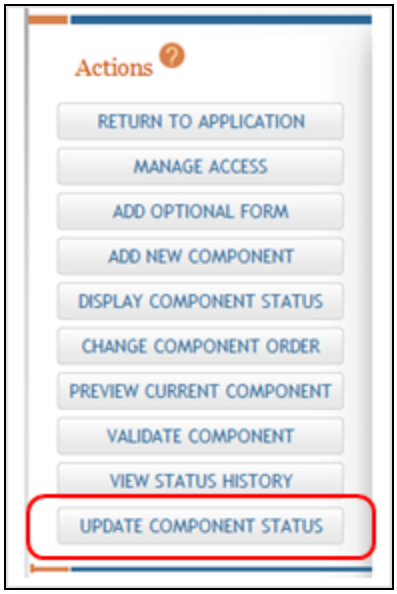
      -OR-
   c. Select the link titled **or continue without adding a comment** to update the status without entering a comment in the provided text box.

      For multi-project grants, continue with the following steps:

4. Select the component needing revision from the Component Type section of the page.



5. Select the Update Component Status button from the **Actions** section of the page.



6. Update the status of the component to *Work in Progress* by selecting it from the drop-down box, entering comments, and selecting the **Add Comment** button.

Once the status of the component is *Work in Progress*, the appropriate component form (s) can be updated.

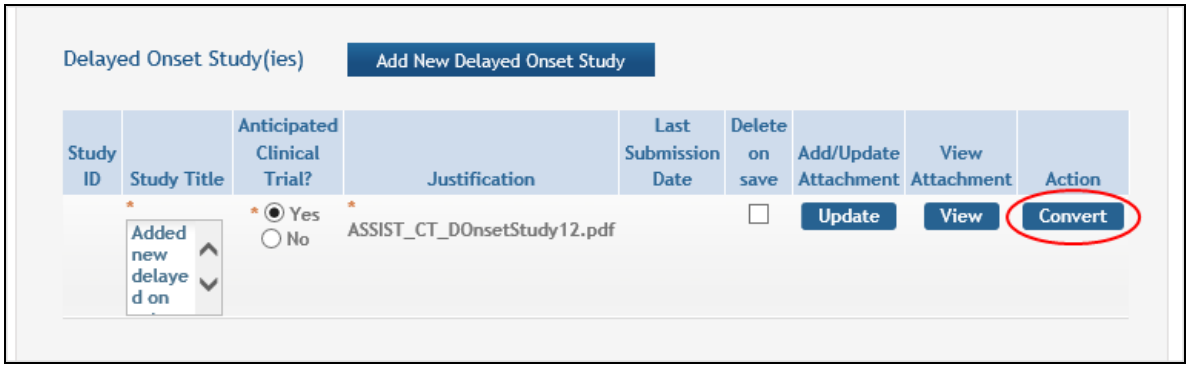
Navigate to the appropriate forms, make the changes, and re-submit the application. Refer to the help topic titled Submit the Application for information on submitting the application.

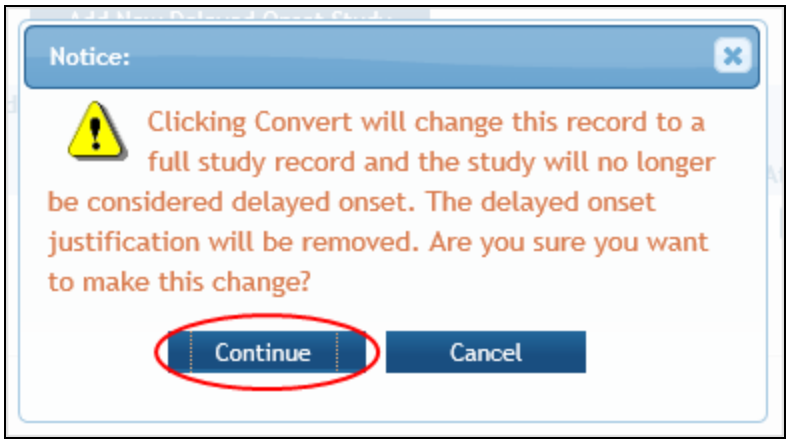
NOTE: Only the signing official (SO) or a delegated contact principal investigator (PI) can submit the application to NIH.

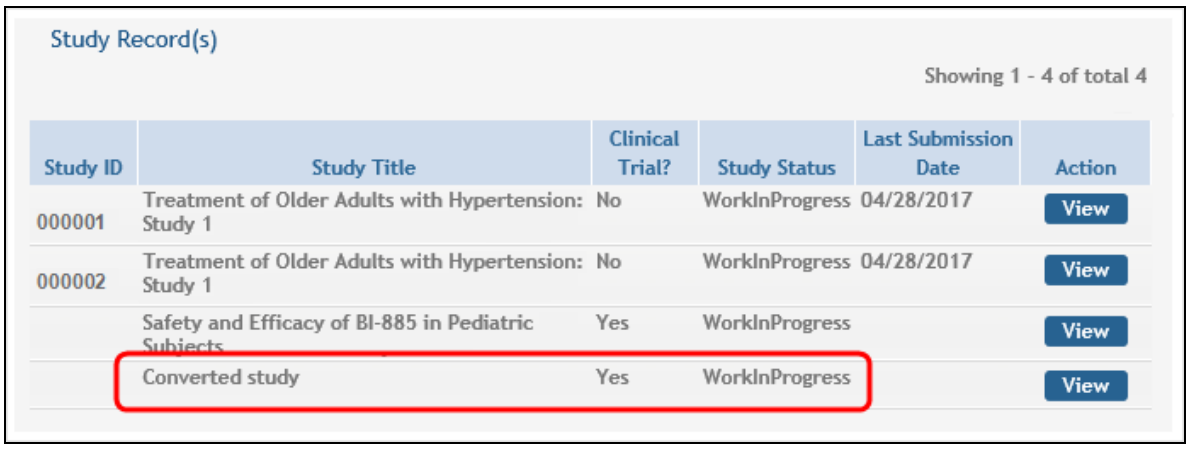
7 Convert Delayed Onset to Full Study Record

Flow:

1. Navigate to the HSCT Post Submission page and click on the **Edit** Button.
2. Identify the delayed onset study that you want to convert. Click the **Convert** button under *Action*- the system displays following warning:
    a. a. Clicking “Convert” will change this record to a full study record and the study will no longer be considered delayed onset. The delayed onset justification will be removed. Are you sure you want to make this change?"
3. If you choose the **Cancel** option, you stay on the Post Submission screen and the Delayed Onset remains as Delayed Onset.
4. If you choose the **Continue** option you are taken to the Study Page with title populated and rest of the fields empty.
5. Select **Save** (and keep or release lock) after completing the fields on the Study Page.
6. The action of saving the study removes the study from the Delayed Onset Study table and a new study is saved and added to the Study Record table.




Notice:
Clicking Convert will change this record to a full study record and the study will no longer be considered delayed onset. The delayed onset justification will be removed. Are you sure you want to make this change?
Continue
Cancel


Study Record(s)
Showing 1 - 4 of total 4
Study ID
Study Title
Clinical Trial?
Study Status
Last Submission Date
Action
000001
Treatment of Older Adults with Hypertension: Study 1
No
WorkInProgress
04/28/2017
View
000002
Treatment of Older Adults with Hypertension: Study 1
No
WorkInProgress
04/28/2017
View
Safety and Efficacy of BI-885 in Pediatric Subjects
Yes
WorkInProgress
View
Converted study
Yes
WorkInProgress
View

8 Study Statuses

A status will be maintained for each study version. There will be two primary values used:

Received by Agency: any new study version will have this status. Studies that come in on initial submission will have this status, and any post-submission of the study will have this status when updates are submitted.

Accepted: when an award occurs, any studies for which the awarded project is the primary project will have this status. The latest version will also be labeled with the relevant FY of the award.

NOTE: The Status of a study version on a contract application should always be set to "Accepted".

9 When Should I Access HSS via the Status Module?

HSS is used to view and maintain human subjects data, including inclusion and clinical trial data, associated with your grant(s). HSS can be accessed in one of two ways, both through the eRA Commons system: via the **Status** module –or– via the RPPR **Section G. Special Reporting Requirements**.

When to Use the Status Module Instead of RPPR

There are several reasons why you might need to access study data through Commons Status rather than through your progress report. For example:

- Before award of a competitive application, changes may be necessary to the human subjects data submitted with the application via Grants.gov.
- Post-award, there may be a requirement to provide more frequent updates to inclusion enrollment in addition to any reporting associated with the RPPR.

Human subjects data cannot always be updated using Status. When application is undergoing peer review, the study information is not accessible in the Human Subjects System. Also, after a grant is awarded, only the **View** links will be available for the studies associated with fiscal year award. The data for a given fiscal year is locked when the award is issued and no further updates can be made. At that point, you can make updates via Status for the record associated with the next fiscal year.

For details on using the Status module for accessing HSS, please refer to Access HSS. You can also access the HSS Online Help by selecting the help icons ('?') on any of the HSS screens.

10 Roles and Privileges

HSS Roles and Privileges:

	Principal Investigator	Signing Official
View study records	X	X
Receive notifications		X
Edit all HSCT and IER fields (except clinical trial code)	X	X
Initiate study record submission	X	X
Submit study record	X (if delegated by SO)	X

*Only the Signing Official (or SO-delegated contact PI) can submit study records

11 Additional Resources (HSCT form and more)

HSS relies on information from more than one source and not all information provided in the HSS online help and PDF guides is exhaustive. Below are links to additional resources to provide greater detail and explanation on the various topics and systems related to HSS.

- HSCT form in ASSIST
  - Basic Information (Study Record - Section 1)
  - Study Population Characteristics (Study Record - Section 2)
  - Protection and Monitoring Plans (Study Record - Section 3)
  - Protocol Synopsis (Study Record - Section 4)
  - Other Clinical Trial-related Attachments (Study Record - Section 5)
  - Inclusion Enrollment Report
  - Participant Level Data Collection
- ASSIST (online help) - HSS leverages ASSIST screens and therefore has the same look and feel.
- HSS Training - Contains links to user guide, video tutorials, IMS to HSS Crosswalk, and infographic of the HSS process
- How to Apply - Application Guide - Use application instructions, along with guidance in the funding opportunity announcement, to submit grant applications to NIH, CDC, and FDA.