

## 4 Editing Studies

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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.

### **4.1 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

### **4.2 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.

Home > Search for Applications > Application Information

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

### 4.2.1 Option 1

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

Summary **HSCT Post Submission**

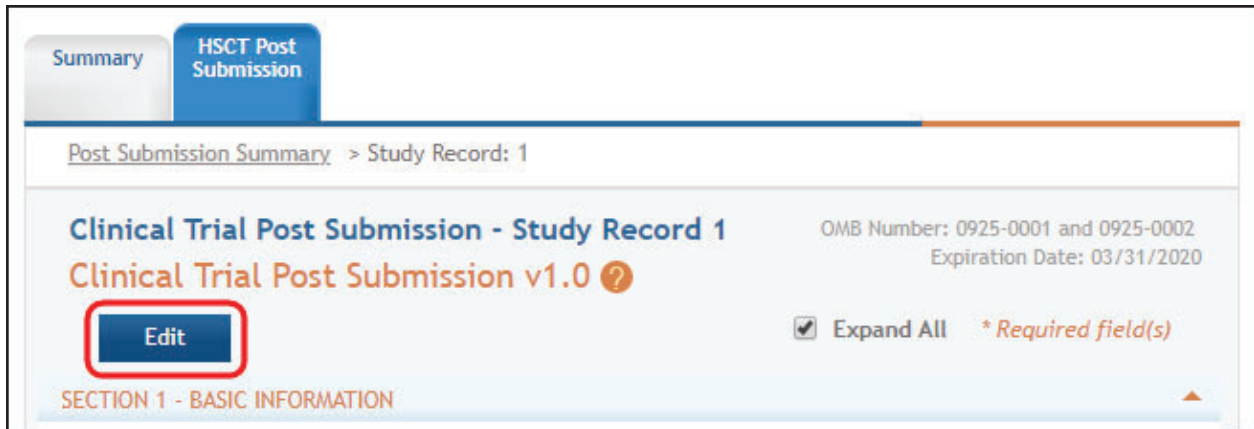
Clinical Trial Post Submission  
 Clinical Trial Post Submission v1.0 ?

Edit

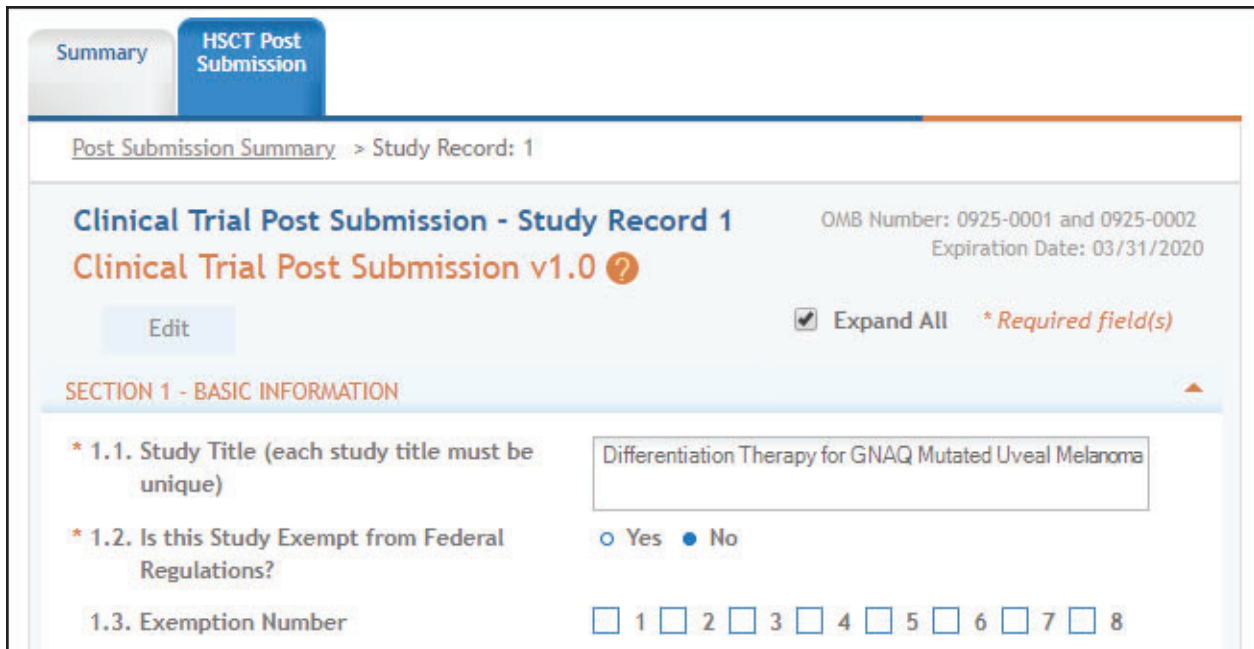
Study Record(s) Showing 1 - 1 of total 1

Study ID	Study Title	Clinical Trial?	Study Status	Last Submission Date	Action
123456	Differentiation Therapy for GNAQ Mutated Uveal Melanoma	Yes	ReceivedByAgency	02/14/2019	<b>View</b> Export XML

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

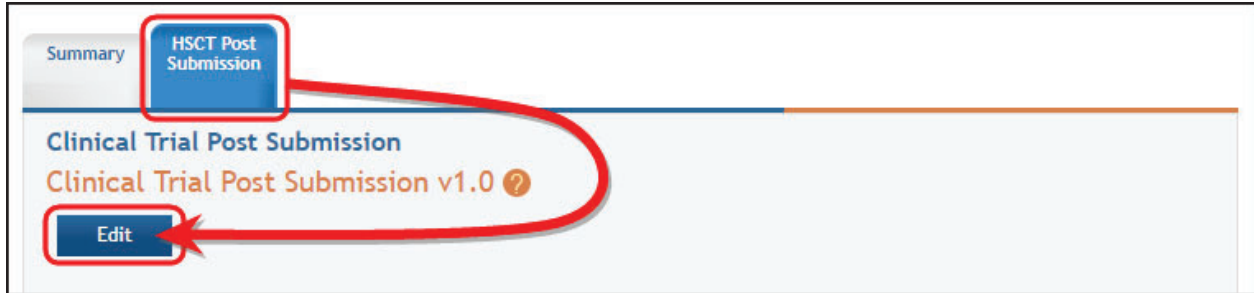


- The study record is opened and the fields can be updated.

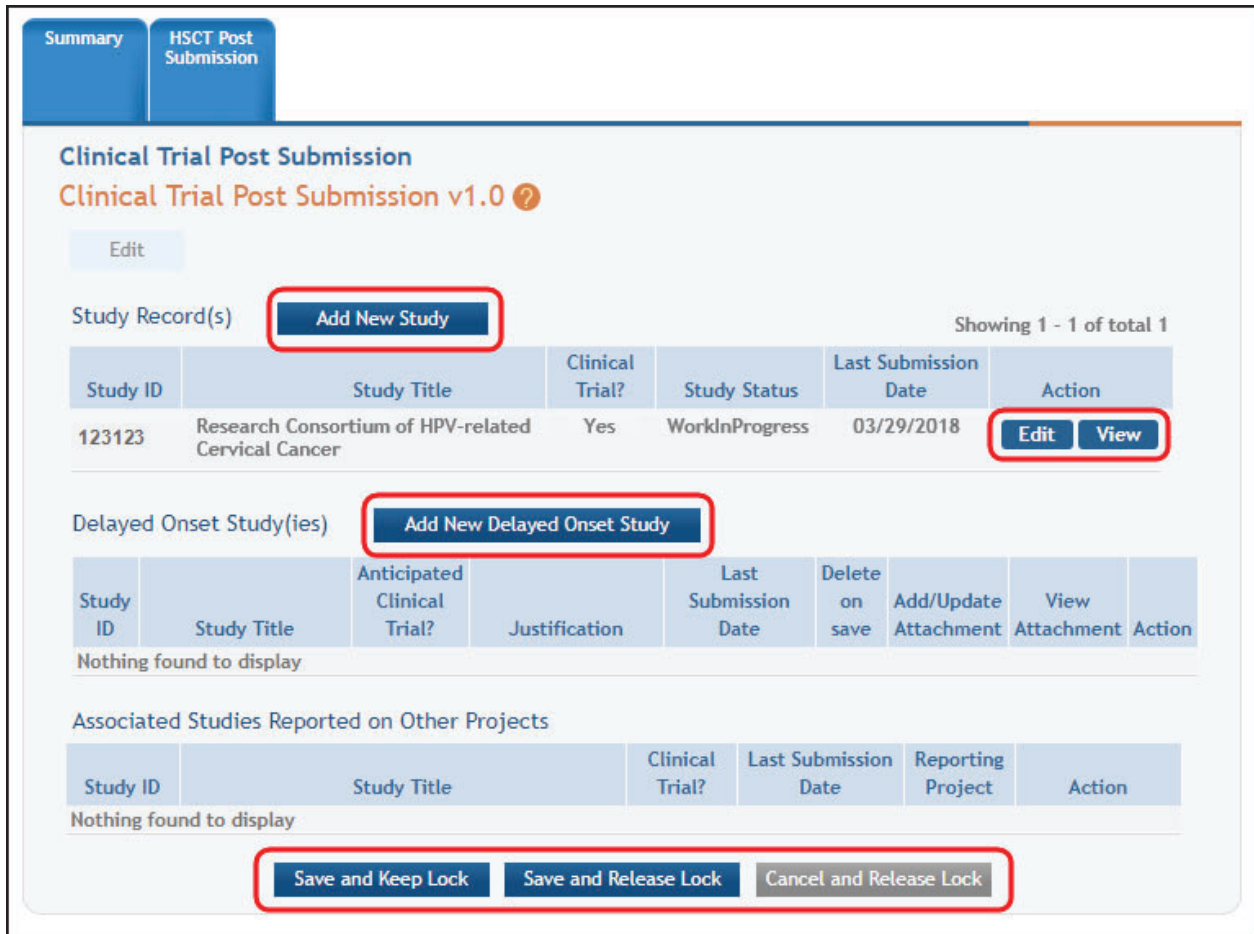


#### 4.2.2 Option 2

- 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.



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

Summary | **HSCT Post Submission**

Post Submission Summary > Study Record: 1

**Clinical Trial Post Submission - Study Record 1** OMB Number: 0925-0001 and 0925-0002  
Expiration Date: 03/31/2020

**Clinical Trial Post Submission v1.0** ?

Edit  Expand All \* Required field(s)

**SECTION 1 - BASIC INFORMATION** ▲

\* 1.1. Study Title (each study title must be unique)

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

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

### 4.2.3 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.

#### **4.2.4 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.

#### **4.2.5 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.

The screenshot shows a form titled "SECTION 1 - BASIC INFORMATION". It contains several fields and questions:

- \* 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**

A red box highlights the "1.5" section, and a red arrow points to the "Populate" button.

### 4.3 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   
Characters Remaining: 600

2. Using an Existing Dataset or Resource  Yes  No

3. Enrollment Location Type  Domestic  Foreign

4. Enrollment Country(ies)

5. Enrollment Location(s)   
Characters Remaining: 255

6. Comments

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



**Planned**

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/Alaska Native	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	0
Asian	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	0
Native Hawaiian or Other Pacific Islander	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	0
Black or African American	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	0
White	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	0
More than One Race	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	0
<b>Total</b>	0	0	0	0	0

**Cumulative (Actual)**

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/Not Reported	Female	Male	Unknown/Not Reported	Female	Male	Unknown/Not Reported	
American Indian/Alaska Native	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	0
Asian	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	0
Native Hawaiian or Other Pacific Islander	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	0
Black or African American	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	0
White	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	0
More than One Race	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	0
Unknown or Not Reported	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	0
<b>Total</b>	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

#### 4.4 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.			

#### 4.4.1 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.

#### 4.4.2 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.

#### **4.4.3 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)**

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	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
<b>Total</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>240</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>240</b>

**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.

**Actions ?**

RETURN TO SUMMARY

**PREVIEW STUDY**

VALIDATE

VIEW STATUS HISTORY

## **4.5 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.

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

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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.

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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.

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

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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](https://era.nih.gov/erahelp/ASSIST/default.htm#ASSIST_Help_Topics/5_Preview_Print_Submit/Revise_Application.htm?Highlight=status)

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