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.

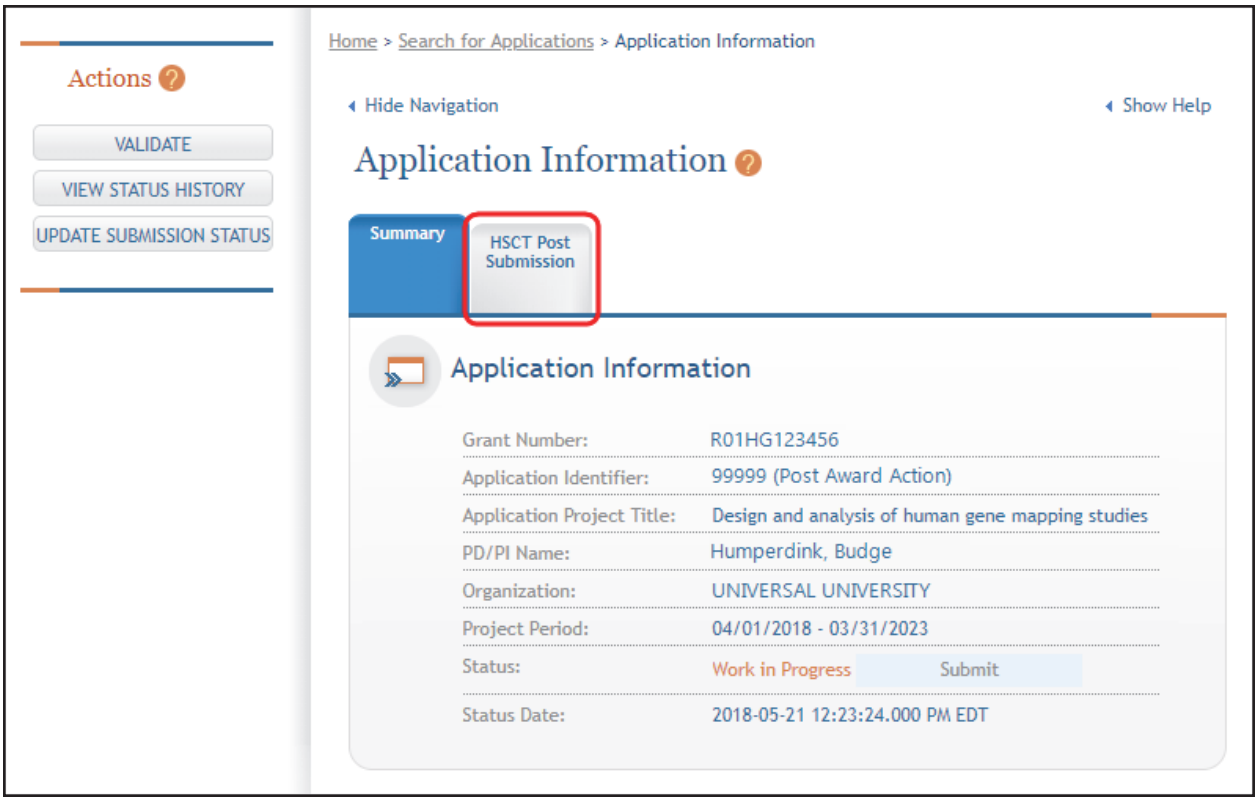
4.1 Human subjects information might need to be updated in the following scenarios:

- 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.

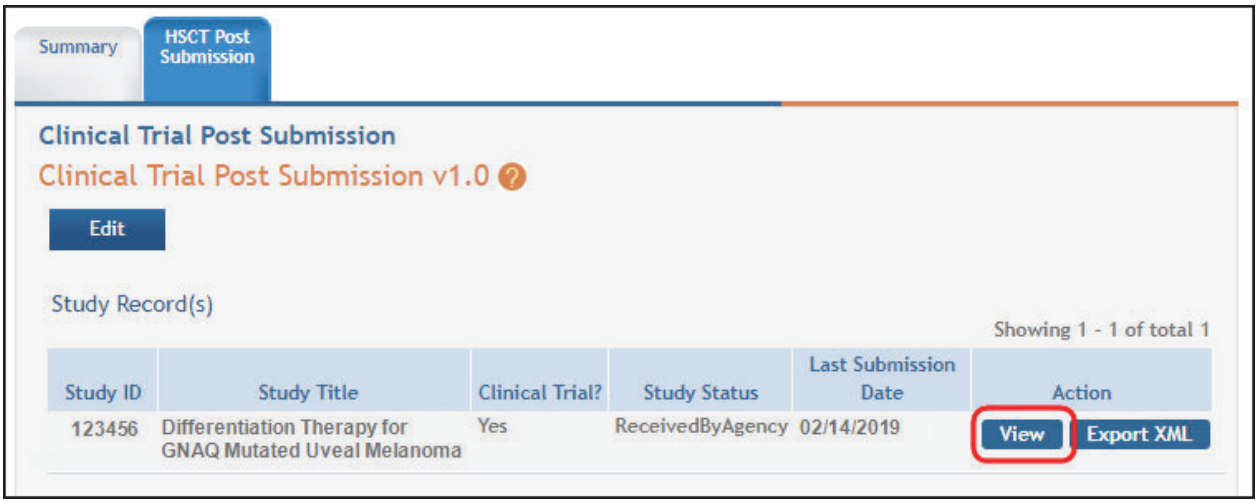
The *Application Information* screen is displayed, showing a summary of your grant. You have two ways of accessing and editing the study data. Both begin by accessing the *HSCT Post Submission* tab.

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.

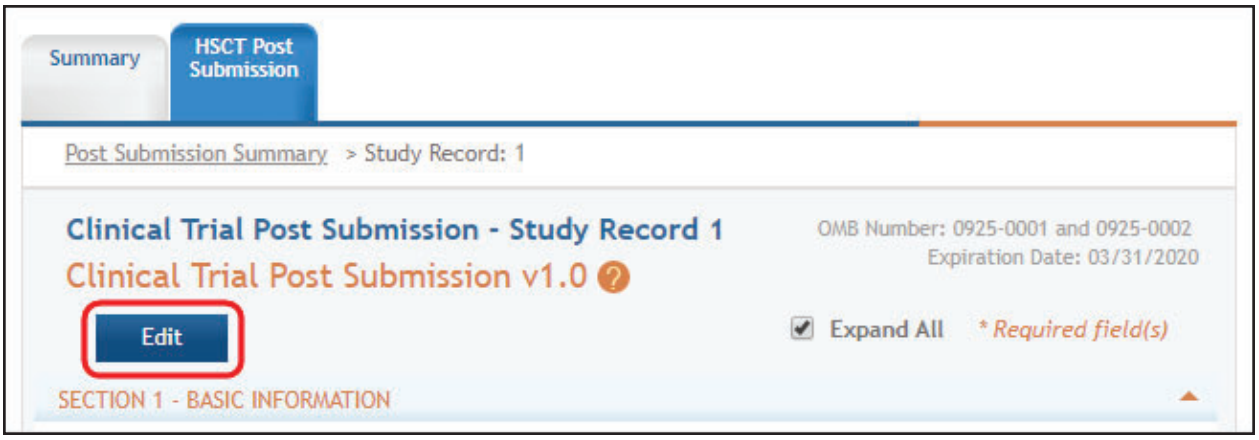


4.2.1 Option 1

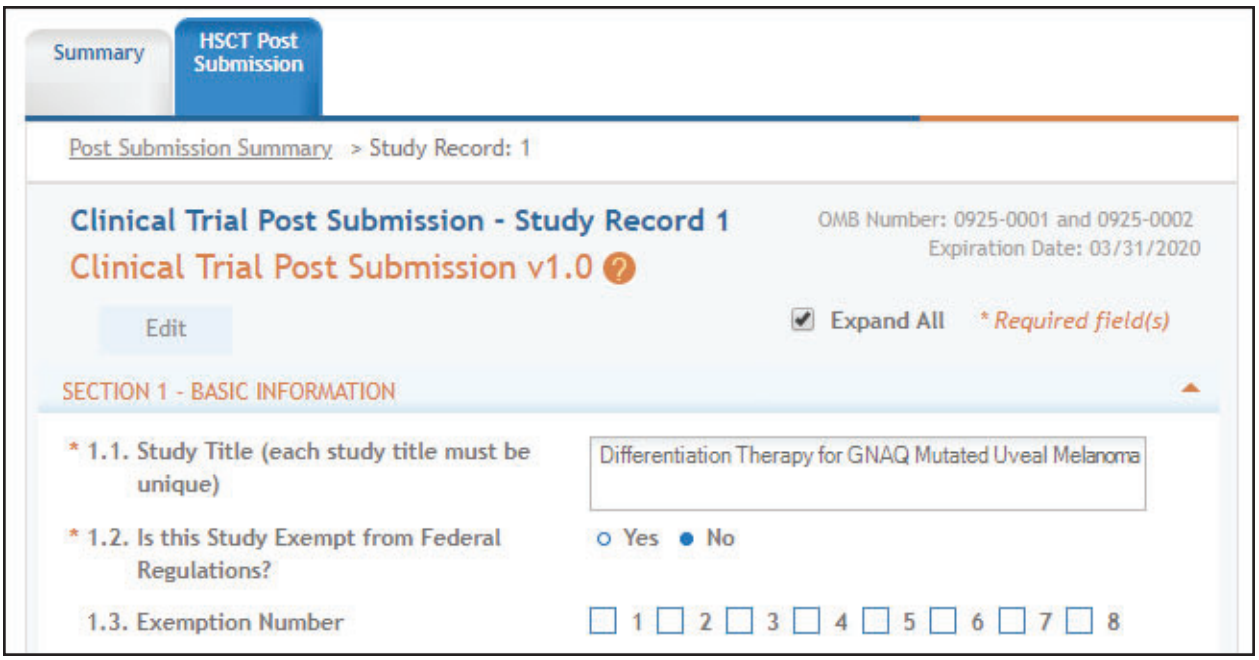
- Click on the **View** button to open the study record data.



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



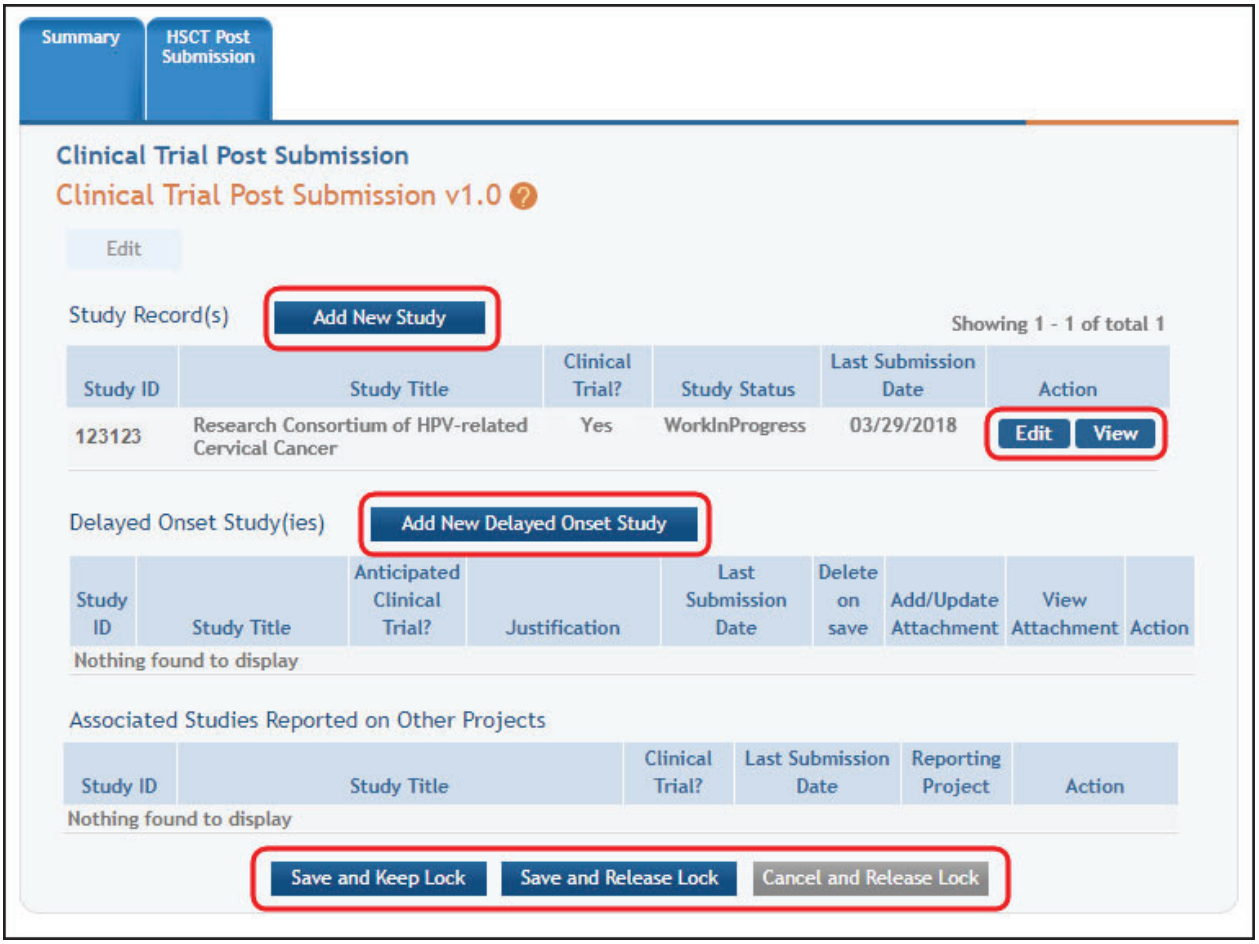
- The study record is opened and the fields can be updated.



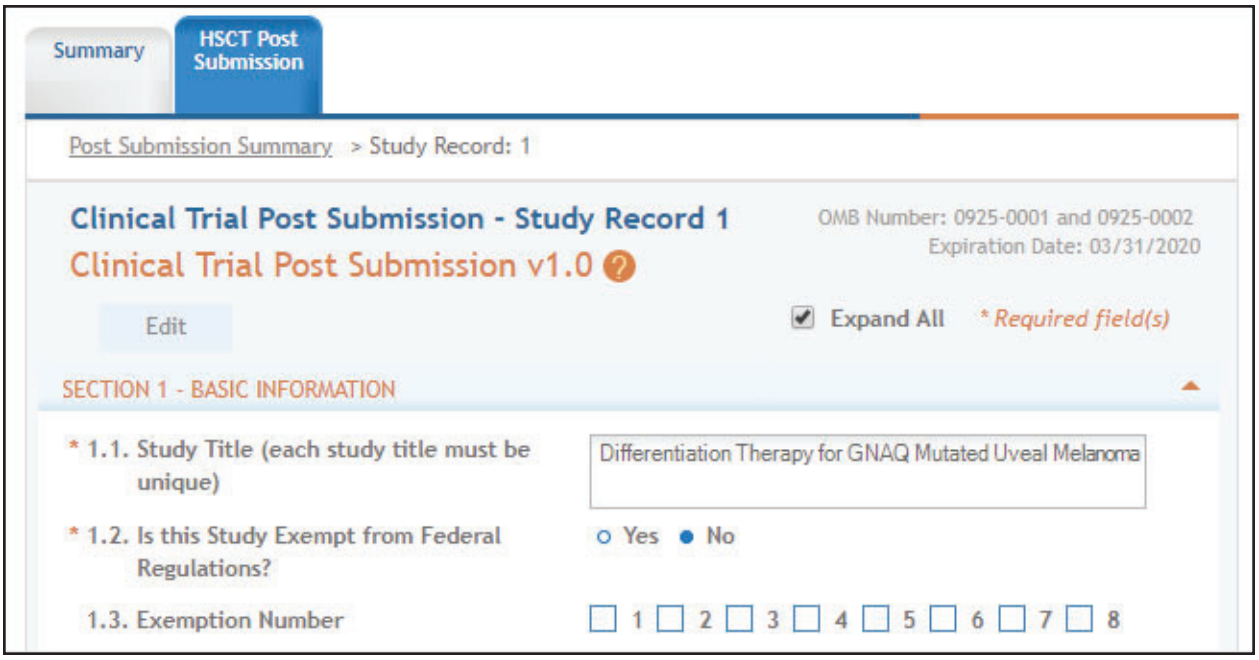
4.2.2 Option 2

- 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.



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.

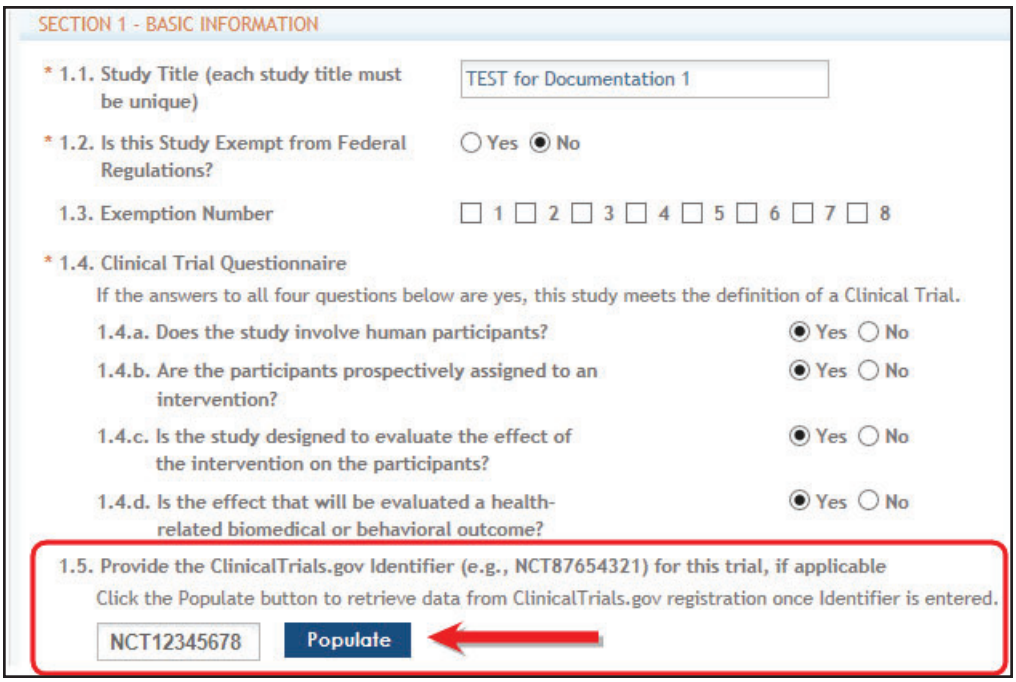
4.2.4 Exporting HSS data for ClinicalTrials.gov registration

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

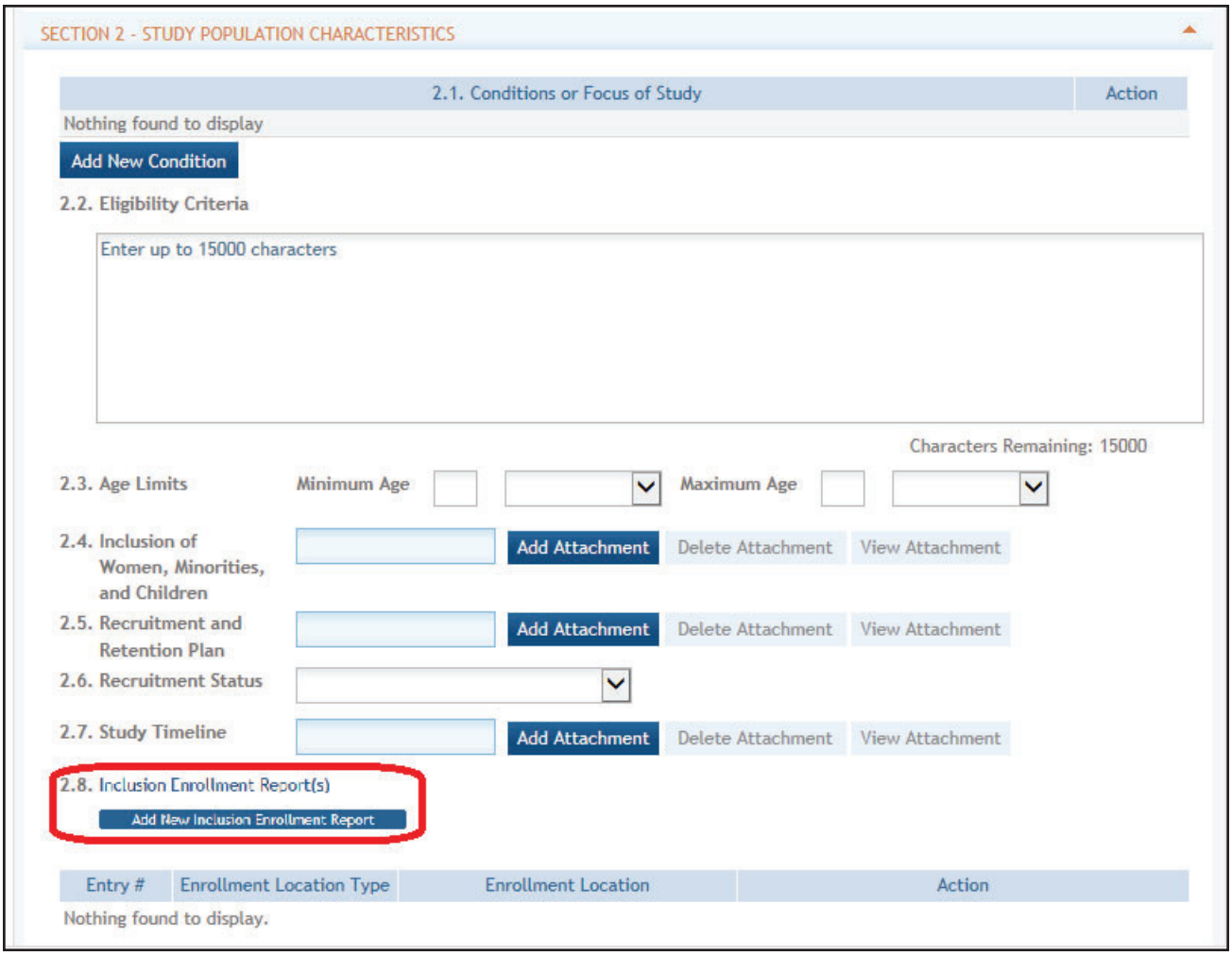
After a clinical trial has been registered in ClinicalTrials.gov, HSS fields that map to ClinicalTrials.gov can be updated with the information available in ClinicalTrials.gov.

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.



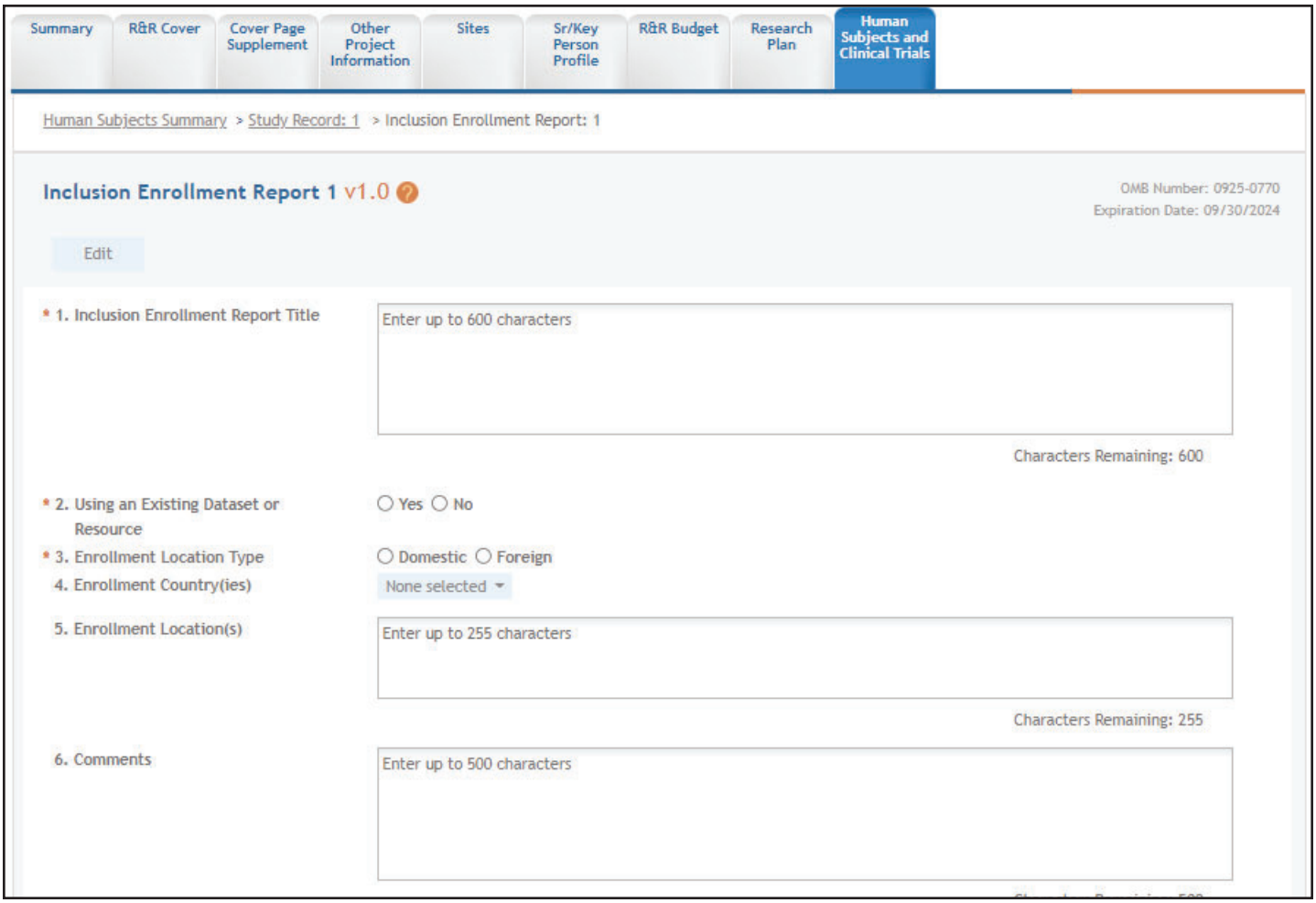
4.3 Inclusion Enrollment Report

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*.



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.



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

Planned

Racial Categories	Ethnic Categories: Not Hispanic or Latino – Female	Not Hispanic or Latino – Male	Hispanic or Latino – Female	Hispanic or Latino – Male	Total
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

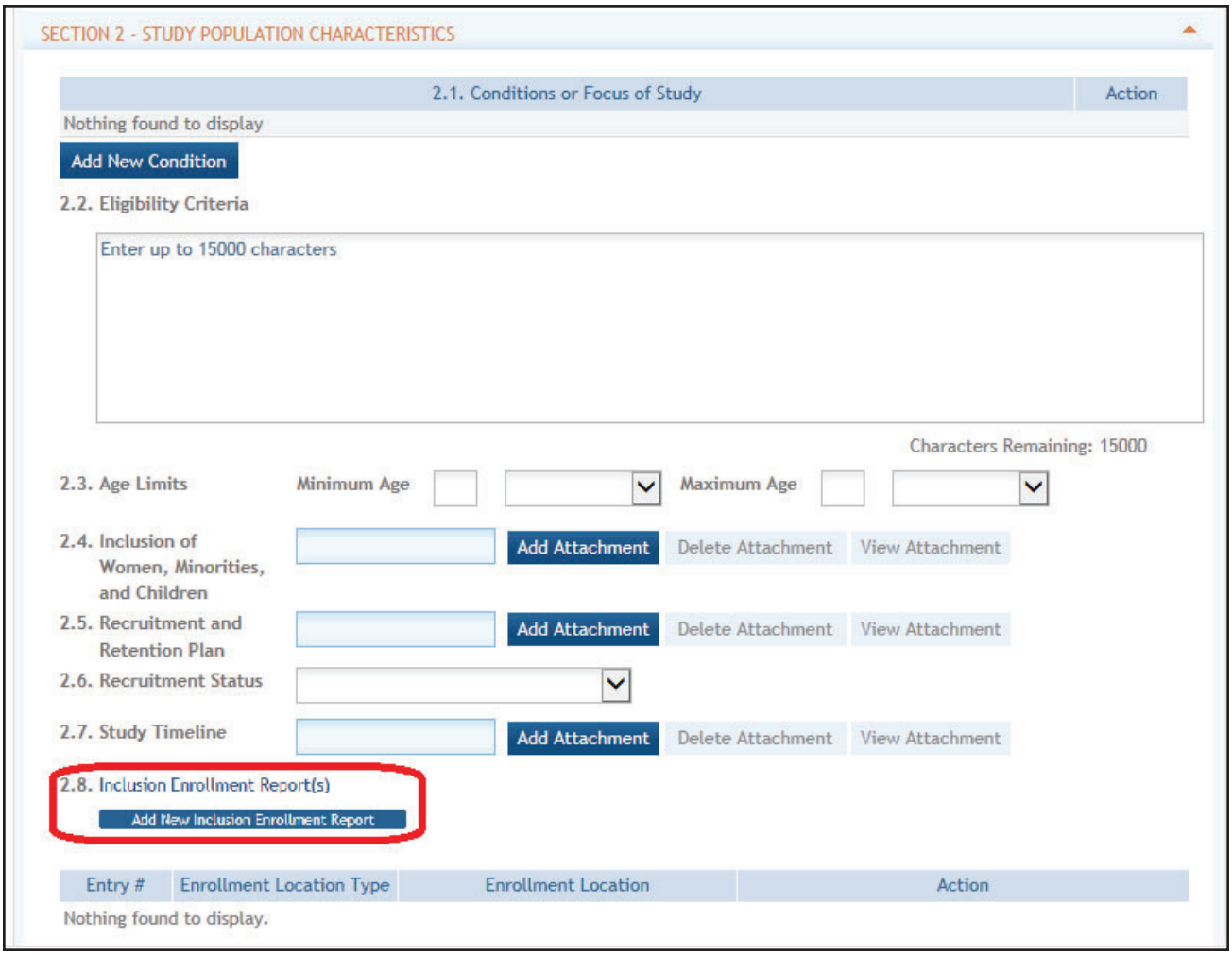
Cumulative (Actual)

Racial Categories	Not Hispanic or Latino – Female	Not Hispanic or Latino – Male	Not Hispanic or Latino – Unknown/Not Reported	Hispanic or Latino – Female	Hispanic or Latino – Male	Hispanic or Latino – Unknown/Not Reported	Unknown/Not Reported Ethnicity – Female	Unknown/Not Reported Ethnicity – Male	Unknown/Not Reported Ethnicity – Unknown/Not Reported	Total
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

4.4 Editing Inclusion Counts

Inclusion data is found at the end of Section 2.



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.

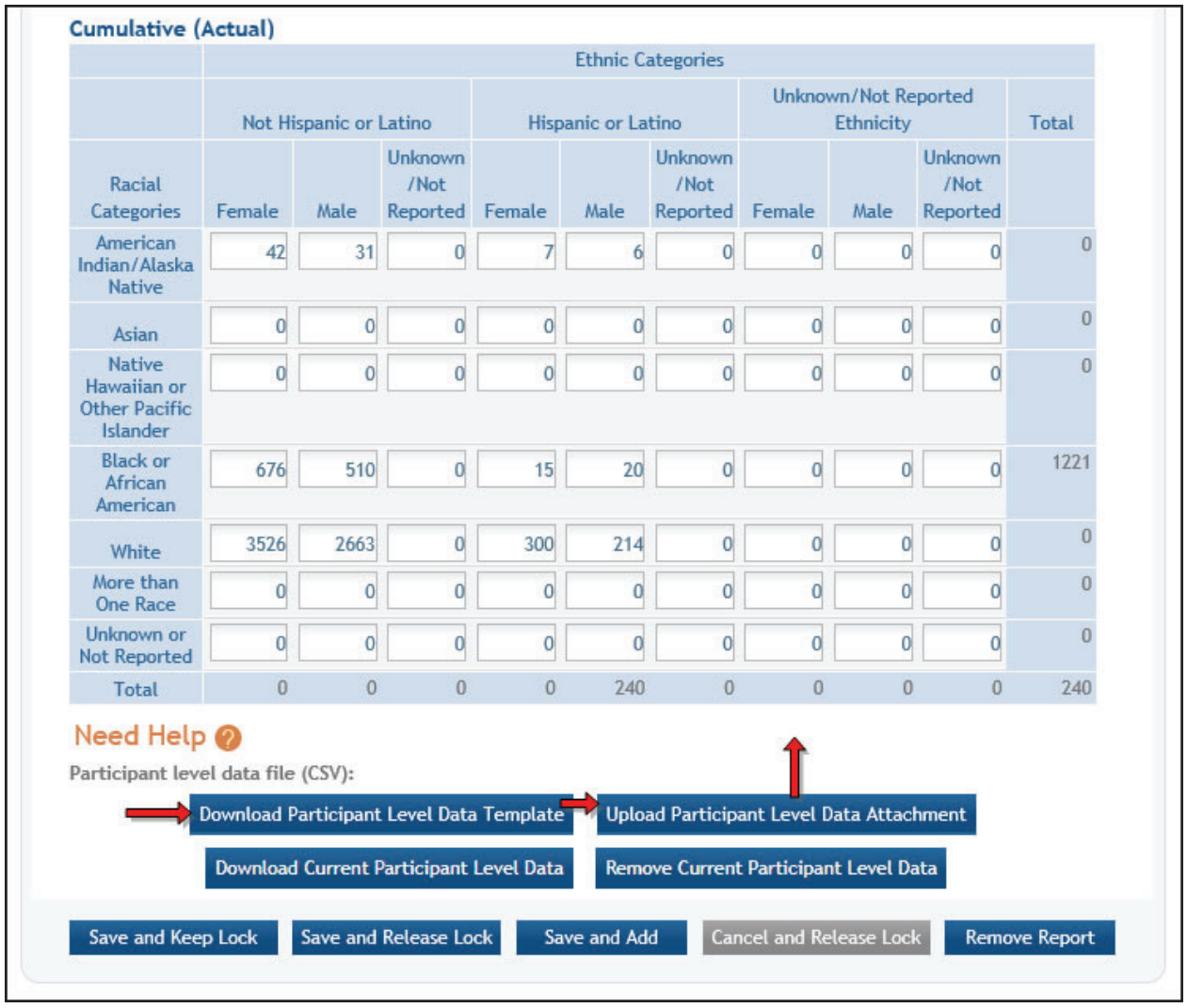
For research from competing applications with due dates January 25, 2019 or later, participant-level data are **required** in progress reports (see NIH Guide Notice NOT-OD-116).

- 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.

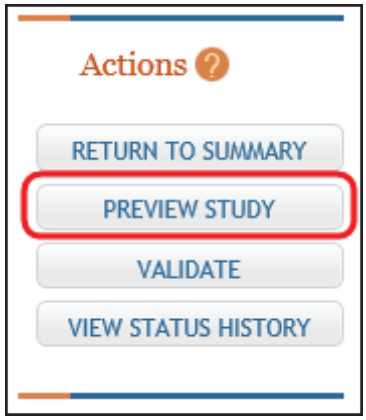
4.4.3 To use the template:

- 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.



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



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.

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.

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.

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

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