Follow these steps to access and complete the inclusion enrollment report as part of Section G of the RPPR:

➢ Click on the Human Subjects link on tab G.4.b. Inclusion Enrollment Data of the RPPR:

G.4.b Inclusion Enrollment Data

❓

Please review the box below to determine if this project meets the definition of clinical research and requires the reporting of cumulative enrollment of subjects and the distribution of sex/gender, ethnicity and race.
Click here for complete instructions about this requirement.

Inclusion Enrollment Report
Human Subjects

It will bring you to this screen:

➢ On the Summary Tab, the status will show as "submitted." Click on the "Update Submission Status" button on the left-hand side of the screen.
➢ Then, click on the "Select the new status" drop down and select "work in progress."
➢ Finally, click the hyperlink that says, "or continue without adding a comment."

U.S. Department of Health & Human Services

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Home > Search for Applications > Application Information

◄ Hide Navigation

Actions ❓

VALIDATE

VIEW STATUS HISTORY

UPDATE SUBMISSION STATUS

RESTORE PREVIOUS VERSION

Human Subjects

Application Information ❓

Summary	HSCT Post Submission

The screen will refresh and show the Status as "work in progress" as shown in the below screenshot:

◂ Hide Navigation   ◂ Show Help

Actions ❓

| VALIDATE |
| VIEW STATUS HISTORY |
| UPDATE SUBMISSION STATUS |
| RESTORE PREVIOUS VERSION |

Human Subjects

Application Information ❓

| Summary | HSCT Post Submission |

Application Information

Project Number:	UM1CA221939
Application Identifier:	426113 (Post Award Action)
Application Project Title:	Center for Research to Optimize Precision Lung Cancer Screening in Diverse Populations
PD/PI Name:	Ritzwoller, Debra P VACHANI, ANIL
Organization:	KAISER FOUNDATION RESEARCH INSTITUTE
Project Period:	04/15/2018 - 03/31/2023
Status:	Work in Progress Submit
Status Date:	2020-01-27 05:01:48.000 PM EST

➢ Now, click on the tab that says: "HSCT Post Submission":

Actions ❓

RETURN TO SUMMARY

VALIDATE

VIEW STATUS HISTORY

RESTORE PREVIOUS VERSION

◂ Hide Navigation   ◂ Show Help

Application Information ❓

| 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
180756	Center for Research to Optimize Precision Lung Cancer Screening in Diverse Populations	No	ReceivedByAgency	04/13/2018	View

➢ Then, click on the edit button:

Actions ❓

RETURN TO SUMMARY
VALIDATE
VIEW STATUS HISTORY
RESTORE PREVIOUS VERSION

◄ Hide Navigation   ◄ Show Help

Application Information ❓

| 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
180756	Center for Research to Optimize Precision Lung Cancer Screening in Diverse Populations	No	ReceivedByAgency	04/13/2018	View

Delayed Onset Study(ies)

Study ID	Study Title	Anticipated Clinical Trial?	Justification	Last Submission Date	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					

The screen below will appear:

 ➢ Click the edit button on that screen.

The study record screen will open:

- ➢ Scroll to "Section 2: Study Population Characteristics" where it says: "Inclusion Enrollment Report(s)".
- ➢ Click on the blue box that says "Add New 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

Inclusion Enrollment Report(s)

Add New Inclusion Enrollment Report

Entry #	Enrollment Location Type	Enrollment Location	Action
180756	Domestic		Edit View

SECTION 3 - PROTECTION AND MONITORING PLANS

It will then open up the screen where you will complete "Inclusion Enrollment Report 2":

➢ Complete #1-5 (3-5 if applicable) as shown in the screenshot below:

Home > Search for Applications > Application Information

‹ Hide Navigation   ‹ Show Help

Application Information ❓

Summary	HSCT Post Submission

Human Subjects Summary > Study Record: 1 > Inclusion Enrollment Report: 2

Inclusion Enrollment Report 2
Clinical Trial Post Submission v1.0 ❓

    Edit

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

➤ Then scroll down and enter the enrollment numbers into the table entitled: "Cumulative (Actual)":

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	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

Instructions for Participant Level Data Upload ❓

Participant level data file (CSV):

[Download Participant Level Data Template]   [Upload Participant Level Data Attachment]

[Save and Keep Lock]   [Save and Release Lock]   [Save and Add]   [Cancel and Release Lock]   [Remove Report]

Depending on the status of your entries: if they are complete, you're still working on them, or you need to add an additional inclusion enrollment report, use the guidelines below to determine which button to at the bottom of the screen when exiting:

- If you plan to make further edits after making some entries, scroll to the bottom of the screen and click the "Save and Keep Lock" button. This will keep the form open for further edits.
- If you enter the information on the table and are now finished, click the "Save and Release Lock Button."
- If there will be multiple inclusion enrollment reports, click the "Save and Add" button if there will be multiple pages of forms.

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	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

Need Help ❓

Participant level data file (CSV):

[Download Participant Level Data Template] [Upload Participant Level Data Attachment]

[Save and Keep Lock] [Save and Release Lock] [Save and Add] [Cancel and Release Lock] Remove Report

Once you are done and the report is ready for submission, you must update the submission status:

➢ To do this go to: "Update Submission Status" tab on the left-hand column of the main screen.
➢ Click "Update Submission Status."

Actions ❓

[VALIDATE]

[VIEW STATUS HISTORY]

[UPDATE SUBMISSION STATUS]

➢ Then, click on the "Select the new status" drop down and select "ready for submission."
➢ Finally, click the hyperlink that says, "or continue without adding a comment" or you may also choose to indicate in the comment box, "the report is ready to be submitted to the sponsor." If you choose to enter a comment, click the blue "Add comment" button once you are done.

The status will then update on the Summary Tab to "Ready for Submission." This will allow the Signing Offical to access it and submit it on your behalf.