The Human Subjects System (HSS)

Global NCD Network Virtual Meeting| September 28, 2023| Rebecca Favor, DrPH, CPH

NIH National Institutes of Health
Office of Extramural Research

Goals

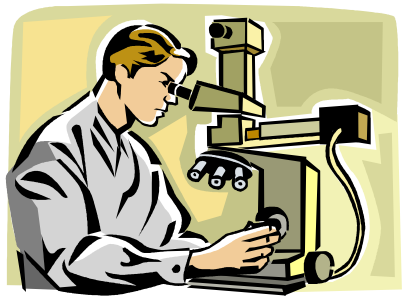
- Understand basic information about the Human Subjects System (HSS)
- Describe methods for navigating HSS
- Recall required information for human subjects research and additional requirements for clinical trials
- Understand how to provide information and updates in HSS

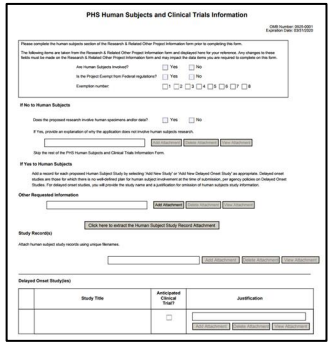
Human Subjects System

Responsible Party

Grant application

Applicant/Recipient





RPPR

Direct updates via Commons

ClinicalTrials.gov

eRA Commons
A program of the National Institutes of Health

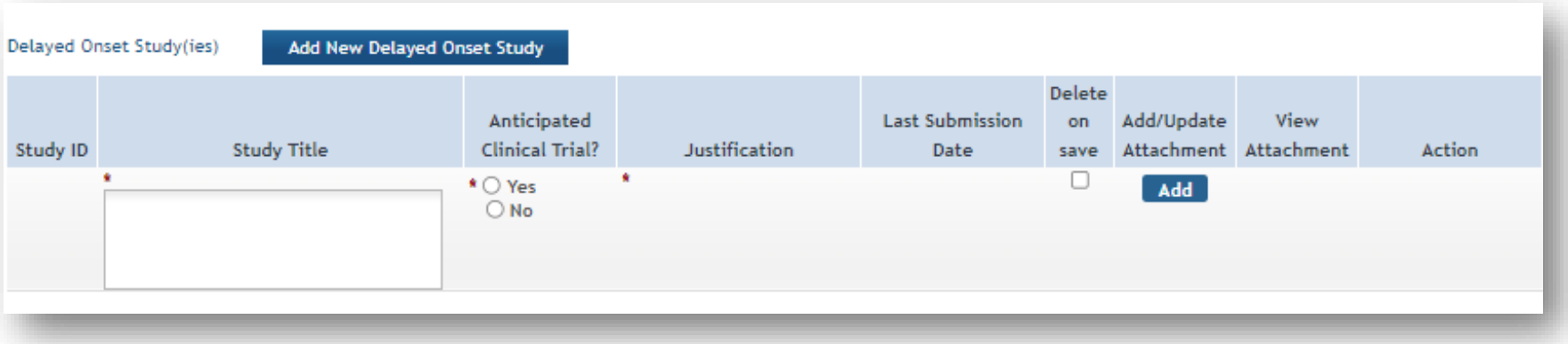
HSS
Human Subjects System

What's required pre-award?

- D43s and K12s: "delayed onset" study record unless otherwise specified in the Notice of Funding Opportunity (NOFO)

- Most other applications: PHS Human Subjects and Clinical Trials Information Form
  - Sections 1 – 3 only for non-trials
  - Sections 1 – 4 for clinical trials

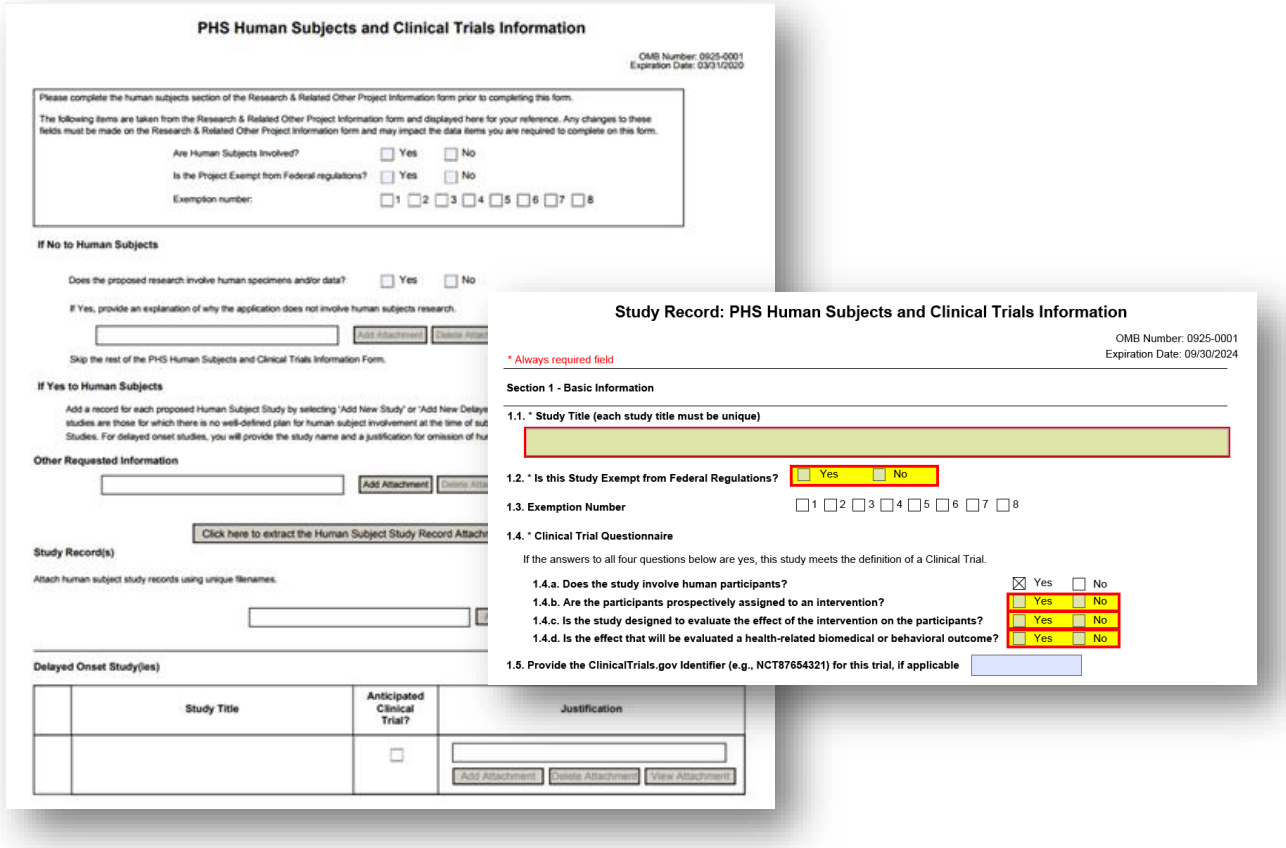
What is a delayed onset record?



- Abbreviated form describing human subjects research that is anticipated, but cannot be described in the application because plans are not definite.
- Delayed onset records
  - Requires a justification attachment

Human Subjects and Clinical Trial Information (HSCT) Form

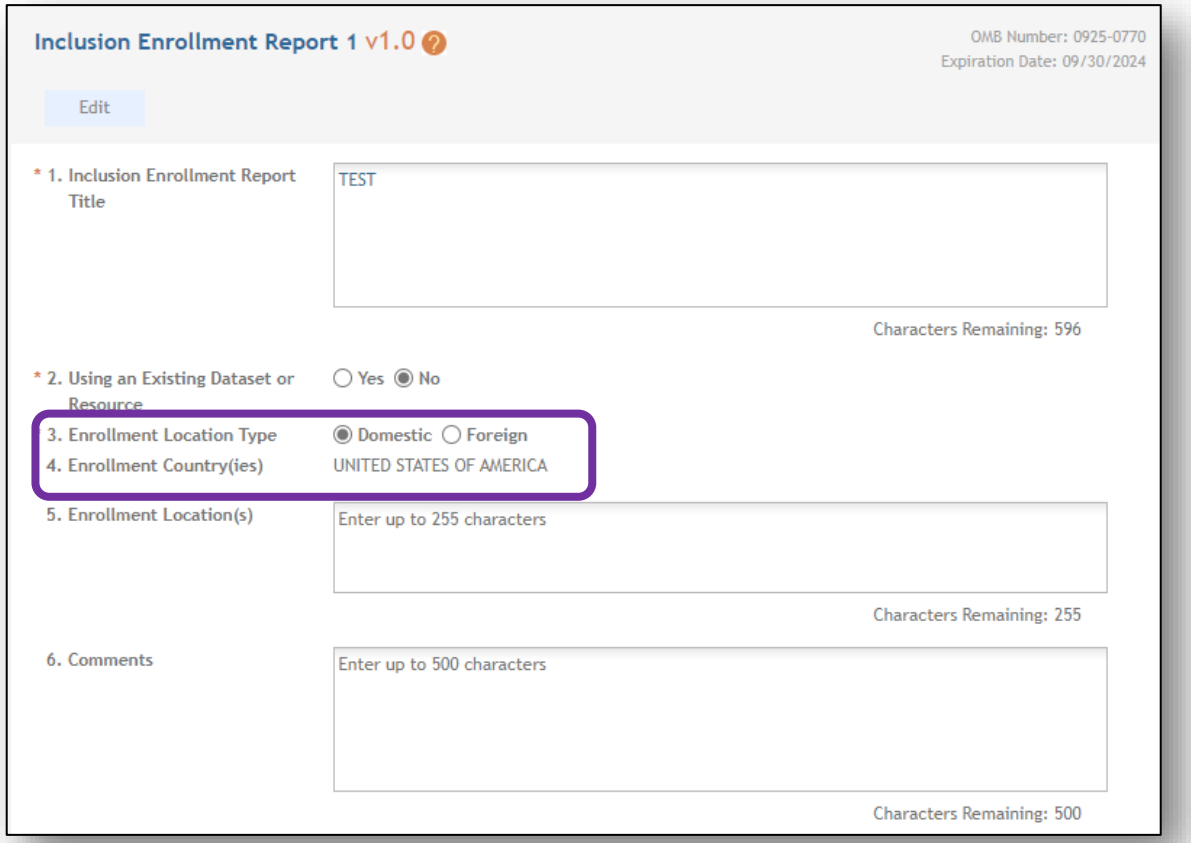
- Houses human subjects and clinical trial information for each study
  - Studies are described in study records within the form
- One project can have multiple study records



See the **Application Guide** for detailed instructions

Inclusion Enrollment: Separate U.S. and non-U.S. Participants

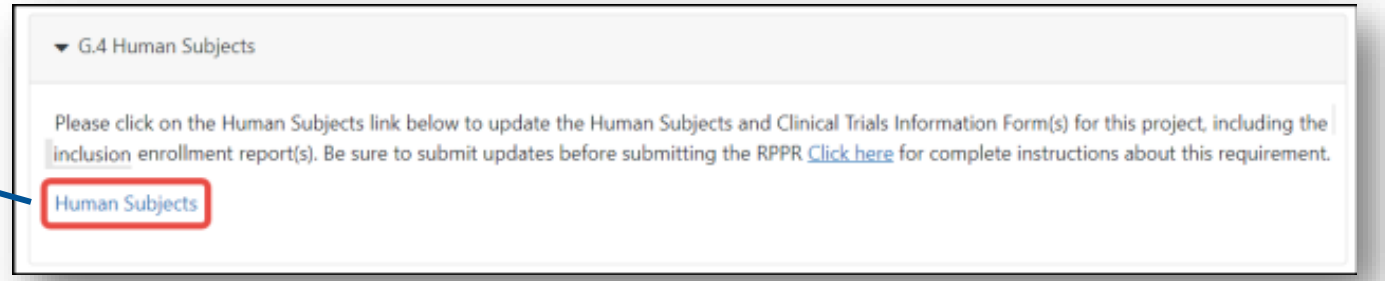
- Create separate inclusion enrollment reports for U.S. and non-U.S. participants
- Participants from multiple non-U.S. countries may be included in one report, or separate reports may be created
- Use the attributes at the top of the report to identify the countries of the non-U.S. participants



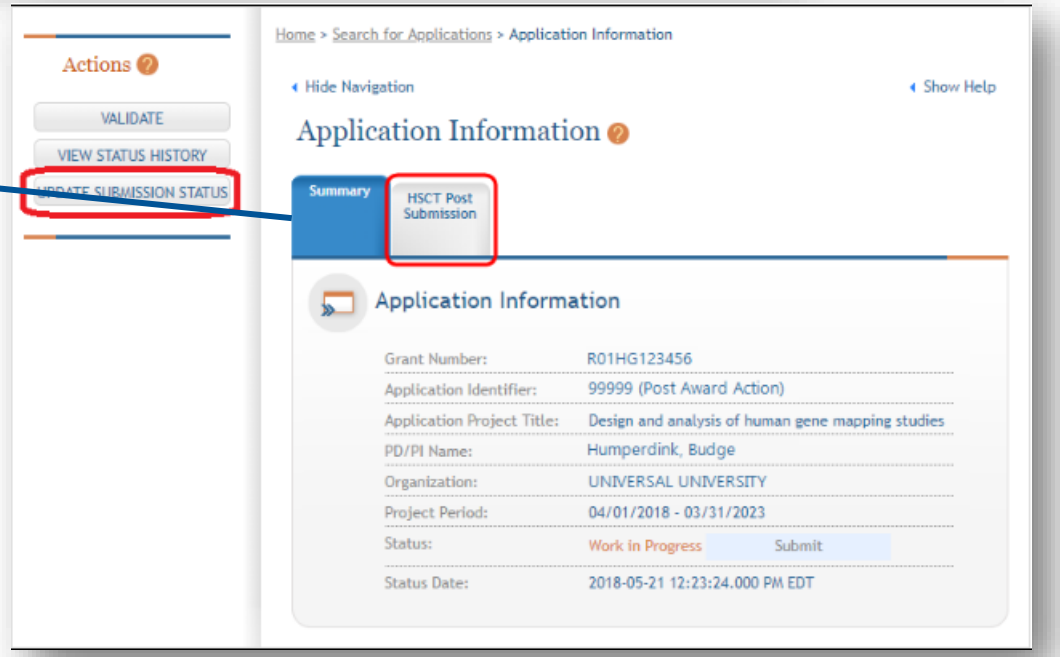
ACCESSING HSS POST SUBMISSION

Access HSS Through the RPPR

In Section G.4, click on the Human Subjects link



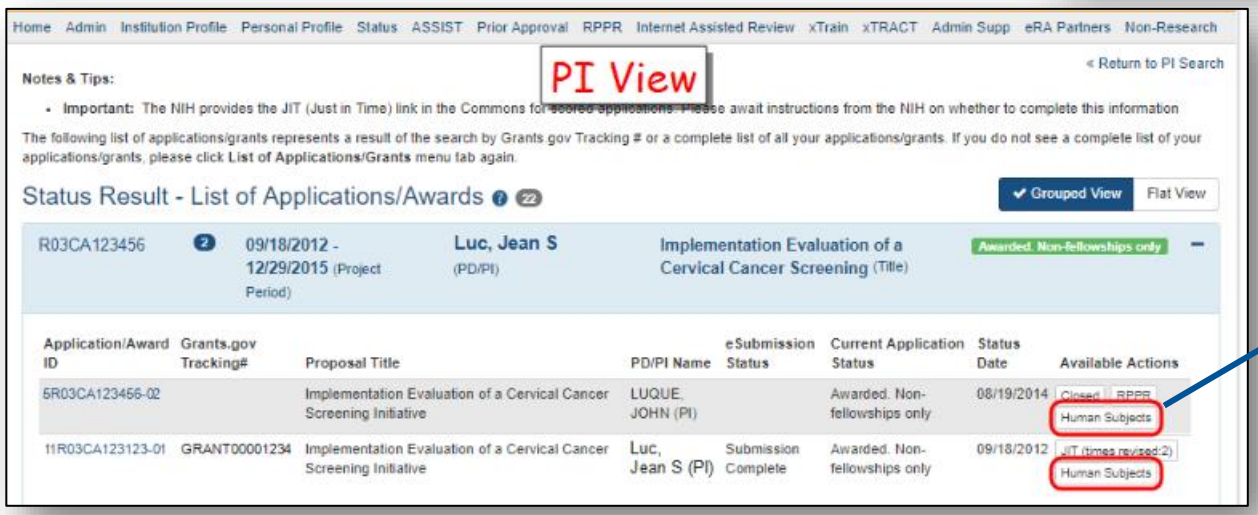
HSS will open to the Application Information screen, on the Summary tab



See the HSS Online Help Chapter How Do I Access HSS for more details.

Access HSS Through the Commons Status Tab

For signing officials, search for and then select the appropriate PI from the list. Click on the Human Subjects link.



For PIs, the Human Subjects link is also included in the list of applications/awards, under the Available Actions column.

UPDATING INFORMATION IN HSS

What information may need to be updated post-award?

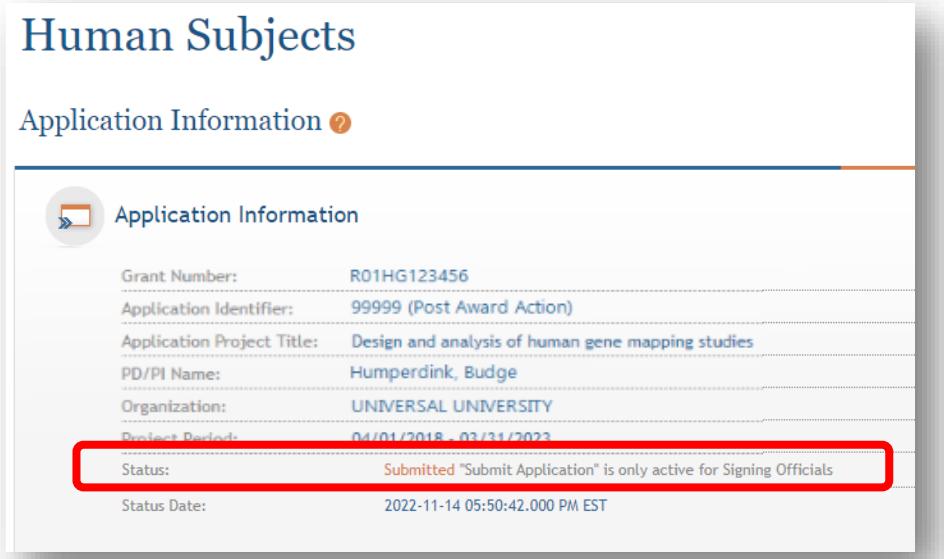
For all study types

- Convert delayed onset study
- Inclusion data
- Recruitment status
- Additional information as required by your IC or program officer

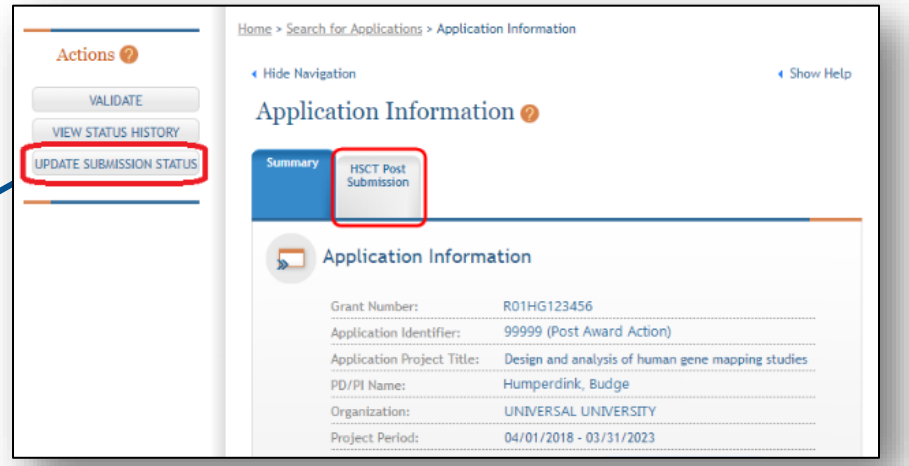
For clinical trials

- NCT
- Inclusion data
- Recruitment status
- Clinical trial milestones (Section 6 of study record)
  - Enrollment of First Participant Date
  - Study Completion Date
  - 25% Enrollment Date, etc.

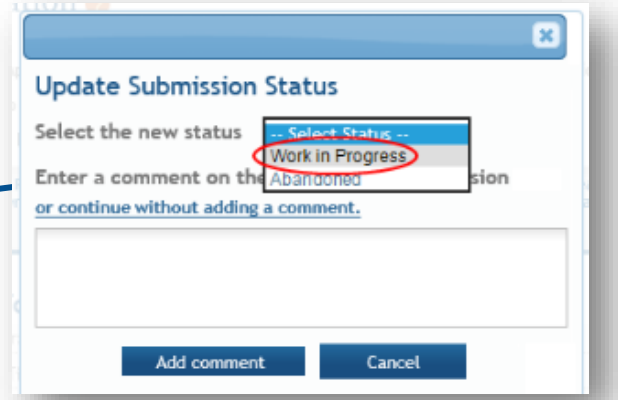
Check the Submission Status



Click on the Update Submission Status button from the Application Information page.



Use the dropdown menu to choose Work in Progress.

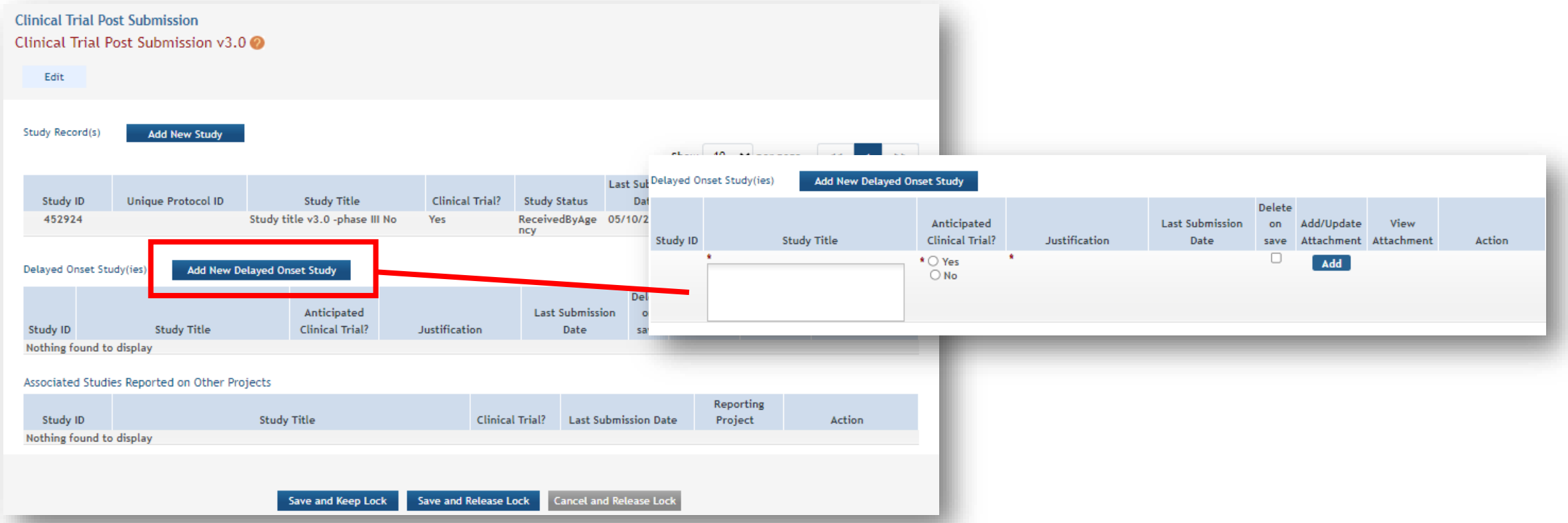


Editing a study record

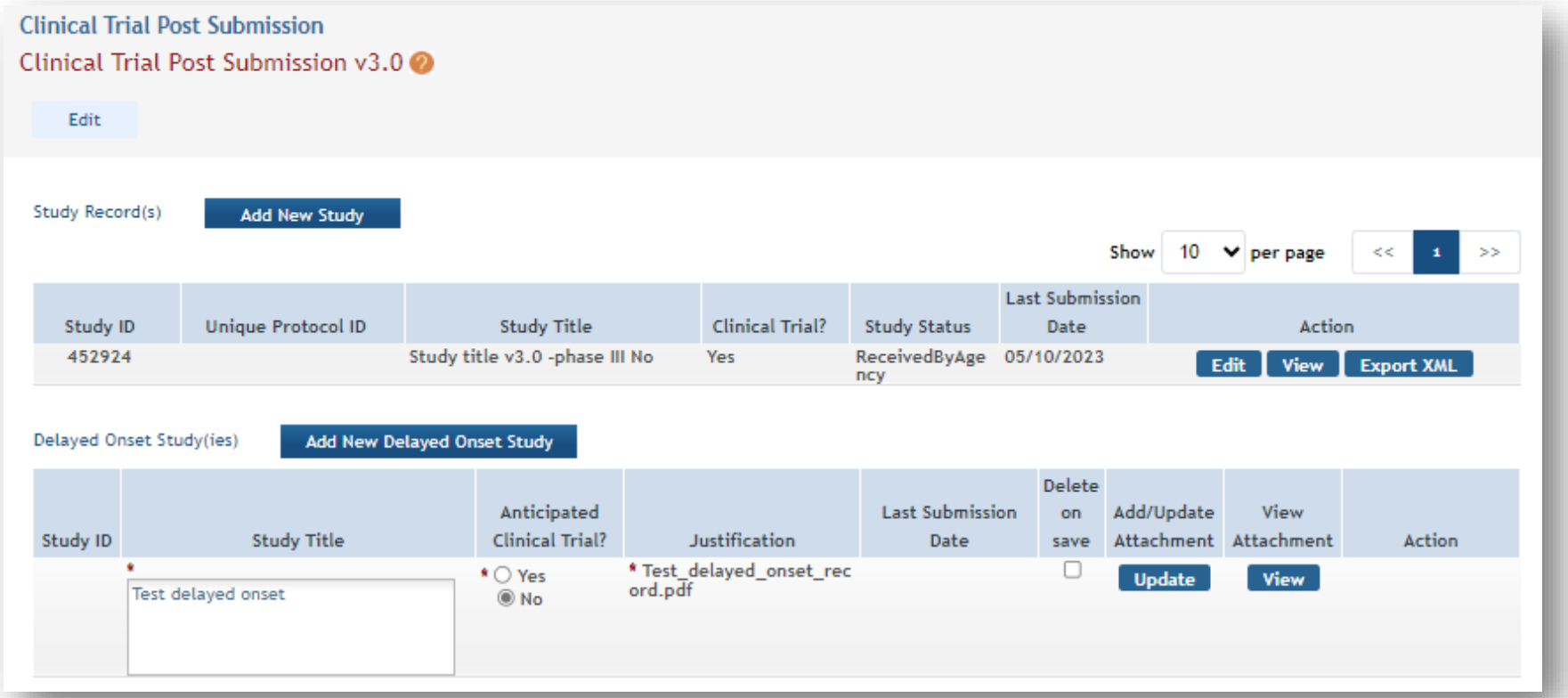
Can also click on the Edit button from the HSCT Post Submission Tab

See also *How Do I Edit Studies?* in the HSS Online Help

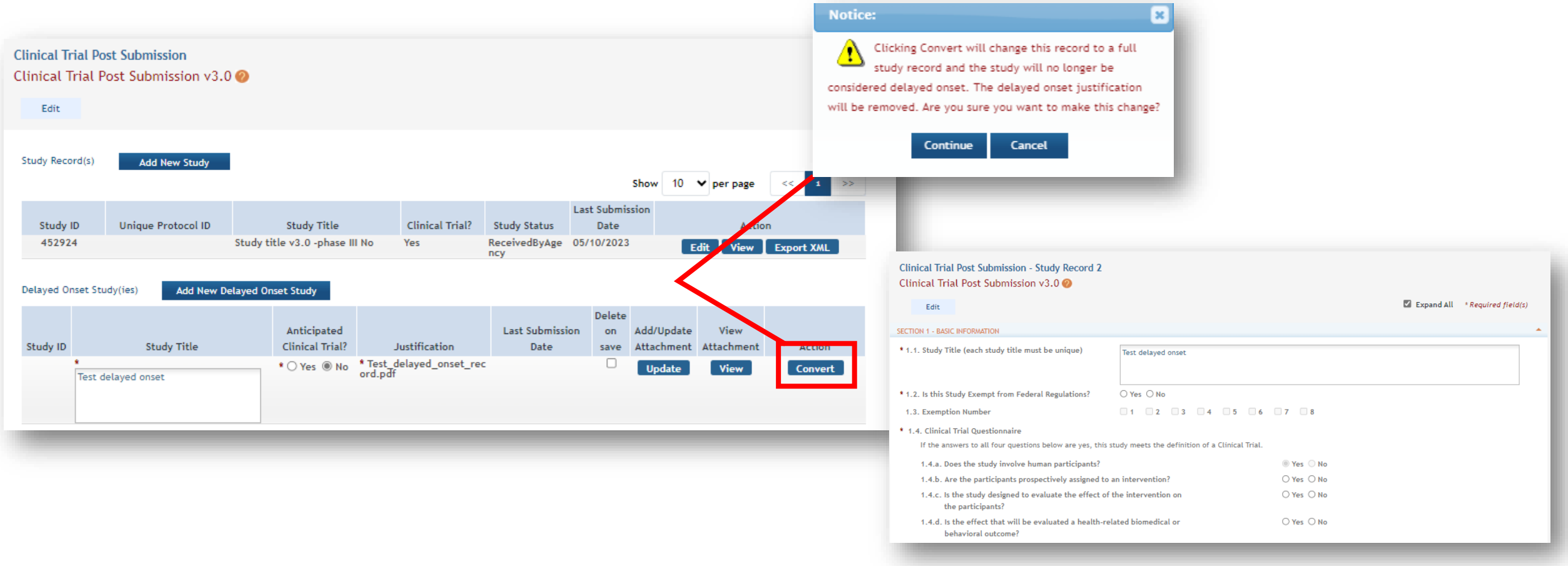
New delayed onset study



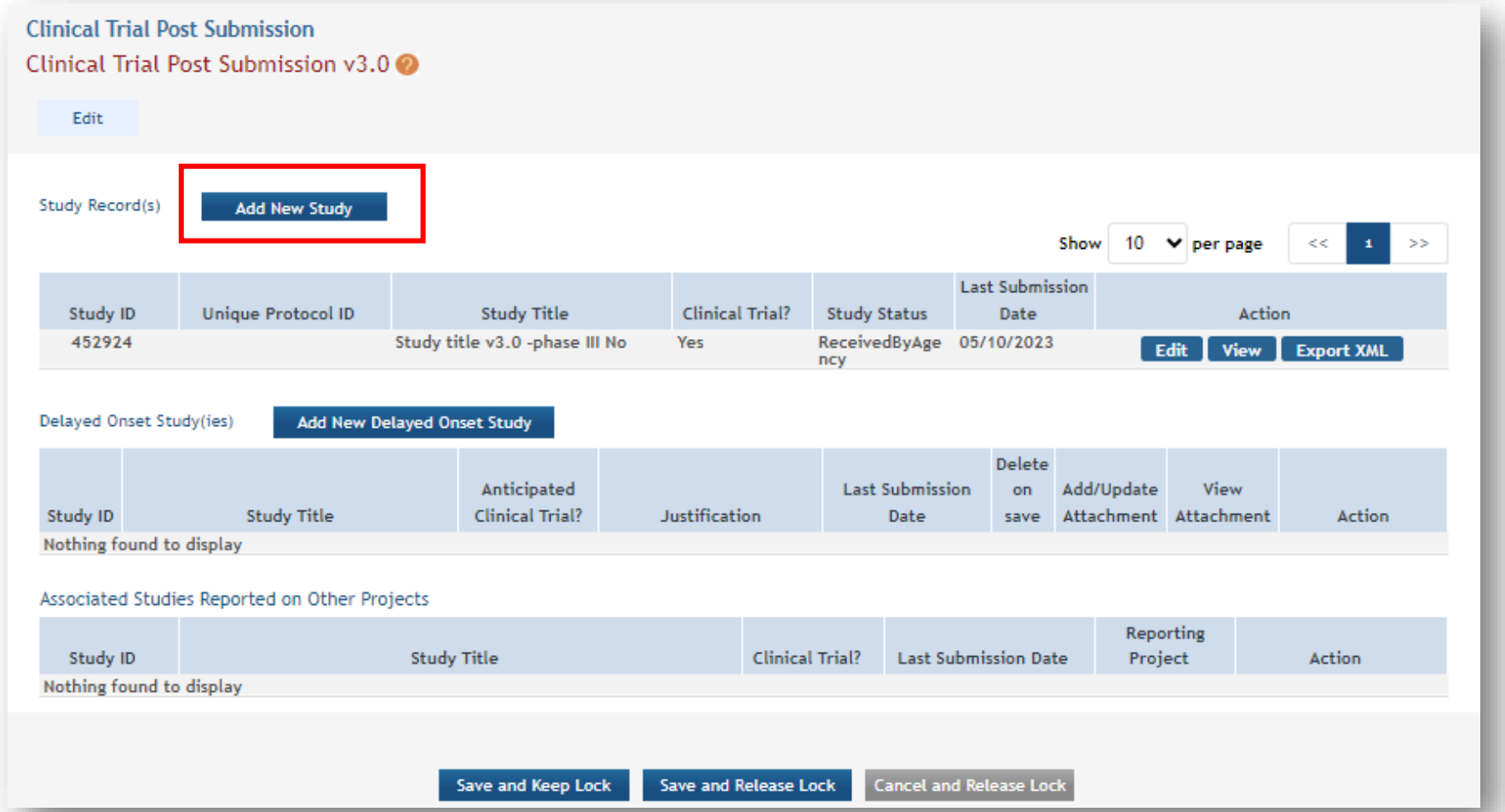
Delayed onset study (cont.)



Converting delayed onset to full record



Adding a new study record

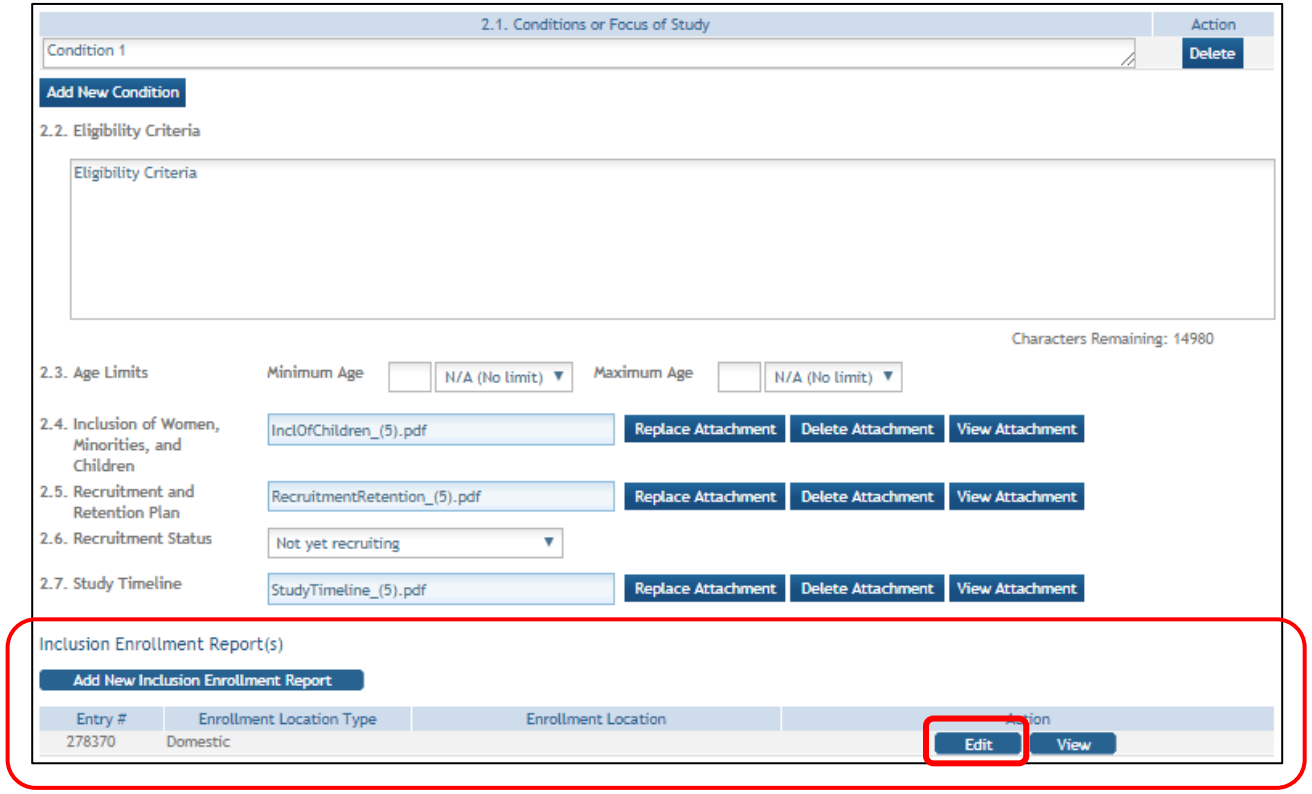


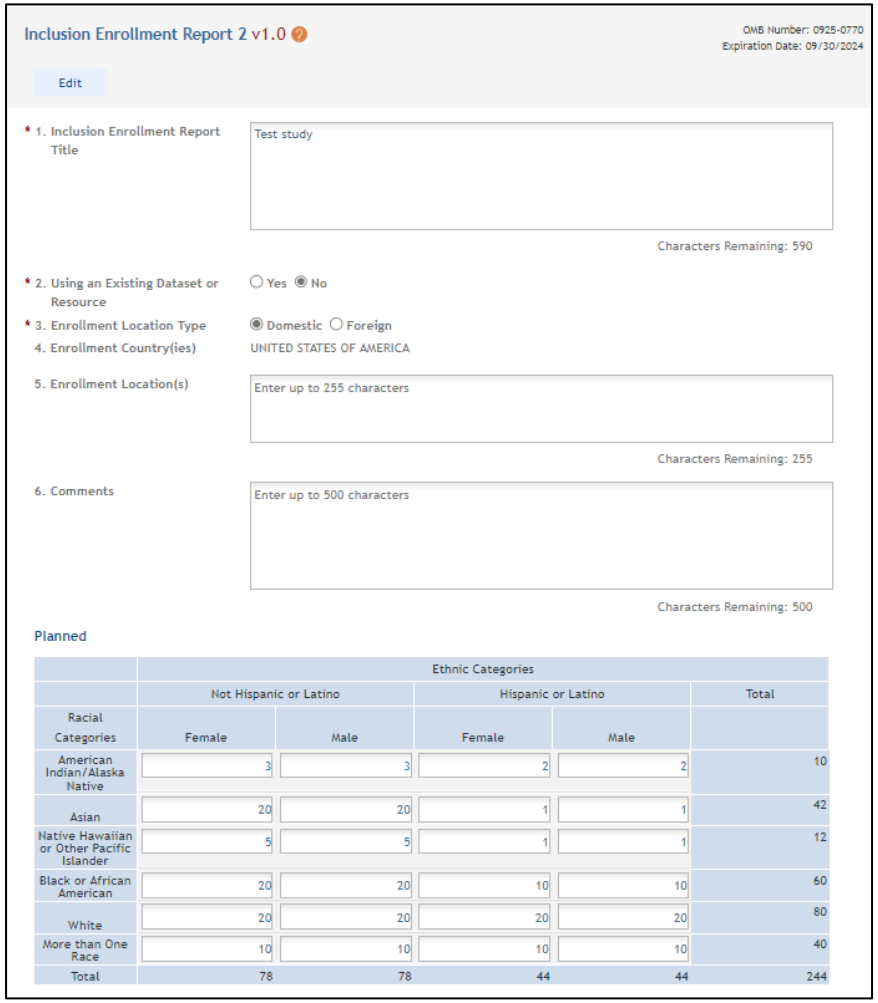
Updating Inclusion Information

Inclusion requirements by activity code

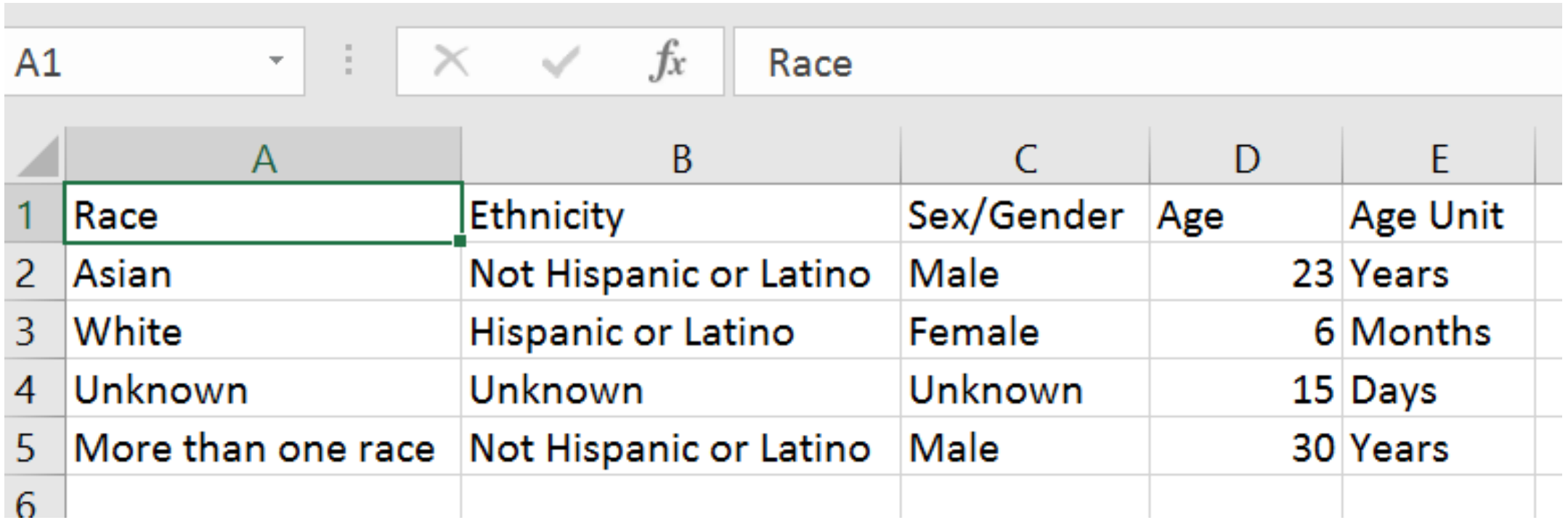
Activity Code	Inclusion required?
D43	No
R awards	Yes
K awards	Usually – not for KL2 and K12 unless specified in the NOFO or by your program officer

Updating Inclusion Enrollment: Edit Inclusion Enrollment Report





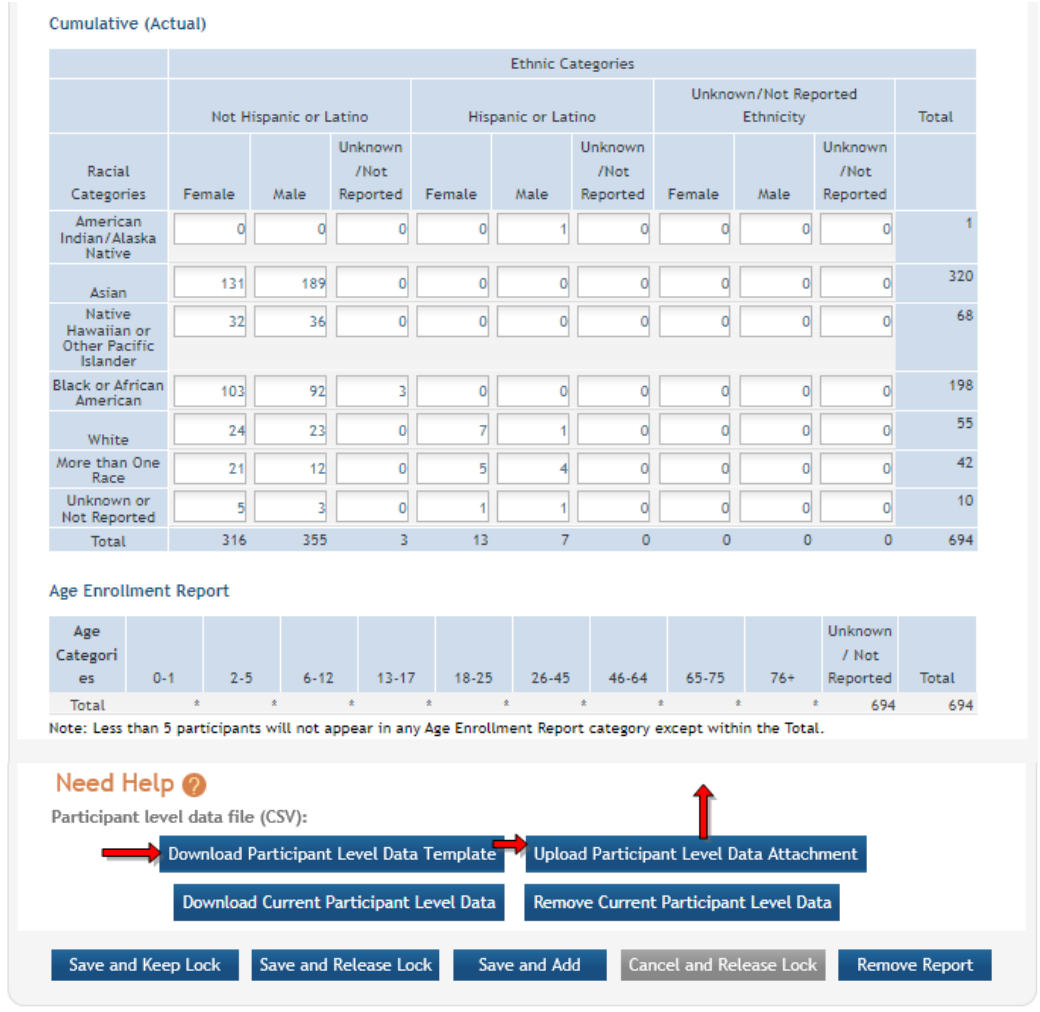
Individual-level Participant Data



	A	B	C	D	E
1	Race	Ethnicity	Sex/Gender	Age	Age Unit
2	Asian	Not Hispanic or Latino	Male	23	Years
3	White	Hispanic or Latino	Female	6	Months
4	Unknown	Unknown	Unknown	15	Days
5	More than one race	Not Hispanic or Latino	Male	30	Years
6					

Download the template from within your Inclusion enrollment report in HSS, from this template link, or from the eRA HSS Training website.

Uploading Participant-Level Data in HSS



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	1	0	0	0	0	1
Asian	131	189	0	0	0	0	0	0	0	320
Native Hawaiian or Other Pacific Islander	32	36	0	0	0	0	0	0	0	68
Black or African American	103	92	3	0	0	0	0	0	0	198
White	24	23	0	7	1	0	0	0	0	55
More than One Race	21	12	0	5	4	0	0	0	0	42
Unknown or Not Reported	5	3	0	1	1	0	0	0	0	10
Total	316	355	3	13	7	0	0	0	0	694

Age Enrollment Report

Age Categories	0-1	2-5	6-12	13-17	18-25	26-45	46-64	65-75	76+	Unknown / Not Reported	Total
Total	*	*	*	*	*	*	*	*	*	694	694

Note: Less than 5 participants will not appear in any Age Enrollment Report category except within the Total.

Need Help

Participant level data file (CSV):

Download Participant Level Data Template | Upload Participant Level Data Attachment

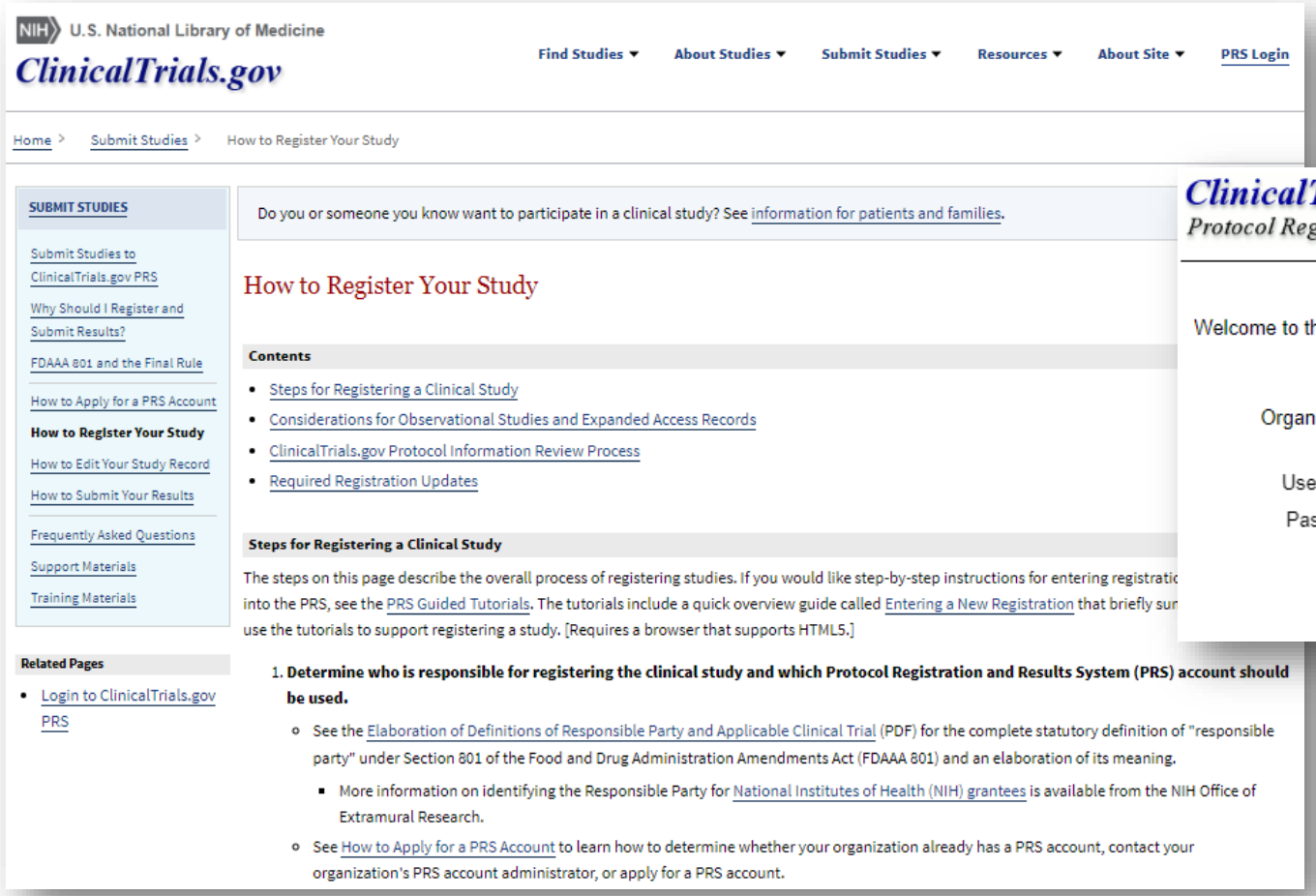
Download Current Participant Level Data | Remove Current Participant Level Data

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

See the eRA HSS Training site https://era.nih.gov/help-tutorials/era-training-hss.htm

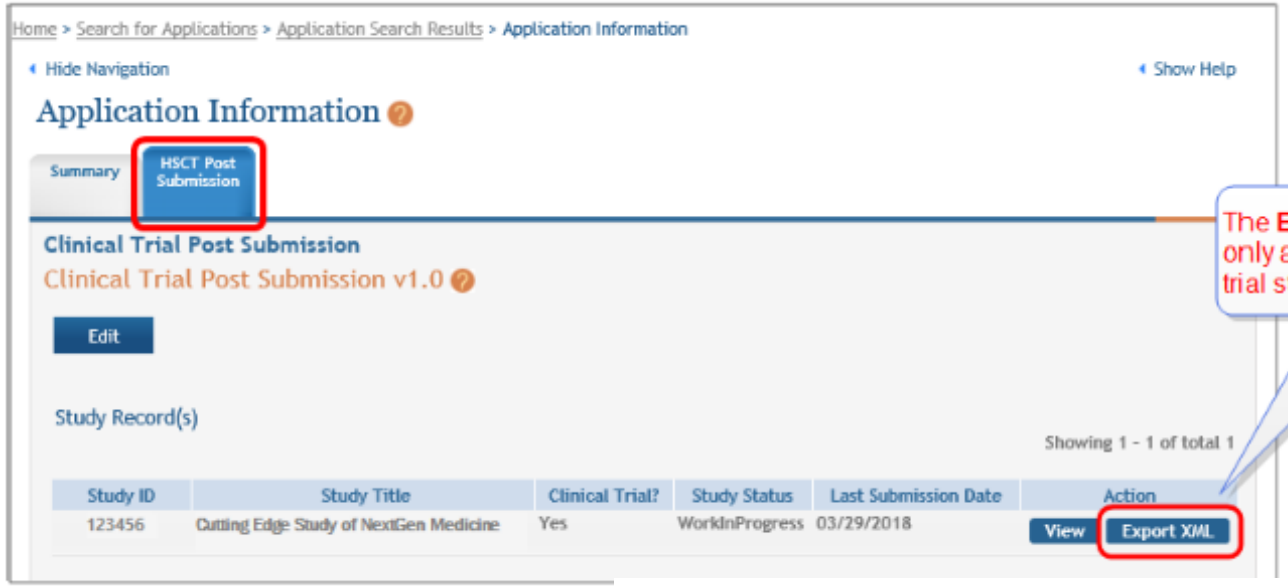
Updating Clinical Trial Information

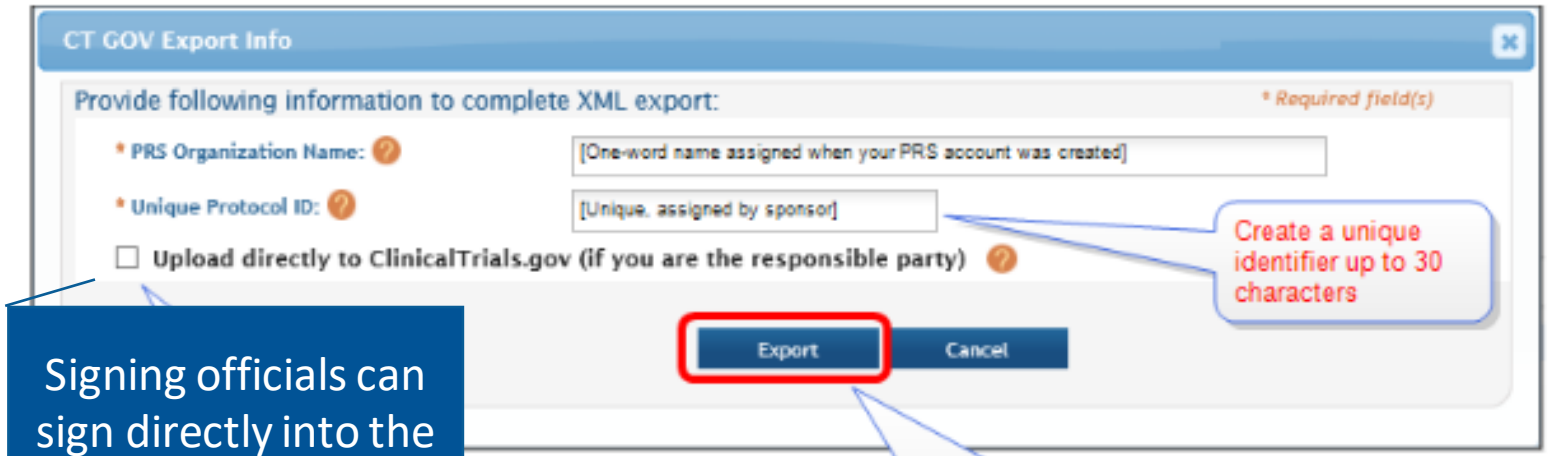
Register in ClinicalTrials.gov



For information on registration, go to [How to Register Your Study - ClinicalTrials.gov]

Export XML file with HSS data



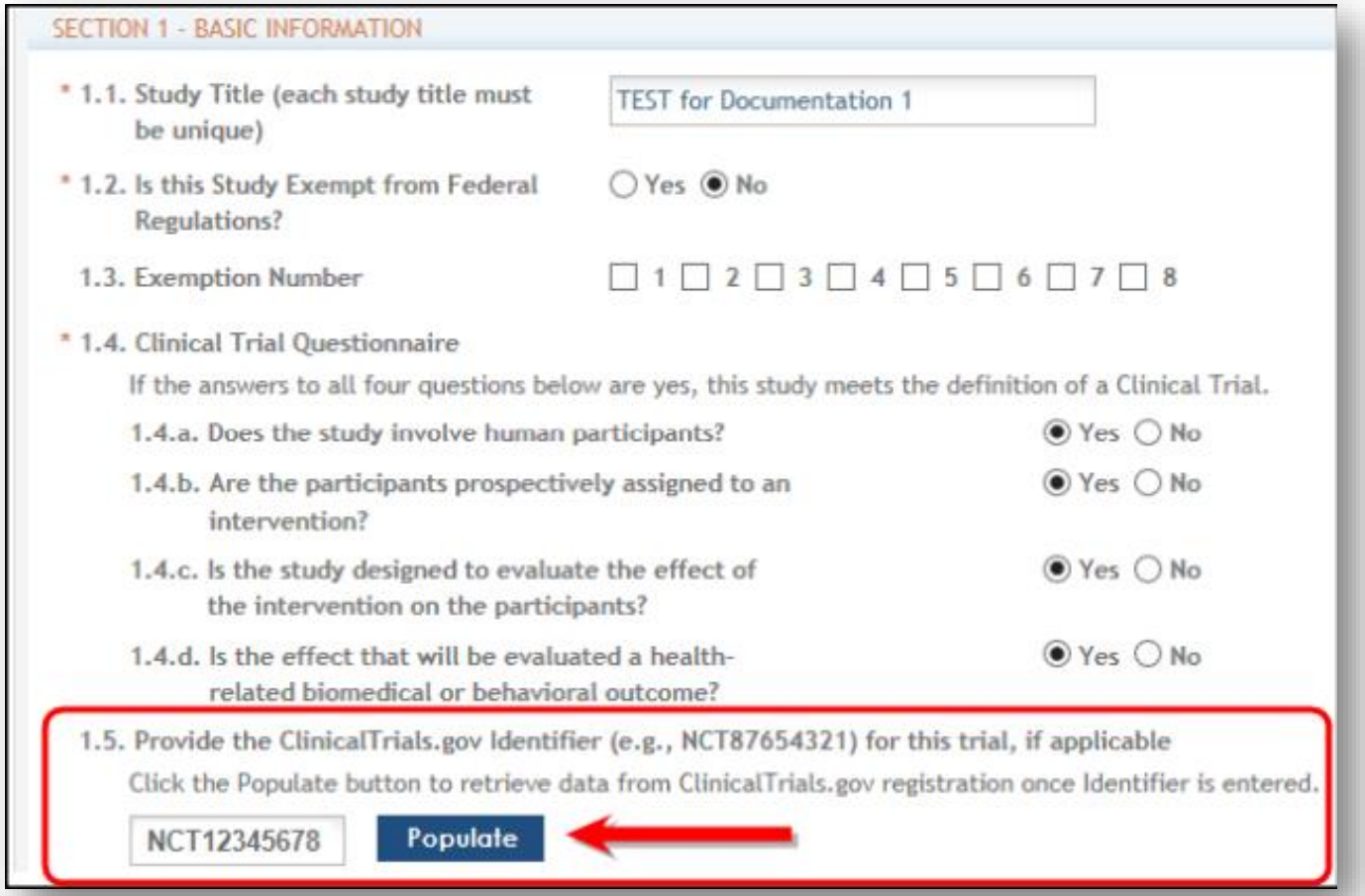


Signing officials can sign directly into the PRS account here.

See Export and Upload Data to ClinicalTrials.gov in the ASSIST online help.

Section 1: Add the NCT
(and use the Populate button!)

Once an NCT is entered, the Populate button can be used to update HSS fields that map to ClinicalTrials.gov



HSS and ClinicalTrials.gov fields:
validated for congruence

Clinicaltrials.gov Fields	HSS Fields	HSCT Form Section
Age Limits	Age Limits	Section 2
Overall Recruitment Status	Recruitment Status	Section 2
Study Phase	Study Phase	Section 4
Masking	Masking	Section 4
Allocation	Allocation	Section 4
Primary Completion Date	Study Primary Completion Date	Section 6
Study Completion Date	Study Final Completion Date	Section 6
Study Start Date	Enrollment of the First Participant	Section 6
Results First Submitted	Reporting of Results in ClinicalTrials.gov	Section 6

List is also available in the *How Do I Edit Studies?* chapter in the HSS Online Help

Remember: key Items to update

All full study records (i.e., not K12s or D43s):

- Update inclusion enrollment information

Clinical Trials:

- Register the clinical trial
- Provide NCT
- Update Clinical Trial milestone dates
- Use the Populate button to update information

System warnings and errors

Policy compliance

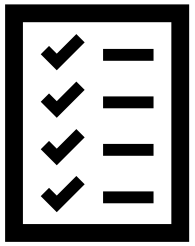
- Overdue clinical trial registration and reporting
- Required field(s) not completed

System validations

- Dates in the past that are set as “anticipated”
- Items completed on a non-clinical trial study record that are intended only for clinical trials

Troubleshooting

- Read the warnings and errors in the RPPR Module and in HSS: they often mention what the problem is
  - E.g., ClinicalTrials.gov and HSS field mismatch



Recommendations

When updating HSS information for your RPPR:

- Change status from *Work in Progress* to *Ready for Submission* and submit **prior to** submitting RPPR
- Describe any challenges or significant issues in narrative of RPPR

Resources: HSCT Form, HSS, and Inclusion

- NIH Application Guide
- eRA HSS Online Help
- eRA HSS Training website
- eRA HSS Help and Tutorials website
- Participant-level Data Tip Sheet
- HSS: Quick Guide for Warnings and Errors
- RPPR Module Online Help Editing the RPPR and Editing Inclusion Enrollment Data chapters
- NIH Inclusion of Women and Minorities Website and FAQs
- NIH Inclusion Across the Lifespan Website and FAQs

QUESTIONS

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