
The Human Subjects System (HSS)

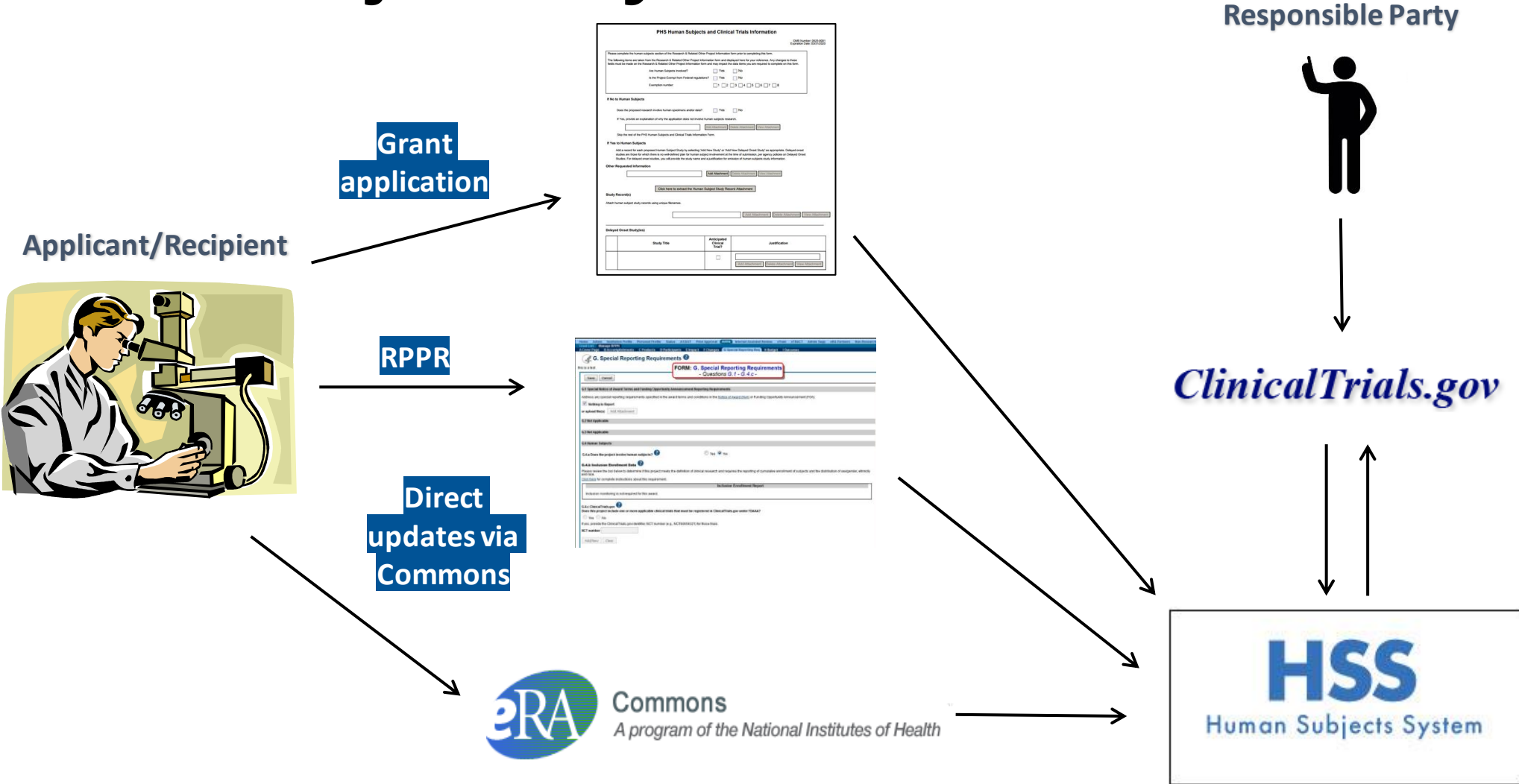
Global NCD Network Virtual Meeting | September 28, 2023 | Rebecca Favor, DrPH, CPH



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



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?

The screenshot shows a web interface for managing delayed onset studies. At the top left, it says "Delayed Onset Study(ies)" and has a blue button "Add New Delayed Onset Study". Below this is a table with the following columns: "Study ID", "Study Title", "Anticipated Clinical Trial?", "Justification", "Last Submission Date", "Delete on save", "Add/Update Attachment", "View Attachment", and "Action". The "Study ID" column has a red asterisk. The "Study Title" column has a text input field. The "Anticipated Clinical Trial?" column has radio buttons for "Yes" and "No", with a red asterisk. The "Delete on save" column has a checkbox. The "Add/Update Attachment" column has a blue "Add" button. The "View Attachment" and "Action" columns are currently empty.

Study ID	Study Title	Anticipated Clinical Trial?	Justification	Last Submission Date	Delete on save	Add/Update Attachment	View Attachment	Action
*	<input type="text"/>	* <input type="radio"/> Yes <input type="radio"/> No	*		<input type="checkbox"/>	<input type="button" value="Add"/>		

- 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

PHS Human Subjects and Clinical Trials Information
OMB Number: 0925-0001
Expiration Date: 03/31/2020

Please complete the human subjects section of the Research & Related Other Project Information form prior to completing this form. The following items are taken from the Research & Related Other Project Information form and displayed here for your reference. Any changes to these fields must be made on the Research & Related Other Project Information form and may impact the data items you are required to complete on this form.

Are Human Subjects Involved? Yes No
Is the Project Exempt from Federal regulations? Yes No
Exemption number: 1 2 3 4 5 6 7 8

If No to Human Subjects
Does the proposed research involve human specimens and/or data? Yes No
If Yes, provide an explanation of why the application does not involve human subjects research.
Skip the rest of the PHS Human Subjects and Clinical Trials Information Form.

If Yes to Human Subjects
Add a record for each proposed Human Subject Study by selecting 'Add New Study' or 'Add New Delayed onset studies are those for which there is no well-defined plan for human subject involvement at the time of submission. For delayed onset studies, you will provide the study name and a justification for omission of human subjects research.

Other Requested Information
Click here to extract the Human Subject Study Record Attachments

Study Record(s)
Attach human subject study records using unique filenames.

Delayed Onset Study(ies)

Study Title	Anticipated Clinical Trial?	Justification
	<input type="checkbox"/>	

Study Record: PHS Human Subjects and Clinical Trials Information
OMB Number: 0925-0001
Expiration Date: 09/30/2024

* Always required field

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

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

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

Inclusion Enrollment Report 1 v1.0 ?

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

Edit

* 1. Inclusion Enrollment Report Title
TEST
Characters Remaining: 596

* 2. Using an Existing Dataset or Resource
 Yes No

3. Enrollment Location Type
 Domestic Foreign

4. Enrollment Country(ies)
UNITED STATES OF AMERICA

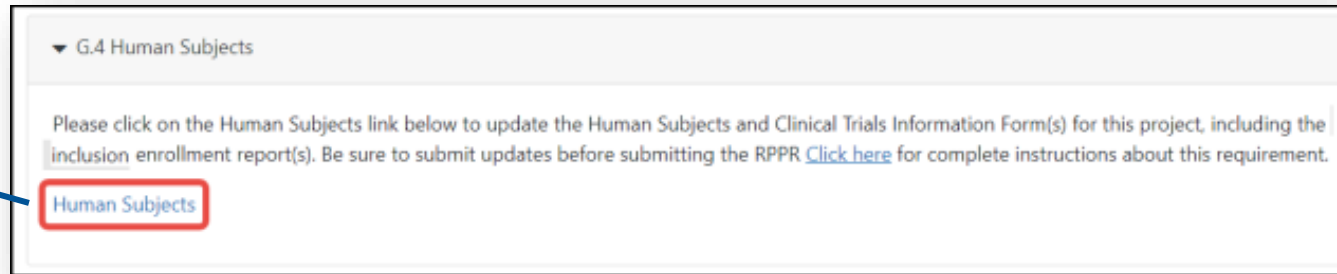
5. Enrollment Location(s)
Enter up to 255 characters
Characters Remaining: 255

6. Comments
Enter up to 500 characters
Characters Remaining: 500

ACCESSING HSS POST SUBMISSION

Access HSS Through the RPPR

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

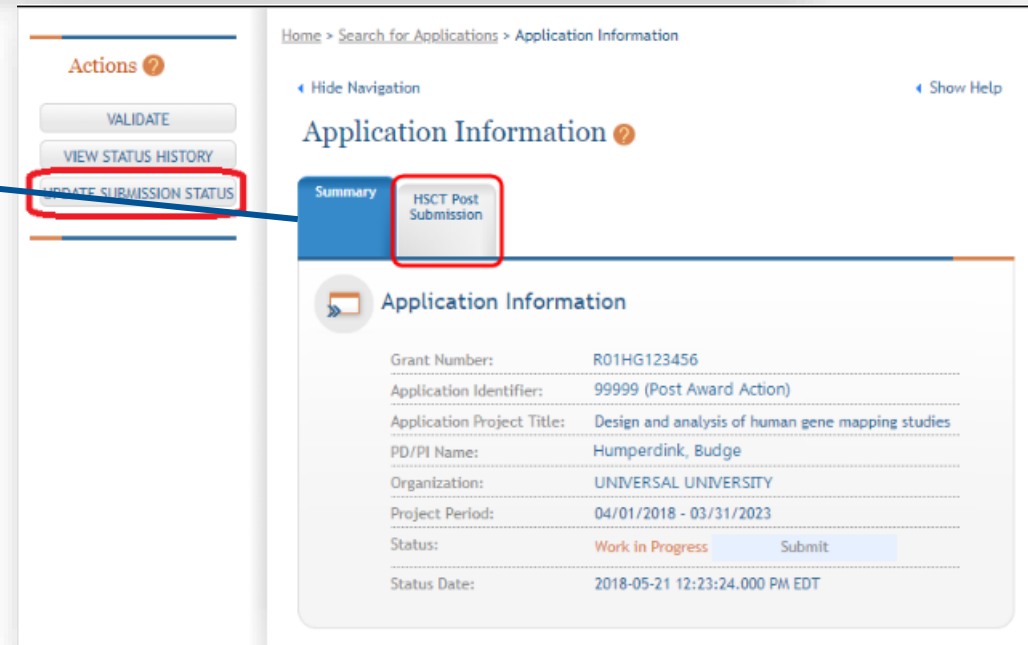


▼ G.4 Human Subjects

Please click on the Human Subjects link below to update the Human Subjects and Clinical Trials Information Form(s) for this project, including the inclusion enrollment report(s). Be sure to submit updates before submitting the RPPR [Click here](#) for complete instructions about this requirement.

[Human Subjects](#)

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



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

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.

SO View

Status Result - General Search

Filter Table [icon] 246 Results [download icon] [grid icon] [1 of 10] [arrow icon]

Application/Award ID	Grants.gov Tracking #	Proposal Title	PD/PI Name	Application Status	Project Period Start	Project Period End	Budget Period Start	Budget Period End
1R01DA050505-01 (MPI)	GRANT13333333	Understanding ... between ... and ado- substance	Kewitt, Hohn	Awarded. Non-fellowships only	05/01/2022	02/28/2027	05/01/2022	02/28/2023

Human Subjects
View Prior eSubmissions

PI View

Home Admin Institution Profile Personal Profile Status ASSIST Prior Approval RPPR Internet Assisted Review xTrain xTRACT Admin Supp eRA Partners Non-Research

Notes & Tips: Important: The NIH provides the JIT (Just in Time) link in the Commons for ... Please await instructions from the NIH on whether to complete this information

The following list of applications/grants represents a result of the search by Grants.gov Tracking # or a complete list of all your applications/grants. If you do not see a complete list of your applications/grants, please click List of Applications/Grants menu tab again.

Status Result - List of Applications/Awards [Grouped View] [Flat View]

Application/Award ID	Grants.gov Tracking#	Proposal Title	PD/PI Name	eSubmission Status	Current Application Status	Status Date	Available Actions
R03CA123456	09/18/2012 - 12/29/2015 (Project Period)	Luc, Jean S (PD/PI)	Implementation Evaluation of a Cervical Cancer Screening (Title)	Awarded. Non-fellowships only			
5R03CA123456-02		Implementation Evaluation of a Cervical Cancer Screening Initiative	LUQUE, JOHN (PI)	Submission Complete	Awarded. Non-fellowships only	08/19/2014	Human Subjects
11R03CA123123-01	GRANT00001234	Implementation Evaluation of a Cervical Cancer Screening Initiative	Luc, Jean S (PI)	Submission Complete	Awarded. Non-fellowships only	09/18/2012	Human Subjects

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

Human Subjects

Application Information ?

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: Submitted "Submit Application" is only active for Signing Officials

Status Date: 2022-11-14 05:50:42.000 PM EST

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

Home > Search for Applications > Application Information

Hide Navigation Show Help

Application Information ?

Summary HSC 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

Use the dropdown menu to choose Work in Progress.

Update Submission Status

Select the new status

Enter a comment on the Abandoned submission or continue without adding a comment.

Add comment Cancel

Editing a study record

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:

Organization:

Project Period:

Status:

Status Date:

Summary HSCT Post Submission

Clinical Trial Post Submission

Clinical Trial Post Submission v1.0

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	View Export XML

Summary HSCT Post Submission

Post Submission Summary > Study Record: 1

Clinical Trial Post Submission - Study Record 1

Clinical Trial Post Submission v1.0

OMB Number: 0925-0001 and 0925-0002
Expiration Date: 03/31/2020

[Edit](#) Expand All * Required field(s)

SECTION 1 - BASIC INFORMATION

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

Clinical Trial Post Submission
Clinical Trial Post Submission v3.0

Edit

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

Study ID	Unique Protocol ID	Study Title	Clinical Trial?	Study Status	Last Submission Date
452924		Study title v3.0 -phase III No	Yes	ReceivedByAgency	05/10/2

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
		<input type="radio"/> Yes <input type="radio"/> No			<input type="checkbox"/>	Add		

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

Study ID	Study Title	Anticipated Clinical Trial?	Justification	Last Submission Date	Delete on save
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**

Delayed onset study (cont.)

Clinical Trial Post Submission
Clinical Trial Post Submission v3.0 ?

Edit

Study Record(s) [Add New Study](#)

Show 10 per page << 1 >>

Study ID	Unique Protocol ID	Study Title	Clinical Trial?	Study Status	Last Submission Date	Action
452924		Study title v3.0 -phase III No	Yes	ReceivedByAgency	05/10/2023	Edit View Export XML

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
	<input type="text" value="Test delayed onset"/>	<input type="radio"/> Yes <input checked="" type="radio"/> No	* Test_delayed_onset_record.pdf		<input type="checkbox"/>	Update	View	

Converting delayed onset to full record

Clinical Trial Post Submission
Clinical Trial Post Submission v3.0 ?

Edit

Study Record(s) [Add New Study](#)


Show 10 per page << 1 >>

Study ID	Unique Protocol ID	Study Title	Clinical Trial?	Study Status	Last Submission Date	Action
452924		Study title v3.0 -phase III No	Yes	ReceivedByAgency	05/10/2023	Edit View Export XML

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
	Test delayed onset	<input type="radio"/> Yes <input checked="" type="radio"/> No	Test_delayed_onset_rec ord.pdf		<input type="checkbox"/>	Update	View	Convert

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](#)

Clinical Trial Post Submission - Study Record 2
Clinical Trial Post Submission v3.0 ?

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

* 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

Adding a new study record

Clinical Trial Post Submission
Clinical Trial Post Submission v3.0 ?

Edit

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

Show 10 per page << 1 >>

Study ID	Unique Protocol ID	Study Title	Clinical Trial?	Study Status	Last Submission Date	Action
452924		Study title v3.0 -phase III No	Yes	ReceivedByAgency	05/10/2023	Edit View Export XML

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

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

2.1. Conditions or Focus of Study

Condition 1 Action Delete

[Add New Condition](#)

2.2. Eligibility Criteria

Eligibility Criteria

Characters Remaining: 14980

2.3. Age Limits

Minimum Age N/A (No limit) Maximum Age N/A (No limit)

2.4. Inclusion of Women, Minorities, and Children

[InclOfChildren_\(5\).pdf](#) [Replace Attachment](#) [Delete Attachment](#) [View Attachment](#)

2.5. Recruitment and Retention Plan

[RecruitmentRetention_\(5\).pdf](#) [Replace Attachment](#) [Delete Attachment](#) [View Attachment](#)

2.6. Recruitment Status

Not yet recruiting

2.7. Study Timeline

[StudyTimeline_\(5\).pdf](#) [Replace Attachment](#) [Delete Attachment](#) [View Attachment](#)

Inclusion Enrollment Report(s)

[Add New Inclusion Enrollment Report](#)

Entry #	Enrollment Location Type	Enrollment Location	Action
278370	Domestic		Edit View

Inclusion Enrollment Report 2 v1.0 OHS Number: 0925-0770 Expiration Date: 09/30/2024

[Edit](#)

* 1. Inclusion Enrollment Report Title

Test study

Characters Remaining: 590

* 2. Using an Existing Dataset or Resource Yes No

* 3. Enrollment Location Type Domestic Foreign

4. Enrollment Country(ies)

UNITED STATES OF AMERICA

5. Enrollment Location(s)

Enter up to 255 characters

Characters Remaining: 255

6. Comments

Enter up to 500 characters

Characters Remaining: 500

Planned

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/Alaska Native	<input type="text"/> 3	<input type="text"/> 3	<input type="text"/> 2	<input type="text"/> 2	10
Asian	<input type="text"/> 20	<input type="text"/> 20	<input type="text"/> 1	<input type="text"/> 1	42
Native Hawaiian or Other Pacific Islander	<input type="text"/> 5	<input type="text"/> 5	<input type="text"/> 1	<input type="text"/> 1	12
Black or African American	<input type="text"/> 20	<input type="text"/> 20	<input type="text"/> 10	<input type="text"/> 10	60
White	<input type="text"/> 20	<input type="text"/> 20	<input type="text"/> 20	<input type="text"/> 20	80
More than One Race	<input type="text"/> 10	<input type="text"/> 10	<input type="text"/> 10	<input type="text"/> 10	40
Total	78	78	44	44	244

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)

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	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

Download Current Participant Level Data

Upload Participant Level Data Attachment

Remove Current Participant Level Data

Updating Clinical Trial Information



Register in ClinicalTrials.gov

NIH U.S. National Library of Medicine
ClinicalTrials.gov

Find Studies ▾ About Studies ▾ Submit Studies ▾ Resources ▾ About Site ▾ PRS Login

Home > Submit Studies > How to Register Your Study

SUBMIT STUDIES

- Submit Studies to ClinicalTrials.gov PRS
- Why Should I Register and Submit Results?
- FDAAA 801 and the Final Rule
- How to Apply for a PRS Account
- How to Register Your Study**
- How to Edit Your Study Record
- How to Submit Your Results
- Frequently Asked Questions
- Support Materials
- Training Materials

Related Pages

- [Login to ClinicalTrials.gov PRS](#)

Do you or someone you know want to participate in a clinical study? See [information for patients and families](#).

How to Register Your Study

Contents

- [Steps for Registering a Clinical Study](#)
- [Considerations for Observational Studies and Expanded Access Records](#)
- [ClinicalTrials.gov Protocol Information Review Process](#)
- [Required Registration Updates](#)

Steps for Registering a Clinical Study

The steps on this page describe the overall process of registering studies. If you would like step-by-step instructions for entering registration into the PRS, see the [PRS Guided Tutorials](#). The tutorials include a quick overview guide called [Entering a New Registration](#) that briefly summarizes the steps and use the tutorials to support registering a study. [Requires a browser that supports HTML5.]

- Determine who is responsible for registering the clinical study and which Protocol Registration and Results System (PRS) account should be used.**
 - See the [Elaboration of Definitions of Responsible Party and Applicable Clinical Trial](#) (PDF) for the complete statutory definition of "responsible party" under Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801) and an elaboration of its meaning.
 - More information on identifying the Responsible Party for [National Institutes of Health \(NIH\) grantees](#) is available from the NIH Office of Extramural Research.
 - See [How to Apply for a PRS Account](#) to learn how to determine whether your organization already has a PRS account, contact your organization's PRS account administrator, or apply for a PRS account.

ClinicalTrials.gov PRS
Protocol Registration and Results System

Login

Welcome to the [ClinicalTrials.gov](#) Protocol Registration and Results System (PRS). OMB NO: 0925-0586
EXPIRATION DATE: 02/28/2023
[Burden Statement](#)

Organization:
One-word organization name assigned by PRS (sent via email when account was created)

Username:

Password: [Forgot password](#)

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

Export XML file with HSS data

Home > Search for Applications > Application Search Results > Application Information

Hide Navigation Show Help

Application Information

Summary **HST 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	Cutting Edge Study of NextGen Medicine	Yes	WorkInProgress	03/29/2018	View Export XML

The **Export XML** button only appears for clinical trial studies

See [Export and Upload Data to ClinicalTrials.gov](#) in the ASSIST online help.

CT GOV Export Info

Provide following information to complete XML export: ** Required field(s)*

- PRs Organization Name:** [One-word name assigned when your PRS account was created]
- Unique Protocol ID:** [Unique, assigned by sponsor]
- Upload directly to ClinicalTrials.gov (if you are the responsible party)

Export Cancel

Create a unique identifier up to 30 characters

Signing officials can sign directly into the PRS account here.

Click **Export** to export the human subject data to an XML file

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

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

* 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.

←

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



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

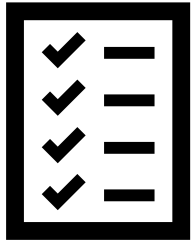
System validations

- 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

