

## PHS Human Subjects and Clinical Trials Information

### Use of Human Specimens and/or Data

\* Does any of the proposed research in the application involve human specimens and/or data?

Yes  No

Answer required for all applications.

Provide an explanation for any use of human specimens and/or data not considered to be human subjects research.

← Only include attachment if proposed research uses human specimens and/or data not considered to be human subjects research.

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

Information populated from R&R Other Project Information form.

### If No to Human Subjects

Skip the rest of the PHS Human Subjects and Clinical Trials Information Form.

### If Yes to Human Subjects

Steps for adding a study record will vary based on submission method used (ASSIST, system-to-system solution, Grants.gov Workspace).

Add a record for each proposed Human Subject Study by selecting "Add New Study" or "Add New Delayed Onset Study" as appropriate. Delayed onset studies are those for which there is no well defined plan for human subject involvement at the time of submission, per agency policies on Delayed Onset Studies. For delayed onset studies, you will provide a study name and justification for omission of human subject study information.

### Other Requested Information

← Only provide an Other Requested Information attachment when specifically requested in the funding opportunity announcement text or application guide.

[Click here to extract the Human Subject Study Record Attachment](#)

### Study Record(s)

Attach human subject study records using unique filenames.

1) Please attach Human Subject Study 1

Add Attachment

Delete Attachment

View Attachment

### Delayed Onset Study(ies)

Cannot add a Delayed Onset Study if you answer No to human subjects question on R&R Other Project Information form.

Delayed onset does NOT apply to a study that can be described but will not start immediately (i.e., delayed start). Multiple delayed onset studies can be grouped in a single record.

#	Study Title	Anticipated Clinical Trial?	Justification
		<input type="checkbox"/>	<input type="text"/> Add Attachment Delete Attachment View Attachment

Required and system enforced for each delayed onset study. Up to 600 characters. Study title must be unique within the application. First 150 characters of title will show in application bookmark.

If Anticipated Clinical Trial box is checked, funding opportunity announcement must allow clinical trials. When multiple studies are included in the same delayed onset record, select Yes if it is anticipated that any study will be a clinical trial.

Required and system enforced for each delayed onset study. In addition to justification, must include information regarding how the study will comply with the NIH single Institutional Review Board (sIRB) policy prior to initiating any multi-site study, as well as, a plan for the dissemination of NIH-funded clinical trial information.

HS = Human Subjects  
CT = Clinical Trials

# Study Record: PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001

Expiration Date: 02/28/2023

\* Always required field

## Section 1 - Basic Information

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

Required and system enforced. Up to 600 characters. Study title must be unique within the application. First 150 characters of title will show in application bookmark.

### 1.2. \* Is this Study Exempt from Federal Regulations?

Yes  No

Answer required and system enforced.

### 1.3. Exemption Number

1  2  3  4  5  6  7  8

If Study Exempt is Yes, must provide exemption number. Exemption must also be selected on Other Project Information form.

### 1.4. \* Clinical Trial Questionnaire

Answers to questionnaire required and system enforced.

If the answers to all four questions below are yes, this study meets the definition of a Clinical Trial.

1.4.a defaults to Yes and is not editable.

#### 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

If four questions are all Yes AND FOA allows clinical trials, then study will be flagged as a Clinical Trial (CT) study.\*

### 1.5. Provide the ClinicalTrials.gov Identifier (e.g., NCT87654321) for this trial, if applicable

Optional. Provide NCT# for this study, if available. Newly proposed studies do not need to be entered in ClinicalTrials.gov at time of application. If building on an existing study, enter NCT# for ancillary study (if available), not the parent study.

## Section 2 - Study Population Characteristics

### 2.1. Conditions or Focus of Study

Required and system enforced unless exemption 4 is only exemption selected. Up to 20 conditions at 255 characters each.

### 2.2. Eligibility Criteria

Required and system enforced unless exemption 4 is only exemption selected or otherwise noted in opportunity.

Dropdown list: Years, Months, Weeks, Days, Hours, Minutes, N/A (No limit)

Dropdown list: Years, Months, Weeks, Days, Hours, Minutes, N/A (No limit)

### 2.3. Age Limits

Minimum Age

Maximum Age

### 2.3.a. Inclusion of Individuals Across the Lifespan

Required and system enforced unless exemption 4 is only exemption selected.

Attachment View Attachment  
if "N/A (No Limit)" selected, do not provide numerical min/max age.

### 2.4. Inclusion of Women and Minorities

Required and system enforced unless exemption 4 is only exemption selected.

### 2.5. Recruitment and Retention Plan

Required and system enforced unless exemption 4 is the only exemption selected or otherwise noted in opportunity.

### 2.6. Recruitment Status

Required and system enforced unless exemption 4 is the only exemption selected or otherwise noted in opportunity.

### 2.7. Study Timeline

Required and system enforced for CT study unless 4 is the only exemption selected or otherwise noted in opportunity.

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### 2.8. Enrollment of First Participant

Date: MM/DD/YYYY.

Dropdown list: Anticipated, Actual

Enrollment of First Participant field is required and system enforced unless exemption 4 is only exemption selected or using existing dataset.

### 2.9. Inclusion Enrollment Report(s)

Inclusion Enrollment Reports required and system enforced unless exemption 4 is only exemption selected or otherwise noted in opportunity.

Add Inclusion Enrollment Report

Up to 20 Inclusion Enrollment Reports can be added.

\* Fellowship (F) and Career Development (K) applications to FOAs that do not allow clinical trials cannot propose independent clinical trial studies led by applicant PD/PI. However, proposing studies under the leadership of a sponsor/mentor that allows for clinical trials research experience is encouraged. Answering Yes to all four Clinical Trial Questionnaire questions will not flag the study as a clinical trial. These studies must include HS information, but will receive a system error if information is included in study fields in sections 4 or 5 of form.

# Inclusion Enrollment Report

**1. \* Inclusion Enrollment Report Title**

Required. Up to 600 characters.

**2. \* Using an Existing Dataset or Resource**

Yes  No

Answer required and system enforced.

**3. \* Enrollment Location Type**

Domestic  Foreign

Answer required and system enforced. Do not mix domestic and foreign enrollment data on the same inclusion enrollment report.

**4. Enrollment Country(ies)**

Multi-select from list of countries.

**5. Enrollment Location(s)**

**6. Comments**

Up to 500 characters.

**Planned**

Planned enrollment information is required and system enforced when answer to "Using an Existing Dataset or Resource" question is No. System enforcement relaxed if Comment is provided.

<b>Racial Categories</b>	<b>Ethnic Categories</b>				
	Not Hispanic or Latino		Hispanic or Latino		<b>Total</b>
	<b>Female</b>	<b>Male</b>	<b>Female</b>	<b>Male</b>	
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
<b>Total</b>	0	0	0	0	0

**Cumulative (Actual)**

Cumulative (Actual) enrollment information is required and system enforced when answer to "Using an Existing Dataset or Resource" question is Yes. System enforcement relaxed if Comment is provided.

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

Report 1 of 1

**Section 3 - Protection and Monitoring Plans**

3.1. Protection of Human Subjects

3.2. Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?

Yes  No  N/A

Answer required and system enforced. "N/A" is only a valid option if study is not exempt from federal regulations (i.e., Question 1.2 is No).

If yes, describe the single IRB plan

3.3. Data and Safety Monitoring Plan

3.4. Will a Data and Safety Monitoring Board be appointed for this study?

Yes  No

Answer required and system enforced for CT study unless otherwise noted in opportunity. Optional for HS study.

3.5. Overall Structure of the Study Team

**Section 4 - Protocol Synopsis** You are not allowed to complete fields in Section 4 (i.e., will receive system error) if FOA does not allow clinical trials and/or you answered No to one of the Clinical Trial Questionnaire questions in Section 1.

**4.1. Study Design**

**4.1.a. Detailed Description**

**4.1.b. Primary Purpose**

Dropdown list: Treatment; Prevention; Diagnostics; Supportive Care; Screening; Health Services Research; Basic Science; Device Feasibility; and Other

**4.1.c. Interventions**

Intervention Type	
Name	<input type="text" value="Up to 200 characters."/>
Description	<input type="text" value="Up to 1,000 characters."/>

Dropdown list: Drug (including placebo); Device (including sham); Biological/Vaccine; Procedure/Surgery; Radiation; Behavioral (e.g., Psychotherapy, Lifestyle Counseling); Genetic (including gene transfer, stem cell and recombinant DNA); and Dietary Supplement (e.g., vitamins, minerals)

**4.1.d. Study Phase**

Dropdown list: Early Phase 1 (or Phase 0); Phase 1; Phase 1/2; Phase 2; Phase 2/3; Phase 3; Phase 4; and N/A

Is this an NIH-defined Phase III clinical trial?  Yes  No

**4.1.e. Intervention Model**

Dropdown list: Single Group; Parallel; Cross-Over; Factorial; Sequential; and Other

**4.1.f. Masking**

Yes  No  
 Participant  Care Provider  Investigator  Outcomes Assessor

**4.1.g. Allocation**

If Masking is Yes, you must select at least 1 of the Participant/Care Provider/Investigator/ Outcomes Assessor check boxes.

**4.2. Outcome Measures** At least one Outcome Measure required and system enforced for CT studies unless otherwise noted in opportunity. Up to 50 Outcome Measures allowed.

<b>Name</b>	<span style="border: 1px solid black; padding: 2px;">Up to 255 characters.</span>
<b>Type</b>	<span style="border: 1px solid black; padding: 2px;">Dropdown list: Primary; Secondary; and Other</span>
<b>Time Frame</b>	<span style="border: 1px solid black; padding: 2px;">Up to 255 characters.</span>
<b>Brief Description</b>	<span style="border: 1px solid black; padding: 2px;">Up to 999 characters.</span>

**4.3. Statistical Design and Power**  Required and system enforced for CT study unless otherwise noted in opportunity. Attachment Delete Attachment View Attachment

**4.4. Subject Participation Duration**  Up to 255 characters. Required and system enforced for CT studies unless otherwise noted in opportunity.

**4.5. Will the study use an FDA-regulated intervention?**  Yes  No Answer required and system enforced for CT study unless otherwise noted in opportunity.

**4.5.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status**

Required and system enforced if Yes. Add Attachment Delete Attachment View Attachment

**4.6. Is this an applicable clinical trial under FDAAA?**  Yes  No

**4.7. Dissemination Plan**  Required and system enforced for CT study. Generally one Dissemination Plan per application is sufficient. Can attach same plan (unique filenames) in multiple studies.

**Section 5 - Other Clinical Trial-related Attachments**

**5.1. Other Clinical Trial-related Attachments** Add Attachments Delete Attachments View Attachments

Form supports up to 10 attachments. Attachments only allowed for CT studies. Only include attachments requested in opportunity.