

## PHS Human Subjects and Clinical Trials Information

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

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.

**Required if Yes to human specimens/data question.**

Add Attachment

Delete Attachment

View Attachment

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

When human subjects is No, applicants answer a single question, provide associated attachment (as applicable), and are done with the form unless instructed in announcement to include Other Requested Information attachment.

Answer required and system enforced when human subjects is No.

### If Yes to Human Subjects

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 the study name and a justification for omission of human subjects study information.

### Other Requested Information

Add Attachment

Delete Attachment

View Attachment

Check Application Guide and opportunity instructions to determine if attachment is needed.

[Click here to extract the Human Subject Study Record 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.**

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.

Multiple delayed onset studies can be grouped in a single record.

Study Title	Anticipated Clinical Trial?	Justification
<input type="text"/>	<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: 03/31/2020

\* 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.

### 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. 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# if available. Newly proposed studies do not need to be entered in ClinicalTrials.gov at time of application.

## Section 2 - Study Population Characteristics

### 2.1. Conditions or Focus of Study

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

### 2.2. Eligibility Criteria

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

Age limits are required and system enforced unless study is exemption 4 or otherwise noted in opportunity.

### 2.3. Age Limits

Minimum Age

Dropdown

Years  
Months

Maximum Age

Dropdown

Years  
Months  
Weeks  
Days  
Hours  
Minutes  
N/A (No limit)

### 2.4. Inclusion of Women, Minorities, and Children

Required and system enforced unless study is exemption 4.

Attachment

View

### 2.5. Recruitment and Retention Plan

Required and system enforced unless study is exemption 4, 1.4.a=No, or otherwise noted in opportunity.

Delete Attachment

View

### 2.6. Recruitment Status

Required and system enforced unless study is exemption 4, 1.4.a=No, or otherwise noted in opportunity.

Dropdown

Not yet recruiting  
Recruiting  
Rolling by invitation  
Active, not recruiting  
Completed  
Suspended  
Terminated (Halted Prematurely)  
Withdrawn (No Participants Enrolled)

### 2.7. Study Timeline

Required and system enforced unless study is exemption 4, 1.4.a=No, or otherwise noted in opportunity.

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

### 2.8. Enrollment of First Subject

Date: MM/DD/YYYY.

Dropdown

Anticipated  
Actual

Required and system enforced unless study is exemption 4, 1.4.a=No, or otherwise noted in opportunity.

### Inclusion Enrollment Report(s)

Inclusion Enrollment Reports required and system enforced unless study is exemption 4 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. Such studies must include HS information, but will receive a system error if information is included in CT study fields in sections 4 or 5 of form.

# Inclusion Enrollment Report

1. \* Using an Existing Dataset or Resource

Yes  No

Answer required and system enforced.

2. \* Enrollment Location Type

Domestic  Foreign

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

3. Enrollment Country(ies)

4. Enrollment Location(s)

5. Comments

**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.

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
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.
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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
<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**

Required and system enforced. Add Attachment Delete Attachment View Attachment

**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 for fellowship, and career development applications OR if study is exempt from federal regulations (i.e., Question 1.2a is Yes).

If yes, describe the single IRB plan

Required and system enforced if Yes. Can attach same plan (unique filenames) in multiple studies. Add Attachment Delete Attachment View Attachment

**3.3. Data and Safety Monitoring Plan**

Required and system enforced for CT study. Optional for HS study. Add Attachment Delete Attachment View Attachment

**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**

Optional. Add Attachment Delete Attachment View Attachment

**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. Brief Summary**

Up to 5000 characters. Required and system enforced for CT studies unless otherwise noted in opportunity.

**4.2. Study Design**

All Study Design fields (4.2.a thru 4.2.g) are required and system enforced for CT studies unless otherwise noted in opportunity.

**4.2.a. Narrative Study Description**

Up to 32,000 characters.

**4.2.b. Primary Purpose**

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

**4.2.c. Interventions**

Up to 20 Interventions allowed.

Health Services Research  
Basic Science  
Device Feasibility  
Other

Intervention Type		
Name	Up to 200 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)
Description	Up to 1,000 characters.	

Dietary Supplement (e.g., vitamins, minerals)  
Combination Product  
Diagnostic Test  
Other

**4.2.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 Other

Early Phase 1 (or Phase 0)  
Phase 1  
Phase 1/2

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

**4.2.e. Intervention Model**

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

Factorial  
Sequential  
Other

**4.2.f. Masking**

Yes  No  
 Participant  Care Provider  Investigator  Outcomes Assessor

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

4.2.g. Allocation

Dropdown list: N/A; Randomized; and Non-randomized

Randomized  
Non-randomized

4.3. 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.

Name	Up to 255 characters.
Type	Dropdown list: Primary; Secondary; and Other
Time Frame	Up to 255 characters. Other
Brief Description	Up to 999 characters.

4.4. Statistical Design and Power

Required and system enforced for CT study unless otherwise noted in opportunity.

Add Attachment

Delete Attachment

View Attachment

4.5. Subject Participation Duration

Up to 255 characters. Required and system enforced for CT studies unless otherwise noted in opportunity.

4.6. Will the study use an FDA-regulated intervention?

Yes

No

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

4.6.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

4.7. 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.

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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.