Complete human subjects section of R&R Other Project Information form prior to completing this form.

# 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

Information populated from R&R Other Project Information form.

**If No to Human Subjects**

Answer required and system enforced when human subjects is No.

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 Att

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.

**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

**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.

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

| | Study Title | Anticipated Clinical Trial? | Justification |
|---|---|---|---|
| | | ☐ | 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, FOA 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.

Cannot add a Study Record if you answer No to Human Subjects question on R&R Other Project Information form.

HS = Human Subjects
CT = Clinical Trials

Check Form for Errors | Save

# 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.

**2.5. Recruitment and Retention Plan** Required and system enforced unless study is exemption 4 or otherwise noted in opportunity.

**2.6. Recruitment Status** Required and system enforced unless study is exemption 4 or otherwise noted in opportunity. Dropdown: Not yet recruiting, Recruiting, Enrolling 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 or otherwise noted in opportunity.

**2.8. Enrollment of First Subject** Date: MM/DD/YYYY. Dropdown: Anticipated, Actual. Required and system enforced unless study is exemption 4 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

* 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)

Multi-select from list of countries.

4. Enrollment Location(s)

5. 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.

| Racial Categories | Ethnic Categories | | | | |
|---|---|---|---|---|---|
| | Not Hispanic or Latino | | Hispanic or Latino | | Total |
| | 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 |
| **Total** | 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 |
| **Total** | 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, career development and D43 applications or if exemption 4.

**If yes, describe the single IRB plan** — Required and system enforced if Yes. Add Attachment | Delete Attachment | View Attachment

**3.3. Data and Safety Monitoring Plan** — Required and system enforced for CT study. Optional for HS study. 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.

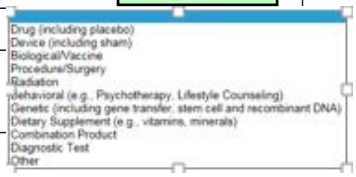
**4.2.a. Narrative Study Description**

Up to 32,000 characters.

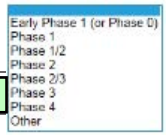
**4.2.b. Primary Purpose** — Dropdown list


**4.2.c. Interventions** — Up to 20 Interventions allowed.

| | |
|---|---|
| **Intervention Type** | Dropdown list |
| **Name** | Up to 200 characters. |
| **Description** | Up to 1,000 characters. |




**4.2.d. Study Phase** — Dropdown list




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

**4.2.e. Intervention Model** — Dropdown list


**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
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, Other) |
| **Time Frame** | Up to 255 characters. |
| **Brief Description** | Up to 999 characters. |

**4.4. Statistical Design and Power**

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

dd 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 in multiple studies.

ew Attachment

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

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**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.