PHS Human Subjects and Clinical Trials Information

The PHS Human Subjects and Clinical Trials Information form is used to collect information on human subjects research, clinical research, and/or clinical trials, including study population characteristics, protection and monitoring plans, and a protocol synopsis.

This form accommodates the full spectrum of all types of clinical trials, including, but not limited to, behavioral, exploratory/development, mechanistic, pilot/feasibility, early phase, efficacy, effectiveness, group-randomized, and others.

Read all the instructions in the Funding Opportunity Announcement (FOA) before completing this form to ensure your application meets all IC-specific criteria. If you are proposing a clinical trial, make sure your FOA accepts clinical trials (i.e., ‘clinical trial required’ or ‘clinical trial optional’).

The PHS Human Subjects and Clinical Trials Information form, together with the rest of your application, should include sufficient information for the evaluation of the project, independent of any other documents (e.g., previous application). Be specific, describe each study clearly, and avoid redundancies. Be especially careful to avoid redundancies with your research strategy.

# Who should use the PHS Human Subjects and Clinical Trials Information form:

All applicants must use the PHS Human Subjects and Clinical Trials Information form regardless of your answer to the question “Are human subjects involved?” on the *R&R Other Project Information Form.*

If you answered “Yes” to the question “Are human subjects involved?” on the [*R&R Other Project Information Form*](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf), see the “*If Yes to Human Subjects*” section for instructions.

If you answered “No” to the question “Are human subjects involved?” on the [*R&R Other Project Information Form*](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf), see the “*If No to Human Subjects*” section for instructions.

Please complete the human subjects section of the Research & Related Other Project Information form prior to completing this form.

Note: There are no page limits for any attachments in the PHS Human Subjects and Clinical Trials Information form.

For additional instructions for Training, Career Development, Fellowship and Multi-project applications please see [G.500 - HS Human Subjects and Clinical Trials Information](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf) of the NIH General Instructions.

# Are Human Subjects Involved? Yes/No

This field is pre-populated from the [*R&R Other Project Information Form*](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf). If the value in this field appears to be incorrect, you may correct it by adjusting it on *the* [*R&R Other Project Information Form*](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf).

**If Yes to Human Subjects:**

1. Add a study record or delayed onset human subject study for each proposed study involving human subjects by selecting “Add New Study” or “Add New Delayed Onset Study”. In some cases a study cannot have defined plans for human subject involvement per agency policies on Delayed Onset Studies. In these cases, select 'Add New Delayed Onset Study' to provide the study name and justification for omission of human subjects study information. See sections below.

**If No to Human Subjects:**

1. Answer the following question(s)
* **Does the proposed research involve human specimens and/or data?** Select “Yes” or “No” to indicate whether the proposed research involves human specimens and/or data.
* If you answered “Yes” to the “Does the proposed research involve human specimens and/or data?” question, you must provide a justification for your claim that no human subjects are involved. This justification should include:
* Information on who is providing the data/biological specimens and their role in the proposed research;
* A description of the identifiers that will be associated with the human specimens and data;
* A list of who has access to subjects’ identities; and
* Information about the manner in which the privacy of research participants and confidentiality of data will be protected.
* Once you have attached the justification, skip the rest of the PHS Human Subjects and Clinical Trials Information form unless otherwise directed by your FOA.
* If you answered “No” to the “Does the proposed research involve human specimens and/or data?” question, you can skip the rest of the PHS Human Subjects and Clinical Trials Information form.
1. Applications involving the use of human specimens or data may not be considered to be research involving human subjects, depending on the details of the materials to be used. To help determine whether your research is classified as human subjects research, refer to the [*Research Involving Private Information or Biological Specimens*](https://grants.nih.gov/grants/policy/hs/PrivateInfoOrBioSpecimensDecisionChart.pdf) flowchart.

**Other Requested Information:**

* Who may provide Other Requested Information:
* Follow the instructions below and any instructions in your FOA to determine whether you are permitted to include the “Other Requested Information” attachment.
* Format:
* Attach this information as a PDF file. See NIH’s [*Format Attachments*](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm) page.
* Content:
* Content is limited to what is described in your FOA or in these instructions. Do not use the “Other Requested Information” attachment to include any other information.
* Renewal applications:
* When preparing a renewal (or resubmission of a renewal), you can provide a list of ongoing studies or ClinicalTrials.gov identifiers (e.g., NCT87654321).
* **Additional Instructions for Multi-project (**for multi-project applications with studies that span components):
* Overall Component: For each study that spans components, describe the components involved with the study.
* Other Components: Each component should include an attachment that indicates that the details of the study are included in the Overall component within this attachment.

# Is the Project Exempt from Federal regulations? Yes/No

This field is pre-populated from the [*R&R Other Project Information Form*](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf). If the value in this field appears to be incorrect, you may correct it by adjusting it on the [*R&R Other Project Information Form*](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf).

# Exemption number: 1, 2, 3, 4, 5, 6, 7, 8

This field is pre-populated from the [*R&R Other Project Information Form*](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf)*.* If the value in this field appears to be incorrect, you may correct it by adjusting it on the [*R&R Other Project Information Form*](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf). You should not have selected exemption 7 or 8, as these are not yet being used.

**Note:** If you change your answer to the “Are Human Subjects Involved” question on the [*R&R Other Project Information Form*](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf) after you have started entering information into the PHS Human Subjects and Clinical Trials Information form, your data in the PHS Human Subjects and Clinical Trials Information form may be lost.

# Study Record(s)

**Adding Study Record Attachment(s):**

* Add a study record for each proposed study involving human subjects. If your study is a delayed onset study, see the instructions for *Delayed Onset Study(ies)*.
* For all submission methods, the Study Record form is used to collect human subjects study data.

**Note:** The steps to add a Study Record attachment(s) may vary with the submission method.

For example, from the ASSIST Human Subjects and Clinical Trials tab, use the ‘Add New Study’ button to access the data entry screens to enter study record information directly into ASSIST. With other submission methods, you may have to extract a blank copy of the Study Record, complete it offline, and then attach it to your application.

The PHS Human Subjects and Clinical Trials Information form accommodates up to 150 separate Study Records.

**Format:**

* All attachments must be PDF files. The study records are already fillable PDFs when extracted. Do not alter the format of the study record file. Use unique file names for each human subject study record.

**Content:**

* Follow the instructions in the “[*Study Record: PHS Human Subjects and Clinical Trials Information*](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#StudyRecord)” section below.

# Delayed Onset Study(ies)

If any of your human subjects studies meet the agency definition of “delayed onset human subject study,” enter the information as instructed below. For any study that you include as a delayed onset study in this section, do not fill out a full study record, as the delayed onset record is sufficient.

**Notes on delayed onset studies:**

* Delayed onset does NOT apply to a study that can be described but will not start immediately (i.e., delayed start).
* If you have multiple delayed onset studies, you can include them together in a single Delayed Onset Study.

**Study Title:**

* This field is required.
* The Study Title can have a maximum of 600 characters.
* Enter a brief, unique title that describes the study the participants will be involved in. Each study within your application must have a unique Study Title. The first 150 characters will display in the application image bookmarks.

**Note on multiple delayed onset studies:** If you are including multiple delayed onset studies in one delayed onset study entry, you may enter “Multiple Delayed Onset Studies” as the title of this record.

**Anticipated Clinical Trial:**

* This field is required.
* Check this box if you anticipate that this study will be a clinical trial. For help determining whether your study meets the definition of clinical trial, see the [*Clinical Trial Questionnaire*](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#1.4).
* Read your FOA carefully to determine whether clinical trials are allowed in your application.

**Note on multiple delayed onset studies:** If you are including multiple delayed onset studies in one delayed onset study entry, and you anticipate that any of these studies will be a clinical trial, check the “Anticipated Clinical Trial?” checkbox.

**Additional Instructions for Career Development:**

CDA applicants who are proposing to gain clinical trial research experience under a mentor’s supervision (i.e., you will not be leading an independent clinical trial): Do not check the “Anticipated Clinical Trial?” box.

**Additional Instructions for Fellowship:**

Do not check the “Anticipated Clinical Trial?” box. Fellowship FOAs do not allow independent clinical trials.

**Justification Attachment:**

* This field is required.
* Attach the justification as a PDF file. See NIH’s [*Format Attachments*](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm) page.
* All delayed onset studies must provide a justification explaining why human subjects study information is not available at the time of application.
* If [*NIH’s Single Institutional Review Board (sIRB) policy*](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html) will apply to your study, this justification must also include information regarding how the study will comply with the policy and state that you will provide a single IRB plan prior to initiating any multi-site study.
* If [*NIH’s Policy on the Dissemination of NIH-Funded Clinical Trial Information*](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-149.html) will apply to your study, this justification must also include the dissemination plan.

**Note on multiple delayed onset studies:** If you are including more than one delayed onset study in any given delayed onset study entry, address all the included studies in a single justification attachment.