Reset Form

FORMS H
HUMAN SUBJECTS QUESTIONNAIRE

Use of Human Specimens and/or Data

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

◯ Yes ◯ No

If Yes to Human Specimens and/or Data, provide an explanation for any use of human specimens and/or data not considered to be human subjects research. Refer to the Research Involving Private Information or Biological Specimens flowchart to determine whether your research is classified as human subjects research. For any human specimens and/or data that is considered human subjects research, you will add a Study Record. Do not duplicate the information in your explanation in any of your Study Records.

The explanation 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.

If No to Human Specimens and/or Data, you do not need to prove an explanation.

Are Human Subjects Involved?

Decision Tool: Am I Doing Human Subjects Research?

◯ Yes ◯ No

Is the Project Exempt from Federal regulations?

◯ Yes ◯ No

Exemption number:

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8

If you have selected Federal Exemption 4, do not fill out Section 2.

NIH Human Subjects' FAQ

Human Subjects Federal Regulations - **45 CFR 46**

If No to Human Subjects

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

If Yes to Human Subjects

Study Record or Delayed Onset Study Required (see below)

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.

FOA SPECIFIC: Other Requested Information (Check FOA for Applicability) [Attachment]

Each unique study record requires a *new* routing form. For multiple study records, please request additional forms from your DS.

Study Record(s)

Enter study title (each study title must be unique)

Delayed Onset Study(ies)

Enter study title (each study title must be unique)

Anticipated Clinical Trial? ◯ Yes ◯ No

[Justification Attachment Required]

STUDY RECORD: PHS HUMAN SUBJECTS AND CLINICAL TRIALS INFORMATION

SECTION 1 - BASIC INFORMATION

Sections 1.2 - 1.3 are repeat questions of the preliminary questions above.

1.4 Clinical Trial Questionnaire

1. Does the study involve human participants? ◯ Yes ◯ No
2. Are the participants prospectively assigned to an intervention? ◯ Yes ◯ No
3. Is the study designed to evaluate the effect of the intervention on the participants? ◯ Yes ◯ No
4. Is the effect that will be evaluated a health-related biomedical or behavioral outcome? ◯ Yes ◯ No

1.5 Provide ClinicalTrials.gov Identifier

Form Section	If you answered "yes" to all the questions in the Clinical Trial Questionnaire	If you answered "no" to any of the questions in the Clinical Trial Questionnaire
Section 2 - Study Population Characteristics	Required	Required
Section 3 - Protection and Monitoring Plans	Required	Required
Section 4 - Protocol Synopsis	Required	Do not complete
Section 5 - Other Clinical Trial-related Attachments	Required if specified in the FOA	Do not complete

SECTION 2 - STUDY AND POPULATION CHARACTERISTICS

*If you have determined that your study involves human subjects **but not human participants**, not all questions are applicable as noted below. If you have selected Federal Exemption 4, do not fill out Section 2.*

2.1 At least 1 entry required, up to 20 entries are allowed. 255-character limit per entry. Provide in a separate document if necessary.

2.1. Conditions or Focus of Study

2.2 List the study's inclusion and exclusion criteria. The entry is limited to a 15,000-character limit, but only 500 characters are usually needed. Provide in a separate document if necessary.

2.2. Eligibility Criteria

2.3. Age Limits

Minimum Age Maximum Age

2.3.a. Inclusion of Individuals Across the Lifespan [Attachment]

2.4. Inclusion of Women and Minorities [Attachment]

2.5. Recruitment and Retention Plan [Attachment] (2.5. Not applicable if you indicated **Exemption 4**)

2.6. Recruitment Status Not yet recruiting (2.6. Not applicable if you indicated **Exemption 4**)

2.7 Study Timeline [Attachment]

Optional if **Exemption 4** or answered "No" to any questions in the "Clinical Trial Questionnaire" section.

2.8. Enrollment of First Participant

Do **NOT** complete if you will answer "Yes" to the question "Using an Existing Dataset or Resource," see 2.9 below, or you indicated **Exemption 4** above.

2.9. Inclusion Enrollment Report(s)

Your DS will provide you with an IER template to complete and return. The IER is required for all human subject studies unless you indicated **Exemption 4**. At least one IER is required, but you can have more than one IER per study record (up to 20).

SECTION 3 - PROTECTION AND MONITORING PLANS

3.1. Protection of Human Subjects [Attachment]

Required for **ALL** human subjects research, including those claiming Exemption 4.

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

If you are an AHRQ applicant, please describe the single IRB plan (attachment). The single IRB plan is NOT required for NIH applicants.

Only select N/A if you selected "Yes" to "Question 1.2 Is this Study Exempt from Federal Regulations" and/or you are a training grant applicant.

3.3. Data and Safety Monitoring Plan [Attachment]

Required for clinical trials and optional for all other human subject research, review guidelines for applicability.

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

☐ Yes ☐ No ☐ N/A

Required for clinical trials and optional for all other human subject research.

3.5. Overall Structure and Study Team [Attachment]

Attachment optional, refer to your specific FOA Required for clinical trials and optional for all other human subject research, review guidelines for applicability.

SECTION 4 - PROTOCOL SYNOPSIS

THIS SECTION ONLY APPLICABLE TO PROJECTS INVOLVING A CLINICAL TRIAL

4.1. Study Design

4.1.a. Detailed Description

Enter a narrative description of the protocol. The description is limited to 32,000 characters but usually only needs 5,000 characters. Should be written in layperson's terms and may repeat some information in the Research Strategy.

4.1.b. Primary Purpose Other

If Other selected, provide a description 255 characters max.

4.1.c. Interventions

Intervention Type Drug (including placebo)

Name

Limited to 200 characters.

Description

Limited to 1,000 characters.

4.1.d. Study Phase Early Phase 1 (or Phase 0)

If your study involves a device or behavioral intervention, choose "Other."

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

4.1.e. Intervention Model Single Group

If Other selected, provide a description. 255 characters max.

4.1.f. Masking **Yes** ☐ **No** ☐

If "Yes" to masking, select one or more types of masking to best describe the protocol.

- ☐ Participant
- ☐ Care Provider
- ☐ Investigator
- ☐ Outcomes Assessor

4.1.g. Allocation N/A

4.2. Outcome Measures

Complete fields for each primary, secondary, and other important measures collected during your proposed clinical trial. You can have more than one primary outcome measure, and you can add up to 50 outcome measures.

Name

Type Primary

Time Frame

Brief Description (up to 999 characters)

4.3. Statistical Design and Power [Attachment]

4.4. Subject Participation Duration

Enter the time in months it will take for each individual participant to complete all study visits. If unknown or not applicable, write "unknown" or "not applicable." This field is limited to 255 characters.

4.5. Will this study use an FDA-regulated intervention?

☐ Yes ☐ No

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

4.6. Is this an applicable clinical trial under FDAAA?

☐ Yes ☐ No

4.7. Dissemination Plan [Attachment]

SECTION 5 - OTHER CLINICAL TRIAL-RELATED ATTACHMENTS

5.1. Other Clinical Trial-related Attachments

Check specific FOA for 5.1 applicability.