G.500 - 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 Notice of Funding Opportunity (NOFO) before completing this form to ensure your application meets all IC-specific criteria. "Section II. Award Information" of the NOFO will indicate whether clinical trials are or are not allowed and whether clinical trial research experience is or is not allowed. The designation of your NOFO will determine how to use these instructions, and subsequently, how to fill out this form.

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.

View larger image

Quick Links

Complete the PHS Human Subjects and Clinical Trials Information form after you have completed the G.220 - R&R Other Project Information Form.

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

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

The designation of your NOFO will determine how to use these instructions, and subsequently, how to fill out this 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 G.220 - R&R Other Project Information Form.

Additional Instructions for Training:

K12 and D43 applicants: If you are proposing any human subject studies in your application, then at the time of application, you must use the PHS Human Subjects and Clinical Trials Information form to submit delayed onset studies. Do not fill in Study Records. Follow the instructions in your NOFO. Post award, you will submit Study Records if applicable.

All other Training applicants: This form is not applicable and will not be available to you.

Additional Instructions for SBIR/STTR:

Please note the Human Subjects and Clinical Trials policies apply to SBIR and STTR applications. The small business applicant needs to answer “Yes” even if human subjects work will not be performed at the small business. Applicants should follow all the guidance in this section and correctly identify the proposed study Human Subjects and/or Clinical Trials. The NIH definition of a Clinical Trial is broader than many applicants realize and applicants should review Clinical Trial Requirements for Grants and Contracts to ensure that studies are coded correctly.

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Note for studies involving only the secondary use of identifiable biospecimens or data: For studies where the only involvement of human subjects is the use of identifiable biospecimens or data originally collected for another purpose, complete the PHS Human Subjects and Clinical Trials Information form with information specific to the current study and not the original collection unless the information associated with the original collection is pertinent to the proposed study. If information about the original collection is necessary, provide context and clearly distinguish between the current study and historical information.

Using the PHS Human Subjects and Clinical Trials Information form:

Everyone must complete the "Use of Human Specimens and/or Data" section of the PHS Human Subjects and Clinical Trials Information form. However, your answer to the “Are human subjects involved?” question will determine which other sections of the PHS Human Subjects and Clinical Trials Information form you must complete. Once you have completed the "Use of Human Specimens and/or Data" section, follow instructions on the form that are specific to your answer to the "Are human subjects involved?" question on the G.220 - R&R Other Project Information Form:

- if you answered "Yes" to the question "Are human subjects involved?" on the G.220 - R&R Other Project Information Form, see the "If Yes to Human Subjects" section for instructions.
- if you answered "No" to the question "Are human subjects involved?" on the G.220 - R&R Other Project Information Form, see the "If No to Human Subjects" section for instructions.

The PHS Human Subjects and Clinical Trials Information form allows you to add Study Record(s) and/or Delayed Onset Study(ies), as applicable.

Within each Study Record, you will add detailed information at the study level. Do not duplicate studies within your application. Each study within the application should be unique and should have a unique study title. Each Study Record is divided into numbered sections:

- Section 1 - Basic Information
- Section 2 – Study Population Characteristics (includes Inclusion Enrollment Report)
- Section 3 – Protection and Monitoring Plans
- Section 4 – Protocol Synopsis
- Section 5 – Other Clinical Trial-related Attachments

Note: The PHS Human Subjects and Clinical Trials Information form will capture detailed information at the study level. Although you are encouraged to refer to information in the PHS Human Subjects and Clinical Trials Information form in your discussion of the Research Strategy, do not duplicate information between the Research Strategy attachment and the PHS Human Subjects and Clinical Trials Information form.

For more information on what a “study” is for the purposes of the PHS Human Subjects and Clinical Trials Information form, see the relevant FAQ on the Applying Electronically FAQ page.

The PHS Human Subjects and Clinical Trials Information form is dynamic and may eliminate sections that are not relevant to your application. The dynamic form behavior may not be enabled on all submission methods.

Note: Some fields in this form match fields within ClinicalTrials.gov and are identified as such within these instructions. Additional information about the fields can be found on the ClinicalTrials.gov Protocol Registration Data Element Definitions website.

Additional Instructions for Research:

R25 applicants who are proposing to provide clinical trial research experience for their participants (i.e., participants will not be leading an independent clinical trial): You will generally follow the standard instructions to complete the PHS Human Subjects and Clinical Trials Information form, but follow relevant Research instructions where they are given. Make sure you are applying to a NOFO that allows Clinical Trial Research Experience (this is noted in "Section II. Award Information" of the NOFO). Additionally, your mentor or co-mentor is required to include a statement to document leadership of the clinical trial. The statement must include the following:

- Source of funding;
- ClinicalTrials.gov identifier (e.g., NCT87654321), if applicable;
- A description of how the mentor's expertise is appropriate to guide participants in any proposed clinical trials research experience; and
- A statement/attestation that the mentor will be responsible for the clinical trial.
    - The mentor must have primary responsibility for leading and overseeing the trial and must describe how she/he will provide this oversight.
    - Include details on the specific roles / responsibilities of the mentor and participants.

This statement must be included in the "Other Attachment" attachment in the G.220 – R&R Other Project Information Form.

R36 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): You will generally follow the standard instructions to complete the PHS Human Subjects and Clinical Trials Information form, but follow relevant Research instructions where they are given. Make sure you are applying to a NOFO that allows Clinical Trial Research Experience (this is noted in "Section II. Award Information" of the NOFO). Additionally, your mentor or co-mentor is required to include a statement to document leadership of the clinical trial. The statement must include the following:

- Source of funding;
- ClinicalTrials.gov identifier (e.g., NCT87654321), if applicable;
- A description of how your expertise is appropriate to guide the applicant in any proposed clinical trials research experience; and
- A statement/attestation that the mentor will be responsible for the clinical trial.
    - The mentor must have primary responsibility for leading and overseeing the trial and must describe how she/he will provide this oversight (be careful not to overstate the candidate's responsibilities).
    - Include details on the specific roles/responsibilities of the applicant and mentor.

This statement must be included in the "Other Attachment" attachment in the G.220 - Other Project Information Form..

All other Research applicants: Follow the standard instructions to complete the PHS Human Subjects and Clinical Trials Information form.

Additional Instructions for Career Development:

There are three primary situations by which K applicants can apply for human subjects and/or clinical trial research.

Career Development Award (CDA) applicants who are not proposing a clinical trial: Follow the standard instructions to complete the PHS Human Subjects and Clinical Trials Information form.

CDA applicants who are proposing an independent clinical trial: Make sure you are applying to a NOFO that allows independent clinical trials (this is noted in "Section II. Award Information" of the NOFO). Follow the standard instructions to complete the PHS Human Subjects and Clinical Trials Information form. (Note that not every Study Record within your application has to be a clinical trial).

For more information on independent clinical trials, see:

- NIH Glossary definitions of Independent Clinical Trial and Ancillary Study
- NIH Definition of Clinical Trial Case Studies
- NIH Clinical Trial Definition FAQs
- Human Subjects and Clinical Trials Information Form FAQs

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): You will generally follow the standard instructions to complete the PHS Human Subjects and Clinical Trials Information form, but follow relevant Career Development instructions where they are given. Make sure you are applying to a NOFO that allows Clinical Trial Research Experience (this is noted in "Section II. Award Information" of the NOFO). Additionally, the mentor or co-mentor is required to include a statement to document leadership of the clinical trial. The statement must include the following:

- Source of funding;
- ClinicalTrials.gov identifier (e.g., NCT87654321), if applicable;
- A description of how your expertise is appropriate to guide the applicant in any proposed clinical trials research experience; and
- A statement/attestation that the mentor will be responsible for the clinical trial.
    - The mentor must have primary responsibility for leading and overseeing the trial and must describe how she/he will provide this oversight (be careful not to overstate the candidate's responsibilities).
    - Include details on the specific roles/responsibilities of the applicant and mentor, keeping in mind that the terms of a CDA award do not always permit the candidate to lead a clinical trial.

This statement must be included in the "Plans and Statements of Mentor and Co-Mentor(s)" attachment in the G.410 - PHS 398 Career Development Award Supplemental Form.

Additional Instructions for Fellowship:

Fellowship candidates are permitted to conduct research involving human subjects; however, they are NOT permitted to lead an independent clinical trial.

For more information, see Clinical Trial-specific Funding Opportunities FAQs, especially those related to Training, Fellowship, and Career Development Awards.

Fellowship candidates who are not proposing a clinical trial: Follow the standard instructions to complete the PHS Human Subjects and Clinical Trials Information form.

Fellowship candidates who are proposing to gain clinical trial research experience under a sponsor's supervision (i.e., you will not be leading an independent clinical trial): You will generally follow the standard instructions to complete the PHS Human Subjects and Clinical Trials Information form, but follow relevant Fellowship instructions where they are given. Make sure you are applying to a NOFO that allows Clinical Trial Research Experience (this is noted in "Section II. Award Information" of the NOFO). Additionally, the sponsor or co-sponsor is required to include a statement to document leadership of the clinical trial. The statement must include the following:

- Source of funding;
- ClinicalTrials.gov identifier (e.g., NCT87654321), if applicable;
- A description of how the sponsor or co-sponsor's expertise is appropriate to guide the applicant in any proposed clinical trials research experience; and
- A statement/attestation that the sponsor will be responsible for the clinical trial
    - The sponsor must have primary responsibility for leading and overseeing the trial and must describe how she/he will provide this oversight (be careful not to overstate the fellow's responsibilities).
    - Include details on the specific roles/responsibilities of the fellow and sponsor, keeping in mind that the terms of a fellowship award do not permit the fellow to lead a clinical trial.

This statement must be included in the "Sponsor(s) Commitment" attachment of the G.430 - PHS Fellowship Supplemental Form.

Additional Instructions for Multi-project:

For multi-project applications with studies that are self-contained within a single component:

Overall Component: Do not complete a Study Record.

Other Component: Complete a separate Study Record for each human subjects study that is self-contained within a single component.

For multi-project applications with studies that span components:

Overall Component: Complete one Study Record for each study if it spans multiple components. This Study Record must include sufficient information for all components that are involved in the particular study. This might occur when an application includes a data coordinating center or recruitment core, or when participant assessments for one study are conducted across multiple components (e.g., the study includes an imaging core and clinical site).

Applicants must follow all policies and requirements related to formatting, proprietary information, human subjects, and clinical trials. See the following pages for more information:

- Format Attachments
- Rules for Text Fields
- NIH Grants Policy Statement, Section 2.3.11.2: Confidentiality of Information
- NIH Grants Policy Statement, Section 2.3.11.2.2: The Freedom of Information Act
- NIH's Human Subjects Research website
- NIH's Clinical Trials website
- Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials

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

PHS Human Subjects and Clinical Trials Information

Applicants must complete the human subjects questions on the G.220 - R&R Other Project Information Form prior to completing this form.

Use of Human Specimens and/or Data

Regardless of your answer to the question "Are Human Subjects Involved?" on the G.220 - R&R Other Project Information Form, answer the following question(s) about the use of human specimens and/or human data.

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

Select "Yes" or "No" to indicate whether the proposed research involves human specimens and/or data.

Note: 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.

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

If you answered "No" to the "Does any of the proposed research in the application involve human specimens and/or data?" question, you do not need to attach an explanation here.

If you answered "Yes" to the "Does any of the proposed research in the application involve human specimens and/or data?" question, you must provide an explanation for any use of human specimens and/or data not considered to be human subjects research. To help determine whether your research is classified as human subjects research, refer to the Research Involving Private Information or Biological Specimens flowchart. Do not describe use of human specimens and / or data considered to be human subjects research here. 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.

Attach the explanation as a PDF file. See NIH's Format Attachments page.

This 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.

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

Are Human Subjects Involved? Yes/No

This field is pre-populated from the G.220 - R&R Other Project Information Form. If the value in this field appears to be incorrect, you may correct it by adjusting it on the G.220 - R&R Other Project Information Form.

Is the Project Exempt from Federal regulations? Yes/No

This field is pre-populated from the G.220 - R&R Other Project Information Form. If the value in this field appears to be incorrect, you may correct it by adjusting it on the G.220 - R&R Other Project Information Form.

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

This field is pre-populated from the G.220 - R&R Other Project Information Form. If the value in this field appears to be incorrect, you may correct it by adjusting it on the G.220 – R&R Other Project Information Form.

Note: If you change your answer to the "Are Human Subjects Involved" question on the G.220 - R&R Other Project Information Form 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.

If No to Human Subjects

If you answered "No" to the question "Are Human Subjects Involved?" on the G.220 - R&R Other Project Information Form, skip the rest of the PHS Human Subjects Clinical Trials Information form unless otherwise directed by your NOFO.

If Yes to Human Subjects

If you answered "Yes" to the question "Are Human Subjects Involved?" on the G.220 - R&R Other Project Information Form, add a Study Record for each proposed study involving human subjects by selecting "Add New Study" or "Add New Delayed Onset Study," as appropriate.

Other Requested Information

Who may provide Other Requested Information:

Follow the instructions below and any instructions in your NOFO 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 page. Hyperlinks and URLs are not allowed unless specified in the funding opportunity.

Content:

Content is limited to what is described in your NOFO 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.

For more information, see the "Where do I enter my human subjects study information in my multi-project application" FAQ on the Applying Electronically FAQ page.

Study Record(s)

Adding Study Record Attachment(s):

Add a study record for each proposed study involving human subjects. Projects involving public health surveillance activities described in 45 CFR 46.102(l)(2) must complete one or more Study Records describing those public health surveillance activities as if the exclusion does not apply. If specific plans for your study involving human subjects can be described in the application but will not begin immediately (i.e., your study has a delayed start), you must add a Study Record for that study. If your study anticipates involving human subjects within the period of award but specific plans cannot be described in the application (i.e., delayed onset), see the instructions for Delayed Onset Study(ies).

For all submission methods, the Study Record 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.

Note on Grouping Studies into Study Records: While there may be more than one way to split or group studies into Study Records, you are encouraged to group studies that use the same human subjects population and same research protocols into a single Study Record, to the extent that the information you provide is accurate and understandable to NIH staff and reviewers.

If information in any attachment is identical across studies, include the complete information only in the first Study Record for which the information is relevant. In the subsequent Study Records for which the identical information is needed, upload an attachment that says, "See information for attachment X in Study Record entitled [include study title]." No other information is needed in the attachment. Do not submit attachments that are duplicated from one Study Record to another. Note that you should not name Study Records by number. Examples of attachments that may be identical across studies include, but are not limited to, the 3.1 Protection of Human Subjects and 3.5 Overall Structure of the Study Team attachments.

See the NIH Glossary definitions of Study and Study Record.

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

Format:

All attachments must be PDF files. If you extract a Study Record, it will already be in a fillable PDF format. Please use this PDF file and do not alter the format of the Study Record file. Use unique filenames for each human subject study record. The filename for each attachment within a study must be unique within the application (i.e., do not use the same filename in multiple Study Records). Use of hyperlinks and URLs is not allowed unless specified in the funding opportunity.

Content:

Follow the instructions in the "Study Record: PHS Human Subjects and Clinical Trials Information" section below.

Delayed Onset Study(ies)

Additional Instructions for Training:

K12 and D43 applicants: At the time of application, you must use the PHS Human Subjects and Clinical Trials Information form to submit delayed onset studies if you are proposing any human subject studies in your application. Follow the instructions in your NOFO. Post award, you will submit Study Records if applicable.

If you anticipate conducting research involving human subjects but cannot describe the study at the time of application (i.e., your study is a delayed onset human subject study), enter a Delayed Onset Study Record as instructed below.

Generally, for any study that you include as a delayed onset study in this section, you will provide a study title, indicate whether the study is anticipated to include a clinical trial, and include a justification attachment. Since by definition, information for a delayed onset study is not available at the time of application, you will not be given the option to complete a full Study Record for a delayed onset study. For delayed onset studies, the Delayed Onset Study 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). Refer to the NIH Glossary definition of Delayed Onset Study and Delayed Start.
- If you anticipate multiple delayed onset studies, you can include them together in a single Delayed Onset Study Record.

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 below.

Read your NOFO 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:

Career Development Award (CDA) applicants who are not proposing a clinical trial: Follow the standard instructions.

CDA applicants who are proposing an independent clinical trial: Follow the standard instructions.

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 NOFOs do not allow independent clinical trials.

Justification Attachment

This attachment is required.

Attach the justification as a PDF file. See NIH's Format Attachments page. Use of hyperlinks and URLs is not allowed unless specified in the funding opportunity.

- 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 Policy on the Dissemination of NIH-Funded Clinical Trial Information 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.

Study Record: PHS Human Subjects and Clinical Trials Information

Section 1 - Basic Information

Who must complete "Section 1 – Basic Information:"

"Section 1 – Basic Information" is required for all studies involving human subjects.

1.1 Study Title (each study title must be unique)

The "Study Title" field is required.

The Study Title can have a maximum of 600 characters.

Enter a brief title that describes the study the participants will be involved in. If there is more than one study (i.e., you are including more than one Study Record and/or delayed onset study in your application), each one must have a unique study title. The first 150 characters will display in the bookmarks of the application image.

Note: When registering a clinical trial in ClinicalTrials.gov, all study titles across your organization must be unique.

Note: This field matches a ClinicalTrials.gov field (Official Title).

1.2 Is this Study Exempt from Federal Regulations?

An answer to the "Is this Study Exempt from Federal Regulations?" question is required.

Indicate whether the study is exempt from Federal regulations for the Protection of Human Subjects.

For more information, see the NIH's Definition of Human Subjects Research website.

1.3 Exemption Number

The "Exemption Number" field is required if you selected "Yes" to the "Is this Study Exempt from Federal Regulations?" question.

Select the appropriate exemption number(s) for this particular study. Multiple selections are permitted. Regardless of whether these exemptions may apply to you in the future, you must fill out your application following the instructions below.

For more information:

The categories of research that qualify for exemption are defined in the Common Rule for the Protection of Human Subjects. These regulations can be found at 45 CFR 46.

Need help determining the appropriate exemption number?

- Refer to NIH's Human Subjects FAQs.
- See the NIH's Human Subjects Exemptions FAQs.

The Office for Human Research Protections (OHRP) guidance states that appropriate use of exemptions described in 45 CFR 46 should be determined by an authority independent from the investigators (for more information, see OHRP's Frequently Asked Questions). Institutions often designate their Institutional Review Board (IRB) to make this determination. Because NIH does not require IRB approval at the time of application, the exemptions designated often represent the opinion of the PD/PI, and the justification provided for the exemption by the PD/PI is evaluated during peer review. See NIH Grants Policy Statement Section 4.1.15 for more information.

1.4 Clinical Trial Questionnaire

The Clinical Trial Questionnaire is required.

Note for basic and mechanistic studies involving human participants: The NIH definition of a clinical trial encompasses a broad range of studies, including studies using human participants that aim to understand fundamental aspects of phenomena, the pathophysiology of a disease, or the mechanism of action of an intervention. This includes many mechanistic studies and studies submitted to Basic Experimental Studies with Humans NOFOs.

Answer "Yes" or "No" to the following questions to determine whether this study involves a clinical trial. Answer the following questions based only on the study you are describing in this Study Record.

Note: The answer to question "1.4.a Does the study involve human participants?" will be pre-populated with "Yes" for all study records. You will not be able to change this answer.

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 you answered "Yes" to all the questions in the Clinical Trial Questionnaire, this study meets the definition of a clinical trial.

Refer to the table below for information about what sections of this form are required, based on your answers to Question 1.4 "Clinical Trial Questionnaire."

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 NOFO	Do not complete

Additional Instructions for Research:

R25 applicants who are proposing to provide clinical trial research experience for their participants (i.e., participants will not be leading an independent clinical trial): Even if you answered "Yes" to all the questions in the Clinical Trial Questionnaire, only certain fields of the PHS Human Subjects and Clinical Trials Information form are required (and other fields are not allowed) because the study is not an independent clinical trial. Do not provide information in "Section 4 – Protocol Synopsis" or in "Section 5 – Other Clinical Trial-related Attachments" of the Study Record. Inputting information into these sections will result in errors and will prevent your application from being accepted.

R36 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): Even if you answered "Yes" to all the questions in the Clinical Trial Questionnaire, only certain fields of the PHS Human Subjects and Clinical Trials Information form are required (and other fields are not allowed) because the study is not an independent clinical trial. Do not provide information in "Section 4 – Protocol Synopsis" or in "Section 5 – Other Clinical Trial-related Attachments" of the Study Record. Inputting information into these sections will result in errors and will prevent your application from being accepted.

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): Even if you answered "Yes" to all the questions in the Clinical Trial Questionnaire, only certain fields of the PHS Human Subjects and Clinical Trials Information form are required (and other fields are not allowed) because the study is not an independent clinical trial. Do not provide information in "Section 4 – Protocol Synopsis" or in "Section 5 – Other Clinical Trial-related Attachments" of the Study Record. Inputting information into these sections will result in errors and will prevent your application from being accepted.

You will generally follow the standard instructions to complete the PHS Human Subjects and Clinical Trials Information form, but follow relevant Career Development instructions where they are given.

Additional Instructions for Fellowship:

Fellowship candidates who are proposing to gain clinical trial research experience under a sponsor's supervision (i.e., you will not be leading an independent clinical trial): Even if you answered "Yes" to all the questions in the Clinical Trial Questionnaire, only certain fields of the PHS Human Subjects and Clinical Trials Information form are required (and other fields are not allowed) because the study is not an independent clinical trial. Do not provide information in "Section 4 – Protocol Synopsis" or in "Section 5 – Other Clinical Trial-related Attachments" of the Study Record. Inputting information into these sections will result in errors and will prevent your application from being accepted.

You will generally follow the standard instructions to complete the PHS Human Subjects and Clinical Trials Information form, but follow relevant Fellowship instructions where they are given.

For more information:

- NIH Glossary's definition of an NIH-defined clinical trial
- NIH's Definition of a Clinical Trial page
- NIH Definition of Clinical Trials Case Studies page
- NIH Clinical Trial Definition FAQs
- NIH's decision tool will help determine whether your human subjects research study is an NIH-defined clinical trial
- Your study may also be subject to additional regulations. Read NIH's Requirements for Registering & Reporting NIH-funded Clinical Trials in ClinicalTrials.gov.

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

If a clinical trial has already been entered into ClinicalTrials.gov, enter the ClinicalTrials.gov identifier (e.g., NCT87654321) for this trial. Enter the identifier only if you are proposing to

work on that specific clinical trial. If you are only getting samples and/or data from a clinical trial that has already been entered into ClinicalTrials.gov, do NOT enter the identifier.

If you are building on an existing study (e.g., ancillary study), enter the ClinicalTrials.gov identifier only for the ancillary study (if registered separately), not the parent study.

Note: The number you enter in this field should match the ClinicalTrials.gov identifier assigned by ClinicalTrials.gov.

Section 2 - Study Population Characteristics

Who must complete "Section 2 - Study Population Characteristics:"

All of "Section 2 – Study Population Characteristics" is required (see exceptions for Question 2.7 Study Timeline and for Question 2.8 Enrollment of First Subject) for all human subjects studies unless the following applies to you:

- If you selected only **Exemption 4** and no other exemptions on the "1.3 Exemption Number" question, then "Section 2 – Study Population Characteristics" is not required.

2.1 Conditions or Focus of Study

At least 1 entry is required, and up to 20 entries are allowed (enter each entry on its own line). Each entry is limited to 255 characters.

Identify the name(s) of the disease(s) or condition(s) you are studying, or the focus of the study. If available, use appropriate descriptors from NLM's Medical Subject Headings (MeSH) so the application can be categorized. Include an entry for each condition.

Note: This field matches a ClinicalTrials.gov field (Primary Disease or Condition Being Studied in the Trial, or the Focus of the Study).

2.2 Eligibility Criteria

List the study's inclusion and exclusion criteria. To provide a bulleted list, use a dash (or other character) followed by a space ("- ") at the start of each bullet. Be sure to check the formatting in the assembled application image. Further explanation or justification should be included in the Recruitment and Retention plan.

Your text entry is limited to 15,000 characters (but typically needs only 500 characters).

Note: This field matches a ClinicalTrials.gov field (Eligibility Criteria).

For more information about formatting text entry fields, see NIH's Rules for Text Fields page and the ClinicalTrials.gov's Protocol Registration and Results System User's Guide.

2.3 Age Limits

Minimum Age

Enter the numerical value for the minimum age a potential participant can be to be eligible for the study. Provide the relevant units of time (i.e., years, months, weeks, days, hours, or minutes). If there is no lower limit or no lower limit is known, enter "N/A (No Limit)" and do not enter a unit of time.

Maximum Age

Enter the numerical value for the maximum age a potential participant can be to be eligible for the study. Provide the relevant units of time (i.e., years, months, weeks, days, hours, or minutes). If there is no upper limit or no upper limit is known, enter "N/A (No Limit)" and do not enter a unit of time.

Note: This field matches a ClinicalTrials.gov field (Age Limits).

2.3.a Inclusion of Individuals Across the Lifespan

Format:

Attach this information as a PDF file. See NIH's Format Attachments page.

Content:

Discuss each of the points listed below. Also include any additional information requested in the NOFO.

You will also have to complete an Inclusion Enrollment Report (IER). Note that you may need to include multiple IERs for each study. Refer to the instructions for the IER below for more information.

Inclusion of Individuals Across the Lifespan

For the purposes of the Inclusion of Individuals Across the Lifespan, exclusion of any specific age or age range group (e.g., children or older adults) should be justified in this section. In addition, address the following points:

- Individuals of all ages are expected to be included in all NIH-defined clinical research unless there are scientific or ethical reasons not to include them. Discuss whether individuals will be excluded based on age and provide a rationale for the minimum and maximum age of study participants, if applicable. Additionally, if individuals will be excluded based on age, provide a scientific or ethical rationale for their exclusion. See the NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects for additional information about circumstances that may justify the exclusion of individuals based on age.
- Include a description of the expertise of the investigative team for working with individuals of the ages included, the appropriateness of the available facilities to accommodate individuals in the included age range, and how the age distribution of participants will contribute to a meaningful analysis relative to the purpose of the study.

When children are involved in research, the policies under HHS' 45 CFR 46, Subpart D - Additional Protections for Children Involved as Subjects in Research apply and must be addressed in the Protection of Human Subjects attachment.

Existing Datasets or Resources. If you will use an existing dataset, resource, or samples that may have been collected as part of a different study, you must address inclusion, following the instructions above. Generally, you must provide details about the sex/gender, race, and ethnicity of the existing dataset/resource and justify the details as appropriate to the scientific goals of the proposed study.

For more information about what is considered an existing dataset or resource for inclusion policy, see the NIH FAQs on Inclusion - Basis of Sex/Gender and Race/Ethnicity.

For more information, see:

- NIH Policy Implementation Page on Inclusion Across the Lifespan
- Inclusion Across the Lifespan: Guidance for Applying the Policy infographic
- NIH FAQs on Inclusion Across the Lifespan
- HHS' 45 CFR 46 Subpart D – Additional Protections for Children
- NIH Grants Policy Statement, Section 4.1.15.7: Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects

2.4 Inclusion of Women and Minorities

Format:

Attach this information as a PDF file. See NIH's Format Attachments page.

Content:

Discuss each of the points listed below and include any additional information requested in the NOFO.

You will also have to complete an Inclusion Enrollment Report (IER). Note that you may need to include multiple IERs for each study. Refer to the instructions for the IER below for more information.

Inclusion of Women and Minorities

Address the following points:

- Describe the planned distribution of subjects by sex/gender, race, and ethnicity.
- Describe the rationale for selection of sex/gender, racial, and ethnic group members in terms of the scientific objectives and proposed study design. The description may include, but is not limited to, information on the population characteristics of the disease or condition under study.
- Describe proposed outreach programs for recruiting sex/gender, racial, and ethnic group members.
- Inclusion and Excluded Groups: Provide a reason for limiting inclusion of any group by sex/gender, race, and/or ethnicity. In general, the cost of recruiting certain groups and/or geographic location alone are not acceptable reasons for exclusion of

particular groups. See the Inclusion of Women and Minorities as Participants in Research Involving Human Subjects for more information.

Existing Datasets or Resources. If you will use an existing dataset, resource, or samples that may have been collected as part of a different study, you must address inclusion, following the instructions above. Generally, you must provide details about the sex/gender, race, and ethnicity of the existing dataset/resource and justify the details as appropriate to the scientific goals of the proposed study.

For more information about what is considered an existing dataset or resource for inclusion policy, see the NIH FAQs on Inclusion - Basis of Sex/Gender and Race/Ethnicity.

NIH-Defined Phase III Clinical Trials. If the proposed research includes an NIH-Defined Phase III Clinical Trial, the "Inclusion of Women and Minorities" attachment MUST address plans for how sex/gender, race, and ethnicity will be taken into consideration in the design and valid analysis of the trial. See the instructions for "Valid Analysis" and "Plans to test for Differences in Effect among Sex/gender, Racial, and/or Ethnic Groups" below.

Additional information about valid analysis is available on the NIH Policy and Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research page.

Valid Analysis (for NIH-Defined Phase III Clinical Trials only):

Address the following issues for ensuring valid analyses:

- Inclusive eligibility criteria – in general, the cost of recruiting certain groups and/or geographic location alone are not acceptable reasons for exclusion of particular groups;
- Allocation of study participants of both sexes/genders and from different racial and/or ethnic groups to the intervention and control groups by an unbiased process such as randomization;
- Unbiased evaluation of the outcome(s) of study participants; and
- Use of unbiased statistical analyses and proper methods of inference to estimate and compare the intervention effects by sex/gender, race, and/or ethnicity, particularly if prior evidence strongly suggests that such differences exist.

Plan to Test for Differences in Effect among Sex/gender, Racial, and/or Ethnic Groups (for NIH-Defined Phase III Clinical Trials only):

Applicants also should address whether they plan to test for differences in effect among sex/gender, racial, and/or ethnic groups and why such testing is or is not appropriate.

This plan must include selection and discussion of one of the following analysis plans:

- Plans to conduct analyses to detect significant differences in intervention effect among sex/gender, racial, and/or ethnic subgroups when prior studies strongly support these significant differences among one or more subgroups, or
- Plans to include and analyze sex/gender, racial, and/or ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups. (Representation of sex/gender, racial, and ethnic groups is not required as subject selection criteria, but inclusion is encouraged.), or

- Plans to conduct valid analyses of the intervention effect in sex/gender, racial, and/or ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect among subgroups.

For more information, see:

- NIH's Inclusion of Women and Minorities as Participants in Research Involving Human Subjects
- HHS' 45 CFR 46 Subpart B – Additional Protections for Pregnant Women, Fetuses, and Neonates
- NIH Grants Policy Statement, Section 4.1.15.8: Inclusion of Women and Minorities as Subjects in Clinical Research and Reporting Sex/Gender, Racial, and Ethnic Participation

2.5 Recruitment and Retention Plan

Who must complete the "Recruitment and Retention Plan" attachment:

The "Recruitment and Retention Plan" attachment is required unless the following applies to you:

- You selected only **Exemption 4** and no other exemptions on the "1.3 Exemption Number" question.

Format:

Attach this information as a PDF file. See NIH's Format Attachments page.

Content:

Describe how you will recruit and retain participants in your study. You should address both planned recruitment activities as well as proposed engagement strategies for retention.

2.6. Recruitment Status

Who must complete the "Recruitment Status" question:

The "Recruitment Status" question is required unless the following applies to you:

- You selected only **Exemption 4** and no other exemptions on the "1.3 Exemption Number" question.

Content:

From the dropdown menu, select the "Recruitment Status" that best describes the proposed study, based upon the status of the individual sites. If any facility in a multi-site study has an individual site status of "recruiting," then choose "recruiting" for this question. Only one selection is allowed. Choose from the following options:

- Not yet recruiting
- Recruiting

- Enrolling by invitation
- Active, not recruiting
- Completed
- Suspended
- Terminated (Halted Prematurely)
- Withdrawn (No Participants Enrolled)

Note: This field matches a ClinicalTrials.gov field (Overall Recruitment Status).

2.7. Study Timeline

Who must complete the "Study Timeline" attachment:

The “Study Timeline” attachment is required if you answered "Yes" to all the questions in the "Clinical Trial Questionnaire" (i.e., your study is a clinical trial).

The "Study Timeline" attachment is optional if either of the following apply to you:

- You selected only **Exemption 4** and no other exemptions on the “1.3 Exemption Number” question.
- You answered "No" to any of the questions in the "Clinical Trial Questionnaire" (i.e., your study is not a clinical trial).

Format:

Attach this information as a PDF file. See NIH's Format Attachments page.

Content:

Provide a description or diagram describing the study timeline. The timeline should be general (e.g., "one year after notice of award"), and should not include specific dates.

Note: Additional milestones or timelines may be requested as just-in-time information or post-award.

2.8. Enrollment of First Participant

Who must complete the "Enrollment of First Participant" question:

Do not complete this field if you will answer "Yes" to the question "Using an Existing Dataset or Resource" in the Inclusion Enrollment Report.

The “Enrollment of First Participant” question is otherwise required unless the following applies to you:

- You selected only **Exemption 4** and no other exemptions on the “1.3 Exemption Number” question.

Content:

Enter the date (MM/DD/YYYY) of the enrollment of the first participant into the study. From the dropdown menu, select whether this date is anticipated or actual.

2.9. Inclusion Enrollment Report(s)

Who must complete the Inclusion Enrollment Report(s):

An Inclusion Enrollment Report is required for all human subjects studies unless, on Question 1.3 "Exemption Number," you selected only Exemption 4 and no other exemptions.

Using the Inclusion Enrollment Report:

Each proposed study, unless it falls under Exemption 4, must contain at least one Inclusion Enrollment Report (IER). However, more than one IER per study is allowed.

Once you have added an IER for a given study, you may edit, remove, or view it.

Note: You can add a maximum of 20 IERs per Study Record. These can be a combination of planned and cumulative reports.

Multi-site studies: Generally, if the application includes a study recruiting subjects at more than one site/location, investigators may create one IER or separate, multiple IERs to enable reporting by study or by site, depending on the scientific goals of the study and whether monitoring of inclusion enrollment would benefit from being combined or separated. At a minimum, participants enrolled at non-U.S. sites must be reported separately from participants enrolled at U.S. sites, even if they are part of the same study. Please review the NOFO to determine whether there are any other specific requirements about how to complete the IER.

Duplicative Inclusion Reports: It is important that the IER for a given study be associated with only one application and be provided only once in a given application (e.g., do not submit the same IER on both the data coordinating center and the research site). If submitting individual application(s) as part of a network or set of linked applications, please provide the IER with the individual site applications unless otherwise directed by the NOFO.

Renewal applications: When preparing a renewal (or resubmission of a renewal), investigators should provide a narrative description regarding the cumulative enrollment from the previous funding period(s) as part of the progress report section of the research strategy attachment in the application. The IER should NOT be used for this purpose. If a given study will continue with the same enrollment or additional enrollment, or if new studies are proposed, provide a new IER for each as described in the instructions below.

Resubmission applications: If IERs were provided in the initial submission application, and if those studies will be part of the resubmission application, complete the IER and submit again with the resubmission application, regardless of whether the enrollment has changed or not. Also, provide any new (additional) IERs.

Revision applications: Provide an IER if new studies are planned as part of the Revision and they meet the NIH definition for clinical research.

Additional Instructions for Multi-project:

For multi-project applications with studies that are self-contained within a single component:

Other Component: Include the IER(s) with the component(s) that involves the study(s), unless otherwise directed by the NOFO.

For multi-project applications with studies that span components:

Overall Component: Should the study span more than one component, include the IER with the Study Record in the Overall Component and insert a comment in the comment field of the IER to indicate what other components it is associated with.

For more information:

Refer to the Inclusion of Women and Minorities as Participants in Research Involving Human Subjects.

1. Inclusion Enrollment Report Title

The "Inclusion Enrollment Report Title" field is required.

The "Inclusion Enrollment Report title can have a maximum of 600 characters.

Enter a unique title for each IER. The title should indicate specific criteria that uniquely identify each report. If the Project Title is pre-populated, you may edit it so that each IER title is unique.

2. Using an Existing Dataset or Resource?

The "Using an Existing Dataset or Resource" question is required.

If the study involves analysis of an existing dataset or resource (e.g., biospecimens) only, answer "Yes" to this question. If the study involves prospective recruitment or new contact with participants answer "No" to this question. Use separate IERs for studies involving use of existing datasets or resources only and for studies that involve prospective recruitment or new contact with study participants.

For additional guidance on what is considered an existing dataset, refer to the NIH FAQs on Inclusion - Basis of Sex/Gender and Race/Ethnicity.

3. Enrollment Location Type (Domestic/Foreign)

The "Enrollment Location Type" field is required.

Select whether the participants described in the IER are based at a U.S. (Domestic) or at a non-U.S. (Foreign) site. Participants at U.S. and non-U.S. sites must be reported separately (i.e., on separate IERs), even if it is for the same study.

For additional guidance on how to complete the IER if you will be working with non-U.S. populations, refer to these FAQs on Inclusion on the Basis of Sex/Gender and Race/Ethnicity.

4. Enrollment Country(ies)

The “Enrollment Country(ies)” field is optional.

Indicate the country or countries in which participants will be enrolled. Multiple U.S. sites can be reported together in one IER. Foreign countries can be reported together in one IER. However, you must use separate IERs for U.S. and non-U.S. sites. You can add up to 200 countries per IER.

5. Enrollment Location(s)

The “Enrollment Location(s)” field is optional.

Indicate the type of enrollment location (e.g., hospital, university, or research center), not the name of the enrollment location.

Enrollment locations are typically where the research is conducted, and can be different from the recruitment site.

6. Comments

Your comments are limited to 500 characters.

Enter information you wish to provide about this IER. This includes, but is not limited to, addressing information about distinctive subpopulations if relevant to the scientific hypotheses being studied. If inclusion monitoring is conducted on another study or NIH grant (e.g., data coordinating center or research site), please indicate here.

Revision applications: If there are no updates to the IER(s) in your original grant application, do not include an IER in your Revision application. Instead, provide a comment in this field to the effect that previous IER(s) are still applicable. If you are revising the IER(s) in your original grant application, provide a comment here to that effect.

Additional Instructions for Multi-project:

For multi-project applications with studies that span components:

Overall Component: Should the study span more than one component, include the IER with the Study Record in the Overall Component and insert a comment here in the comment field to indicate what other components it is associated with.

Planned

Who must complete planned enrollment tables:

All studies must enter planned enrollment counts unless your proposed study will use only an existing dataset or resource. Planned enrollment generally means that individuals will be recruited into the study and/or that individuals have already been recruited and continue to be part of the study.

For more information about what is considered an existing dataset or resource for inclusion policy, see the NIH FAQs on Inclusion on the Basis of Sex/Gender and Race/Ethnicity.

For more information on racial categories, see the NIH Glossary definition of Racial Categories.

For more information on ethnic categories, see the NIH Glossary definition of Ethnic Categories.

Racial Categories

American Indian/Alaska Native:

These fields are required.

Enter the expected number of females and males (in the respective fields) who are both American Indian/Alaska Native **and** Not Hispanic or Latino. Enter the expected number of females and males (in the respective fields) who are both American Indian/Alaska Native **and** Hispanic or Latino.

Asian:

These fields are required.

Enter the expected number of females and males (in the respective fields) who are both Asian **and** Not Hispanic or Latino. Enter the expected number of females and males (in the respective fields) who are both Asian **and** Hispanic or Latino.

Native Hawaiian or Other Pacific Islander:

These fields are required.

Enter the expected number of females and males (in the respective fields) who are both Native Hawaiian or Other Pacific Islander **and** Not Hispanic or Latino. Enter the expected number of females and males (in the respective fields) who are both Native Hawaiian or Other Pacific Islander **and** Hispanic or Latino.

Black or African American:

These fields are required.

Enter the expected number of females and males (in the respective fields) who are both Black or African American **and** Not Hispanic or Latino. Enter the expected number of females and males (in the respective fields) who are both Black or African American **and** Hispanic or Latino.

White:

These fields are required.

Enter the expected number of females and males (in the respective fields) who are both White **and** Not Hispanic or Latino. Enter the expected number of females and males (in the respective fields) who are both White **and** Hispanic or Latino.

More than One Race:

These fields are required.

Enter the expected number of females and males (in the respective fields) who both identify with more than one racial category **and** are Not Hispanic or Latino. Enter the expected number of females and males (in the respective fields) who both identify with more than one racial category **and** are Hispanic or Latino.

Total:

The total fields at the bottom will be automatically calculated and reflect the totals of all racial categories for females, males, and individuals of unknown/not reported sex/gender who are Not Hispanic or Latino and of all racial categories for females, males, and individuals of unknown/not reported sex/gender who are Hispanic or Latino. The "Total" fields in the right column will be automatically calculated to total all individuals.

Cumulative (Actual)

Who must complete cumulative (actual) enrollment tables:

You must enter cumulative enrollment counts if your proposed study will use an existing dataset or resource.

For more information about what is considered an existing dataset or resource for inclusion policy, see the NIH FAQs on Inclusion on the Basis of Sex/Gender and Race/Ethnicity.

For more information on racial categories, see the NIH Glossary definition of Racial Categories.

For more information on ethnic categories, see the NIH Glossary definition of Ethnic Categories.

Racial Categories

American Indian/Alaska Native:

These fields are required.

Enter the number of females and males (in the respective fields) who are both American Indian/Alaska Native **and** Not Hispanic or Latino. Enter the number of females and males (in the respective fields) who are both American Indian/Alaska Native **and** Hispanic or Latino. Use the "Unknown/Not Reported" fields as needed (i.e., race and/or ethnicity is unknown).

Asian:

These fields are required.

Enter the number of females and males (in the respective fields) who are both Asian **and** Not Hispanic or Latino. Enter the expected number of females and males (in the respective fields) who are both Asian **and** Hispanic or Latino. Use the "Unknown/Not Reported" fields as needed (i.e., race and/or ethnicity is unknown).

Native Hawaiian or Other Pacific Islander:

These fields are required.

Enter the number of females and males (in the respective fields) who are both Native Hawaiian or Other Pacific Islander **and** Not Hispanic or Latino. Enter the expected number of females

and males (in the respective fields) who are both Native Hawaiian or Other Pacific Islander **and** Hispanic or Latino. Use the "Unknown/Not Reported" fields as needed (i.e., race and/or ethnicity is unknown).

Black or African American:

These fields are required.

Enter the number of females and males (in the respective fields) who are both Black or African American **and** Not Hispanic or Latino. Enter the expected number of females and males (in the respective fields) who are both Black or African American **and** Hispanic or Latino. Use the "Unknown/Not Reported" fields as needed (i.e., race and/or ethnicity is unknown).

White:

These fields are required.

Enter the number of females and males (in the respective fields) who are both White **and** Not Hispanic or Latino. Enter the expected number of females and males (in the respective fields) who are both White **and** Hispanic or Latino. Use the "Unknown/Not Reported" fields as needed (i.e., race and/or ethnicity is unknown).

More than One Race:

These fields are required.

Enter the number of females and males (in the respective fields) who both identify with more than one racial category **and** are Not Hispanic or Latino. Enter the expected number of females and males (in the respective fields) who both identify with more than one racial category **and** are Hispanic or Latino. Use the "Unknown/Not Reported" fields as needed (i.e., race and/or ethnicity is unknown).

Unknown or Not Reported:

These fields are required.

Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) whose race is unknown/not reported **and** who are Not Hispanic or Latino. Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) whose race is unknown/not reported **and** who are Hispanic or Latino. Enter the number of females, males, and individuals of unknown/not reported sex/gender (in the respective fields) who are both of unknown/not reported race and of unknown/not reported ethnicity. Use the "Unknown/Not Reported" fields as needed (i.e., race and/or ethnicity is unknown).

Total:

The total fields at the bottom will be automatically calculated and reflect the totals of all racial categories for females, males, and individuals of unknown/not reported sex/gender who are Not Hispanic or Latino and of all racial categories for females, males, and individuals of unknown/not reported sex/gender who are Hispanic or Latino. Use the "Unknown/Not Reported" fields as needed (i.e., race and/or ethnicity is unknown). The "Total" fields in the right column will be automatically calculated to total all individuals.

Section 3 – Protection And Monitoring Plans

Who must complete "Section 3 – Protection and Monitoring Plans:"

All of "Section 3 – Protection and Monitoring Plans" is required for all studies involving human subjects, unless otherwise noted.

3.1 Protection of Human Subjects

The "Protection of Human Subjects" attachment is required.

Format:

Attach this information as a PDF file. See NIH's Format Attachments page.

Do not use the "Protection of Human Subjects" attachment to circumvent the page limits of the Research Strategy.

For Human Subjects Research Claiming Exemptions: If you are claiming that your human subjects research falls under any exemptions, justify why the research meets the criteria for the exemption(s) that you have claimed. This justification should explain how the proposed research meets the criteria for the exemption claimed. Do not merely repeat the criteria or definitions themselves.

For Studies that involve Non-Exempt Human Subjects Research: For any proposed non-exempt study involving human subjects, NIH requires a Protection of Human Subjects attachment that is commensurate with the risks of the study, its size, and its complexity. Organize your attachment into four sections, following the headings and specified order below, and discuss each of the points listed below. Start each section with the appropriate section heading – Risks to Human Subjects, Adequacy of Protection Against Risks, Potential Benefits of the Proposed Research to Research Participants and Others, and Importance of the Knowledge to be Gained. Also include any additional information requested in the NOFO.

1. Risks to Human Subjects

a. Human Subjects Involvement, Characteristics, and Design

- Briefly describe the overall study design.
- Describe the subject population(s) to be included in the study; the procedures for assignment to a study group, if relevant; and the anticipated numbers of subjects for each study group.
- List any collaborating sites where human subjects research will be performed, and describe the role of those sites and collaborating investigators in performing the proposed research.

b. Study Procedures, Materials, and Potential Risks

- Describe all planned research procedures (interventions and interactions) involving study subjects; how research material, including biospecimens, data, and/or records, will be obtained; and whether any private identifiable information will be collected in the proposed research project.

- For studies that will include the use of previously collected biospecimens, data or records, describe the source of these materials, whether these can be linked with living individuals, and who will be able to link the materials.
- Describe all the potential risks to subjects associated with each study intervention, procedure or interaction, including physical, psychological, social, cultural, financial, and legal risks; risks to privacy and/or confidentiality; or other risks. Discuss the risk level and the likely impact to subjects.
- Where appropriate, describe alternative treatments and procedures, including their risks and potential benefits. When alternative treatments or procedures are possible, make the rationale for the proposed approach clear.

2. Adequacy of Protection Against Risks

a. Informed Consent and Assent

- Describe the process for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. When appropriate, describe how potential adult subjects' capacity to consent will be determined and the plans for obtaining consent from a legally authorized representative for adult subjects not able to consent.
    - **For research involving children:** If the proposed studies will include children, describe the process for meeting HHS regulatory requirements for parental permission and child assent (45 CFR 46.408). See the HHS page on Research with Children FAQs and the NIH page on Requirements for Child Assent and Parent/Guardian Permission.
- If a waiver of some or all of the elements of informed consent will be sought, provide justification for the waiver. Do not submit informed consent document(s) with your application unless you are requested to do so.

b. Protections Against Risk

- Describe planned strategies for protecting against or minimizing all potential risks identified, including strategies to manage and protect the privacy of participants and confidentiality of research data.
- Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects on participants.
- Describe plans for handling incidental findings, such as those from research imaging, screening tests, or paternity tests.

c. Populations that are vulnerable to coercion or undue influence and pregnant women, fetuses and neonates, if relevant to your study

Explain the rationale for the involvement of populations that are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons or others who may be considered vulnerable populations. 'Prisoners' includes all subjects involuntarily incarcerated (for example, in detention centers). Additionally, explain the rationale for the involvement of pregnant women, human fetuses and neonates.

Pregnant Women, Fetuses, and Neonates or Children

If the study involves subjects afforded additional protections under Subparts B and D (pregnant women, fetuses, and neonates or children), provide a clear description of the risk level and additional protections necessary to meet the HHS regulatory requirements.

- HHS' Subpart B - Additional Protections for Pregnant Women, Fetuses, and Neonates
- HHS' Subpart D - Additional Protections for Children
- OHRP Guidance on Subpart D Special Protections for Children as Research Subjects and the HHS 407 Review Process

Prisoners

If the study involves vulnerable subjects afforded additional protections under Subpart C (prisoners), describe how proposed research meets the additional regulatory requirements, protections, and plans to obtain OHRP certification for the involvement of prisoners in research.

Refer to HHS regulations, and OHRP guidance:

- HHS' Subpart C - Additional Protections Pertaining to Prisoners as Subjects
- OHRP Subpart C Guidance on Involvement of Prisoners in Research

3. Potential Benefits of the Proposed Research to Research Participants and Others

- Discuss the potential benefits of the research to research participants and others.
- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to research participants and others.
- **Note:** Financial compensation of subjects should not be presented as a benefit of participation in research.

4. Importance of the Knowledge to be Gained

- Discuss the importance of the knowledge to be gained as a result of the proposed research.
- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

For more information:

- Refer to the NIH's Human Subjects Research website.

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?

Select "Yes" or "No" to indicate whether this is a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site.

Select "N/A" only if any of the following apply (do not select "N/A" if none of the following apply):

- You answered "Yes" to "Question 1.2 Is this Study Exempt from Federal Regulations? (Yes/No)"
- You are a training grant applicant.

Applicants who check "Yes" and are subject to the revised Common Rule are expected to use a single Institutional Review Board (sIRB) to conduct the ethical review required by HHS regulations for the Protections of Human Subjects Research unless review by a sIRB would be prohibited by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe).

Applicants who check "Yes" and are subject only to the NIH sIRB policy are expected to use a single Institutional Review Board (sIRB) to conduct the ethical review required by HHS regulations for the Protections of Human Subjects Research unless review by a sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy.

> **Note:** The NIH sIRB policy applies to participating domestic sites. Foreign sites participating in NIH-funded, multi-site studies are not expected to follow this policy.

Additional Instructions for Training:

Check "N/A," as the sIRB policy does not apply to training awards.

For more information:

- HHS regulations and requirements for the Protections of Human Subjects can be found at 45 CFR 46.
- See NIH's Single IRB Policy for Multi-site Research for more information.
- See Human Subjects and Clinical Trials Information FAQs.
  - "Do I need a single IRB if I answer "No" to the PHS Human Subjects and Clinical Trials Information Form question 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?

Single IRB Plan Attachment

For NIH Applicants, the single IRB plan is no longer required. See additional information in the content section below.

For AHRQ applicants, if this is a research project that involves more than one institution and that will be conducted in the United States, Applicants are expected to use a single Institutional Review Board (sIRB) to conduct the ethical review required by HHS regulations for the Protections of Human Subjects Research, and include a single IRB plan as instructed below, unless review by a sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy.

Note: The sIRB requirement applies to participating sites in the United States. Foreign sites participating in AHRQ-funded, cooperative research studies are not expected to follow this requirement.

Format:

Attach this information as a PDF file. See NIH's Format Attachments page.

Although one sIRB plan attachment per application is sufficient, you must include a file for each study within your application. All filenames within your application must be unique. You may either attach the same sIRB plan (with different filenames) to different studies or attach a file that refers to the sIRB plan in another study within your application. For example, you may attach a file that says “See sIRB plan in the 'My Unique Study Name' study.”

Content:

For NIH applicants, the single IRB plan is no longer required. Do not provide an attachment. The applicant must provide a statement naming the sIRB of record in the Just-in-Time submission prior to award.

For more information:

- NIH's Single IRB Policy for Multi-site Research page
- NIH's FAQs on Single IRB Policy for Multi-site Research

For AHRQ applicants, the single IRB plan should include the following elements:

- Describe how you will comply with the single IRB review requirement under the Revised Common Rule at 45 CFR 46.114 (b) (cooperative research). If available, provide the name of the IRB that you anticipate will serve as the sIRB of record.
- Indicate that all identified participating sites will agree to rely on the proposed sIRB and that any sites added after award will rely on the sIRB.
- Briefly describe how communication between sites and the sIRB will be handled.
- Indicate that all participating sites will, prior to initiating the study, sign an authorization/reliance agreement that will clarify the roles and responsibilities of the sIRB and participating sites.
- Indicate which institution or entity will maintain records of the authorization/reliance agreements and of the communication plan.
- Note: Do not include the authorization/reliance agreement(s) or the communication plan(s) documents in your application.
- Note: If you anticipate research involving human subjects but cannot describe the study at the time of application, include information regarding how the study will comply with the single Institutional Review Board (sIRB) requirement prior to initiating any multi-site study in the delayed onset study justification.

For Studies with Legal-, Regulatory-, or Policy-based Claims for Exception as described by the sIRB Policy: Indicate that review by a sIRB will not be possible for all or some sites (specify which sites) because local IRB review is required by an existing federal/state/tribal law or policy. Include a specific citation to the relevant law, policy, or regulation.

For more information:

- AHRQ Guide Notice on Single IRB
- AHRQ Protection of Human Subjects page

3.3 Data and Safety Monitoring Plan

A "Data and Safety Monitoring Plan" attachment is required if you answered "Yes" to all the questions in the "Clinical Trial Questionnaire." The "Data and Safety Monitoring Plan" attachment is optional for all other human subjects research.

For human subjects research that does not involve a clinical trial: Your study, although it is not a clinical trial, may have significant risks to participants, and it may be appropriate to include a data and safety monitoring plan. If you choose to include a data and safety monitoring plan, you may follow the content criteria listed below, as appropriate.

For AHRQ Applicants, Data and Safety Monitoring (DSM) plans are required in all non-exempt research applications when support is sought to study the effect of a health-related intervention on outcomes in human subjects where there is greater than minimal risk.

If you seek AHRQ support to conduct non-exempt research to study the effect of a health-related intervention on outcomes in human subjects where there is greater than minimal risk, a "Data and Safety Monitoring Plan" attachment is required.

Refer to AHRQ Data and Safety Monitoring Policy

Format:

Attach this information as a PDF file. See NIH's Format Attachments page.

Content:

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): Include only the following information in your data and safety monitoring plan (i.e., do not follow the standard instructions for the data and safety monitoring plan):

- The names of the individual(s) or group that will be responsible for trial monitoring (i.e., the lead investigator of the clinical trial)
- If applicable, the name of an independent safety monitor or a data and safety monitoring board

Additional Instructions for Fellowship:

Fellowship candidates who are proposing to gain clinical trial research experience under a sponsor's supervision (i.e., you will not be leading an independent clinical trial): Include only the following information in your data and safety monitoring plan (i.e., do not follow the standard instructions for the data and safety monitoring plan):

- The names of the individual(s) or group that will be responsible for trial monitoring (i.e., the lead investigator of clinical trial)
- If applicable, the name of an independent safety monitor or a data and safety monitoring board

For any proposed clinical trial, NIH requires a data and safety monitoring plan (DSMP) that is commensurate with the risks of the trial, its size, and its complexity. Provide a description of the DSMP, including:

- Indicate how many people and what type of entity will provide the monitoring. Include such details as whether a single person, multiple people, or a data safety monitoring board will provide monitoring. Also indicate what type of entity will provide the monitoring (e.g., PD/PI, Independent Safety Monitor/Designated Medical Monitor, Independent Monitoring Committee, Safety Monitoring Committee, Data and Safety Monitoring Board, etc.).
- The overall framework for safety monitoring and what information will be monitored.
- The frequency of monitoring, including any plans for interim analysis and stopping rules (if applicable).
- The process by which Adverse Events (AEs), including Serious Adverse Events (SAEs) such as deaths, hospitalizations, and life threatening events and Unanticipated Problems (UPs), will be managed and reported, as required, to the IRB, the person or group responsible for monitoring, the awarding IC and the Food and Drug Administration.
- The individual(s) or group that will be responsible for trial monitoring and advising the appointing entity. Because the DSMP will depend on potential risks, complexity, and the nature of the trial, a number of options for monitoring are possible. These include, but are not limited to, monitoring by a:
    - PD/PI: While the PD/PI must ensure that the trial is conducted according to the approved protocol, in some cases (e.g., low risk trials, not blinded), it may be acceptable for the PD/PI to also be responsible for carrying out the DSMP.
    - Independent safety monitor/designated medical monitor: a physician or other expert who is independent of the study.
    - Independent Monitoring Committee or Safety Monitoring Committee: a small group of independent experts.
    - Data and Safety Monitoring Board (DSMB): a formal independent board of experts including investigators and biostatisticians. NIH requires the establishment of DSMBs for multi-site clinical trials involving interventions that entail potential risk to the participants, and generally, for all Phase III clinical trials, although Phase I and Phase II clinical trials may also need DSMBs. If a DSMB is used, please describe the general composition of the Board without naming specific individuals.

For more information:

- NIH Grants Policy Statement, Section 4.1.15.6: Data and Safety Monitoring
- NIH Data and Safety Monitoring Policies
- NIH Policies and IC Guidance for Data and Safety Monitoring of Clinical Trials

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

The "Data Safety and Monitoring Board" question is required if you answered "Yes" to all the questions in the "Clinical Trial Questionnaire." This question is optional for all other human subjects research.

Check the appropriate box to indicate whether a Data Safety and Monitoring Board (DSMB) will be appointed for this study.

3.5 Overall Structure of the Study Team

The "Overall Structure of the Study Team" attachment is optional. Refer to your specific NOFO for specific instructions on the "Overall Structure of the Study Team" attachment.

Format:

Attach this information as a PDF file. See NIH's Format Attachments page.

Content:

Provide a brief overview of the organizational/administrative structure and function of the study team, particularly the administrative sites, data coordinating sites, enrollment/participating sites, and any separate laboratory or testing centers. The attachment may include information on study team composition and key roles (e.g., medical monitor, data coordinating center), the governance of the study, and a description of how study decisions and progress are communicated and reported.

Note: Do not include study team members' individual professional experiences (i.e., biosketch information).

Section 4 – Protocol Synopsis

Who must complete "Section 4 – Protocol Synopsis:"

If you answered "Yes" to all the questions in the "Clinical Trial Questionnaire:" All the questions in the "Protocol Synopsis" section are required.

If you answered "No" to any question in the "Clinical Trial Questionnaire:" Do not provide information in this section. Inputting information in this section will result in errors and will prevent your application from being accepted.

Additional Instructions for Research:

R25 applicants who are proposing to provide clinical trial research experience for their participants (i.e., participants will not be leading an independent clinical trial): Do not provide information in "Section 4 - Protocol Synopsis." Inputting information in this section will result in errors and will prevent your application from being accepted.

R36 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 provide information in "Section 4 - Protocol Synopsis." Inputting information in this section will result in errors and will prevent your application from being accepted.

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 provide information in "Section 4 - Protocol Synopsis." Inputting information in this section will result in errors and will prevent your application from being accepted.

Additional Instructions for Training:

K12 and D43 applicants who are proposing to provide clinical trial research experience for their Scholars/Trainees (i.e., Scholars/Trainees will not be leading an independent clinical trial): At the time of your application, do not provide information in "Section 4 – Protocol Synopsis." Inputting information in this section will result in errors and will prevent your application from being accepted. Post-award, while you will be required to fill out Study Records, you must still not provide information in "Section 4 – Protocol Synopsis."

Additional Instructions for Fellowship:

Fellowship candidates proposing to gain clinical trial research experience under a sponsor's supervision (i.e., you will not be leading an independent clinical trial): Do not provide information in "Section 4 - Protocol Synopsis." Inputting information in this section will result in errors and will prevent your application from being accepted.

4.1. Study Design

4.1.a. Detailed Description

Enter a narrative description of the protocol. Studies differ considerably in the methods used to assign participants and deliver interventions. Describe your plans for assignment of participants and delivery of interventions. You will also need to show that your methods for sample size and data analysis are appropriate given those plans. For trials that randomize groups or deliver interventions to groups, special methods are required; additional

information is available at the Research Methods Resources webpage. The Narrative Study Description is not meant to be a repeat of the Research Strategy.

The narrative description is limited to 32,000 characters (but typically needs only 5,000 characters), should be written in layperson's terms, and may repeat some of the information in the Research Strategy.

Note: This field matches a ClinicalTrials.gov field (Detailed Description).

For more information about formatting text entry fields, see NIH's Rules for Text Fields page.

4.1.b. Primary Purpose

Enter or select from the dropdown menu a single "Primary Purpose" that best describes the clinical trial. Choose from the following options:

- Treatment
- Prevention
- Diagnostics
- Supportive Care
- Screening
- Health Services Research
- Basic Science
- Device Feasibility
- Other (If you select "Other," provide a description in the space provided. Your response is limited to 255 characters.)

Note: This field matches a ClinicalTrials.gov field (Primary Purpose).

4.1.c. Interventions

Complete the "Interventions" fields for each intervention to be used in your proposed protocol. If an arm of the study to which subjects will be assigned (as discussed in 4.1.a. Detailed Description) includes more than one intervention (e.g., drug plus educational intervention), complete this section for each intervention. You can add up to 20 interventions.

Intervention Type: Enter or select from the dropdown menu the intervention type the clinical trial will administer during the proposed award. Choose from the following options:

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

Name: Enter the name of the intervention. The name is limited to 200 characters.

Description: Enter a description of the intervention. The description is limited to 1,000 characters.

Note: This field matches a ClinicalTrials.gov field. (Interventions, including Intervention Type and Intervention Name(s)).

For more information on how to answer this question for behavioral research trials, refer to the Human Subjects and Clinical Trials Information FAQs page.

4.1.d. Study Phase

Enter or select from the dropdown menu a "Study Phase" that best describes the clinical trial. If your study involves a device or behavioral intervention, choose “N/A”.

Choose from the following options:

- Early Phase 1 (or Phase 0)
- Phase 1
- Phase 1/2
- Phase 2
- Phase 2/3
- Phase 3
- Phase 4
- N/A

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

Select "Yes" or "No" to indicate whether the study includes an NIH-defined Phase III clinical trial. Device and behavioral intervention studies may select “Yes” here even if the answer above is “Other”.

For more information on how to answer this question for devices or behavioral interventions, refer to the Human Subjects and Clinical Trials Information FAQs page.

4.1.e. Intervention Model

Enter or select from the dropdown menu a single "Intervention Model" that best describes the clinical trial. If you select “Other,” provide a description in the space provided. Choose from the following options:

- Single Group
- Parallel
- Cross-Over
- Factorial
- Sequential
- Other (If you select “Other,” provide a description in the space provided. Your response is limited to 255 characters.)

Note: This field matches a ClinicalTrials.gov field (Interventional Study Model).

For more information: Definitions of intervention models may be found in ClinicalTrials.gov’s Glossary of Common Site Terms or in the ClinicalTrials.gov’s description of Study Design.

4.1.f. Masking

Select "Yes" or "No" to indicate whether the protocol uses masking. Note that masking is also referred to as “blinding.”

If you answered “Yes” to the “Masking” question, select one or more types of masking that best describes the protocol. Choose from the following options:

- Participant
- Care Provider
- Investigator
- Outcomes Assessor

Note: This field matches a ClinicalTrials.gov field (Masking).

4.1.g. Allocation

Enter or select from the dropdown menu a single "Allocation" that best describes how subjects will be assigned in your protocol. If allocation is not applicable to your clinical trial, select “N/A” (e.g., for a single-arm trial). Choose from the following options:

- N/A
- Randomized
- Non-randomized

Note: This field matches a ClinicalTrials.gov field (Allocation).

4.2. Outcome Measures

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

Name: Enter the name of the individual outcome measure. The outcome measure must be unique within each Study Record.

Type: Enter or select from the dropdown menu the type of the outcome measure. Choose from the following options:

- Primary – select this option for the outcome measures specified in your protocol that are of greatest importance to your study
- Secondary – select this option for outcome measures specified in your protocol that are of lesser importance to your study than your primary outcomes
- Other – select this option for additional key outcome measures used to evaluate the intervention.

Time Frame: Indicate when a measure will be collected for analysis (e.g., baseline, post-treatment).

Brief Description: Describe the metric used to characterize the outcome measure if the metric is not already included in the outcome measure name. Your description is limited to 999 characters.

NIH-Defined Phase III Clinical Trials: If the proposed research includes an NIH-Defined Phase III Clinical Trial, then outcomes for required analyses by sex/gender, race, and ethnicity should be entered.

Additional information about valid analysis is available on the NIH Policy and Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research page.

Note: This field matches a ClinicalTrials.gov field (e.g., Primary Outcome Measure Information, which includes Title, Description, and Time Frame).

For more information on listing outcome measures, refer to the Human Subjects and Clinical Trials Information FAQs page.

4.3. Statistical Design and Power

Format:

Attach this information as a PDF file. See NIH's Format Attachments page.

Content:

Specify the number of subjects you expect to enroll, the expected effect size, the power, and the statistical methods you will use with respect to each outcome measure you listed in 4.2 Outcome Measures.

You will need to show that your methods for sample size and data analysis are appropriate given your plans for assignment of participants and delivery of interventions. For trials that randomize groups or deliver interventions to groups, special methods are required; additional information is available at the Research Methods Resources webpage.

4.4 Subject Participation Duration

Enter the time (e.g., in months) it will take for each individual participant to complete all study visits. If the participation duration is unknown or not applicable, write "unknown" or "not applicable." The subject participation duration is limited to 255 characters.

4.5 Will the study use an FDA-regulated intervention?

Select "Yes" or "No" to indicate whether the study will use an FDA-regulated intervention (see the definition of "FDA Regulated Intervention" under the Oversight section of the ClinicalTrials.gov Protocol Registration Data Element Definitions for Interventional and Observational Studies page).

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

This attachment is required if you answered "Yes" to the "Will the study use an FDA-regulated intervention?" question.

Format:

Attach this information as a PDF file. See NIH's Format Attachments page.

This attachment's typical length is approximately 3,000 characters.

Content:

Provide a summary describing the availability of study agents and support for the acquisition and administration of the study agent(s).

Please indicate, if applicable, the IND/IDE status of the study agent, including whether a clinical investigation is exempt from the IND/IDE requirement. Also indicate whether the investigators have had any interactions with the FDA (e.g., indicate if the FDA has stated that research may proceed). If the study agent currently has an IND/IDE number, provide that information.

Do not include the IND/IDE application, manufacturer's product specifications, study protocol, or protocol amendments in this attachment.

Additional information such as FDA letters or correspondence with the FDA may be requested in the NOFO.

Note: The awarding component may request consultation with the FDA and the IND/IDE sponsor about the proposed clinical trial after peer review and prior to award.

4.6 Is this an applicable clinical trial under FDAAA?

Select "Yes" or "No" to indicate whether the study is an applicable clinical trial (ACT) under the Food and Drug Administration Amendments Act (FDAAA).

For more information:

- NIH Glossary's definition of an applicable clinical trial
- FAQs on the ClinicalTrials.gov & FDAAA
- ClinicalTrials.gov FAQs

4.7 Dissemination Plan

Format:

Attach this information as a PDF file. See NIH's Format Attachments page.

Although one Dissemination Plan per application is sufficient, you must include a file for each study within your application. All filenames within your application must be unique. You may either attach the same Dissemination Plan to different studies or attach a file that refers to the Dissemination Plan in another study within your application. For example, you may attach a file that says "See Dissemination Plan in the 'My Unique Study Name' study."

Content:

Explain briefly your plan for the dissemination of NIH-funded clinical trial information and address how the expectations of the policy will be met. The plan must contain sufficient information to assure the following:

- the applicant will ensure that clinical trial(s) under the award are registered and results information is submitted to ClinicalTrials.gov as outlined in the policy and according to the specific timelines stated in the policy;
- informed consent documents for the clinical trial(s) will include a specific statement relating to posting of clinical trial information at ClinicalTrials.gov; and
- the recipient organization has an internal policy in place to ensure that clinical trials registration and results reporting occur in compliance with policy requirements.

Note: Do not include informed consent documents in the Dissemination Plan attachment.

Note: If your human subjects study meets the definition of "Delayed Onset," include the Dissemination Plan attachment in the delayed onset study justification.

For more information:

- See the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information
- See the NIH Guide Notice on the Delayed Enforcement and Short-Term Flexibilities for Some Requirements Affecting Prospective Basic Science Studies Involving Human Participants
- See the NIH Grants Policy Statement, Section 4.1.3.1 NIH Policy on Dissemination of NIH-Funded Clinical Trial Information.

Section 5 – Other Clinical Trial-related Attachments

Who must complete "Section 5 – Other Clinical Trial-related Attachments:"

If you answered "Yes" to all the questions in the "Clinical Trial Questionnaire:" Include an attachment only if your NOFO specifies that an attachment(s) is required or permitted; otherwise, do not include any Other Clinical Trial-related attachments.

If you answered "No" to any question in the "Clinical Trial Questionnaire:" Do not provide information in this section. Inputting information in this section will result in errors and will prevent your application from being accepted.

Additional Instructions for Research:

R25 applicants who are proposing to provide clinical trial research experience for their participants (i.e., participants will not be leading an independent clinical trial): Do not provide information in "Section 5 – Other Clinical Trial-related Attachments." Inputting information in this section will result in errors and will prevent your application from being accepted.

R36 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 provide information in "Section 5 – Other Clinical Trial-related Attachments." Inputting information in this section will result in errors and will prevent your application from being accepted.

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 provide information in "Section 5 – Other Clinical Trial-related Attachments." Inputting information in this section will result in errors and will prevent your application from being accepted.

Additional Instructions for Training:

K12 and D43 applicants who are proposing to provide clinical trial research experience for their Scholars/Trainees (i.e., Scholars/Trainees will not be leading an independent clinical trial): At the time of your application, do not provide information in "Section 5 – Other Clinical Trial-related Attachments." Inputting information in this section will result in errors and will prevent your application from being accepted. Post-award, while you will be required to fill out Study Records, you must still not provide information in "Section 5 – Other Clinical Trial-related Attachments."

Additional Instructions for Fellowship:

Fellowship candidates proposing to gain clinical trial research experience under a sponsor's supervision (i.e., you will not be leading an independent clinical trial): Do not provide information in "Section 5 – Other Clinical Trial-related Attachments." Inputting information in this section will result in errors and will prevent your application from being accepted.

5.1 Other Clinical Trial-related Attachments

Format:

Attach this information as a PDF file. See NIH's Format Attachments page.

A maximum of 10 PDF attachments is allowed in the "Other Clinical Trial-related Attachments" section.

Content:

Provide additional trial-related information only if your NOFO specifically requests it. Include only attachments requested in the NOFO, and use requested filenames. If a specific filename is not given in the NOFO, use a meaningful filename since it will become a bookmark in the assembled application image. Each attachment included in the application must have a unique filename. Do not use the same file name in multiple study records. If the NOFO requires a specific filename, add unique numbers at the end of the filenames for each study record (e.g. study_filename1, study_filename2). File name sizes are limited to 50 characters.