

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.

If you are proposing on a solicitation for work involving human subjects, the PHS Human Subjects and Clinical Trials Information form is required to be submitted with your proposal.

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5.1 [Other Clinical Trial-related Attachments](#)

The PHS Human Subjects and Clinical Trials Information 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 solicitation will prescribe when the form PHS Human Subjects and Clinical Trials Information must be completed. If the solicitation requires the completion of the form, you must submit the completed form with your proposal.

If activities involving human subjects are planned at any time during the proposed project at any performance site, check "Yes." Check "Yes" even if the proposed project is exempt from regulations for the Protection of Human Subjects, or if activities involving human subjects are anticipated within the period of award but plans are indefinite.

If activities involving human subjects are not planned at any time during the proposed project at any performance site, select "No" and skip the rest of the "Are Human Subjects Involved" section.

Need help determining whether your proposal includes human subjects? Check out the NIH [Research Involving Human Subjects](#) website for information, including an [Infopath Questionnaire](#) designed to walk Offerors through the decision process.

Note on the use of human specimens or data: Offerors submitting a proposal involving the use of human specimens or data may or may not be considered to be proposing research involving human subjects, depending on the details of the materials to be used. If you check "No" to "Are Human Subjects Involved?" but the solicitation requires use of human specimens or data, you will be required to provide a clear justification about why this use does not constitute human subjects research.

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.

For more information on human biospecimens or data: Refer to the NIH page on [Frequently Asked Questions on Human Specimens, Cell Lines, or Data](#) and the [Research Involving Private Information or Biological Specimens](#) flowchart.

Using the PHS Human Subjects and Clinical Trials Information form:

The PHS Human Subjects and Clinical Trials Information form allows you to add study record(s). *Please note: Delayed onset section is not applicable to contract proposals.*

Within each Study Record: PHS Human Subjects and Clinical Trials Information, you will add detailed information at the study level. Add a separate [study record](#) for each protocol involving human subjects proposed. Do not duplicate studies within your proposal. Each [study](#) within the proposal 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.

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

Offerors 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](#)
- [Research Involving Human Subjects](#)
- [NIH's Clinical Trials](#) website

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

Are Human Subjects Involved? Yes/No

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

Is the Project Exempt from Federal regulations? Yes/No

Select “Yes” or “No” to indicate whether the proposed research is exempt from Federal regulations.

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

Select applicable exemption that applies to the proposed research. You should not have selected exemption 7 or 8, as these are not yet being used.

If No to Human Subjects

If you answered “No” to the question “[Are Human Subjects Involved?](#)”

Does the proposed research involve human specimens and/or data?

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

Proposals involving the use of human specimens or data may not be considered to be research involving human subjects, depending on the details of the materials to be used. To help determine whether your research is classified as human subjects research, refer to the [Research Involving Private Information or Biological Specimens](#) flowchart.

Note: If you answered “No” to the “Does the proposed research involve human specimens and/or data?” question, skip the rest of the PHS Human Subjects and Clinical Trials Information form unless otherwise directed by your solicitation.

If Yes, provide an explanation of why the proposal does not involve human subjects research.

If you answered “Yes” to the “Does the proposed research involve human specimens and/or data?” question, you must provide a justification for your claim that no human subjects are involved.

Attach the justification as a PDF file.

This justification should include:

- information on who is providing the data/biological specimens and their role in the proposed research;
- a description of the identifiers that will be associated with the human specimens and data;
- a list of who has access to subjects’ identities; and
- information about the manner in which the privacy of research participants and confidentiality of data will be protected.

Note: Once you have attached the justification, skip the rest of the PHS Human Subjects and Clinical Trials Information form unless otherwise directed by your solicitation.

If Yes to Human Subjects

If you answered “Yes” to the question “[Are Human Subjects Involved?](#)” add a study record for **each** proposed study involving human subjects by selecting “Add New Study”. *Please note that “Add New Delayed Onset Study” is inapplicable to contract proposals; therefore, this should not be selected.*

Other Requested Information

Who may provide Other Requested Information:

If the solicitation requires you to submit Other Requested Information, include the “Other Requested Information” attachment. If the solicitation does not specifically require it, do not use this section.

Format:

Attach this information as a PDF file.

Content:

Content is limited to what is requested in the solicitation. Do not use the “Other Requested Information” attachment to include any other information.

Study Record(s)

Adding Study Record Attachment(s):

Add a study record for each proposed study involving human subjects. Please note that “Add New Delayed Onset Study” is inapplicable to contract proposals; therefore, this should not be selected.

The Study Record is used to collect human subjects study data. To complete the Study Record, download a blank copy, complete it offline, and then attach it to the PHS Human Subjects and Clinical Trials Information form.

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

Format:

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

Content:

Follow the instructions in the [“Study Record: PHS Human Subjects and Clinical Trials Information”](#) section below.

Delayed Onset Study(ies)

Please note that “Add New Delayed Onset Study” is inapplicable to contract proposals; therefore, this should not be selected.

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 in your proposal), each one must have a unique study title. The first 150 characters will display in the bookmarks of the proposal image.

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

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 [Exempt Human Subjects Research infographic](#).

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. **Do not select exemption 7 or 8, as these are not yet being used.** Regardless of whether these exemptions may apply to you in the future, you must fill out your proposal following the instructions below. The instructions do not take exemptions 7 and 8 into account.

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 Research Involving Human Subjects [Frequently Asked Questions](#).

The Office of 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](#)).

1.4 Clinical Trial Questionnaire

The Clinical Trial Questionnaire is required.

Note for mechanistic studies: Many [mechanistic studies](#) (i.e., those designed to understand a biological or behavioral process, the pathophysiology of a disease, or the mechanism of action of an intervention) meet the NIH definition of a clinical trial.

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.

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 <u>all</u> the questions in the Clinical Trial Questionnaire	If you answered "no" to <u>any</u> 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 RFP	Do not complete

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
- [FAQs](#) on the NIH Clinical Trial Definition
- 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.

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

Section 2 - Study Population Characteristics

Who must complete “Section 2 - Study Population Characteristics:”

All of “Section 2 – Study Population Characteristics” is required for all human subjects studies unless either one or both of the following apply 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.
- If you selected “**No**” to the "[1.4.a. Does the study involve human participants?](#)” question, then certain questions in “Section 2 – Study Population Characteristics” are not required, as noted in the individual field instructions below.

2.1 Conditions or Focus of Study

At least one entry is required, and up to 20 entries are allowed. 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 proposal can be categorized. Include an entry for each condition.

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. Further explanation or justification should be included in the [Recruitment and Retention plan](#).

Your text entry is limited to 15,000 characters.

2.3 Age Limits

Minimum Age

Enter the numerical value for the minimum age a potential participant can 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 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.

2.4 Inclusion of Women, Minorities, and Children

Format:

Attach this information as a PDF file.

Content:

Organize your attachment into two sections, following the headings and specified order below, and discuss each of the points listed below. Start each section with the appropriate section heading – "Inclusion of Women and Minorities" and "Inclusion of Children." Also include any additional information requested in the solicitation.

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.

1. Inclusion of Women and Minorities

- **Please refer to the provision in Section L of the solicitation entitled "Inclusion of Women and Minorities in Research Involving Human Subjects."**
- See the [Inclusion of Women and Minorities as Participants in Research Involving Human Subjects - Policy Implementation Page](#) 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 Monitoring Inclusion When Working with Existing Datasets and/or Resources](#).

NIH-Defined Phase III Clinical Trials.

- **Please refer to the provision in Section L of the solicitation entitled “Inclusion of Women and Minorities in Research Involving Human Subjects.”**

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](#).

2. Inclusion of Children

- **Please refer to the provision in Section L of the solicitation entitled “Inclusion of Children in Research Involving Human Subjects.”**
- See the [NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects](#) for additional information about circumstances that may justify the exclusion of children.
- 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.

For more information, see:

- NIH's [Policy Implementation Page on the Inclusion of Women and Minorities](#)
- NIH's [Policy Implementation Page on the Inclusion of Children](#)
- HHS’ [45 CFR 46 Subpart B – Additional Protections for Pregnant Women, Fetuses, and Neonates](#)
- HHS’ [45 CFR 46 Subpart D – Additional Protections for Children](#)
- [NIH Grants Policy Statement, Section 4.1.15.7: Inclusion of Children as Subjects in Clinical Research](#)
- [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 either one or both of the following apply to you:

- You selected only **Exemption 4** and no other exemptions on the “[1.3 Exemption Number](#)” question.
- You selected “**No**” to the “[1.4.a. Does the study involve human participants?](#)” question.

Format:

Attach this information as a PDF file.

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 either one or both of the following apply to you:

- You selected only **Exemption 4** and no other exemptions on the "[1.3 Exemption Number](#)" question.
- You selected "**No**" to the "[1.4.a. Does the study involve human participants?](#)" question.

Content:

From the dropdown menu, select a single "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)

2.7. Study Timeline

Who must complete the "Study Timeline" attachment:

The "Study Timeline" attachment is required unless either one or both of the following apply to you:

- You selected only **Exemption 4** and no other exemptions on the "[1.3 Exemption Number](#)" question.
- You selected "**No**" to the "[1.4.a. Does the study involve human participants?](#)" question.

Format:

Attach this information as a PDF file.

Content:

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

2.8. Enrollment of First Subject

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

The "Enrollment of First Subject" question is required unless either one or both of the following apply to you:

- You selected only **Exemption 4** and no other exemptions on the "[1.3 Exemption Number](#)" question.
- You selected "**No**" to the "[1.4.a. Does the study involve human participants?](#)" question.

Content:

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

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: The IER format should NOT be used for collecting data from study participants.

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 proposal 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 solicitation 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 proposal and be provided only once in a given proposal (i.e., do not submit an IER on both the data coordinating center and the research site). If submitting multiple proposals, and proposing multiple sites, you must submit a separate IER for each proposal.

For more information:

Refer to the [Inclusion of Women and Minorities as Participants in Research Involving Human Subjects - Policy Implementation Page](#).

1. Using an Existing Dataset or Resource?

The “Using an Existing Dataset or Resource” question is required.

Indicate whether this study involves the use of an [existing dataset](#) or resource.

For additional guidance on what is considered an existing dataset, refer to the NIH [FAQs on Monitoring Inclusion When Working with Existing Datasets and/or Resources](#).

2. 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. At a minimum, 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 Monitoring Inclusion in Non-US Research Participants](#).

3. Enrollment Country(ies)

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

Indicate the enrollment country or countries for the participants. Multiple U.S. sites submitted under *one proposal* can be reported together in one IER. Foreign countries submitted under *one proposal* 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.

4. 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.

5. 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 contract (e.g., data coordinating center or research site), please indicate here.

Planned

Who must complete planned enrollment tables:

You must enter planned enrollment counts must be submitted if your proposed study will **not** use 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 Monitoring Inclusion When Working with Existing Datasets and/or Resources](#).

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 Monitoring Inclusion When Working with Existing Datasets and/or Resources](#).

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.

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.**

Content:

- **Please refer to the provision in Section L of the solicitation entitled “Instructions to Offerors Regarding Protection of Human Subjects.”**

Prisoners

- **Please refer to the provision in Section L of the solicitation entitled “Research Involving Prisoners as Subjects.”**

If the study involves vulnerable subjects subject to 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](#)

For more information:

Refer to the NIH’s [Research Involving Human Subjects](#) site.

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? \(Yes/No\)](#)”

Offerors who check “Yes” 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.

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.

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.

If yes, describe the single IRB plan

Format:

Attach this information as a PDF file.

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

Content:

- **Please refer to the provision in Section L of the solicitation entitled "Single Institutional Review Board Plan."**
- **For Studies with Legal-, Regulatory-, or Policy-based Claims for Exception as described by the sIRB Policy:**
- **For sites requesting an exception based on compelling justification:**
- **Please refer to the provision in Section L of the solicitation entitled "Exceptions to the Single Institutional Review Board (sIRB) Policy."**

For more information:

- NIH Office of Science Policy Clinical Research [IRB Review](#) page
- [FAQs](#) on NIH Policy on the Use of a Single IRB for Multi-Site Research Costs
- [FAQs](#) on Implementation of the sIRB policy
- NIH Guide Notice on the [Final NIH Policy on sIRB](#)

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.

Format:

Attach this information as a PDF file.

Content:

Please refer to the provision in Section L of the solicitation entitled “Data and Safety Monitoring in 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 required if you answered “Yes” to all the questions in the “[Clinical Trial Questionnaire](#).” This question is optional for all other human subjects research.

Format:

Attach this information as a PDF file.

Content:

Provide a brief overview of the organizational structure of the study team, particularly the administrative sites, data coordinating sites, enrollment/participating sites, and any separate laboratory or testing centers.

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 or your proposal will be rejected.

4.1 Brief Summary

Enter a brief description of objectives of the protocol, including the primary and secondary endpoints. The Brief Summary is limited to 5,000 characters.

4.2. Study Design

4.2.a. Narrative Study 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 description is limited to 32,000 characters.

4.2.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.)

4.2.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 [4.2.a. Narrative Study 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 must be unique within each study record. The name is limited to 200 characters.

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

4.2.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, choose "Other."

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
- Other (If you select "Other," provide a description in the space provided. Your response is limited to 255 characters.)

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](#).

4.2.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.)

4.2.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

4.2.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

4.3. 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.

4.4. Statistical Design and Power

Format:

Attach this information as a PDF file.

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 4.3 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](#) page.

4.5 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.

4.6 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).

4.6.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.

Content:

Describe the availability of study agents and support for the acquisition and administration of the study agent(s). Please indicate the IND/IDE status of the study agent, if applicable, and whether the investigators have had any interactions with the FDA. If the study agent currently has an IND/IDE number, provide that information. **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.

4.7 Dissemination Plan

Format:

Attach this information as a PDF file.

Although one Dissemination Plan per proposal is sufficient, you must include a file for each study within your proposal. All file names within your proposal 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 proposal. For example, you may attach a file that says "See Dissemination Plan in the 'My Unique Study Name' study."

Content:

- **Please refer to the provision in Section L of the solicitation entitled "Plan for the Dissemination of Information of NIH-Funded Clinical Trial."**

Note: Do not include informed consent documents in your proposal.

For more information:

See the [NIH Policy on the 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 the solicitation 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 or your proposal will be rejected.

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 solicitation specifically requests it