

HS = Human Subjects
CT = Clinical Trials

Study Record: PHS Human Subjects and Clinical Trials Information

THIS FORM IS A NON-INTERACTIVE PDF FOR PLANNING PURPOSES ONLY

OMB Number: 0925-0001
Expiration Date: 12/31/2027

* Always required field

Section 1 - Basic Information

1.1. * Study Title (each study title must be unique)

Required and system enforced. Up to 600 characters. Study title must be unique within the application. First 150 characters of title will show in application bookmark.

1.2. * Is this Study Exempt from Federal Regulations?

☐ Yes ☐ No

Answer required and system enforced.

1.3. Exemption Number

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8

If Study Exempt is Yes, must provide exemption number. Exemption must also be selected on Other Project Information form.

1.4. * Clinical Trial Questionnaire

Answers to questionnaire required and system enforced.

If the answers to all four questions below are yes, this study meets the definition of a Clinical Trial.

1.4.a. Does the study involve human participants?

☒ Yes ☐ No

1.4.b. Are the participants prospectively assigned to an intervention?

☐ Yes ☐ No

1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?

☐ Yes ☐ No

1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?

☐ Yes ☐ No

If four questions are all Yes AND funding opportunity allows clinical trials, then study will be flagged as a Clinical Trial (CT) study.

1.4.a defaults to Yes and is not editable.

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

Optional. Provide NCT# for this study, if available. Newly proposed studies do not need to be entered in ClinicalTrials.gov at time of application. If building on an existing study, enter NCT# for ancillary study (if available), not the parent study.

Section 2 - Study Population Characteristics

2.1. Conditions or Focus of Study

Required and system enforced unless exemption 4 is only exemption selected. Up to 20 conditions at 255 characters each.

2.2. Eligibility Criteria

Required and system enforced unless exemption 4 is only exemption selected or otherwise noted in funding opportunity.

Required and system enforced unless exemption 4 is only exemption selected or otherwise noted in funding opportunity.

Dropdown list: Years, Months, Weeks, Days, Hours, Minutes, N/A (No limit)

Dropdown list: Years, Months, Weeks, Days, Hours, Minutes, N/A (No limit)

2.3. Age Limits

Minimum Age

Maximum Age

2.3.a. Inclusion of Individuals Across the Lifespan

Required and system enforced unless exemption 4 is only exemption selected.

2.4. Inclusion of Women and Minorities

Required and system enforced unless exemption 4 is only exemption selected.

2.5. Recruitment and Retention Plan

Required and system enforced unless exemption 4 is the only exemption selected or otherwise noted in funding opportunity.

2.6. Recruitment Status

Required and system enforced unless exemption 4 is the only exemption selected or otherwise noted in funding opportunity.

2.7. Study Timeline

Required and system enforced for CT study unless 4 is the only exemption selected or otherwise noted in funding opportunity.

2.8. Enrollment of First Participant

Date: MM/DD/YYYY.

Dropdown list: Anticipated, Actual

Enrollment of First Participant field is required and system enforced unless exemption 4 is only exemption selected or using existing dataset.

2.9. Inclusion Enrollment Report(s)

Inclusion Enrollment Reports required and system enforced unless exemption 4 is only exemption selected or otherwise noted in funding opportunity.

Add Inclusion Enrollment Report

Up to 20 Inclusion Enrollment Reports can be added.

* Fellowship (F) and Career Development (K) applications to FOAs that do not allow clinical trials cannot propose independent clinical trial studies led by applicant PD/PI. However, proposing studies under the leadership of a sponsor/mentor that allows for clinical trials research experience is encouraged. Answering Yes to all four Clinical Trial Questionnaire questions will not flag the study as a clinical trial. These studies must include HS information, but will receive a system error if information is included in study fields in sections 4 or 5 of form.

PHS Inclusion Enrollment Report

1. * Inclusion Enrollment Report Title

Required. Up to 600 characters.

2. * Using an Existing Dataset or Resource

☐ Yes ☐ No

Answer required and system enforced.

3. * Enrollment Location Type

☐ Domestic ☐ Foreign

Answer required and system enforced. Do not mix domestic and foreign enrollment data on the same inclusion enrollment report.

4. Enrollment Country(ies)

Multi-select from list of countries.

5. Enrollment Location(s)

6. Comments

Up to 500 characters.

Planned

Planned enrollment information is required and system enforced when answer to "Using an Existing Dataset or Resource" question is No. System enforcement relaxed if Comment is provided.

Racial Categories	Ethnic Categories				
	Not Hispanic or Latino		Hispanic or Latino		Total
	Female	Male	Female	Male	
American Indian/ Alaska Native	0	0	0	0	0
Asian	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	0	0	0	0	0
White	0	0	0	0	0
More than One Race	0	0	0	0	0
Total	0	0	0	0	0

Cumulative (Actual)

Cumulative (Actual) enrollment information is required and system enforced when answer to "Using an Existing Dataset or Resource" question is Yes. System enforcement relaxed if Comment is provided.

Racial Categories	Ethnic Categories									
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			Total
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

Report 1 of 1

Section 3 - Protection and Monitoring Plans

3.1. Protection of Human Subjects

Required and system enforced.

Add Attachment

Delete Attachment

View Attachment

3.2. Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?

☐ Yes ☐ No ☐ N/A

Answer required and system enforced. "N/A" is only a valid option if study is not exempt from federal regulations (i.e., Question 1.2 is No).

Single IRB plan attachment

NIH: If Yes, not required.
AHRQ: If Yes, required.

Add Attachment

Delete Attachment

View Attachment

3.3. Data and Safety Monitoring Plan

Required and system enforced for CT study. Optional for HS study.

View Attachment

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

☐ Yes ☐ No

Answer required and system enforced for CT study unless otherwise noted in funding opportunity. Optional for HS study.

3.5. Overall Structure of the Study Team

Optional.

Add Attachment

Delete Attachment

View Attachment

Section 4 - Protocol Synopsis

You are not allowed to complete fields in Section 4 (i.e., will receive system error) if funding opportunity does not allow clinical trials and/or you answered No to one of the Clinical Trial Questionnaire questions in Section 1.

4.1. Study Design

4.1.a. Detailed Description

Up to 32,000 characters.

4.1.b. Primary Purpose

Dropdown list: Treatment; Prevention; Diagnostics; Supportive Care; Screening; Health Services Research; Basic Science; Device Feasibility; and Other

4.1.c. Interventions

Up to 20 Interventions allowed.

Intervention Type	
Name	Up to 200 characters.
Description	Up to 1,000 characters.

Dropdown list: 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); and Dietary Supplement (e.g., vitamins, minerals)

4.1.d. Study Phase

Dropdown list: Early Phase 1 (or Phase 0); Phase 1; Phase 1/2; Phase 2; Phase 2/3; Phase 3; Phase 4; and N/A

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

4.1.e. Intervention Model

Dropdown list: Single Group; Parallel; Cross-Over; Factorial; Sequential; and Other

4.1.f. Masking

☐ Yes ☐ No

☐ Participant

☐ Care Provider

☐ Investigator

☐ Outcomes Assessor

If Masking is Yes, you must select at least 1 of the Participant/Care Provider/Investigator/Outcomes Assessor check boxes.

4.1.g. Allocation

Dropdown list: N/A; Randomized; and Non-randomized

4.2. Outcome Measures

At least one Outcome Measure required and system enforced for CT studies unless otherwise noted in funding opportunity. Up to 50 Outcome Measures allowed.

Name	Up to 255 characters.
Type	Dropdown list: Primary; Secondary; and Other
Time Frame	Up to 255 characters.
Brief Description	Up to 999 characters.

4.3. Statistical Design and Power

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

4.4. Subject Participation Duration

☐ Up to 255 characters. Required and system enforced for CT studies unless otherwise noted in funding opportunity.

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

☐ Yes

☐ No

Answer required and system enforced for CT study unless otherwise noted in funding opportunity.

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

☐ Required and system enforced if Yes.

4.6. Is this an applicable clinical trial under FDAAA?

☐ Yes

☐ No

4.7. Dissemination Plan

☐ Required and system enforced for CT study. Generally one Dissemination Plan per application is sufficient. Can attach same plan (unique filenames) in multiple studies.

Section 5 - Other Clinical Trial-related Attachments

5.1. Other Clinical Trial-related Attachments

Form supports up to 10 attachments. Attachments only allowed for CT studies. Only include attachments requested in funding opportunity.