This is a TIP SHEET that covers common questions and issues. Section G.500 of the NIH Application Guide contains the complete guidance, policies and requirements for completion of the form.

Study Record: PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001
Expiration Date: 09/30/2024

Section 1 - Basic Information

Required, must be unique (600 characters max). If a CT, title must match the "Official Title" registered in ClinicalTrials.gov. If Title is not the same as the one on the IRB and/or the PI name on the IRB does not match the lead of the study, then an IRB letter of congruence is needed.

1.1. * Study Title (each study title must be unique)* Is this Study Exempt from Federal Regulations?

1.2. Exemption Number Multiple selections are permitted ☐ Yes ☐ No

1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐

1.3. * Clinical Trial Questionnaire Once "NO" is selected, all subsequent responses must also be "No." It's a CT only if all responses are Yes.

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

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

Registration of a CT is required 21 days after enrollment of the first participant; then include the NCT# on the next RPPR.

Section 2 - Study Population Characteristics

2.1 Conditions or Focus of Study Can enter up to 20 conditions. Identify the name(s) of the disease(s) or condition(s) you are studying, or the focus of the study. Use appropriate descriptors from NLM's Medical Subject Headings (MeSH) so the application can be categorized. Include an entry for each condition. If a CT, this field should match the ClinicalTrials.gov field Primary Disease or Condition Being Studied in the Trial, or the Focus of the Study.

x

Add New Condition

2.2. Eligibility Criteria List the study's inclusion and exclusion criteria; if a CT, should match the ClinicalTrials.gov field (Eligibility Criteria).

NOTE for 2.3 – 2.4: If using an existing dataset, resource, or samples that may have been collected as part of a different study, you must address inclusion as above and provide details about the sex/gender, race, and ethnicity for the existing dataset/resource and justify the details as appropriate to the scientific goals of the proposed study.

2.3. Age Limits **Minimum Age** **Maximum Age**

For CT, matches ClinicalTrials.gov field (Age Limits).

2.3.a. Inclusion of Individuals Across the Lifespan Add Attachment | Delete Attachment | View Attachment

Exclusion of any specific age or age range group (e.g., children or older adults) should be justified in this section.

2.4. Inclusion of Women and Minorities Add Attachment | Delete Attachment | View Attachment

Describe the planned distribution of subjects by sex/gender, race, and ethnicity and scientifically justify any exclusions.

2.5. Recruitment and Retention Plan Add Attachment | Delete Attachment | View Attachment

Required unless research is X4 and X4 is the only exemption chosen, or if an existing database is being used.

2.6. Recruitment Status choose from menu

Not required for X4. For CTs, should match ClinicalTrials.gov field (Overall Recruitment Status).

2.7. Study Timeline Add Attachment | Delete Attachment | View Attachment

Optional except for CT

2.8 Enrollment of First Participant Required unless it's an existing database or only X4 research

2.9 Inclusion Enrollment Report(s) Required unless it's only X4 research. A Study Record can have more than one IER and IERs should represent each participant once and not duplicate participants in different IERs. If it is a CT, use one Study Record with one IER, so that it will match up with what will be registered with clinicaltrials.gov. Manually enter planned enrollment. For RPPRs, when entering Cumulative enrollment, use the Participant Level Data template, which will auto-populate ages. For RPPRs for CTs, first update enrollment at clincialtrials.gov and then upload the data into the HSS system.

Add Inclusion Enrollment Report

OMB Number: 0925-0[illegible]
Expiration Date: 09/30/202[illegible]

Inclusion Enrollment Report

Remove Inclusion Enrollment Report

1. Inclusion Enrollment Report Title (unique title if more than 1 IER)

2. Using an Existing Dataset or Resource? Yes No
If YES, enter enrollment in the Cumulative Table and not under Planned Enrollment.

3. Enrollment Location Type Domestic Foreign
IDeA: foreign sites not allowed; non-IDeA Domestic sites allowed only if funded by non-IDeA sources

4. Enrollment Country(ies) optional

Add New Country

5. Enrollment Location(s) optional. This is the site of the research not the recruitment site

6. Comments (optional)

Planned

	Ethnic Categories				
	Not Hispanic or Latino		Hispanic or Latino		Total
Racial Categories	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)

	Ethnic Categories									
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			Total
Racial Categories	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

Instructions for Participant Level Data Upload

Participant level data file (CSV):

Download Participant Level Data Template | Upload Participant Level Data Attachment

Save and Keep Lock | Save and Release Lock | Save and Add | Cancel and Release Lock | Remove Repo

Section 3 - Protection and Monitoring Plans.

3.1. Protection of Human Subjects Add Attachment | Delete Attachment | View Attachment

If Claiming Exemptions: justify why the research meets the criteria for the exemption(s) claimed. If non-exempt, response must be commensurate with the study's risk level, size, and complexity. Must have 4 sections: 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. Be sure that informed assent is included if applicable and appropriate protections for vulnerable populations is addressed, as applicable.

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?
Answer only if this is non-exempt human subjects research; Note that only the sIRB letter is needed and NIGMS does not request or review reliance agreements.

☐ Yes ☐ No ☐ N/A

Single IRB plan attachment Add Attachment | Delete Attachment | View Attachment

3.3. Data and Safety Monitoring Plan Add Attachment | Delete Attachment | View Attachment

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

☐ Yes ☐ No

3.3 and 3.4 Required for CTs, otherwise optional but if the research is more than minimal risk or a vulnerable population is involved, then NIGMS wants a DSMP, which should include oversight by either an IMM (Independent Medical Monitor) or a Data Safety and Monitoring Board (DSMB). **A DSMB is required if the risk is substantial** even if not a CT. NIGMS requires notification of serious adverse effects within 24 hours.

3.5. Overall Structure of the Study Team Only required for CTs | Add Attachment | Delete Attachment | View Attachment

Section 4 - Protocol Synopsis Entire Section 4 is only required for CTs. Refer to instructions for required content.

4.1. Study Design

4.1.a. Detailed Description

4.1.b. Primary Purpose

4.1.c. Interventions

X	**Intervention Type**	
	Name	
	Description	

Add New Intervention

4.1.d. Study Phase

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

4.1.e. Intervention Model

4.1.f. Masking ☐ Yes ☐ No

☐ Participant ☐ Care Provider ☐ Investigator ☐ Outcomes Assessor

4.1.g. Allocation

4.2. Outcome Measures

X	**Name**	
	Type	
	Time Frame	
	Brief Description	

Add New Outcome

4.3. Statistical Design and Power consult a statistician! Add Attachment Delete Attachment View Attachment

4.4. Subject Participation Duration

4.5. Will the study use an FDA-regulated intervention? ☐ Yes ☐ No

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

Add Attachment Delete Attachment View Attachment

4.6. Is this an applicable clinical trial under FDAAA? ☐ Yes ☐ No

4.7. Dissemination Plan Add Attachment Delete Attachment View Attachment

Requirements: Agree to register trial in ClinicalTrials.gov no later than 21 days after enrolling the 1st participant, include statement in consent forms that clinical trial information will be posted at ClinicalTrials.gov, agree to report results no later than one year after primary completion date in ClinicalTrials.gov. Note that PI must ensure this gets done if Project Lead does not.

NOTES for CT: All clinical trials must post a copy of a consent form used during the study on a Federal website, English language consent forms can be posted at ClinicalTrials.gov or Regulations.gov. Non-English consent forms can only be posted to Regulations.gov. Must be posted AFTER enrollment closes and no later than 60 days after the last study visit of any participant.NOT BEFORE enrollment closes.

Section 5 - Other Clinical Trial-related Attachments Only required for CTs AND only if required by the FOA.

5.1. Other Clinical Trial-related Attachments Add Attachments Delete Attachments View Attachments

In HSS, you will need to add Section 6. Milestones pre-award or at the next RPPR. If it's a CT, the milestones must match what's in CT.gov.