Utilize https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.500-phs-human-subjects-and-clinical-trials-information.htm as an in depth guide when completing this form.

Study Record: PHS Human Subjects and Clinical Trials Information

HS = Human Subjects
CT = Clinical Trials

Clinical Trials - complete sections 1 - 6
Greater than minimal risk studies - complete sections 1, 2, 3.1 and 3.2
Minimal Risk studies - complete sections 1, 2, 3.1 and 3.2
Exemption 1-3; 5-8 studies - complete sections 1, 2, 3.1 and 3.2
Exemption 4 only studies - complete sections 1, 3.1 and 3.2

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

* Always required field

Section 1 - Basic Information

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

Required - Up to 600 characters. Study title must match IRB Approved research title.

1.2. * Is this Study Exempt from Federal Regulations? ☐ Yes ☐ No — Answer required.

1.3. Exemption Number ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 — If Study Exempt is Yes, must provide exemption number.

1.4. * Clinical Trial Questionnaire — Answers to questionnaire required.

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

1.4.a defaults to Yes and is not editable.

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, the study will be flagged as a Clinical Trial (CT) study.

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

If selected for funding, all studies meeting the NIH definition of a clinical trial must be registered on ClinicalTrials.gov and have an NCT number assigned to the study. Registration of the CT protocol on CT.gov is required prior to enrollment of the first participant. Please work with Samiha Mateen, PhD at CTSC, to register your protocol on ClinicalTrials.gov (SMateen@salud.unm.edu)

Section 2 - Study Population Characteristics

2.1. Conditions or Focus of Study

Required - unless 4 is the only exemption selected. Up to 20 conditions at 255 characters each.

2.2. Eligibility Criteria

Required - unless 4 is the only exemption selected. limited to 15,000 characters (but typically needs only 500 characters).

2.3. Age Limits — Required - unless 4 is the only exemption selected.

Minimum Age — Dropdown list: Years; Months; Weeks; Days; Hours; Minutes; N/A (No limit)

Maximum Age — Dropdown list: Years; Months; Weeks; Days; Hours; Minutes; N/A (No limit)

If "N/A (No Limit)" selected, do not provide numerical min/ max age.

2.3.a. Inclusion of Individuals Across the Lifespan — Required - unless 4 is the only exemption selected. Use provided template. View Attachment

2.4. Inclusion of Women and Minorities — Required - unless 4 is the only exemption selected. Use provided template View Attachment

2.5. Recruitment and Retention Plan — Required - unless 4 is the only exemption selected. Use provided template. View Attachment

2.6. Recruitment Status — Required - unless 4 is the only exemption selected.

Dropdown list:
Not yet recruiting; Recruiting; Enrolling by invitation; Active, not yet recruiting; Completed; Suspended; Terminated (Halted Prematurely); Withdrawn (No Participants Enrolled)

2.7. Study Timeline — Required - unless 4 is the only exemption selected. Use provided template.

2.8. Enrollment of First Participant — Date: MM/DD/YYYY. Enrollment of First Participant field is required unless 4 is only exemption selected or using existing dataset.

Dropdown list: Anticipated; Actual

2.9. Inclusion Enrollment Report(s)

Add Inclusion Enrollment Report

Inclusion Enrollment Reports required unless 4 is only exemption selected. Up to 20 Inclusion Enrollment Reports can be added.

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PHS Inclusion Enrollment Report

1. * Inclusion Enrollment Report Title

Required. Up to 600 characters.
Can be same as project title.

2. * Using an Existing Dataset or Resource ☐ Yes ☐ No — Required

3. * Enrollment Location Type ☐ Domestic ☐ Foreign — Required. Do not mix domestic and foreign enrollment data on the same inclusion enrollment report Must create two reports.

4. Enrollment Country(ies)

Multi-select from list of countries. You can add up to 200 countries per IER

5. Enrollment Location(s)

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

Up to 500 characters.

Required - All studies must enter planned enrollment counts unless your proposed study will use **only** an existing dataset or resource or 4 is the only exemption selected.
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.

Planned

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 when answer to "Using an Existing Dataset or Resource" question is Yes.

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 for all projects. Use template provided. 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 Required for all projects. "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 Required If Yes, use template provided. Add Attachment | Delete Attachment | View Attachment

3.3. Data and Safety Monitoring Plan Required for CT study. Optional for all other HS studies. Use template provided. View Attachment

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

☐ Yes ☐ No Answer required for CT study. Optional for all other HS studies

3.5. Overall Structure of the Study Team Required for CT study. Optional for all other HS studies. use template provided. View Attachment

Section 4 - Protocol Synopsis Section 4 required for CT studies only

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 (limited to 255 characters)

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 (If your study involves a device or behavioral intervention, choose "N/A".)

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

https://grants.nih.gov/grants/glossary.htm#NIH-DefinedPhaseIIIClinicalTrial

4.1.e. Intervention Model Dropdown list: Single Group; Parallel; Cross-Over; Factorial; Sequential; and Other (limited to 255 characters)

4.1.f. Masking ☐ Yes ☐ No If Masking is Yes, you must select at least 1 of the Participant, Care Provider, Investigator, Outcomes Assessor check boxes.

☐ Participant ☐ Care Provider ☐ Investigator ☐ Outcomes Assessor

4.1.g. Allocation Dropdown list: N/A; Randomized; and Non-randomized If allocation is not applicable to your clinical trial, select "N/A" (e.g., for a single-arm trial)

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

Name	Up to 255 characters.
Type	Dropdown list: **Primary;** outcome measures specified in your protocol that are of greatest importance to your study **Secondary;** outcome measures specified in your protocol that are of lesser importance to your study than your primary outcomes **Other** - additional key outcome measures used to evaluate the intervention.
Time Frame	Up to 255 characters.
Brief Description	Up to 999 characters.

4.3. Statistical Design and Power Required - use template provided Add Attachment Delete Attachment View Attachment

4.4. Subject Participation Duration Up to 255 characters. Required for CT studies

4.5. Will the study use an FDA-regulated intervention? ☐ Yes ☐ No Answer required for CT study

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

Required if Yes Use template provided Add Attachment Delete Attachment View Attachment

4.6. Is this an applicable clinical trial under FDAAA? ☐ Yes Trials of Drugs and Biologics: Controlled, clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation; Trials of Devices: Controlled trials with health outcomes, other than small feasibility studies, and pediatric post market surveillance.

4.7. Dissemination Plan Required for CT study. Use template provided. Add Attachment Delete Attachment View Attachment

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Section 5 - Other Clinical Trial-related Attachments Section 5 Optional for CT studies only

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

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