

Study Record: PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001
Expiration Date: 01/31/2026

* Always required field

Section 1 - Basic Information

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

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

1.3. Exemption Number

1

2

3

4

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☐☐☐☐☐☐☐☐

1.4. * Clinical Trial Questionnaire

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

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

Section 2 - Study Population Characteristics

2.1. Conditions or Focus of Study

X

Add New Condition

2.2. Eligibility Criteria

2.3. Age Limits

Minimum Age

Maximum Age

2.3.a. Inclusion of Individuals Across the Lifespan

Add Attachment

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2.4. Inclusion of Women and Minorities

Add Attachment

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2.5. Recruitment and Retention Plan

Add Attachment

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2.6. Recruitment Status

2.7. Study Timeline

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2.8. Enrollment of First Participant

2.9. Inclusion Enrollment Report(s)

Add Inclusion Enrollment Report

Inclusion Enrollment Report

Remove Inclusion Enrollment Report

1. * Inclusion Enrollment Report Title

2. * Using an Existing Dataset or Resource

☐ Yes ☐ No

3. * Enrollment Location Type

☐ Domestic ☐ Foreign

4. Enrollment Country(ies)

X

Add New Country

5. Enrollment Location(s)

6. Comments

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)

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

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Section 3 - Protection and Monitoring Plans

3.1. Protection of Human Subjects

[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

Single IRB plan attachment

3.3. Data and Safety Monitoring Plan

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

☐ Yes ☐ No

3.5. Overall Structure of the Study Team

Section 4 - Protocol Synopsis

4.1. Study Design

4.1.a. Detailed Description

4.1.b. Primary Purpose

4.1.c. Interventions

☐	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

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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

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4.6. Is this an applicable clinical trial under FDAAA?

☐ Yes

☐ No

4.7. Dissemination Plan

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Section 5 - Other Clinical Trial-related Attachments

5.1. Other Clinical Trial-related Attachments

Add Attachments

Delete Attachments

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