Study Record: PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001 and 0925-0002

Expiration Date: 02/28/2023

* 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 ☐ 5 ☐ 6 ☐ 7 ☐ 8

1.4 *Clinical Trial Questionnaire

If the answers to all four questions 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 effectiveness 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 Clinical Trials.gov Identifier (eg. NCT87654321) for this trial, if applicable

Section 2 - Study Population Characteristics

2.1 Conditions or Focus of Study

2.2 Eligibility Criteria

2.3 Age Limits **Minimum Age** **Maximim Age**

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

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

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

2.6. Recruitment Status

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

2.8. Enrollment of First Participant

2.9. Inclusion Enrollment Report(s) Add Inclusion Enrollment Report

Inclusion Enrollment Report

(NEW) OMB Number: 0925-XXXX

Expiration Date: 02/28/2023

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

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 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

3.5. Overall structure of the Study Team | Add Attachment | Delete Attachment | View Attachment

Section 4 - Protocol Synopsis

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	
	Timeframe	
	Brief Description	

Add New Outcome

4.3. Statistical Design and Power | 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

Section 5 - Other Clinical Trial-related Attachments

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

SECTION 6 - Clinical Trial Milestone Plan

6.1. Study Primary Completion Date	○ Anticipated ○ Actual
6.2. Study Final Completion Date	○ Anticipated ○ Actual
6.3. Enrollment and randomization	
Enrollment of the first subject (Study Start Date)	○ Anticipated ○ Actual
25% of planned enrollment recruited by	○ Anticipated ○ Actual
50% of planned enrollment recruited by	○ Anticipated ○ Actual
75% of planned enrollment recruited by	○ Anticipated ○ Actual
100% of planned enrollment recruited by	○ Anticipated ○ Actual
6.4. Completion of primary endpoint data analyses	○ Anticipated ○ Actual
6.5. Reporting of results in ClinicalTrials.gov	○ Anticipated ○ Actual
6.6. Is this an applicable clinical trial under FDAAA?	○ Yes ○ No