Study Record: PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001 and 0925-0002

Expiration Date: 03/31/2020

* 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

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

If yes, describe single IRB plan 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