

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)

Text input field for study title

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

Text input field for Clinical Trials.gov Identifier

Section 2 - Study Population Characteristics

2.1 Conditions or Focus of Study

Text input field for Conditions or Focus of Study with a redacted area

2.2 Eligibility Criteria

Text input field for Eligibility Criteria

2.3 Age Limits Minimum Age   Maximim Age

2.3.a. Inclusion of Individuals Across the Lifespan

2.4 Inclusion of Women and Minorities

2.5 Recruitment and Retention Plan

2.6. Recruitment Status

2.7. Study Timeline

2.8. Enrollment of First Participant

2.9. Inclusion Enrollment Report(s)

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  ▼

**5. Enrollment Location(s)**

**6. Comments**

**Planned**

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	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
<b>Total</b>	0	0	0	0	0

**Cumulative (Actual)**

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

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

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

Add Attachment

Delete Attachment

View Attachment

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## Section 4 - Protocol Synopsis

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### 4.1. Study Design

#### 4.1.a. Detailed Description

4.1.b. Primary Purpose

#### 4.1.c. Interventions

X	Intervention Type	<input type="text"/>
	Name	<input type="text"/>
	Description	<input type="text"/>
<p>Add New Intervention</p>		

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	<input type="text"/>
	Type	<input type="text"/>
	Timeframe	<input type="text"/>
	Brief Description	<input type="text"/>
<p>Add New Outcome</p>		

4.3. Statistical Design and Power

Add Attachment

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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

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

4.7. Dissemination Plan

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View Attachment

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**Section 5 - Other Clinical Trial-related Attachments**

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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