\* Always required field

**Study Record: PHS Human Subjects and Clinical Trials Information**

OMB Number: 0925-0001

Expiration Date: 01/31/2026

Section 1 - Basic Information

* 1. **\* Study Title (each study title must be unique)**
	2. **\* Is this Study Exempt from Federal Regulations?**
	3. **Exemption Number**

1 2 3 4 5 6 7 8

Yes No

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

Section 2 - Study Population Characteristics

* 1. **Conditions or Focus of Study**

x

Add New Condition

* 1. **Eligibility Criteria**
	2. **Age Limits Minimum Age Maximum Age**
		1. **Inclusion of Individuals Across the Lifespan**

View Attachment

Add Attachment Delete Attachment

* 1. **Inclusion of Women and Minorities**

View Attachment

Add Attachment Delete Attachment

* 1. **Recruitment and Retention Plan**

View Attachment

Add Attachment Delete Attachment

* 1. **Recruitment Status**
	2. **Study Timeline**

View Attachment

Add Attachment Delete Attachment

* 1. **Enrollment of First Participant**
	2. **Inclusion Enrollment Report(s)**

Add Inclusion Enrollment Report

**Inclusion Enrollment Report**

OMB Number: 0925-0770

Expiration Date: 09/30/2024

Remove Inclusion Enrollment Report

1. **\* Inclusion Enrollment Report Title**
2. **\* Using an Existing Dataset or Resource**

Yes No

1. **\* Enrollment Location Type**

Domestic Foreign

1. **Enrollment Country(ies)**

x

Add New Country

1. **Enrollment Location(s)**
2. **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 |

**Report 1 of 1**

**< Previous Report**

**Next Report >**

**|<< First Report**

**Delete Report**

**Last Report >>|**

Section 3 - Protection and Monitoring Plans

* 1. **Protection of Human Subjects**

View Attachment

Add Attachment Delete Attachment

* 1. **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** |  |  |
|  |  |  |

* 1. **Study Design**
		1. **Detailed Description**
		2. **Primary Purpose**
		3. **Interventions**

|  |  |
| --- | --- |
| x **Intervention Type** |  |
| **Name** |  |
| **Description** |  |

Add New Intervention

* + 1. **Study Phase**

Is this an NIH-defined Phase III clinical trial?

Yes No

* + 1. **Intervention Model**
		2. **Masking**

Yes Participant

No

Care Provider Investigator Outcomes Assessor

* + 1. **Allocation**
	1. **Outcome Measures**

|  |  |
| --- | --- |
| x **Name** |  |
| **Type** |  |
| **Time Frame** |  |
| **Brief Description** |  |

Add New Outcome

* 1. **Statistical Design and Power**

View Attachment

Add Attachment Delete Attachment

* 1. **Subject Participation Duration**
	2. **Will the study use an FDA-regulated intervention?** Yes No
		1. **If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status**

View Attachment

Add Attachment Delete Attachment

* 1. **Is this an applicable clinical trial under FDAAA?** Yes No
	2. **Dissemination Plan**

View Attachment

Add Attachment Delete Attachment

Section 5 - Other Clinical Trial-related Attachments

* 1. **Other Clinical Trial-related Attachments**

View Attachments

Add Attachments Delete Attachments