**HUMAN SUBJECTS**

**(*If applicable – see below*)**

**Human Subjects and Clinical Trials Information**

**Are Human Subjects Involved? Yes No**

**If No to Human Subjects**

Does the proposed research involve human specimens and/or data? **Yes No**

Provide an explanation for any use of human specimens and/or data not considered human subjects research:

Click or tap here to enter text.

**If Yes to Human Subjects:**

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

**Is your study Delayed Onset? Yes  No**

*If yes, please answer questions on the last page of this document*

**Section 1 – Basic Information**

1.1 Study Title (each study title must be unique): Click or tap here to enter text.

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 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 for this trial, if applicable

Click or tap here to enter text.

**Section 2 – Study Population Characteristics**

2.1. Conditions or Focus of Study Click or tap here to enter text.

2.2. Eligibility Criteria Click or tap here to enter text.

2.3. Age Limits **Minimum Age** Click or tap here to enter text.

**Maximum Age** Click or tap here to enter text.

2.3a. Inclusion of Individuals Across the Lifespan

Click or tap here to enter text.

2.4. Inclusion of Women, Minorities, and Children

Click or tap here to enter text.

2.5. Recruitment and Retention Plan

Click or tap here to enter text.

2.6. Recruitment Status (check one)

Not yet recruiting

Recruiting

Enrolling by invitation

Active, not recruiting

Completed

Suspended

Terminated (Halted Prematurely)

Withdrawn (No Participants Enrolled)

2.7. Study Timeline

Click or tap here to enter text.

2.8. Enrollment of First Subject

**Date: (MM/DD/YYYY)** Click or tap here to enter text.

**Anticipated or Actual** Click or tap here to enter text.

**Inclusion Enrollment Report**

1. **Inclusion Enrollment Report Title:** Click or tap here to enter text.
2. Using an Existing Dataset or Resource **Yes  No**
3. Enrollment Location Type **Domestic  Foreign**
4. Enrollment Country/ies Click or tap here to enter text.
5. Enrollment location(s) Click or tap here to enter text.
6. Comments (up to 500 characters) Click or tap here to enter text.

**Planned Enrollment Table**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Racial Categories** | **Ethnic Categories** | | | | |
| # of Not Hispanic or Latino | | # of Hispanic or Latino | | **Total #** |
| **Female** | **Male** | **Female** | **Male** |  |
| American Indian/Alaska Native |  |  |  |  |  |
| Asian |  |  |  |  |  |
| Native Hawaiian or Other Pacific Islander |  |  |  |  |  |
| Black or African American |  |  |  |  |  |
| White |  |  |  |  |  |
| More than One Race |  |  |  |  |  |
| **Total** |  |  |  |  |  |

**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 |  |  |  |  |  |  |  |  |  |  |
| Asian |  |  |  |  |  |  |  |  |  |  |
| Native Hawaiian or Other Pacific Islander |  |  |  |  |  |  |  |  |  |  |
| Black or African American |  |  |  |  |  |  |  |  |  |  |
| White |  |  |  |  |  |  |  |  |  |  |
| More than One Race |  |  |  |  |  |  |  |  |  |  |
| Unknown or Not Reported |  |  |  |  |  |  |  |  |  |  |
| **Total** |  |  |  |  |  |  |  |  |  |  |

*NOTE: If you need additional inclusion/enrollment reports, please copy the forms above and add them to your final proposal.*

**Section 3 – Protection and Monitoring Plans**

3.1. Protection of Human Subjects

Click or tap here to enter text.

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 the single IRB Plan Click or tap here to enter text.

3.3. Data and Safety Monitoring Plan

Click or tap here to enter text.

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

**Yes  No**

3.5. Overall Structure of the Study Team

Click or tap here to enter text.

**Section 4 – Protocol Synopsis *(Note: this section is only required if you are conducting a clinical trial)***

**4.1 Study Design**

4.1.a. Detailed Description: Click or tap here to enter text.

4.1.b Primary Purpose

Treatment

Prevention

Diagnostics

Supportive Care

Screening

Health Services Research

Basic Science

Device Feasibility

Other

4.1.c. Interventions

Intervention Type:

Drug (including placebo)

Device (including sham)

Biological/Vaccine

Procedure/Surgery

Radiation

Behavioral (e.g., Psychotherapy, Lifestyle Counseling)

Genetic (including gene transfer, stem cell and recombinant DNA)

Dietary Supplement (e.g. vitamins, minerals)

Combination Product

Diagnostic Test

Other

Name: Click or tap here to enter text.

Description: Click or tap here to enter text.

If additional Interventions need to be added, indicate here and include the above information for each intervention:

4.1.d. Study Phase

Early Phase 1 (or phase 0)

Phase 1

Phase 1-2

Phase 2

Phase 2-3

Phase 3

Phase 4

Other

Is this an NIH-defined Phase III clinical trial? **Yes  No**

4.1.e Intervention Model

Single Group

Parallel

Cross-over

Factorial

Sequential

Other

4.1.f. Masking **Yes  No**

**Participant  Care Provider  Investigator  Outcomes Assessor**

4.1.g. Allocation

N/A

Randomized

Non-Randomized

4.2. Outcome Measures

Name Click or tap here to enter text.

Type **Primary  Secondary  Other**

Time Frame Click or tap here to enter text.

Brief Description Click or tap here to enter text.

If Additional Outcomes, Click or tap here to enter text.

4.3. Statistical Design and Power Click or tap here to enter text.

4.4. Subject Participation Duration Click or tap here to enter text.

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

Click or tap here to enter text.

4.6 Is this an applicable clinical trial under FDAA?  **Yes  No**

4.7. Dissemination Plan, Click or tap here to enter text.

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

5.1 Other Clinical Trial-related Attachments, Click or tap here to enter text.

**Delayed Onset Study Section**

**Study Title:** Click or tap here to enter text.

**Anticipated Clinical Trial? Yes  No**

**Justification for Delayed Onset:** Click or tap here to enter text.