**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 Withdrawn (No Participants Enrolled) [ ]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.