**Required** Human Subjects Study Information [https://public.era.nih.gov/**assist**](https://public.era.nih.gov/assist)

PI First Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Last Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PI Middle Initial or Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Applicant Organization\Institution \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Project Start Date (mo/dd/yr) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Project End Date (mo/dd/yr) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**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 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 to be evaluated a health-related biomedical or behavioral outcome? ⬜ Yes ⬜ No

1.5. Provide the ClinicalTrials.gov Identifier (e.g., 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 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Maximum 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 ⬜ Pending (mo/dd/yr) \_\_\_\_\_\_\_\_\_\_\_ ⬜ Active ⬜ Completed (mo/dd/yr) \_\_\_\_\_\_

2.7. Study Timeline (attachment option)

2.8. Enrollment of First Participant (See SECTION 6.3) Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2.9. Inclusion Enrollment Reports(s): ***Attach / provide newest Inclusion Enrollment Reports IER***

Enrollment Location(s) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Stand-alone PHS Inclusion Enrollment Report forms are no longer used. Instead, data collection for up to 20 Inclusion Enrollment Reports has been folded into each Study Record. For each Inclusion Enrollment Report, applicants will need to indicate whether an existing dataset or resource will be used and whether the enrollment location type is* ⬜  *domestic or*  ⬜  *foreign. See sample IERs below*

**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 the 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 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**SECTION 4 - PROTOCOL SYNOPSIS**

4.1. Study Design \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

4.1.a. Detailed Description (up to 32,000 characters) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

4.1.b. Primary Purpose \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

4.1.c. Interventions: Type, Name, Description \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

4.1.g. Allocation

4.2. Outcome Measures \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

4.3. Statistical Design and Power \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

4.6. Is this an applicable clinical trial under FDAAA? (SEE SECTION 6.6) ⬜ Yes ⬜ No

4.7. Dissemination Plan \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

5.1.3.9 **Participant Level** Data Collection (including age). Required for progress reports. **See template.**

1. Participant level data sheet will include with 5 fields for each Human Subject:

Race, Ethnicity, Gender, Age, Age Unit.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Race | Ethnicity | Gender | Age | Age Unit |
| 1 |  |  |  |  |  |

Race, Ethnicity, Sex/Gender must contain valid values per OMB standards (consistent with Grants.gov form).

**Race:** American Indian, Asian, Black, Hawaiian, More than one race, Unknown, White

**Ethnicity**: Not Hispanic or Latino, Hispanic or Latino, Unknown

**Age**: must be a whole number between 0 and 9999 (four digits).

**Age Units**: May be minutes, hours, days, weeks, months, years, 90-plus, or Unknown.

If the age units are any value other than 90-plus or Unknown, an age number is required.

If 90-plus or Unknown is specified as the age unit, the age number must be blank. Use template.

**SECTION 6 - Clinical Trial Milestone Plan**

6.1. Study Primary Completion Date (mo/day/yr): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ⬜ Anticipated ⬜ Actual

6.2. Study Final Completion Date (mo/day/yr): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ⬜ Anticipated ⬜ Actual

6.3. Enrollment and randomization

Enrollment of first participant (Study start date) (mo/day/yr): \_\_\_\_\_\_\_\_\_\_\_\_\_ ⬜ Anticipated ⬜ Actual

25% of planned enrollment recruited by (mo/day/yr): \_\_\_\_\_\_\_\_\_\_\_\_\_ ⬜ Anticipated ⬜ Actual

50% of planned enrollment recruited by (mo/day/yr): \_\_\_\_\_\_\_\_\_\_\_\_\_ ⬜ Anticipated ⬜ Actual

75% of planned enrollment recruited by (mo/day/yr): \_\_\_\_\_\_\_\_\_\_\_\_\_ ⬜ Anticipated ⬜ Actual

100% of planned enrollment recruited by (mo/day/yr): \_\_\_\_\_\_\_\_\_\_\_\_\_ ⬜ Anticipated ⬜ Actual

6.4. Completion of primary endpoint data analyses (mo/day/yr): \_\_\_\_\_\_\_\_\_\_\_\_\_ ⬜ Anticipated ⬜ Actual

6.5. Reporting of results in ClinicalTrials.gov (mo/day/yr): \_\_\_\_\_\_\_\_\_\_\_\_\_ ⬜ Anticipated ⬜ Actual

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

IERs below | required

**Planned Inclusion Enrollment**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Racial Categories** | **Ethnic Categories** | | | | | | Total |
| **Not Hispanic or Latino** | | **Hispanic or Latino** | | **Not Reported or Unknown Ethnicity** | |
| Female | Male | Female | Male | Female | Male |  |
| American Indian/Alaska Native |  |  |  |  |  |  |  |
| Asian |  |  |  |  |  |  |  |
| Native Hawaian or Other Pacific Islander |  |  |  |  |  |  |  |
| Black or African American |  |  |  |  |  |  |  |
| White |  |  |  |  |  |  |  |
| More Than Once Race |  |  |  |  |  |  |  |
| Unknown or Not Reported |  |  |  |  |  |  |  |
| **Total** |  |  |  |  |  |  |  |

**Cumulative Inclusion Enrollment (Actual)**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Racial Categories** | **Ethnic Categories** | | | | | | | | | Total |
| **Not Hispanic or Latino** | | | **Hispanic or Latino** | | | **Not Reported or Unknown Ethnicity** | | |
| 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 Once Race |  |  |  |  |  |  |  |  |  |  |
| Unknown or Not Reported |  |  |  |  |  |  |  |  |  |  |
| **Total** |  |  |  |  |  |  |  |  |  |  |

end