Required Human Subjects Study Information 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