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.

<table>
<thead>
<tr>
<th></th>
<th>Race</th>
<th>Ethnicity</th>
<th>Gender</th>
<th>Age</th>
<th>Age Unit</th>
</tr>
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</tbody>
</table>

   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**

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<th>Racial Categories</th>
<th>Ethnic Categories</th>
<th>Not Hispanic or Latino</th>
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**Cumulative Inclusion Enrollment (Actual)**

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