Section 1 - Basic Information

1.1. * Study Title (each study title must be unique)

K23 Cluster-Randomized Trial

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

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 (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 Min Age: Max 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
2.7. Study Timeline
2.8. Enrollment of First Participant

Inclusion Enrollment Reports

Entry#	Enrollment Location Type	Enrollment Location
The study does not have any IERs		

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
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

❑ Participant ❑ Care Provider ❑ Investigator ❑ Outcomes Assessor

4.1.g. Allocation

4.2. Outcome Measures

Type	Name	Time Frame	Brief Description

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? ❍ Yes ❍ No

4.7. Dissemination Plan

Section 5 - Other Clinical Trial-related Attachments

5.1. Other Clinical Trial-related Attachments