FRIENDS RESEARCH INSTITUTE, INC.
INSTITUTIONAL REVIEW BOARD
1040 Park Avenue, Suite 103
Baltimore, Maryland 21201
410-837-3977 (phone) 410-752-4218 (fax)

Application for Continuing Review

Name of Investigator: IRB Study #:
Title of Protocol: Date of Submission:

Date of Initial Approval: Date of Last Continuing Review Approval:

Please submit this completed form, along with the latest approved protocol, consent form(s), and any recruitment materials to the IRB office.

I. SUBJECT/PARTICIPANT RECRUITMENT	
1. Date recruitment began:	
2. End date of anticipated recruitment:	
3. Number of anticipated subjects/participants for the study site.	
4. Number of subjects/participants enrolled (randomized) since this project was approved**.**	
a. Number of male subjects/participants enrolled (randomized)	
b. Number of female subjects/participants enrolled (randomized)	
5. Number of subjects/participants enrolled (randomized) since the last continuing review.	
a. Number of male subjects/participants enrolled (randomized)	
b. Number of female subjects/participants enrolled (randomized)	
6. If applicable, please provide a brief summary of any difficulty obtaining subjects/participants or obtaining informed consent during the entire approval period.	
7. If this is a Multi-Center study:	
a. Total number of anticipated subjects/participants	
b. Total number of subjects enrolled (randomized) from all sites since this project was approved.	
c. Total number of subjects enrolled (randomized) from all sites since the last continuing review.	

II. SUBJECT/PARTICIPANT WITHDRAWAL	
1. How many subjects/participants voluntarily withdrew from study at their own request?	
2. If subjects/participants voluntarily withdrew, please state the reasons for their withdrawal.	
3. How many subjects/participants were withdrawn from the study at the request of the PI?	
4. If subjects/participants were withdrawn at the request of the PI, please state the reasons for their withdrawal.	
5. If applicable, please provide a brief summary of any difficulty retaining subjects/participants. Additionally,	

please indicate if there have been any complaints about the research.

III. BREAKDOWN OF SUBJECTS/PARTICIPANTS IN RANDOMIZED TRIALS		
**Note – Please complete this section only if study subjects/participants are randomized.*		
1. Number Assessed for Eligibility		N/A ☐
a. Number Eligible for Participation		N/A ☐
b. Number Not Eligible for Participation		N/A ☐
c. Number Refused Participation Before Being Randomized		N/A ☐
d. Number Excluded (prior to randomization) for Other Reasons		N/A ☐
e. Reasons for Exclusion:		
2. Number of Subjects/Participants Who Provided Informed Consent		N/A ☐
3. Number of Subjects/Participants Randomized		N/A ☐
a. Number Allocated to Intervention A		N/A ☐
b. Number Allocated to Intervention B		N/A ☐
c. Number Allocated to Intervention C		N/A ☐
d. Number Allocated to Intervention D		N/A ☐
4. Number of Subjects/Participants Withdrawn Following Randomization		N/A ☐
a. Number of Subjects/Participants Who Withdrew Voluntarily		N/A ☐
b. Number of Subjects/Participants Withdrawn From Study By The PI		N/A ☐
c. Number of Subjects/Participants Who Died		N/A ☐
5. Percentage of Follow-Ups Completed of Follow-Ups Due To Date		N/A ☐

IV. SERIOUS ADVERSE EVENTS

1. Have there been any serious adverse events or unexpected reactions/complications since the last continuing review?
☐ Yes ☐ No (*If yes, please describe below.*)

2. If you answered yes above, please discuss whether adequate safeguards are in place to protect human subjects/participants and if the benefits of the study still outweigh the risks.

V. NEW FINDINGS

1. Have there been any recent studies or developments in the area of this research that would have an impact on this study and/or affect the risks associated with this research?
☐ Yes ☐ No (*If yes, please describe below.*)

2. Have there been any significant new findings (either good or bad) that should be disclosed to study participants?
☐ Yes ☐ No (*If yes, please describe below.)*

VI. PROGRESS REPORT
1. Please provide a summary of the research results or submit a separate progress report. The progress report should include a summary of the research activities, including preparatory tasks for recruitment, which have occurred since the last continuing review. Please include any interim findings and DSMB reports (if applicable).
2. Do you anticipate collecting data from subjects/participants during the next approval period? ☐ Yes ☐ No If no, please describe what work will be done in this time period.

VII. EXPEDITED REVIEW		
Please answer the following questions to determine if your study qualifies for expedited review.		
1. Did this research qualify for expedited review at the time of initial review? ***(If yes, please submit an Application for Expedited Review.)***		☐ Yes ☐ No
2a. Will the identification of the subjects and/or their responses place them at risk of criminal or civil liability or be damaging to the subjects/participants' financial standing, employability, insurability, reputation, or be stigmatizing? ***(If yes, answer 2b.)***		☐ Yes ☐ No
2b. Will reasonable and appropriate protections be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal? ***(If no, this study does not qualify for expedited review.)***		☐ Yes ☐ No
3. Does this research utilize classified research (research that has been designated as Top Secret, Secret, or Confidential by a federal agency) involving human subjects/participants? ***(If yes, this study does not qualify for expedited review.)***		☐ Yes ☐ No
There are 4 categories in which your study may be eligible for an expedited continuing review. These categories are only applicable if your research was previously reviewed at a ***convened meeting****.*		
1	a. Has the IRB determined and documented at a convened meeting that the research involves no greater than minimal risk? b. Have additional risks been identified? c. Is there a vulnerable[1] subject/participant population involved with this study? ***(If yes to 1a, no to 1b, and no to 1c, this study qualifies for expedited review.)***	☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No
2	a. Is the research permanently closed to the enrollment of new subjects/participants? b. Have all subjects/participants completed all research-related interventions? c. Is the research remaining active only for long-term follow-up of subjects/participants? ***(If yes to all questions, this study qualifies for expedited review.)***	☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No
3	a. Have subjects/participants been enrolled since the initial approval of the study? b. Have additional risks been identified? ***(If no to both questions, this study qualifies for expedited review.)***	☐ Yes ☐ No ☐ Yes ☐ No
4	Are the remaining research activities limited to data analysis? ***(If yes, this study qualifies for expedited review.)***	☐ Yes ☐ No

_____ _____

Principal Investigator's Signature Date

[1] Vulnerable subjects/participants include children; prisoners; pregnant women; elderly persons; economically disadvantaged persons; employees of the Sponsor or Investigator; individuals with psychiatric, cognitive, or developmental disorders; substance abusers; or any other individual who may be decisionally impaired.