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 Bio-Medical Study Review

IRB #:

I. PROJECT INFORMATION			
1. Project Title:			
2. Principal Investigator:			
Address:			
Telephone Number:		*Fax Number*:	
E-Mail Address:			
3. Co-Investigator:			
Address:			
Telephone Number:		*Fax Number*:	
E-Mail Address:			
4. Primary Contact Person:			
Address:			
Telephone Number:		*Fax Number*:	
E-Mail Address:			
5. Any Additional Co-Investigators?	☐ Yes ☐ No *If yes, please attach additional contact information*		

II. INVESTIGATOR'S ASSURANCE

The Principal Investigator must assure the Board that all procedures performed under the project will be conducted in strict accordance with all applicable Federal, State and Local regulations and laws regarding the protection of human subjects/participants in research including, but not limited to:

1. Use of qualified personnel to conduct the project according to the protocol approved by the IRB.
2. Ensuring that no changes are made to the approved protocol or consent form without prior IRB approval (except in an emergency to safeguard the well-being of subjects/participants or others).
3. Using the most current, approved, stamped consent form to obtain informed consent from subjects/participants or their legally responsible representative.
4. Prompt reporting of serious adverse events (SAEs) and unanticipated problems to the IRB in writing within 48 hours of discovery, and 24 hours for deaths. For greater than minimal risk studies, all SAEs and unanticipated problems need to be reported. For minimal risk studies, only SAEs and unanticipated problems which are possibly or definitely related to the research study need to be reported.
5. If I will be unavailable to direct this research personally, as when on leave or vacation, I will arrange for a co-investigator to be directly responsible for this study in my absence.

_____

Signature of Principal Investigator Date

III. FUNDING	
Funding Source:	
Contract or Grant Title:	
Contract or Grant #:	

IV. STUDY SITE
Specify the location where the research will be conducted. *Note: If any facilities are indicated that are not associated with FRI, a letter of support is required, and IRB approval from that institution may be required.*

V. SUMMARY INFORMATION			
If the research involves any of the following, check the appropriate boxes			
☐	a. Audio/video recordings	☐	g. Deception
☐	b. Controlled substances	☐	h. Genetic research
☐	c. PI or co-PI is the treating clinician	☐	i. HIV/AIDS
☐	d. Behavioral observations	☐	j. Investigational drugs
☐	e. Biohazardous waste	☐	k. Investigational devices
☐	f. Collection of biological specimens for banking	☐	l. Multicenter clinical trial

VI. PROTOCOL SUMMARY
Please fill out the information requested in the following categories or cite page numbers if separate study protocol is attached. If the item does not apply to your research, simply indicate that the question is not applicable.
1. Purpose of the study: What are the specific scientific aims of this study?
2. Background: State the background of the study, including a critical evaluation of existing knowledge and the information gaps that this research proposes to fill. Describe previous work that provides a basis for the proposed research and that supports the expectations of obtaining useful information without undue risk to human subjects/participants. Please include relevant citations.
3. Study Design: Describe the study design (e.g., single-blind, double-blind, crossover, etc.) and sequentially list all procedures, drugs or devices to be used on human subjects/participants. Describe any use of placebos and indicate whether subjects/participants will be randomized in this study.
4. Methodology and Data Collection: Describe the research procedures that will be followed. Please indicate those that are experimental and those that may be considered to be standard treatment. Describe all activities involving human subjects/participants and explain the frequency and duration of each activity.
5. Please delineate the data analysis plans for this study. Include planned statistical analyses and explanation of determination sample size.

VII. STUDY POPULATION
1. Describe the characteristics of the subject/participant population such as the anticipated number, age range, gender, ethnic background and health status. Provide a candid discussion of potential problems related to the subject/participant population.
2. Inclusion of Women: Address the inclusion of women unless there is a compelling rationale for proposed exclusion of any sex/gender group.
3. Inclusion of Minorities: Address the inclusion of minorities unless there is a compelling rationale for proposed exclusion

of any racial/ethnic group.

4. Inclusion of Children: Address the inclusion of children, if applicable. *{Children are defined in the HHS regulations as "persons who have not attainted the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted" [45 CFR 46.402(a)].}* (For research involving children, please complete and include the Supplementary Application for Research Involving Children.)

5. Inclusion of Prisoners: Address the inclusion of prisoners, if applicable. *{Prisoner is defined in the HHS regulations as "any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing" [45 CFR 46.303(c)].}*
(For research involving prisoners, please complete and include the Supplementary Application for Research Involving Prisoners.)

6. Decisionally Impaired: Address the inclusion of this group if there is a clear/compelling reason to include them.

7. Indicate the criteria for exclusion and inclusion and explain the system for equitable selection of subjects/participants.

8. How is eligibility determined and by whom?

VIII. RECRUITMENT

What methods will be used to identify and recruit potential subjects/participants? Attach a copy of all planned advertisements, flyers, and letters, etc. targeted at or to be sent to potential subjects/participants.

IX. INFORMED CONSENT

1. Please identify by name, degree, and training the individual(s) who will be authorized to describe the research to subjects/participants, or their representatives, and to administer the consent process. *The personnel administering the consent must have appropriate training and background to insure that subjects/participants give complete and truly informed consent, and to be able to answer any questions regarding the research that subjects/participants may have.*

2. Will all subjects/participants have the capacity to give informed consent? If not, describe the likely range of impairment and explain how, and by whom, their capacity to consent will be determined.

3. Process of Consent: Please discuss how the consent process will be conducted, describing the following elements:
   a) the environment and location where the informed consent will be solicited;
   b) opportunities for the potential subjects/participants to discuss their participation with family or others before signing the consent form;
   c) the types of forms used (e.g., adult consent form, assent form for youth, translations to other languages, etc.).

4. Will any information about the research purpose and design be withheld from subjects/participants? If so, please explain the non-disclosure and describe plans for post-study debriefing.

X. RISK/BENEFIT ASSESSMENT

Note: The potential benefits of the research must justify the risks to human subjects/participants. The risk/benefit ratio of the research must be at least as favorable for the subjects/participants as that presented by standard treatments for their condition. When comparing the risk/benefit ratio of research with that of available alternatives, the alternative of doing nothing should be included in the analysis.

1. Describe the potential benefits, if any, the subjects/participants may receive as a result of their participation in the research and what benefits to society, if any, may be expected.

2. What therapeutic alternative(s) are reasonably available to potential subjects/participants should they choose not to participate in the study? *(These may be research or non-research-based alternatives.)*

3. Describe any potential risks or likely adverse effects of the drugs, biologics, devices or procedures subjects/participants may encounter in the study. State the potential risks – physical, psychological, social, legal or other – connected with the proposed procedures and assess their likelihood and seriousness. *(These must be included in the consent form.)*

4. Describe the procedures for minimizing any potential risks. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subject/participant. Where appropriate describe the provisions for monitoring the data collected to ensure the safety of the subjects/participants.

5. Data and Safety Monitoring Board/Plan: Provide a general description of a monitoring plan that establishes the overall framework for data/adverse event monitoring.

6. Risk Classification: Please check the level* of risk associated with this study.

   ***According to HHS/FDA regulations minimal risk means, "The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." When the risks that are associated with a new procedure or product are unknown, they cannot be classified as minimal.*

   ☐ minimal ☐ greater than minimal ☐ unknown

XI. DATA COLLECTION & MANAGEMENT

1. How will the data be collected and recorded? If your study uses surveys, questionnaires, or psychological tests, please describe the provisions for administering these measures, the mode of administration, the setting, and if special training or qualifications are necessary.

2. How will the data be coded to protect confidentiality and personal privacy?

3. How will the data be stored during the study?

4. Who will have access to the data and the data codes? If data with subject/participant identifiers will be released, specify the person(s) and agencies to whom this information will be released.

5. What will happen to the data when the study is completed?

XII. FINANCIAL CONSIDERATIONS

1. Describe all plans to compensate subjects/participants, including provision of services, and other reimbursements, and the conditions that subjects/participants must fulfill to receive full or partial payment.

2. Will subjects/participants have to pay for any of the tests or treatments that they receive as part of the research? (*Please clarify who will pay for the procedures associated with the study as well as procedures that may be part of standard clinical care. Clarify that insurance and other third party payers may not cover standard procedures if they are associated with a research project.)*

3. Emergency Care and Compensation for Research-Related Injury: If the research presents a greater than minimal risk, the financial liability for the costs of care associated with potential research related illness/injury must be specified. *(If no funds are available, please see the consent form template for the standard language to explain this to potential subjects/participants.)*

XIII. REQUIRED DOCUMENTS	
☐	1. Application for Bio-Medical Study Review
☐	2. Informed consent form(s)
☐	3. Detailed research protocol
☐	4. CV/Biographical sketch
☐	5. Certification of education in research ethics and the protection of human subjects
☐	6. Financial Disclosure form
	If Applicable:
☐	7. If special populations are involved: • Supplementary Application for Research Involving Prisoners • Supplementary Application for Research Involving Children • Supplementary Application for Research Involving Pregnant Women, Human Fetuses, and Neonates
☐	8. Assent/parental permission forms
☐	9. If an investigational drug is involved: a. Investigational New Drug (IND) Application from FDA b. Supplementary Application: Indications for IND and IDE c. Supplementary Application: Investigational Drug Information Record d. Investigator's Brochure e. Statement of Investigator Form (Form FDA 1572)
☐	10. If an FDA approved drug or device is involved: • Package insert or FDA approved label for the drug or device for the FDA approved application
☐	11. If an investigational medical device is involved: • Investigational Device Exemption (IDE) from FDA • Supplementary Application: Indications for IND and IDE • Investigator's Brochure • Statement of Investigator Form (Form FDA 1572)
☐	12. If research involves DNA/Tissue/Sample Banks: • Supplementary Application for Research Involving DNA/Tissue/Sample Banks
☐	13. If eligible for expedited review, fill out Application for Expedited Review
☐	14. All surveys, questionnaires, etc. that are indicated in the protocol
☐	15. Subject/Participant recruitment materials, if used (e.g., flyers, advertisements, copy of radio ads)
☐	16. If outside facilities or agencies are used as research sites: letters of agreement (on the facility's letterhead). If these facilities have an IRB, include a copy of the letter of approval for this study.