***FRIENDS RESEARCH INSTITUTE, INC.***
***INSTITUTIONAL REVIEW BOARD***
***1040 Park Avenue, Suite 103***
***Baltimore, Maryland 21201***
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# ***Application for Expedited Review***

Name of Investigator: IRB Study #:

Title of Protocol: Date of Submission:

Under an expedited review procedure, the review may be carried out by the IRB Chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB.

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| 1. Is this study classified as greater than minimal risk?<br>*(Minimal risk is defined as "the risk of harm anticipated in the proposed research that is not greater, considering the probability and magnitude, than those ordinarily encountered in daily life of a healthy individual or during the performance of routine physical or psychological examinations or tests.")*<br>***(If yes, this study does not qualify 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' 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?<br>***(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?<br>***(If yes, this study does not qualify for expedited review.)*** | ☐ Yes ☐ No |

| ***The following categories may be reviewed by the IRB through an expedited review procedure. Please check off the category which describes your research. If you cannot, then your review is not eligible for an expedited review.*** | |
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| ☐ | 1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.<br>☐ a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)<br>☐ b. Research on medical devices for which (i) an investigational device exemption application (21CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling. |
| ☐ | 2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:<br>☐ a. From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amount drawn may not exceed 500 ml in an 8 week period and collection may not occur more frequently than 2 times per week.<br>☐ b. From adults and children, considering the age, weight, and health of the subjects, the collection procedures, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week. |

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| ☐ | 3. Prospective collection of biological specimens for research purpose by noninvasive means.<br>Examples:<br>☐ a. Hair and nail clippings in a nondisfiguring manner;<br>☐ b. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;<br>☐ c. Permanent teeth if routine patient care indicates a need for extraction;<br>☐ d. Excreta and external secretions (including sweat);<br>☐ e. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;<br>☐ f. Placenta removed at delivery;<br>☐ g. Amniotic fluid obtained at the time of rupture of the membrane before or during labor;<br>☐ h. Supragingival and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;<br>☐ i. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;<br>☐ j. Sputum collected after saline mist nebulization.<br>☐ k. Other; Explain: |
| ☐ | 4. Collection of data through noninvasive procedures (not involved general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications. Examples:<br>☐ a. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;<br>☐ b. Weighing or testing sensory acuity;<br>☐ c. Magnetic resonance imaging;<br>☐ d. Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography;<br>☐ e. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual. |
| ☐ | 5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis.)<br>(Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects, 45 CFR 46.101 (b) (4). This listing refers only to research that is not exempt.) |
| ☐ | 6. Collection of data from voice, video, digital, or image recordings made for research purposes. |
| ☐ | 7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.<br>(Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects, 45 CFR 46.101 (b) (2) and (b) (3). This listing refers only to research that is not exempt.) |

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Principal Investigator's Signature Date