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 Exemption from IRB Review

I. PROJECT INFORMATION			
1. Project Title:			
2. Principal Investigator:			
Address:			
Telephone Number:		*Fax Number*:	
Email 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
1. I certify that the information provided in this application is complete and correct. 2. I understand that as Principal Investigator, I have ultimate responsibility for the conduct of the study, the ethical performance of the project, and the protection of the rights and welfare of human subjects. 3. I agree to comply with all FRI policies and procedures, as well as applicable Federal, State, and Local laws regarding the protection of human subjects/participants in research. 4. I will assure that this study is performed by qualified personnel adhering to the certified protocol. 5. I will not modify the certified protocol or consent materials without first submitting an amendment to the previously certified Claim of Exemption. 6. If applicable, I agree to obtain legally effective informed consent from human subjects. _____ Signature of Principal Investigator Date

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

IV. EXEMPTION CATEGORIES

Exempt status applies to research activities in which the only involvement of human subjects/participants will fall in one or more of the categories listed below. Check-off the appropriate categories that apply to your research project.

Note: These exemptions do NOT apply to research:

a) involving prisoners, fetuses, pregnant women, or human in vitro fertilization;
b) when there is additional involvement of human subjects/participants beyond the categories listed below;
c) when deception of subjects/participants may be an element of research; or
d) when the activity might expose the subject/participant to discomfort or harassment beyond levels encountered in daily life.

☐ 1. 45 CFR 46.101 (b) (1) – Research conducted in established or commonly accepted educational settings involving normal educational practices, such as
   i) research on regular and special educational instructional strategies, OR
   ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

   Note: This exemption is applicable to individuals with mental handicaps only if research involves no change in the content, location, or procedures of instruction from those normally experienced by the subject/participant.

☐ 2. 45 CFR 46.101 (b) (2) – Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless:
   i) information is recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects; AND
   ii) any disclosure of the subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

   Note: The exemption regarding educational tests is applicable to children. However, the exemption for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, except for research involving observations of public behavior when the investigator(s) does not participate in the activities being observed.

☐ 3. 45 CFR 46.101 (b) (3) – Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under category 2 above, if:
   i) the human subjects are elected or appointed public officials or candidates for public office; OR
   ii) federal statue(s) require(s) without exception that the confidentiality of personally identifiable information will be maintained throughout the research and thereafter.

☐ 4. 45 CFR 46.101 (b) (4) – Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

☐ 5. 45 CFR 46.101 (b) (5) – Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
   i) public benefit or service programs;
   ii) procedures for obtaining benefits or services under those programs;
   iii) possible changes in or alternatives to those programs or procedures; OR
   iv) possible changes in methods or levels of payment for benefits or services under these programs.

☐ 6. 45 CFR 46.101 (b) (6) – Taste and food quality evaluation and consumer acceptance studies,
   i) if wholesome foods without additives are consumed OR
   ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

V. SUMMARY INFORMATION
1. Briefly describe the purpose of the project. (Attach a copy of the research protocol.)
2. Please indicate the number of participants:
3. Please describe the study population.

COMPLETE THIS SECTION IF YOU ARE REQUESTING EXEMPTION UNDER CATEGORIES #1, 2, 3, 5, or 6.
1. In order to insure voluntary participation, briefly describe the recruitment procedures. Attach a copy of any material (verbal or written) used to recruit subjects (e.g., flyers, cover letters, verbal recruitment, etc.).
2. Describe the study procedures. If survey instruments will be used, describe the time that it will take subjects/participants to complete them, the frequency of administration, and the setting in which they will be administered. Please submit a copy of all instruments for this study, including all surveys, questionnaires, etc. *(Note: exploration of sensitive or private topics is not an exempt activity.)*
3. Will subjects/participants be identifiable either by name or through demographic data? ☐ Yes ☐ No If yes, please describe how the confidentiality of subjects/participants' identities will be maintained and plans for maintaining or destroying identifying links to subjects/participants after the study is completed.
4. Will data be recorded by audiotape or videotape? ☐ Yes ☐ No If yes, please describe how participants will be identified in the study records/taped responses.
5. How will informed consent be obtained? If participation is anonymous, an information sheet is recommended. If participation is not anonymous, an appropriate informed consent document[1] is recommended.

COMPLETE THIS SECTION IF YOU ARE REQUESTING EXEMPTION UNDER CATEGORY #4.	
1. Which of the following will you be collecting and/or studying? ☐ data ☐ documents ☐ records ☐ biological specimens	
2. Specify what you will be collecting and/or studying.	
3. Are the data/documents/records/biological specimens originally collected solely for research purposes? *(If "yes" is checked, please attach a copy of the IRB notice and approved consent form for the research responsible for the original data collection.)*	☐ Yes ☐ No
4. What is the source of the existing or archived data/documents/records/biological specimens?	
5. Is the source publicly available[2]?	☐ Yes ☐ No
6. How will the data/documents/records/biological specimens be identified when they are made available to you? ☐ Direct Identifier (e.g., subject/participant name, address, social security number, medical record number, etc.) ☐ Indirect Identifier (e.g., an assigned code used to track specimens) ☐ No Identifier (neither the researcher nor the source providing the data/biological specimens can identify a subject/participant based upon information provided with the data/biological specimens)	
7. If you are requesting permission to study biological specimens, will the identifier provided with the specimens be removed and destroyed upon receipt?	☐ Yes ☐ NO* ☐ N/A
8. If you are requesting permission to study archived data, will you abstract and record any subject/participant identifiers as part of the data collection process?	☐ YES* ☐ No ☐ N/A

[1] "An appropriate informed consent document" can consist of a consent form, information sheet, survey cover letter, verbal consent script, or a letter to the subjects/participants.

[2] "Publicly available" means that the general public can obtain the data/documents/records/biological specimens. Sources are not considered "publicly available" if access is limited to researchers.

9. Will any data/documents/records/biological specimens be collected from subjects/participants after submission of this application?	☐ YES* ☐ No
** Your research protocol does not qualify for exemption from IRB review.*	