

Institutional Review Board for Human Investigation

The Institutional Review Board has reviewed the proposal and informed consent

Submitted by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Entitled: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_



Please be advised that with respect to: (1) The rights and welfare of individuals

 (2) The appropriateness of the methods to be used to
 secure informed consent

 (3) The risks and potential benefits of the investigation

The Board considers this project, IRB protocol # \_\_\_\_\_\_\_\_\_\_:

\_\_\_\_\_\_**Fully Acceptable**, without reservations; approved through \_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_**Approved contingent on revisions**

\_\_\_\_\_\_**Not Acceptable** for reasons noted

\_\_\_\_\_\_**Exempt** (see reasons below)

Protocols involving children approved under

\_\_\_\_\_45 CFR 46.404 \_\_\_\_\_45CFR 46.405 \_\_\_\_\_45CFR 46.406

REMARKS:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Date of Approval Signature of Reviewer

Type of Project: \_\_\_New \_\_\_Renewal \_\_\_Addendum

Human Risk: \_\_\_Yes (minimal) \_\_\_Yes (significant) \_\_\_No

Source of Support: \_\_\_None \_\_\_Departmental \_\_\_Outside Funding

 Agency (Potential) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Agency Number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Are any of the following involved? \_\_\_\_No \_\_\_Yes, those checked below:

\_\_\_Minors \_\_\_Prisoners \_\_\_Pregnant Women \_\_\_Mentally Disabled \_\_\_Mentally Retarded

**The Gettysburf College IRB opeates under the
HHS Multiple Project Assurance of Compliance Number FWA 0000 2006**

**CC: Investigator**

** Request for Review of Faculty Research Project Involving Human Subjects**

**(FOR OFFICE USE ONLY)**

**Project #**

**Date Rec’d:**

**Date Appr’d:**

**Type:**

All faculty research projects involving human subjects must undergo a review process for
 human subjects protection. In order to facilitate the initial review, please complete this
 application and send it with a copy of your proposal to the Office of the Provost, Box. 410.
Questions may be direct to ext. 6835. This application meets the requirements of both our
 Federal Wide Assurance for human subjects research and College institutional policy.

According to Gettysburg policy, all research must be certified to conduct research with
 human subjects. Certification indicates that appropriate training in human subjects
 protection has been received. Certification can be obtained through a tutorial offered

 online on the Gettysburg IRB website ([www.gettysburg.edu/academics](http://www.gettysburg.edu/academics)......).

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**Section A. Applicant Information and Assurances**

|  |  |
| --- | --- |
| Researcher’s Name |  |
| Title of ProposedResearch |  |
| Anticipated StartDate of Project |  Anticipated  Ending Date |
| Department |  Box Number |
| E-mail |  Phone |
| Co-Researcher(s), if applicable |  |
| Source of funding,if applicable |  |

**Faculty Assurance**

I certify to the following:

1. The research will not be initiated until written approval is obtained from the IRB.
2. I have completed the appropriate training for human subjects protection.
3. I will obtain prior written approval for modifications to this project, including but not limited to changes in procedures.
4. I will report to the IRB any unanticipated problems and adverse effects, as well as my findings during the course of the study that may affect the risks or benefits to the subjects.
5. I agree to keep records of IRB approved documents and to retain research data with appropriate confidentiality.
6. I understand that this research is subject to continuing review and approval by the IRB.
7. The information in this application is correct.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Researcher #1 Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Researcher #2 Date

**Section B. Exemption Criteria Checklist**

Your project may qualify for an exemption from further IRB review. You are encouraged to review the exemption criteria checklist below to determine if your research qualifies as exempt. In each case, the **risk to the subject must be no more than** **minima**l i.e., no greater than the risk encountered in normal day-to-day activities or during routine physical or psychological examinations. **Research classified as involving more than minimal risk may not be exempt from review. Also, if the project includes any research activity with human subjects not listed below, the research is not exempt from further IRB review is required.**

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, observation of public behavior, **unless** the information is obtained and recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects; **and** any disclosure of the human subjects’ responses outside the research could reasonable place the subject at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.

**N.B.** The exemption for survey and interview research (#2 above) does not apply to research in which the subjects are children, except for research involving observation of public behavior where the researcher does not participate in the activities being observed.

1. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, or observation of public behavior that is not exempt under item #2 above; **if** the human subjects are elected or appointed public officials or candidates for public office; **or** federal statute(s) require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
2. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if there sources are publicly available, or if the information is recorded by the Researcher in such a manner that subjects cannot be identified directly, or through identifiers linked to the subjects.
3. 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 methods and procedures of public benefit or service programs.
4. Taste and food quality evaluation and consumer acceptance studies, **if** wholesome foods without additives are consumed, or a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or an agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDP or approved by the EPA or the USDA.

**Section C. Review Criteria Checklist**

Please answer the following questions, even if you think your research qualifies as exempt.

1. Does you research involve minors (under the age of 18)? Yes\_\_\_\_\_ No\_\_\_\_\_
2. Does your research involve pregnant women, infants, prisoners, or cognitively

Impaired human subjects? Yes\_\_\_\_\_ No\_\_\_\_\_

1. Does your research involve any people who are psychiatric inpatients or

institutionalized (e.g., mental health facility, nursing home, halfway house)?

**If yes, please identify the subject group\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** Yes\_\_\_\_\_ No\_\_\_\_\_

1. Does your research use deception of the subjects by the researcher? Yes\_\_\_\_\_ No\_\_\_\_\_
2. Could any disclosure of a research subject’s identity or responses outside the

research environment reasonably place the subject at risk of criminal or

civil liability or be damaging to the subject’s financial standing, employability,

or reputation (e.g., illegal drug use, alcoholism, gambling, perpetrator of abuse)? Yes\_\_\_\_\_ No\_\_\_\_

If you answered “yes” to any of the above five questions, your research must be subject to review by the full IRB.

1. Does your research involve collection of blood samples by finger stick, heel stick,

ear stick or venipuncture from healthy, non-pregnant adults who weigh at least

 110 pounds? Yes\_\_\_\_\_ No\_\_\_\_

1. Does your research involve collection of biological specimens by noninvasive

means (e.g., hari and nail clippings, saliva, skin cells collected by swab or

mouth washings, sweat)? Yes\_\_\_\_\_ No\_\_\_\_

1. Does your research involve collection of data through noninvasive procedures

routinely employed in clinical practice, excluding procedures involving x-rays

or microwaves? Examples include physical sensors placed on the body;

weighing or testing sensory acuity; moderate exercise, muscular strength
testing, body composition assessment, and flexibility testing where appropriate
given the age, weight, and health of the individual. Yes\_\_\_\_ No\_\_\_\_

1. Does your research involve materials (data, documents, records, or

specimens) that have been collected, or will be collected solely for

nonresearch purposes? Yes\_\_\_\_ No\_\_\_\_

1. Does your research involve collection of data from voice, video, digital, or

Image recordings made for research purposes? Yes\_\_\_\_ No\_\_\_\_

1. Does your research involve surveys, questionnaires, interviews, focus groups,

program evaluations, human factors evaluation, or quality assurance

methodologies? **If yes, please attach a copy of these materials to this form.**  Yes\_\_\_\_\_ No\_\_\_\_

1. Will your research be done 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)? Yes\_\_\_\_ No\_\_\_\_

If you answered “yes” to questions 6-12, your research may be eligible for expedited review, if not already deemed exempt. For further clarification on expedited categories, please refer to Section F.

1. Will the study target or exclude a particular gender or ethnic or racial group?
 **If yes, please identify.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** Yes\_\_\_\_ No\_\_\_\_
2. Will your data be collected and recorded in such a manner that the human

subjects can be identified, either directly or through identifiers linked to the

subjects? Yes\_\_\_\_\_ No\_\_\_\_

1. Will this study use advertising, brochures, or recruitment posters or letters to

Recruit subjects? **If yes, please attach a copy of these materials.**  Yes\_\_\_\_ No\_\_\_\_

1. Will you conduct any part of this research outside of the United States?
**If yes, please indicate where.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** Yes\_\_\_\_ No\_\_\_\_

**Section D. Project Description**

Briefly answer the following questions: *(Attach additional pages as needed)*

1. What is the purpose of the study?
2. How will you conduct the research? Describe all procedures that will involve subjects and estimate how long each procedure will take. Please attach surveys, interview questions, focus group questions, or other instruments that will be used in your research.
3. Describe the participation of human subjects in the research. Who will they be? How many will be involved? How will you select participants? Will this study target or exclude a particular ethnic or racial group?
4. What are the risks to human subjects associated with this project (e.g., breach of confidentiality) and how will these risks be minimized? What are the benefits of this study?
5. How will you record the data collected in this study? Will it be anonymous (no identifiers between subject and data) or confidential (you will be able to link data to a specific individual, but you will not reveal this information to anyone outside the project)? How will you store the data to ensure privacy is maintained? Who will have access to the data?
6. How will you get consent from the participants? If you want a waiver of written informed consent, please indicate that here.

N.B.—A waiver of written consent is appropriate when the only record linking the subject and the research is the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. The waiver does not eliminate the need to obtain verbal consent from the research participant.

1. How will your research findings be disseminated? Please check all that apply.

\_\_\_ Presentation at a workshop or conference

\_\_\_Poster presentation

\_\_\_Publication (please describe)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_Other (please describe)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Section E. Elements of Informed Consent**

Every research study needs an informed consent document, even those that are exempt. Be sure to include the elements listed below in the document. If your data will be anonymous (i.e., not linking individual names with data nor recording any names of research subjects and/or information that can be identified to a particular research subject), you may request a waiver of written informed consent. Please attach a separate sheet indicating this request.

♦ Introduction (with a statement that this is research).
♦ Purpose of study.
♦ Description of study procedures.

♦ Duration of subject involvement.

♦ Identification of potential risks or discomforts to the subjects for participation in the study.

♦ Identification of potential benefits to subjects for participating in the study.

♦ Confidentiality of records statement—how this will be accomplished.

♦ Contact persons for questions related to the research.

♦ Statement of voluntary participation, including the option for subjects to withdraw from the study at
 any time without penalty.

Also, follow the guidelines for the informed consent document:

♦ Use simple language targeted at a 6th grade reading level.

♦ Use font size 12 point or larger and no more than 6 lines per inch.

♦ Use reasonable margins and include a blank line at the bottom of the header and the top of the

 footer to keep them separated from the text.

♦ Avoid scientific and technical terms.

♦ Consent forms written in the second person are preferred, but first person is allowed. Pronoun use

 must be consistent throughout the document.

♦ Use more than one consent form, if appropriate, and add a qualification to the consent document
 title to identify the target population (e.g., children, adults, etc.)



**Office Use Only**

\_\_\_\_\_\_ This research project is **exempt** from IRB review based on 45 CFR 46.101(b)\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_This project is **approved** as submitted.

\_\_\_\_\_\_This project is **approved contingent** on the changes listed below.

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_A **waiver** of informed consent is granted.

Name of Reviewer \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Phone\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Box #\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_E-mail \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**F. Information on Expedited Review**

An expedited review procedure consists of a review of research involving human subjects by the IRB Chairperson and his/her designate without review of the protocol by the entire IRB. To qualify for expedited review, the study must

1. present no more than minimal risk i.e., the probability and magnitude of harm or discomfort to the subject from participation in the research are no greater than that encountered in normal day-to-day activities or during routine physical or psychological examinations or tests **AND**
2. qualify under one of the following categories:

1.a. Clinical studies of drugs for which an investigational new drug application is not required.

1.b. Clinical studies of medical devices for which an investigational device exemption application is not required or 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: a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collect may not occur more frequently than two times per week; or b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, 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 less of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than two times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means. *Examples:* a) hair and nail clippings in a non-disfiguring manner; b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; c) permanent teeth if routine patient care indicates a need for extraction; d0 excreta and external secretions (including sweat); e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or way or by applying a dilute citric solution to the tongue; f) supra- 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; g) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; h) sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving 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 generally not eligible for expedited review, including studies of cleared medical devices for new indications. *Examples:* 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; b) weighing or testing sensory acuity; c) magnetic resonance imaging; d) electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; 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 nonresearch purposes.

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.