

BROWN UNIVERSITY
INSTITUTIONAL REVIEW BOARD
HUMAN RESEARCH PROTOCOL

Protocol Title: _____

Principal Investigator: _____

Funding Source (if no external funding for the project, enter "University"):

- (1) Attach to this form the information required for a complete protocol, as outlined on the IRB Form #1 Instructions and Information pages. In addition, please review the document "What Makes a Complete Protocol" (an appendix to the 'Brown University Policies and Procedures for the Protection of Human Participants in Research') at <http://research.brown.edu/policies/hrpo.php>.
- (2) Select the appropriate type (and category number) of review. (See the following pages for a description of the exempt and expedited categories. If no exempt or expedited categories completely describe the proposed research, select 'Full Board'.) **Exempt #** **Expedited #** **Full Board**
- (3) **Principal Investigator Conflict of Interest Statement:** (1) Do you have a conflict of interest on this project, as defined by the University 'Conflict of Interest Policy for Officers of Instruction and Research' (at <http://www.brown.edu/Administration/Provost/policies/coi/policy>)? **YES** **NO**
(2) If YES, has this conflict been disclosed according to University policy? **YES** **NO**

Principal Investigator certifies to the following: (1) The rights and welfare of the participants are adequately protected. (2) The risks to an individual are outweighed by the potential benefits to him/her or by the importance of the knowledge to be gained. (3) This protocol is accurate and complete; and if the project scope or design is later changed, the PI will resubmit for review. (4) All research personnel, including the PI, has been, or will be, adequately educated in human research protections prior to beginning work on the project. (5) Where a conflict exists, the PI has disclosed all relevant information regarding Conflict of Interest according to University policy.

Principal Investigator signature: _____ **Date:** _____

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(Advisor's signature is required for all graduate/medical student projects.)

Advisor certifies to the following: Advisor has read the protocol and approves of the project.

Advisor's signature: _____ **Date:** _____

Print name: _____

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Undergraduate student investigator signature: _____ **Date:** _____

Print name: _____ (optional signature)

For IRB Use Only

FULL BOARD PROTOCOLS - Institutional Review Board Members: If approving the proposed project, please certify to the best of your knowledge to the following: (1) IRB Member is familiar with the above described proposed research. (2) The rights and welfare of the research participants will be adequately safeguarded by the procedures described. (3) The potential benefits justify the risks involved. (4) IRB Member has no vested interest in the project.

IRB Member Signature: _____ Date: _____

Signature of the Authorized Official of the IRB: _____ **Date:** _____

IRB Form #1 Instructions and Information

(DO NOT INCLUDE THIS PAGE WITH YOUR PROTOCOL SUBMISSION.)

The following information must be provided by the person responsible for the project and attached to the completed IRB Form #1:

- A. A brief (1-3 page) lay-person summary of the proposed project, including page references (when necessary) for the location of where more information can be found in the protocol. (Note: This summary will also be required for future related submissions such as progress reports and modification requests.)
- B. Application/proposal for funding/support (if an application/proposal of any kind was/will be submitted, either internally to Brown University or externally, in order to obtain funding/support of the project, attach a copy of the full application/proposal.)
- C. Describe the specific aims of this project and the methodology including a description of the project, purpose, procedures, participant population (criteria for inclusion/exclusion including the attempts made to include women and members of minority groups), recruitment procedures, and how confidentiality of data will be maintained.
- D. Describe the possible risks to participants (including how the project is designed to minimize those risks) and describe anticipated benefits (if any) to participants or to the body of science.
- E. Describe the methods to be used in securing the informed consent (or, when involving minors, assent) of the participants. If an informed consent (or assent) form is to be used, attach it. If consent (assent) is conducted verbally, attach a written copy of the script. (See the next page for the basic elements of informed consent.)
- F. Complete and attach the 'Protocol Checklist and Submission Procedures' page.
- G. Attach the following, if applicable to your research project: all interview/survey questions, focus group topics, survey instruments, anticipated letters/emails to participants, recruitment materials, letters of support from groups/organizations, copies of other IRB approvals, a completed 'Checklist Form for Research Involving the Use of Prisoners as Study Participants', and a completed 'Checklist Form for Research Involving Children as Study Participants'.

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The following are the basic elements of informed consent:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others which may reasonably be expected from the research;
4. A statement of appropriate alternative procedures (or courses of treatment), if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6. For research involving more than minimal risk, an explanation as to whether any compensation or any medical treatments are available if injury occurs during the conduct of the study; and, if so, what they consist of, or where further information may be obtained;
7. An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the subject; and
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the individual is otherwise entitled; and s/he may discontinue participation at any time without penalty or loss of benefits to which the s/he is otherwise entitled.

(See OHRP regulations at 45CFR46, section 46.116 for additional elements of information that may be provided to participants in the consent procedure, when appropriate.)

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Categories of EXEMPT REVIEW:

- (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 or observation of public behavior unless: (i) information obtained is recorded in such a manner that human research participants can be identified, directly or through identifiers linked to the participants; and (ii) any disclosure of the human subject's responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.
- (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 number (2) above, if : (i) the human participants are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- (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 participants cannot be identified, directly or through identifiers linked to the participants.
- (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 those programs.
- (6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if the 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.

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EXPEDITED REVIEW¹ – applicability and categories of review

Applicability

- (A) Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by [45 CFR 46.110](#) and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
- (B) The categories in this list apply regardless of the age of subjects, except as noted.
- (C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- (D) The expedited review procedure may not be used for classified research involving human subjects.
- (E) IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.
- (F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Categories of Review

- (1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
 - (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.);
 - (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR 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.

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Expedited Review (con't.)

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children², considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, 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.

(3) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring 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; (d) excreta and external secretions (including sweat); (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; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) 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; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) 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 not generally 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) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, 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 non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human research participants. 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.

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Expedited Review (con't.)

- (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. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human research participants. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)
- (8) Continuing review of research previously approved by the convened IRB as follows:
- (a) where (i) the research is permanently closed to the enrollment of new participants; (ii) all participants have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of participants; or (b) where no participants have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.
- (9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

¹ An expedited review procedure consists of a review of research involving human research participants by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

² Children are defined in the HHS regulations as "persons who have not attained 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).