

**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)

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**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'.

## **IRB Form #1 Instructions and Information**

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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.





