UNIVERSITY OF JAMESTOWN: INSTITUTIONAL REVIEW BOARD
APPLICATION TO USE HUMAN SUBJECTS IN RESEARCH (STUDENT/SPONSORED)

1. **PROJECT REVIEW:**

   The Faculty Advisor(s), Principle Investigator, and Co-Investigator(s) MUST complete the NIH Protecting Human Research Participants Online Training before submitting IRB application (see Policy and Procedures at http://www.uj.edu/irb). Include a completed copy of your NIH PHRP Completion Certificate with the IRB application.

   ☐ New IRB Project

   ☐ IRB Resubmission project; Previous review: (_____)

2. **PROJECT TITLE**: _____

   _____

3. **DATA COLLECTION DATES**: From (_____) to (_____)

   Required information; data collection dates should give time for the IRB to review your protocol. Please allow four weeks from the date you turn the application in as the protocol start date.

4. **INVESTIGATOR(S)**:

   Principle Investigator Name: _____
   Department: _____ Phone: _____ Ext._____
   Email Address: _____

   Co-Investigator Name: _____
   Department: _____ Phone: _____ Ext._____
   Email Address: _____

   Co-Investigator Name: _____
   Department: _____ Phone: _____ Ext._____
   Email Address: _____

   Advisor/Sponsor Name: _____
   Department: _____ Phone: _____ Ext._____
   Email Address: _____

   This research is for:

   ☐ Thesis/Dissertation (graduate) ☐ Independent Study

   ☐ Special Project (undergraduate) ☐ Course:_____

   ☐ Special Project (graduate) ☐ Other:_____

5. **PARTICIPANTS** (approximate number and all applicable categories):

Number of participants proposed: _____

☐ Female ☐ Male

☐ Children (17 or younger) ☐ Adults (18 years of age or older)

☐ Patients in institutions ☐ UJ students

☐ Prisoners ☐ Faculty or external reviewers

☐ Pregnant women ☐ Child Development Center

☐ Other: _____

6. **FUNDING:** Project period from (_____) to (_____)

Are you seeking funding for this research? ☐ No ☐ Yes
If yes, submit one copy of the proposal summary or abstract with the application.

Does the funding agency require IRB approval? ☐ No ☐ Yes ☐ N/A
If yes, provide all relevant forms, instructions, etc. with this application.

7. **REVIEW CATEGORY**: Please mark all items that apply.

Note: Most research with children cannot be reviewed under administrative review. The protocol would require either expedited or full board review. See OHRP regulations.

☐ **EXEMPT REVIEW** (based on the following categories)

☐ Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

☐ Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met: (A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by Federal Regulations.

☐ (A) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by Federal Regulations. (B) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. (C) Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else. (D) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

☐ Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: (A) The identifiable private information or identifiable biospecimens are publicly available; (B) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; (C) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of ''health care operations'' or ''research'' as those terms are defined at 45 CFR 164.501 or for ''public health activities and purposes'' as described under 45 CFR 164.512(b); or (D) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

☐ Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended. (A) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency

conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

☐ Taste and food quality evaluation and consumer acceptance studies: (A) If wholesome foods without additives are consumed, or (B) 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.

☐ Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by Federal Regulations.

☐ Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met: (A) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with Federal Regulations; (B) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with Federal Regulations; (C) An IRB conducts a limited IRB review and makes the determination required by Federal Regulations and makes the determination that the research to be conducted is within the scope of the broad consent referenced in Federal Regulations; and (D) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

☐ **EXPEDITED REVIEW** (See OHRP Expedited Review Criteria List):

☐ Collection of data from voice, digital, or image recordings made for research purposes

☐ 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.

☐ 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).

☐ Non-manipulative, non-stressful research on individual or group behavior

☐ Collection of biological specimens by noninvasive means

☐ Collection of blood samples by finger prick, heel stick, ear stick or venipuncture

☐ Study of existing data, documents, records, or pathological or diagnostic specimens

☐ Other: _____

☐ **FULL BOARD REVIEW**: Involves vulnerable populations including children, prisoners, pregnant women, neonates, and fetuses. Note: include original application and one copy

8. **ATTACHMENTS**: All relevant project materials and documents, if applicable.

☐ Description of Research Project Form (Required)

☐ NIH Training Certificates (Required)

☐ Include letters of approval/permission on letterhead from cooperating agencies, schools, board of education, school districts, and other agencies.

☐ Participant recruitment procedure and materials (e.g., fliers, advertisements)

☐ Informed Consent Form

☐ Assent script for children

☐ Surveys, questionnaires, interviews, and measurement instruments

☐ Debriefing statement or explanation sheet

☐ Debriefing services available (e.g., social work, psychology, counselling)

☐ Other: _____

AFFIRMATION OF COMPLIANCE:

Note: Investigators or researchers are required to notify the IRB of substantive changes to protocol, unanticipated adverse, serious events experienced by participants, and project completion. Projects lasting longer than one year require an annual Request for Continuation (Protocol Renewal) or Notice of Project Ending by emailing the Research Compliance Officer at svoorhee@uj.edu. The consent forms and data must be kept at least three years after the study ends.

I agree to follow the procedures outlined herein and to ensure that the rights and welfare of human participants are properly protected. I will commence the study only after receiving approval from the IRB and having complied with required modifications. I will promptly report additions, changes, or problems involving the rights or welfare of human participants to the IRB by contacting the Research Compliance Officer at svoorhee@uj.edu. If the project continues for more than one year from the approval date, I will submit the required documentation.

I affirm that I have read and reviewed the accuracy of this application and accept responsibility for the ethical conduct of this research, supervision of human participants, and maintenance of data and informed consent documentation as required by the IRB.

Signature of Principle Investigator	E-mail Address
Signature of Co-Investigator	E-mail Address
Signature of Co-Investigator	E-mail Address
Signature of Advisor/Sponsor	E-mail Address
Signature of Chair	E-mail Address

APPROVAL OF FACULTY ADVISOR/SPONSOR:

I affirm that I have proofread and reviewed the accuracy of this application and accept responsibility for the ethical conduct of research, student supervision, and documentation maintenance.

I agree to follow the procedures outlined herein for my student(s) and to ensure that the rights and welfare of human participants are properly protected. I will ensure the study does not commence until the study has been approved by the UJ IRB and having complied with required modifications. I will promptly report additions, changes, or problems involving the rights or welfare of human participants to the IRB by contacting the Research Compliance Officer at svoorhee@uj.edu. If the project continues for more than one year from the approval date, I will submit the required documentation.

_____

Printed Name of Faculty Advisor/Sponsor UJ Department Phone Ext

_____

Signature of Faculty Advisor/Sponsor UJ E-mail Address