UNIVERSITY OF JAMESTOWN: INSTITUTIONAL REVIEW BOARD
APPLICATION TO USE HUMAN SUBJECTS IN RESEARCH

1. **PROJECT REVIEW:**

The Principal Investigator, and Co-Investigator(s) MUST complete the NIH Protecting Human Research Participants Online Training before submitting IRB application (see Policy and Procedures at https://my.uj.edu/ICS/Academics/WEB/IRB100/Always-IRB100-IRB100/). Please include a completed copy of your NIH PHRP Completion Certificate with the IRB application.

☐ New IRB Project

☐ IRB Project Renewal; 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)**:

Principal Investigator Name: _____
Department: _____ Phone: (____) ____-_____ Ext._____
Email Address: _____

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

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

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

This research is for:

☐ Thesis/Dissertation (graduate) ☐ Independent Study

☐ Special Project (graduate) ☐ Course: _____

☐ Scholarly Project (faculty) ☐ 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: Research with children cannot be reviewed under "Exempt 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, 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.

☐ 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 subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human 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.

☐ 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 paragraph (b) (2) of this section, if:(i) the human subjects 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.

☐ 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.

☐ 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.

☐ 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.

☐ **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 (see full list at link below)
- ☐ 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)
- ☐ IRB/NIH Training Certificates (Required)
- ☐ Approval of Faculty Advisor
- ☐ Approval of Licensed Medical Physician
- ☐ 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 rzaruba@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 rzaruba@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 Principal Investigator E-mail Address

_____

Signature of Co-Investigator E-mail Address

_____

Signature of Co-Investigator E-mail Address

_____

Signature of Co-Investigator E-mail Address

_____

Signature of Department Chair E-mail Address