**Harrisburg University of Science and Technology**

**Institutional Review Board**

**APPLICATION TO USE HUMAN SUBJECTS IN RESEARCH**

**For Exempt Studies Only**

***IRB ETHICS TRAINING****: The participating Faculty member(s), Graduate Student Researcher(s), and any External Researcher(s) MUST have a valid completion certificate from the CITI Course in Human Subjects Online Training before submitting an IRB application for projects involving human subjects. Include a copy of your CITI Training Completion Certificate with your IRB application if one is not already on file.*

1. PROPOSED DATA COLLECTION DATES: From (MM/DD/YYYY) to (MM/DD/YYYY)

Data collection dates should allow time for the IRB to review your protocol. Please allow at least one (1) week from the date you turn in the application for processing.

2. INVESTIGATOR(S):Copy and paste additional investigator names as needed. *If an undergraduate student project, the faculty advisor should be listed as a Co-Investigator and as the approving faculty advisor).*

 Investigator Name: Click or tap here to enter text.

 Program: Click or tap here to enter text.

 Email: Click or tap here to enter text.

 Faculty Advisor Name: Click or tap here to enter text.

 Program: Click or tap here to enter text.

 Email: Click or tap here to enter text.

 For all students, this research is for (*check all that apply*):

 [ ]  Master’s Thesis/Project [ ]  Independent Study

 [ ]  PhD Dissertation  [ ]  GRAD695 Course requirement

 [ ]  Undergraduate Project [ ]  Other: (describe project here)

3. **PROJECT TITLE**: Click or tap here to enter text.

4. PARTICIPANTS:

a. Number of participants proposed/anticipated: (enter number here)

b. Type(s) of participants:

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

[ ]  Patients in institutions [ ]  HU students (18 years of age or older)

[ ]  Prisoners [ ]  Faculty or external collaborators

[ ]  Pregnant women [ ]  Other: (describe population here)

5. FUNDING:

Are you seeking funding for this project/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*.

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

*Note: Research with children or pregnant women often cannot be reviewed under expedited review. Please consult with the IRB Administrator to see if your protocol involving these subjects would require full board review.*

 **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; (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 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.

Less likely types in the exempt category include the following:

[ ]  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.

7. **ADDITIONAL INFORMATION REQUIRED**:

You may insert the required information below in this section OR include it in your submission as separate documents:

* 1. Project Topic or Research Question(s): Click or tap here to enter text.
	2. Explanation of why the data collected is anonymous.
		1. Methodology (the design of the study) Click or tap here to enter text.
		2. Data Collection (what elements and how you will collect data)

*This is often met by including the actual survey form with both the introduction and questions.*

 Click or tap here to enter text.

8. **AFFIRMATION OF COMPLIANCE:**

**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 Completion. Failure to submit may result in adverse actions IAW IRB Policy. All 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 IRB Chair. 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.***

Click or tap here to enter text.

Signature of Investigator HU E-mail Address Date (MM/DD/YYYY)

*(Written or digital)*

Click or tap here to enter text.

Signature of Co-investigator HU E-mail Address Date (MM/DD/YYYY)

*(Written or digital)*

*(Cut and Paste additional investigator signature lines as needed).*

**APPROVAL OF FACULTY ADVISOR OR SPONSOR (if a student project or thesis):**

***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.***

***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 HU IRB and have 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 IRB Chair. If the project continues for more than one year from the approval date, I will submit the required documentation.***

*Copy and paste additional faculty advisor approval signatures and contact information lines as needed below.)*

Printed Name of Faculty Advisor: Click or tap here to enter text.

Program: Click or tap here to enter text.

Phone: Click or tap here to enter text.

HU E-mail Address: Click or tap here to enter text.

Signature of Faculty Advisor Date (MM/DD/YYYY)

*(Written or digital)*