**Harrisburg University of Science and Technology**

**Institutional Review Board**

**APPLICATION TO USE HUMAN SUBJECTS IN RESEARCH**

**For FULL BOARD APPROVAL ONLY**

***Full Board Review: Involves vulnerable populations including children, prisoners, pregnant women, challenged persons OR more than minimal risk to subjects.***

***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. Certificates are valid for 3 years.*

 *Training is available at: citiprogram.org using your HU email address to register.*

**APPLICATION STATUS:** [ ]  New submission [ ]  Resubmission with revisions [IRB No.]

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 three (3) months from the date you turn in this application for processing unless approved for special handling by the IRB Chair.*

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 other study here)

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

4. **PARTICIPANTS:**

1. Number of participants proposed/anticipated: (click to enter number here)

*Please enter or attach your power analysis to justify your sample size*.

1. Proposed participant genders included in the study:

[ ]  Female only [ ]  Male only [ ]  All genders

1. 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 [ ]  Adults with diminished capacity

[ ]  Economically disadvantaged [ ]  Adults with limited language skills

[ ]  Other: (describe population here)

***Attach or enter justification for use of any persons from vulnerable populations.***

*If using HU staff, stakeholders or students, indicate protocols for avoiding conflict of interest and coercion. Researcher convenience is not sufficient justification.*

:Click or tap here to enter text.

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*.

*If yes, enter the total project period*: From (MM/DD/YYYY) to (MM/DD/YYYY)

*If yes, affirm there is no conflict of interest* [ ]  *Provide documentation of COI training if required by funding source*

Does the funding agency require IRB approval? [ ]  No [ ]  Yes [ ]  N/A

 *If yes, provide all relevant form and instructions from funding source with this application*.

Is this study a collaborative research project with other US Institutions that relies on a single IRB of record? [ ]  No [ ]  Yes [ ]  N/A

6. **SUBMIT ALL RELEVANT PROJECT MATERIALS AND DOCUMENTS:**

**Attach the following materials/documents:**

**SURVEYS, QUESTIONNAIRES, INTERVIEW SCRIPTS OR MEASUREMENT INSTRUMENTS**

**LETTERS OF APPROVAL, COLLABORATION, OR SITE PERMISSION, AS APPLICABLE**

**RECRUITMENT OF PARTICIPANTS (required)**:

Attach or enter your ‘recruitment of participants’ section below:

Click or tap here to enter text.

***Please delete the instructions below when section is complete.***

1. *Describe sources of potential participants, how they will be selected and recruited, and how and where you will contact them. Include all relevant characteristics with regard to age, ethnicity, sex, institutional status (i.e., patients or prisoners), and general state of physical and mental health. Include any Inclusion/exclusion criteria.*
2. *Participant recruitment materials (fliers, advertisements, etc.)*

*Note: Recruitment issues can be especially critical when any federally defined “vulnerable population” is involved. This includes children, pregnant women, prisoners, others who are institutionalized, and anyone who might be at particular risk or whose cooperation might be dependent on coercions, no matter how slight.*

**DESCRIPTION OF THE PROJECT (required)**:

Attach or enter your ‘description of the project’ section below:

Click or tap here to enter text.

***Please delete the instructions below when section is complete*.**

*Briefly describe the objectives and methodology of your research (including hypothesis and/or research questions), data collection procedures, and features of the research design that involve specific procedures or special conditions for participants (including frequency, duration, and location of participation.*

*Include your project description first before proceeding to the subheadings below (Project Description should be from 3 paragraphs to 1 page in length)*

*It would be most helpful to organize this section with the following sub-headings:*

1. *Objectives of the Study*
2. *Hypothesis or Research Questions*
3. *Methodology (the design of the study)*
4. *Data Collection (the who, what, when, where, and how you will collect the data)*
5. *Procedures involving subjects, if applicable*
6. *Special conditions or anticipated problems or risks, if applicable*
7. *Dissemination (how will you present and publish your research: this includes presenting at a conference, publishing in a journal, thesis, or dissertation, etc.)*

**CONFIDENTIALITY OF DATA (required)**:

Attach or enter your ‘confidentiality of data’ section below:

Click or tap here to enter text.

***Please delete the instructions below when section is complete.***

*Clearly indicate specific procedures (e.g., coding of responses, aggregate reporting, etc.) to protect the confidentiality of participants and safeguard identifiable records and data. This includes safe and secure storage of the collected information and when the data will be destroyed after the data collection process has been completed. If not possible, state why. Again, this is the how, what, when, where, and how you will store and secure the data you have collected. If collecting your data through interviews or focus groups be specific as to the type of recordings (i.e., audio, video, photograph) and type of recording devices used (i.e., analog or digital). If transferring from analog (tape recordings) how will you transcribe the data and what will you do with the tape recordings after transcription. Also include how will you destroy the tape recording after transcription (i.e., demagnetize, shred, etc.). If digital recordings will you be transferring the data from the digital recording device to a computer and what will be done with the data in the digital recording device after you have downloaded the data to the computer (i.e., data will be erased, deleted, etc.).*

**RISKS AND BENEFITS (required)**:

Attach or enter your ‘risk and benefits’ section below:

Click or tap here to enter text.

***Please delete the instructions below when section is complete*.**

*Describe in detail any immediate, short-term, or long-range risks that may arise for participants as a result of procedures associated with your study. Risks may be physical, psychological, social, legal, or economic; they would include side effects, risks of placebo, delay in customary treatment, etc. Indicate any precautions that will be taken to minimize risks. Also indicate any anticipated benefits to participants and/or society from the knowledge that may reasonably be expected to result from the study. Risks and benefits MUST BE included in the protocol and in the informed consent document.*

**INFORMED CONSENT (required)**:

Informed Consent templates are available in this forms folder and on the HU IRB webpage.

Attach or enter your ‘Informed Consent’ section below:

Click or tap here to enter text.

***Please delete the instructions below when section is complete*.**

*Informed consent is usually written; however, in some circumstances it may be oral or electronic in nature. Waivers of informed consent may be granted under certain limited conditions, and any request for such should include explicit justification. Remember that the informed consent should be unique to each study being proposed and should also be written at the 7th grade reading level or lower if needed. (An example of an informed consent format is provided on the IRB website though you do not have to follow this example, but it must include the below items a through i).*

*The IRB requires a text of the proposed statement to be used for oral or electronic consent. Like the written consent document, they should include:*

1. *Identification of the researcher(s)*
2. *The nature and purpose of the study*
3. *Expected duration of participant involvement*
4. *How confidentiality or anonymity will be maintained*
5. *The voluntary nature of participation*
6. *Participants’ right to withdraw at any time without penalty*
7. *Information about foreseeable risks and benefits (or none)*
8. *Contact information for questions or additional information*
9. *First paragraph should have a statement that the research has been approved by the Institutional Review Board of Harrisburg University of Science and Technology*

**A copy of the Informed Consent or text for oral consent must be provided to the IRB.**

For non-English-speaking participants, be sure to include an accurate translation.

**CHILD ASSENT** **(if applicable):**

A Child Assent templatefor Full Board Review studies is available on the IRB webpage.

Attach or enter your ‘child assent’ section below:

Click or tap here to enter text.

*“Assent” is defined by the regulations as follows: “Assent” means a child’s affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent. (See federal regulation at* [*45 CFR 46.402 (b)*](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.402)*) and OHRP questions and answers at* [*http://answers.hhs.gov/ohrp/questions/7202*](http://answers.hhs.gov/ohrp/questions/7202)*)*

*This means the child must actively show his or her willingness to participate in the research, rather than just complying with directions to participate and not resisting in any way. When judging whether children are capable of assent, the Institutional Review Board (IRB) is charged with taking into account the ages, maturity, and psychological state of the children involved. The IRB has the discretion to judge children’s capacity to assent for all the children to be involved in a proposed research activity, or on an individual basis.*

**DEBRIEFING STATEMENT (if applicable)**:

Attach or enter your ‘debriefing statement’ section below:

Click or tap here to enter text.

*A debriefing statement is usually required only if any type of deception or psychological effects are used in the study. Participants may also be debriefed about their behavioral response(s) to the study. The two major goals of debriefing are de-hoaxing and de-sensitizing. Any undesirable influences the study may have on participants should be minimized or eliminated.*

*The debriefing statement should describe the reason(s) for conducting the research, how participants can obtain results of the study, and contact information for additional details or answers to questions. Any potential predictions about study outcomes should be non-directional. It would also be advisable, for methodological purposes, to request that participants not reveal the nature of the study to other potential participants. Note that debriefing is normally only used when deception is utilized in the research otherwise it does not need to be included. If you are a student researcher, please check with your faculty advisor on whether you should include a debriefing statement.*

*Also, some researchers use an information form at the end to include relevant follow-up contact information of the faculty or student investigator(s). This may also include additional information for counseling services or emergency hotline numbers for those experiencing distress after a research/study procedure has ended and results in the participant recalling past instances of psychological or physical trauma. You may include an information or emergency contact form (so titled) if needed but please refer to your faculty advisor if you are a student researcher.*

7. **AFFIRMATION OF COMPLIANCE (required):**

*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 IRB Chair. Failure to submit may result in adverse actions per IRB Policy. All consent forms and data must be kept at least three years after the study ends.*

***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 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.***

Signature of Investigator: Date: Click or tap to enter a date.

*(written or digital)*

Program: Click or tap here to enter text.

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

Signature of Co-investigator Date: Click or tap to enter a date.

*(written or digital)*

Program: Click or tap here to enter text.

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

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

**APPROVAL OF FACULTY ADVISOR OR SPONSOR:**

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

***I agree to follow the procedures outlined herein 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.***

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: Click or tap to enter a date.

*(written or digital)*

**APPROVAL OF LICENSED PHYSICIAN (if applicable):**

*This signature is* ***required only if the project involves medical procedures*** *and neither the investigator nor the faculty advisor is a licensed physician.*

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

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

Phone: Click or tap here to enter text.

Signature of Physician Date: Click or tap to enter a date.

*(written or digital)*