**Harrisburg University of Science and Technology**

**Institutional Review Board**

**APPLICATION TO USE HUMAN SUBJECTS IN RESEARCH**

**For Expedited 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 other project here)

Other: (describe other 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: Total project period from (MM/DD/YYYY) to (MM/DD/YYYY)

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.*

**Expedited** **Review** (based on the following categories):

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 involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt, 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.

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

Moderate exercise, muscular strength testing, body composition and

flexibility testing from healthy volunteers (excludes x-rays, or microwaves)

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

7. **ATTACHMENTS OR TEXT ENTRY REQUIRED**:

1. Project or Research Question(s): Click or tap here to enter text.
2. Methodology (the design of the study): Click or tap here to enter text.
3. Data Collection (who, what, when, where, and how you will collect data)
   1. Explanation of how the collected data will be extracted, stored, and archived/destroyed to assure confidentiality and blinding of anyone participating in its analysis: Click or tap here to enter text.
   2. Explanation of why the personally identifiable data collected is necessary to answer your question(s): Click or tap here to enter text.

8. **CONFIDENTIALITY OF DATA**: Include the confidentiality of data section below:

Click or tap here to enter text.

***Please delete the instructions below when 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…).*

9. **INFORMED CONSENT**:

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.

10. **DEBRIEFING STATEMENT**:

**A debriefing statement is usually *required only if any type of deception is 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.

11. **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 IRB Chair. 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.***

Signature of Investigator HU E-mail Address Date

Signature of Co-investigator HU E-mail Address Date

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

**APPROVAL OF FACULTY ADVISOR OR SPONSOR:**

***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