WORCESTER POLYTECHNIC INSTITUTE
Institutional Review Board
Human Subjects Research Exemption Application

WPI IRB use only
IRB # _____
Date: _____

Principal Investigator (PI) or Project Faculty Advisor: (*NOT a student or fellow; must be a WPI employee)*

Name: _____ Tel No: _____ E-Mail Address: _____

Department: _____

Co-Investigator(s): *(Co-PI(s)/non students)*

Name: _____ Tel No: _____ E-Mail Address: _____

Name: _____ Tel No: _____ E-Mail Address: _____

Student Investigator(s):

Name: _____ Tel No: _____ E-Mail Address: _____

Name: _____ Tel No: _____ E-Mail Address: _____

Check if: ☐ **Undergraduate project** *(MQP, IQP, Suff., other)* _____

☐ **Graduate project** *(M.S. Ph.D., other)* _____

Has an IRB ever suspended or terminated a study of any investigator listed above?
No ☐ Yes ☐ *(Attach a summary of the event and resolution.)*

Vulnerable Populations: The proposed research will involve the following (Check all that apply):
pregnant women ☐ human fetuses ☐ neonates ☐ minors/children ☐ prisoners ☐
students ☐ individuals with mental disabilities ☐ individuals with physical disabilities ☐

Collaborating Institutions: (*Please list all collaborating Institutions.)*

Locations of Research: (*If at WPI, please indicate where on campus. If off campus, please give details of locations.)*

Project Title: _____

Funding: *(If the research is funded, please enclose one copy of the research proposal or most recent draft with your application.)*

Funding Agency: _____ WPI Fund: _____

Human Subjects Research: *(**All** study personnel having direct contact with subjects **must** take and pass a training course on human subjects research. There are links to web-based training courses that can be accessed under the Training link on the IRB web site http://www.wpi.edu/offices/irb/training.html. **The IRB requires a copy of the completion certificate from the course or proof of an equivalent program**.)*

Anticipated Dates of Research:
Start Date of Research: _____ End Date of Research: _____

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INSTRUCTIONS: Answer all questions. If you are asked to provide an explanation, please do so with adequate details. If needed, attach itemized replies. Any incomplete application will be returned.

1.) Applicable Exemption Number: Please provide the applicable exemption number from the list below which best describes the reasons your research is exempt from IRB review.

Exemption Number : ☐

Complete Text of Exemptions List
(from 45 CFR Part 46)

1. 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.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
   a.) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
   b.) 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.
3. 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:
   a.) the human subjects are elected or appointed public officials or candidates for public office; or
   b.) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. 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.
5. 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:
   a.) Public benefit or service programs;
   b.) procedures for obtaining benefits or services under those programs;
   c.) possible changes in or alternatives to those programs or procedures; or
   d.) possible changes in methods or levels of payment for benefits or services under those programs.
6. 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.

2.) Purpose of Study: *(Please provide a concise statement of the background, nature and reasons for the proposed study. Insert below using non-technical language that can be understood by non-scientist members of the IRB.)*

3.) Study Protocol: *(Please attach sufficient information for effective review by non-scientist members of the IRB. Define all abbreviations and use simple words. Unless justification is provided this part of the application must not exceed 5 pages. Attaching sections of a grant application is not an acceptable substitute.)*

4.) Subject Information:

A.) Please provide the number of subjects you plan to enroll in this study and describe your subject population. *(eg. WPI students, WPI staff, UMASS Medical patient, other)*

Males: _____ Females: _____ Description: _____

B.) Will subjects who do not understand English be enrolled?
No ☐ Yes ☐ *(Please insert below the language(s) that will be translated on the consent form.)*

C.) Are there any circumstances under which your study population may feel coerced into participating in this study?
No ☐ Yes ☐ *(Please insert below a description of how you will assure your subjects do not feel coerced.)*

D.) Are the subjects at risk of harm if their participation in the study becomes known?
No ☐ Yes ☐ *(Please insert below a description of possible effects on your subjects.)*

E.) Are there reasons for excluding possible subjects from this research?
No ☐ Yes ☐ *(If yes, please explain.)*

F.) How will subjects be recruited for participation? *(Check all that apply.)*

☐ Referral: *(By whom)* _____
☐ Other: *(Identify)* _____
☐ Database: *(Describe how database populated)*

Have the subjects in the database agreed to be contacted for research projects? No ☐ Yes ☐ N/A ☐

☐ Direct subject advertising, including: *(Please provide a copy of the proposed ad. All direct subject advertising must be approved by the WPI IRB prior to use.)*

- ☐ Newspaper
- ☐ Radio
- ☐ Television
- ☐ Internet
- ☐ Bulletin board
- ☐ Flyers
- ☐ Letters
- ☐ E-mail

G.) Are the subjects being paid for participating? *(Consider all types of reimbursement, ex. stipend, parking, travel.)*
No ☐ Yes ☐ *(Check all that apply.)* ☐ Cash ☐ Check ☐ Gift certificate ☐ Other: _____

Amount of compensation _____

5.) Potential Risks: *(A risk is a potential harm that a reasonable person would consider important in deciding whether to participate in research. Risks can be categorized as physical, psychological, sociological, economic and legal, and include pain, stress, invasion of privacy, embarrassment or exposure of sensitive or confidential data. All potential risks and discomforts must be minimized to the greatest extent possible by using e.g. appropriate monitoring, safety devices and withdrawal of a subject if there is evidence of a specific adverse event.)*

A.) What are the risks / discomforts associated with each intervention or procedure in the study?

B.) What procedures will be in place to prevent / minimize potential risks or discomfort?

6.) Potential Benefits:

A.) What potential benefits other than payment may subjects receive from participating in the study?

B.) What potential benefits can society expect from the study?

7.) Data Collection, Storage, and Confidentiality:

A.) How will data be collected?

B.) Will a subject's voice, face or identifiable body features *(eg. tattoo, scar)* be recorded by audio or videotaping?
No ☐ Yes ☐ *(Explain the recording procedures you plan to follow.)*

C.) Will personal identifying information be recorded? No ☐ Yes ☐ *(If yes, explain how the identifying information will be protected. How will personal identifying information be coded and how will the code key be kept confidential?)*

D.) Where will the data be stored and how will it be secured?

E.) What will happen to the data when the study is completed?

F.) Can data acquired in the study adversely affect a subject's relationship with other individuals? *(i.e. employee-supervisor, student-teacher, family relationships)*

G.) Do you plan to use or disclose identifiable information outside of the investigation personnel?
No ☐ Yes ☐ *(Please explain.)*

H.) Do you plan to use or disclose identifiable information outside of WPI including non-WPI investigators?
No ☐ Yes ☐ *(Please explain.)*

8.) Incidental findings: *In the conduct of information gathering, is it possible that the investigator will encounter any incidental findings? If so, how will these be handled? (An incidental finding is information discovered about a subject which should be of concern to the subject but is not the focus of the research. For example, a researcher monitoring heart rates during exercise could discover that a subject has an irregular heartbeat.)*

9.) Deception: *(Investigators must not exclude information from a subject that a reasonable person would want to know in deciding whether to participate in a study.)*

Will the information about the research purpose and design be withheld from the subjects?
No ☐ Yes ☐ *(Please explain.)*

10.) Adverse effects: *(Serious or unexpected adverse reactions or injuries must be reported to the WPI IRB within 48 hours using the IRB Adverse Event Form found out at http://www.wpi.edu/offices/irb/forms.html. Other adverse events should be reported within 10 working days.)*

What follow-up efforts will be made to detect any harm to subjects and how will the WPI IRB be kept informed?

Investigator's Assurance:

I certify the information provided in this application is complete and correct.

I understand that I have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the WPI IRB.

I agree to comply with all WPI policies, as well all federal, state and local laws on the protection of human subjects in research, including:

- ensuring the satisfactory completion of human subjects training.
- performing the study in accordance with the WPI IRB approved protocol.
- implementing study changes only after WPI IRB approval.
- promptly reporting significant adverse effects to the WPI IRB.

Signature of Principal Investigator _____ Date _____

Print Full Name and Title _____

Please return a signed hard copy of this application to the WPI IRB c/o Ruth McKeogh 2nd Floor Project Center
Or email an electronic copy to irb@wpi.edu
If you have any questions, please call (508) 831-6699.