WORCESTER POLYTECHNIC INSTITUTE

Institutional Review Board

WPI IRB Application

IRB File #

Date:

IRB Office Use

Worcester Polytechnic Institute IRB# 1
HHS IRB # 00007374

indicates that further documents may be required to explain your study

This application is for: *(Please check one)* ☐ Expedited Review ☐ Full Review

WPI IRB use only

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: _____

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: _____

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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: _____ Completion Date: _____

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.) 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.)*

2.) 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.)*

A.) For **biomedical, engineering and related research**, please provide an outline of the actual experiments to be performed. Where applicable, provide a detailed description of the experimental devices or procedures to be used, detailed information on the exact dosages of drugs or chemicals to be used, total quantity of blood samples to be used, and descriptions of special diets.

B.) For applications in the **social sciences, management and other non-biomedical disciplines** please provide a detailed description of your proposed study. Where applicable, include copies of any questionnaires or standardized tests you plan to incorporate into your study. If your study involves interviews please submit an outline indicating the types of questions you will include.

C.) If the study involves **investigational drugs or investigational medical devices**, and the PI is obtaining an Investigational New Drug (IND) number or Investigational Device Exemption (IDE) number from the FDA, please provide details.

D.) Please note if any **hazardous materials** are being used in this study.

E.) Please note if any **special diets** are being used in this study.

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3.) Subject Information:

A.) Please provide the exact 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)*

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

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

H.) 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 _____

4.) Informed Consent:

A.) Who will discuss the study with and obtain consent of prospective subjects? *(Check all that apply.)*
☐ Principal Investigator ☐ Co-Investigator(s) ☐ Student Investigator(s)

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B.) Are you aware that subjects must read and sign an Informed Consent Form prior to conducting any study-related procedures and agree that all subjects will be consented prior to initiating study related procedures? No ☐ Yes ☐

C.) Are you aware that you must consent subjects using only the IRB-approved Informed Consent Form? No ☐ Yes ☐

D.) Will subjects be consented in a private room, not in a public space? No ☐ Yes ☐

E.) Do you agree to spend as much time as needed to thoroughly explain and respond to any subject's questions about the study, and allow them as much time as needed to consider their decision prior to enrolling them as subjects? No ☐ Yes ☐

F.) Do you agree that the person obtaining consent will explain the risks of the study, the subject's right to decide not to participate, and the subject's right to withdraw from the study at any time? No ☐ Yes ☐

G.) Do you agree to either 1.) retain signed copies of all informed consent agreements in a secure location for at least three years or 2.) supply copies of all signed informed consent agreements in .pdf format for retention by the IRB in electronic form? No ☐ Yes ☐

(If you answer No to any of the questions above, please provide an explanation.)

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?

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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.)*

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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.)*

11.) Conflict of Interest: *(A conflict of interest occurs when an investigator or other key personnel in a study may enjoy material benefits based on study results. Relationships that give rise to a conflict of interest or the appearance of a conflict of interest must be disclosed in the informed consent statement provided to study subjects. More information, including examples of relationships that require disclosure and those that do not, can be found here.)*

A.) Do any of the investigators listed on this application have a potential or actual conflict of interest with regard to this study?

a. Investigator (name) _ _____ No ☐ Yes ☐
b. Investigator (name) _ _____ No ☐ Yes ☐
c. Investigator (name) _ _____ No ☐ Yes ☐
d. Investigator (name) _ _____ No ☐ Yes ☐

B.) If any of the answers to 11A. are "Yes," please attach 📄 an explanation of the nature of the conflict to this application and identify appropriate language for use in the consent form. Examples of consent language are found on the IRB website, here.

C.) Does each WPI faculty or staff member named as an investigator have a current WPI conflict of interest disclosure form on file with the appropriate supervisor/department head? No ☐ Yes ☐

12.) Informed consent: (*Documented informed consent must be obtained from all participants in studies that involve human subjects. You must use the templates available at http://www.wpi.edu/offices/irb/forms.html to prepare these forms.* ***Informed consent forms must be included*** 📄 ***with this application.*** *Under certain circumstances the WPI IRB may waive the requirement for informed consent.)*

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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.
- obtaining informed consent from subjects using only the WPI IRB approved consent form.
- promptly reporting significant adverse effects to the WPI IRB.

_____

Signature of Principal Investigator

_____

Print full name and title

Date _____

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.