

Saint Joseph's College of Maine Institutional Review Board (IRB)

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IRB Human Subjects Research Proposal Form
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Project Title: _____

Anticipated: Start Date: _____ End Date: _____

Principle Investigator: Student Faculty

Name: _____ Department: _____

Campus email: _____ Campus phone: _____

Faculty Supervisor (if Principle Investigator is a student):

Name: _____ Department: _____

Campus email: _____ Campus phone: _____

I, the Principle Investigator, have read the Guidelines for Submission of Human Subjects Research Proposals for IRB Review. I understand those guidelines, and based on that understanding, I am submitting my research for the following type of review:

Please check one:

Exempt Review Expedited Review Regular Review

This type of review is appropriate for this project because:

Part I: Training

Please complete the online training module for investigators provided by the National Institutes of Health. This training module is “designed to prepare investigators involved in the design and/or conduct of research involving human subjects to understand their obligations to protect the rights and welfare of subjects in research. The course material presents basic concepts, principles, and issues related to the protection of research participants.”

The training is free, and takes approximately two hours. It is not necessary to complete the entire module in one sitting. You can complete one section, sign out, and then return later and complete additional sections.

The link to the training is: <http://phrp.nihtraining.com/users/login.php>

- Print the Certificate of Completion that is provided when you complete the training. Save a copy for your records and attach one copy to this form. The IRB will keep the Certificate on file.

Part II: Narrative

Please attach a typed narrative that provides the following information. Your narrative should clearly follow the structure and numbering provided. Each numbered section should include the title of that section in the heading (for example, the first section should begin with “1. Description of Research”). You can answer briefly, and include details as necessary. Remember that some reviewers are not specialists in your field; therefore, write your narrative so that an educated but naïve person will understand it.

1. Description of Research: Describe the following:
 - a. Purpose of research
 - b. Nature of the data to be collected
 - c. Data collection procedures
 - d. Data collection instruments (if surveys, etc., please attach copies)
 - e. Methods for selection/recruitment of participants
 - f. Information about participants (age, number, sex, etc.)
 - g. Incentives or compensation for participation.
2. Risks: Describe in detail any psychological, social, legal, economic, or physical risks to which participants might be exposed. Describe how subjects will be protected from these risks.
3. Benefits: Federal guidelines require that risks of participation be outweighed by potential benefits to participants and/or to humankind in general.
 - a. Describe any benefits to participants resulting from this research
 - b. Describe any benefits to humankind in general resulting from this research
4. Informed Consent: Describe the consent process to be followed in the research. If your research requires written documentation of informed consent, attach a copy of the informed consent form. If deception is to be used, explain the justification for the use of deception.
5. Debriefing: Describe the debriefing process that will be used. If no debriefing process is planned, explain why.
6. Vulnerable Populations: If minors or other vulnerable populations will be included as research participants, describe the procedures to be used in obtaining their agreement (assent) to participate, in addition to the consent of their authorized representative.
7. Confidentiality: Describe how the confidentiality of participant information will be maintained and how participant information will be kept secure. Note whether or not data collection will be anonymous.
8. Dissemination: Describe how results will be disseminated to the research community (e.g., publication or presentation at professional meetings) and/or to other interested groups (e.g., an on-campus poster session).

Part III: Summary Checklist

Please complete the following brief checklist. Some of these items address information that is also covered in the Narrative (Part II of this form).

1. Who will be participating in the study? (check all that apply):
 - Adults
 - Children / minors (individuals younger than 18 years old)
 - Students
 - Pregnant women
 - Institutionalized people (e.g., prisoners)
 - Other; please list:

2. How will participants be recruited? (check all that apply):
 - Class announcements
 - Advertisement
 - Telephone
 - Email
 - Letter
 - Other; please list:

3. Will the participants be healthy volunteers?
 - Yes
 - No

4. Will anyone under the age of 18 be participating in the study?
 - Yes
 - No

5. Will participant data be collected in a way that allows the Investigator to identify individual participants and link individual participants to their data?
 - Yes
 - No, data will be anonymous (this is not the same thing as confidential)

6. Will participant data be available to anyone other than the Investigators?
 - Yes
 - No

7. Will participants be offered inducements or compensation for participation?
 - Yes
 - No

8. Will participants be exposed to *more than minimal risk*, as defined in the Guidelines?
 - Yes
 - No

9. Will participants experience some discomfort or distress?
- Yes
 - No
10. Will participants be misled or deceived in any way?
- Yes
 - No
11. Will participants sign informed consent forms?
- Yes
 - No
12. Will informed consent be obtained from the parents or guardians of any participating minors (individuals younger than 18 years old)?
- Yes
 - No
 - No minors will be participating in the research
13. Will any participant data be collected from institutional files or archives?
- Yes
 - No
14. Will participants be debriefed?
- Yes
 - No
15. Will research results be disseminated beyond the SJC campus?
- Yes
 - No

Part IV: Signatures

1. Name and signature of Principal Investigator:

I understand that, as the Principal Investigator, it is my responsibility to ensure that all researchers involved in this project understand and comply with the applicable ethical guidelines for protecting human subjects.

Name: _____

Signature: _____ Date: _____

2. Names and signatures of all the researchers involved in this project:

Name: _____

Signature: _____ Date: _____

Name: _____

Signature: _____ Date: _____

Name: _____

Signature: _____ Date: _____

Name: _____

Signature: _____ Date: _____

Name: _____

Signature: _____ Date: _____