Saint Joseph's College of Maine

Institutional Review Board (IRB)

Human Subjects Research Proposal Form

Project Title: _____

_____

Anticipated: Start Date: _____ End Date: _____

Principle Investigator: ⬜ Student ⬜ Faculty

Print Name: _____ Department:_____

Campus email: _____ Campus phone: _____

I, the Principle Investigator, have read the Guidelines for Submission of Human Subjects Research Proposals for IRB Review, available at: http://www.sjcme.edu/resources/institutional-review-board

Signature of Principle Investigator: _____

Faculty Supervisor (Required for Student Research): By signing this form, the faculty supervisor attests that (s)he has read this research proposal and agrees to provide appropriate education and supervision of the student investigator, above.

Print Name: _____ Department: _____

Campus email: _____ Campus phone: _____

Signature of Faculty Supervisor: _____

Part I: Training

Please complete the online training for investigators provided by the U.S. Department of Health and Human Services:

https://www.hhs.gov/ohrp/education-and-outreach/human-research-protection-training/human-research-protection-foundational-training/index.html

At the website, you will take the following:

- Lesson 1: When HHS Regulations Apply
- Lesson 2: What is Human Subjects Research
- Lesson 3: What are IRBs

The training is free to you and can take up to three hours. Be sure to print your Certificate of Completion for each lesson – you will need to submit this Certificate to the IRB. If you have existing training certificates, please submit a copy of those with this proposal form.

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. 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.
6. 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.
7. 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:

   Please attach copies of any documents or materials that will be used for recruitment.

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

4. 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 <u>not</u> the same thing as confidential)

5. Will participants be offered compensation for participation?
   - □ Yes
   - □ No

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

7. Will any participant data be collected from institutional files or archives?
   - □ Yes
   - □ No

8. Will any institutions besides SJC be involved in this research project?
   - □ Yes – If yes, list the institutions in the space below.
   - □ 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: _____