

**University Of Maine at Farmington  
Human Subjects Review Board (HSRB)**

*Application for Review of Research*

Title of Study: \_\_\_\_\_

Principal Investigator: \_\_\_\_\_

Co-Investigators: \_\_\_\_\_

Status of Principal Investigator:

- Faculty
- Student – Advisor’s Name (for study) \_\_\_\_\_
- Staff
- Other – please explain \_\_\_\_\_

Department: \_\_\_\_\_

Address: \_\_\_\_\_

E-mail address: \_\_\_\_\_

Phone number: \_\_\_\_\_

Funding Source (if this is grant-related): \_\_\_\_\_

*Attach copy of Funding Proposal with Grant Face Page if applicable.*

Estimated Project Duration:

Start Date: \_\_\_\_\_

Completion Date: \_\_\_\_\_

Signatures: All procedures performed under the project will be conducted by individuals qualified and legally entitled to do so. No deviation from the approved protocol will be undertaken without prior approval of the Board. Faculty Sponsors are responsible for oversight of research conducted by their students.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Principal Investigator

\_\_\_\_\_  
Faculty Sponsor

\_\_\_\_\_  
Co-Investigator

\_\_\_\_\_  
Co-Investigator

1. Characteristics of Participants (Special Populations): Check all that apply
  - Minors (under age 18)
  - Pregnant Women
  - Fetuses or Products of Delivery
  - Prisoners
  - People with Physical Disabilities
  - People with Mental Illness
  - People with Developmental Disabilities
  - People with Diminished Capacity to Give Informed Consent
  - Elected or Campaigning Official
  
2. Age of Subjects:
  - 0-7 (Requires Written Parental Permission and Oral Child Assent)
  - 8-17 (Requires Written Parental Permission and Written Child Assent)
  - 18-65
  - 65+
  
3. Gender of Subjects:
  - Males       Females
  
4. Does this study involve any of the following procedures? Check all that apply.
  - Deception or punishment
  - Use of drugs
  - Covert observation
  - Induction of mental and/or physical stress
  - Procedures which may risk physical harm to the subject
  - Procedures which may risk mental harm to the subject
  - Materials/issues commonly regarded as socially unacceptable
  - Information relating to sexual attitudes, preferences or products
  - Information relating to the use of alcohol, drugs, or other addictive products
  - Information relating to illegal conduct
  - Genetic Information
  - Information normally recorded in a patient's medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination
  - Information pertaining to an individual's psychological well being or mental health
  - Information that if released could reasonably damage an individual's financial standing, employability, or reputation within the community
  - Procedures that might be regarded as an invasion of privacy

## 5. Research Proposal Information

All research involving human subjects must be reviewed and approved prior to commencement of the research, including research that you believe falls into a federal exempt category. Please respond to the following numbered points, in the order given, on separate paper (using these headings).

- a. **Summary of the Proposal:** Describe the rationale of the study and precisely what you intend to do (in clear, concise, and nontechnical language).
- b. **Subject recruitment:** Describe the process whereby potential participants will be identified and recruited. If subjects are to be compensated, clearly explain the type and amount of compensation that will be provided.
- c. **Informed consent:** Describe the procedures that will be followed to ensure the informed consent of the participants (and attach the relevant informed consent forms to your proposal). Per federal regulations, written and signed informed consent is required unless an alteration is justifiable. If you need an alteration or waiver of informed consent, draft a justification statement, in which you describe EITHER why informed consent must be waived for this research to be conducted OR why the requirement to obtain a signature on the consent form must be waived for this research to be conducted.
  - i. If you are obtaining consent from non-English speaking subjects describe how the consent will be translated, as well as the language and cultural expertise of the investigators. *Provide a copy of the translated consent document(s) with this application.*
  - ii. If you or any investigators participating in this study have a significant financial interest(s) in any organization that would reasonably appear to be affected by the outcome of this research. Please include the following statement in the informed consent document: "Please note that the responsible investigator and/or other members of the research team have a significant financial interest in [choose one: the sponsor of this research OR the product being investigated in this study]."
- d. **Confidentiality:** Describe the precautions that will be taken to ensure the confidentiality of the subjects and the confidentiality of the data (including data gathered with audio and/or visual recording devices). Include information on how long the data will be kept and how it will be disposed of at the end of this period.
- e. **Risks to subjects.** Describe in detail any possible physical, psychological, social, legal, economic, or other risks to the subjects (either immediate or long term). You should include here a discussion of the potential risks associated with the procedures you identified in Question #4 of this proposal.

- f. **Benefits:** Assess the benefits of the research to the subjects and to others. If there are risks to the subjects (identified in 'e' above), explain how the benefits outweigh the risks involved.
- g. **Debriefing:** If the study involved deception, when and how will the subjects be debriefed? *Include or attach the debriefing script or letter.*
- h. **Personnel:** Provide a list of the names of key personnel handling or collecting data (e.g., PI, Co-PI, Research Assistant, etc.)
- i. **Other Institutions Involved in the Project:** If this study is being conducted at other institutions, please list the institution names and attach a copy of the HSRB Approval from each other institution.
- j. **Dissemination of Results:** Describe how the results of the investigation will be made public (anticipated conference presentations, journal articles, etc.).
- k. **Questionnaires & Surveys:** As an appendix to the proposal, include copies of all questionnaires and surveys that will be employed in the investigation.

If this research is an ongoing research project, please note that the approval is limited to one year. At the end of this period, the principal investigator will need to submit a form for continuing review.

Please contact Steven Quackenbush, Chair of the HSRB, for further clarifications or questions [steven.quackenbush@maine.edu](mailto:steven.quackenbush@maine.edu)