



HANDWRITTEN SUBMISSIONS ARE NOT ACCEPTED

REQUEST FOR IRB REVIEW

- The USM Assurance for the protection of human subjects prohibits the start of any research, including the recruitment of subjects or advertising that has not been reviewed and approved by the IRB.
- The Primary Investigator, all key personnel, including Faculty Advisors, must complete the CITI Training module.

PRINCIPAL INVESTIGATOR			
Principal Investigator:	Email:	Are you: <input type="checkbox"/> Faculty <input type="checkbox"/> Staff <input type="checkbox"/> Graduate Student <input type="checkbox"/> Undergraduate Student <input type="checkbox"/> Other	External Review: <input type="checkbox"/> Yes <input type="checkbox"/> No Estimated Project Duration: Start Date: End Date:
Address:		Department:	Phone Number: ()
Study Title:			
Faculty Mentor:		Email:	Phone Number:

RESEARCH INFORMATION		
1. Type of Funding: <input type="checkbox"/> Federal Health and Human Services (ACF, AoA, AHRQ, CMS, FDA, HRSA, HIS, NIH, PSC, SAMHSA) <input type="checkbox"/> Federal, Other (DoD, DoE, ED, EPA, DoJ) <input type="checkbox"/> State of Maine (all agencies) <input type="checkbox"/> University of Southern Maine (Faculty Senate Grant, CONHP, etc) <input type="checkbox"/> Other/Private <input type="checkbox"/> Not Funded	2. Special Populations: <input type="checkbox"/> Minors (under 18) <input type="checkbox"/> Pregnancy Women <input type="checkbox"/> Prisoners <input type="checkbox"/> Physically or mentally Challenged <input type="checkbox"/> Diminished Capacity to give informed consent.	3. Subject Age: <input type="checkbox"/> 0-7 (parental permission and oral child assent) <input type="checkbox"/> 8-17 (parental permission and child assent) <input type="checkbox"/> 18-65 <input type="checkbox"/> 65+
4. Will in this study offer compensation for participation? <input type="checkbox"/> Yes If Yes, how much? <input type="checkbox"/> No	5. Why is this research being conducted? <input type="checkbox"/> Master's thesis <input type="checkbox"/> Doctoral Dissertation <input type="checkbox"/> Other (please specify):	6. Please list any key personnel handling or collecting data:

PROJECT ATTRIBUTES		
7. Does this study involve any of the following procedures (check all that apply)?		
YES	NO	
<input type="checkbox"/>	<input type="checkbox"/>	Deception or Punishment
<input type="checkbox"/>	<input type="checkbox"/>	Use of Drugs
<input type="checkbox"/>	<input type="checkbox"/>	Covert Observation
<input type="checkbox"/>	<input type="checkbox"/>	Induction of mental and/or physical stress
<input type="checkbox"/>	<input type="checkbox"/>	Procedures which may risk physical/mental harm to the subjects
<input type="checkbox"/>	<input type="checkbox"/>	Materials/issues commonly regarded as socially unacceptable
<input type="checkbox"/>	<input type="checkbox"/>	Information relating to sexual attitudes, preferences, or practices
<input type="checkbox"/>	<input type="checkbox"/>	Information relating to the use of alcohol, drugs or other addictive products
<input type="checkbox"/>	<input type="checkbox"/>	Information pertaining to illegal conduct
<input type="checkbox"/>	<input type="checkbox"/>	Information normally recorded in a patient's medical record of which, if released, could lead to social stigmatization or discrimination

<input type="checkbox"/>	<input type="checkbox"/>	Information that, if released, could reasonably damage an individual's financial standing, employability, or reputation within the community
<input type="checkbox"/>	<input type="checkbox"/>	Procedures that might be regarded as an invasion of privacy
8. Check all that apply:		
<input type="checkbox"/>	Use of recruitment materials (i.e. flyers, emails, letters, etc.)	<input type="checkbox"/> Focus Groups
<input type="checkbox"/>	Surveys/Questionnaires	<input type="checkbox"/> Audio or video recording
<input type="checkbox"/>	Administration of tests	<input type="checkbox"/> Medical procedures
<input type="checkbox"/>	Interviews	<input type="checkbox"/> Use of existing data
9. Will this study use an <u>online survey</u> in its methodology?		9a. If yes, please describe:
<input type="checkbox"/> Yes		
<input type="checkbox"/> No		
10. Will you be requesting an alteration or waiver for informed consent?		
<input type="checkbox"/>	Yes	All of the following must apply for an alteration or waiver to be granted (45 CFR 46.116 (d)) (1) the research involves no more than minimal risk to the subjects. (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects
<input type="checkbox"/>	No	(3) the research could not practicably be carried out without the waiver or alteration; (4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.
*If YES, provide a justification statement, in which you describe EITHER why informed consent <i>must</i> be altered or waived for this research to be conducted OR why the requirement to obtain a <u>signature</u> on the consent form <i>must</i> be waived for this research to be conducted.		
11. Per federal regulations written and signed informed consent are required unless an alteration or waiver of informed consent is justifiable. For information on the required elements of informed consent, please visit: http://www.usm.maine.edu/orc/irb/invest_vi.htm#vib. Please provide a copy of the written consent form.		
12. Do you or any investigator 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? (*A financial interest is a "significant financial interest" which must be disclosed if income from one company is expected to exceed \$10,000, or represents 5% or more ownership interest (total ownership interest of the faculty member, spouse and dependent children.)		
<input type="checkbox"/> Yes (If yes , was this interest reported on that individual's most recent conflict of interest disclosure form?)		
<input type="checkbox"/> No		
13. Will this study involve the transfer from a covered entity as defined under HIPPA of protected health information (PHI) to you?		13a. Prior to the transfer of this information, will all 18 identifiers be stripped?
<input type="checkbox"/> Yes (If yes, continue to number 13a)		<input type="checkbox"/> Yes
<input type="checkbox"/> No (If no, continue to number 15)		<input type="checkbox"/> No
14. Will you be submitting a Data Use Agreement or Business Associates Agreement?	14a. Has the Data Use Agreement or Business Associates Agreement been reviewed by system council?	15. Is this study being conducted at other institutions? *If YES, please list other institutions and attach a copy of IRB Approval from each.
<input type="checkbox"/> Yes (If yes, continue to number 14a)	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes
<input type="checkbox"/> No (If no, continue to number 15)	<input type="checkbox"/> No	<input type="checkbox"/> No
		A.
		B.
		C.
		D.

ADDITIONAL DOCUMENTATION

16. Please attach a brief summary (2-3 pages maximum) of your research proposal. Be sure to include copies of the instruments used for data collection such as questionnaires and consent forms. Use the headings listed below and provide a separate document, labeled as Research Proposal Summary.

- A. Introduction
- B. Specific Aims
- C. Methods of Data Collection and Analysis (Qualitative and Quantitative)
- D. Description of the subject population, research setting, subject recruitment procedures
- E. Informed Consent
- F. Provisions for subject and data confidentiality
- G. Statement of potential research risks to subjects (e.g. breach of confidentiality, treatment complications)
- H. Statement of potential research benefits to subjects (Monetary compensation is not a benefit of participation)
- I. Investigator experience – Attach a current copy of your C.V. or resume. We do not keep copies on file

SIGNATURES

Original Signatures are required. The application will not be processed until all signatures are obtained.

Signature of Principal Investigator

The undersigned accept(s) responsibility for the study, including adherence to DHHS, FDA, and USM policies regarding protections of the rights and welfare of human subjects participating in this study. In the case of student protocols, the faculty supervisor and the student share responsibility for adherence to policies.

Print Name of Principal Investigator:

Signature of Principal Investigator:

Date:

Signature of Faculty Research Supervisor – Required for Student Research

By signing this form, the faculty research supervisor attests that (s)he has read the attached protocol submitted for IRB review, and agrees to provide appropriate education and supervision of the student investigator, above.

Print Name of Faculty Supervisor:

Signature of Faculty Supervisor:

Date:

Office of Research Compliance

Inter-Campus Mail:

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Portland Campus

U.S. Mail

Office of Research Compliance
University of Southern Maine
P.O. Box 9300
Portland, ME 04104-9300

Drop box

Located at the entrance to the New Science Wing, across from room 178

Questions? Please call: (207) 780-4268

E-mail: usmirb@usm.maine.edu