



UNIVERSITY OF
SOUTHERN MAINE

INSTRUCTIONS FOR REQUESTING AN EXEMPTION FROM IRB REVIEW

Complete the REQUEST FOR STUDY EXEMPTION FROM IRB REVIEW to request an IRB exemption from research review. Only studies that fit into one or more eligible categories (see below) may be considered for an exemption. Studies that include the collection of sensitive information (see below) or include special subject populations (see below) are generally not eligible for an exemption. These studies require IRB review. Please complete a Request for IRB Review form. The USM Assurance for the Protection of Human Subjects prohibits the start of any research (including recruitment of subjects or advertising) that has not been reviewed and approved or exempted by the IRB or its designee. Please sign this form and include a brief description of the research. Return these materials to the Research Compliance Office for official assessment. The Primary Investigator and all key personnel, including Faculty Advisors, must complete the CITI Training module as a condition of IRB Approval or Exemption. Please submit a copy of your CITI completion certificate, and those of key personnel, with your application. CITI web site: <http://www.citiprogram.org/>.

Please note: Oral histories, audio-taped interviews, and focus groups are not eligible for exemptions. Please fill out the complete Request for IRB Review form at: http://www.usm.maine.edu/orc/irb/form_review.htm

Categories Eligible for Exemption

- (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- (5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
- (6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Categories of Sensitive Information (generally not eligible for exemption)

1. Information relating to sexual attitudes, preferences, or practices.
2. Information relating to the use of alcohol, drugs or other addictive products.
3. Information pertaining to illegal conduct.
4. Information that if released could reasonably damage an individual's financial standing, employability, or reputation within the community.
5. Information that would normally be recorded in a patient's medical record and the disclosure of which could reasonably lead to social stigmatization or discrimination.
6. Information pertaining to an individual's psychological well-being or mental health.
7. Genetic information.

Special Subject Populations (generally not eligible for exemption)

1. Minors (under 18 years of age). Please contact the Office of Research Compliance for more information.
2. Fetuses or products of labor and delivery
3. Pregnant women (in studies that may influence maternal health)
4. Prisoners
5. Individuals with a diminished capacity to give informed consent



HANDWRITTEN SUBMISSIONS ARE NOT ACCEPTED

REQUEST FOR STUDY EXEMPTION FROM IRB REVIEW

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	Estimated Project Duration:
			Start Date:
			End Date:
Address:		Department:	Phone Number: ()
Study Title:			
Faculty Mentor:		E-mail:	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. Will existing or archived data, documents, records, or biological specimens be used? (Please Check) <input type="checkbox"/> Yes <input type="checkbox"/> No		2a. When was the existing data or specimen collected?
2b. Is the data or specimen source publicly available? <input type="checkbox"/> Yes <input type="checkbox"/> No	2c. Is the information recorded in such a manner that subjects can be identified, directly or through identifying links (eg. name, medical record, addresses, telephone number): <input type="checkbox"/> Yes <input type="checkbox"/> No		2d. Will any additional data or biological specimens be collected from subjects after the study begins? <input type="checkbox"/> Yes <input type="checkbox"/> No	
3. Will surveys/interviews/tests be used to collect data during the study? (Please check) <input type="checkbox"/> Yes <input type="checkbox"/> No		3a. Is the information sensitive (see categories of sensitive information on page 1) and recorded such that human subjects can be identified directly or indirectly? <input type="checkbox"/> Yes <input type="checkbox"/> No		5. Please describe how the data will be used:
4. Does the study include a special subject population (see special subject categories on page 1)? <input type="checkbox"/> Yes <input type="checkbox"/> No		6. Will this study use an online survey in its methodology? <input type="checkbox"/> Yes <input type="checkbox"/> No		
7. Will this study offer compensation for participation? <input type="checkbox"/> Yes If Yes, how much? <input type="checkbox"/> No		8. Will this study involve the transfer from a covered entity as defined under HIPPA of protected health information (PHI) to you? <input type="checkbox"/> Yes (If yes, continue to number 8a) <input type="checkbox"/> No (If no, continue to number 10)		6a. If yes, please describe:
9. Will you be submitting a Data Use Agreement or Business Associates Agreement? <input type="checkbox"/> Yes (If yes, continue to number 9a) <input type="checkbox"/> No (If no, continue to number 10)		9a. Has the Data Use Agreement or Business Associates Agreement been reviewed by system council? <input type="checkbox"/> Yes <input type="checkbox"/> No		8a. Prior to the transfer of this information, will all 18 identifiers be stripped? <input type="checkbox"/> Yes <input type="checkbox"/> No
10. Please list any key personnel:				

If you answered YES to questions 2c, 2d, 3a, or 4, **your research protocol is generally not eligible for an exemption** and will require IRB review. Please complete the **Request for IRB Review form**.

ADDITIONAL DOCUMENTATION

10. 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 and 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:
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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:
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Office of Research Compliance

Inter-Campus Mail:

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Portland Campus

U.S. Mail

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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