



REQUEST FOR STUDY EXEMPTION FROM IRB REVIEW

Fill in Title and all Principal Investigator & Funding Information Below:

1. Study/Protocol Title

(cell will expand)

2. Principal Investigator Information

Name of Principal Investigator:		Are You? (Please check)	
		<input type="checkbox"/>	Faculty
		<input type="checkbox"/>	Staff
Mailing Address:		<input type="checkbox"/>	Undergraduate Student
		<input type="checkbox"/>	Graduate Student
Department:		<input type="checkbox"/>	Postdoctoral fellow
E-mail address:		<input type="checkbox"/>	Other
Phone Number:		Fax:	

3. Funding. Please submit a complete copy of funding proposal including grant face page:

<input type="checkbox"/>	Federal, Health and Human Services (ACF, AoA, AHRQ, ATSDR, CDC, CME, CMS, FDA, HRSA, IHS, 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 Award, etc.)
<input type="checkbox"/>	Other/ Private (Please specify)
<input type="checkbox"/>	Not Funded

4. Will existing or archived data, documents, records, or biological specimens be used? (Please check)

<input type="checkbox"/>	Yes (If Yes, please answer questions A-D below)	<input type="checkbox"/>	No
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A. When was the existing data or specimen collected?

(cell will expand)

B. Is the data or specimen source publicly available?

<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
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C. Is the information recorded in such a manner that subjects **can** be identified, directly or through identifying links (e.g. name, medical record #, addresses, telephone numbers, codes)?

<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
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D. Will any additional data or biological specimens be collected from subjects after the study begins?

<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
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5. Will surveys/interviews/tests be used to collect data during the study? (Please check)

<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
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A. Is the information sensitive (see categories of sensitive information page 1) **and** recorded such that human subjects can be identified directly or indirectly?

<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
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6. Does the study include a special subject population (see special subject categories page 1)? (Please check)

<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
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If you answered Yes to questions 4C, 4D, 5A, or 6, your research protocol is generally not eligible for an exemption and will require IRB review. Please complete the Request for IRB Review Form.

7. Please describe how the data will be used:

(cell will expand)

8. Please describe the subject population that will be recruited (include age range).

(cell will expand)

HANDWRITTEN SUBMISSIONS ARE NOT ACCEPTED

The following is **REQUIRED**:

9. Please provide the following items in a *Research Proposal Summary*, labeled and presented in this order, on a separate sheet:

- 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 procedure (if consent needed)
- 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. The ORC does not keep copies on file.)

**ATTACH ANY RELEVANT RESEARCH INSTRUMENTS
(SURVEYS, INTERVIEW QUESTIONS, CONSENT FORMS, LETTERS, RECRUITMENT POSTERS, ETC.)**

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 Research Supervisor:		Signature of Faculty Research Supervisor :		Date:	
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