

## **INSTRUCTIONS FOR REQUESTING AN EXEMPTION FROM FULL HSRB REVIEW**

To request an exemption from a full review of your research project, **please complete the second page of this form and attach a brief description of the research and informed consent procedures (as well as all interview and survey questions).** 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 or include special subject populations (see below) are generally not eligible for an exemption. **These studies require HSRB review. Please complete the standard "Review of Research" form that can be found on the HSRB website (<http://hsrb.umf.maine.edu/>)**

### 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

**REQUEST FOR STUDY EXEMPTION FROM FULL HSRB REVIEW**

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**Study/Protocol Title**

**Principal Investigator Information**

Name of Principal Investigator)		Are You? (Please check)	
		<input type="checkbox"/>	Faculty
Mailing Address:		<input type="checkbox"/>	Staff
		<input type="checkbox"/>	Undergraduate Student
Department:		<input type="checkbox"/>	Other (explain below)
E-mail address:			
Phone Number:			
Anticipated <b>starting date</b> of project:			

<p><b>ATTACH A DESCRIPTION OF THE RESEARCH PROJECT, A STATEMENT CONCERNING INFORMED CONSENT PROCEDURES (WITH RELEVANT FORMS) ANY ALL RESEARCH INSTRUMENTS (SURVEYS, INTERVIEW QUESTIONS, RECRUITMENT POSTERS, ETC.) THAT WILL BE USED IN THE INVESTIGATION</b></p>
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**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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