

UNIVERSITY OF MAINE -- APPLICATION FOR APPROVAL OF RESEARCH WITH HUMAN SUBJECTS  
(See instructions on reverse for completing application)

PRINCIPAL INVESTIGATOR: \_\_\_\_\_ email: \_\_\_\_\_  
CO-INVESTIGATOR(S): \_\_\_\_\_  
FACULTY SPONSOR (if any): \_\_\_\_\_  
TITLE OF PROJECT: \_\_\_\_\_  
PROJECT START DATE: \_\_\_\_\_ PI DEPARTMENT: \_\_\_\_\_  
MAILING ADDRESS: \_\_\_\_\_ TELEPHONE: \_\_\_\_\_  
FUNDING AGENCY (if any): \_\_\_\_\_ CONTRACT/GRANT #: \_\_\_\_\_  
STATUS OF PI (circle one):

FACULTY/STAFF/GRADUATE/UNDERGRADUATE/OTHER \_\_\_\_\_

- If PI is a student, is this research to be performed:  
 for an honors thesis?  for a master's thesis?  
 for a doctoral dissertation?  for a course project?  
 other (specify) \_\_\_\_\_
- Does this application modify a previously approved project? \_\_\_\_\_. If yes, please give assigned number ( if known) of previously approved project: \_\_\_\_\_
- Do you believe this project is exempt from further review requirements? \_\_\_\_\_ (Y/N, unsure). Information regarding exemption categories may be found on pages 4-5 of the Policies and Procedures (<http://www.umaine.edu/research/Ethical/humanpolicy.pdf>).
- Is an expedited review requested? \_\_\_\_\_ (Y/N). Information regarding expedited review procedures may be found on pages 8-11 of the Policies and Procedures (<http://www.umaine.edu/research/Ethical/humanpolicy.pdf>).
- Has everyone named in this application completed the mandatory training on the Protection of Human Subjects of Research? \_\_\_\_\_. (Y/N). Approval will not be granted until training has been completed. The tutorial is found at [www.umaine.edu/irb](http://www.umaine.edu/irb).

**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. By signing this application page, the Faculty Sponsor ensures that the conduct of such research will be in accordance with the University of Maine's *Policies and Procedures for the Protection of Human Subjects of Research*.

_____	_____	_____
Date	Principal Investigator	Faculty Sponsor
	_____	_____
	Co-Investigator	Co-Investigator

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FOR BOARD USE ONLY Application # \_\_\_\_\_ Date received \_\_\_\_\_ Review (F/E): \_\_\_\_  
ACTION TAKEN:

- \_\_\_\_\_ Judged Exempt; category \_\_\_\_\_. Modifications required? \_\_\_\_\_. (Y/N) Accepted (date) \_\_\_\_\_
- \_\_\_\_\_ Approved as submitted. Date of next review: by \_\_\_\_\_.
- \_\_\_\_\_ Approved pending modifications. Date of next review: by \_\_\_\_\_.
- \_\_\_\_\_ Modifications accepted (date): \_\_\_\_\_.
- \_\_\_\_\_ Not approved. (See attached statement.)

Date: \_\_\_\_\_ Chair's Signature: \_\_\_\_\_

## INSTRUCTIONS

Please respond to the following numbered points, in the order given, on separate paper. Attach to application. To avoid delays in review, type all responses. For inclusion on the monthly agenda of the Protection of Human Subjects Review Board (IRB), submit to the Board by the first Friday of the month. **PLEASE PAGE NUMBER THE ENTIRE DOCUMENT.**

- 1. Summary of the proposal.** Describe the rationale of the study and precisely what you intend to do, in concise, non-technical language. **Attach** a copy of any questionnaire, interview schedule, or training schedule for project staff.

For investigators who may gather, generate, access, or share subjects' personal health information, please be aware that the research may be subject to the Privacy Rule (a federal regulation under the Health Insurance Portability and Accountability Act, HIPAA). At UMaine, this will most likely occur in collaboration with doctors, hospitals, etc. At this time, the Cutler Health Center is the only UMaine covered entity. If you are from that area, additional information/ documents will be necessary. If your study may involve personal health information, please contact Gayle Anderson, 1-1498, as soon as possible; she will be in contact with University Counsel for advice on studies that are subject to the Privacy Rule. Please see document, "What is HIPAA" (available on the human subjects website).

- 2. Personnel.** Identify and specify the qualifications of the person(s) who will have contact with the subjects and/or with identifiable data.
- 3. Subject recruitment.** Describe the characteristics of the subject population (e.g., number, sex, age group, ethnic group, state of health, etc.). Describe subject identification and recruitment procedures. If the research is to be conducted at another institution, please be aware that you will need to get permission from that institution to access subjects and, if applicable, get approval from that institution's review board. **Attach** letters, flyers, advertisements, etc., that may be used to recruit subjects.

**Please note:** The Board requires special measures of protection for subjects of diminished autonomy. (See Policies and Procedures) Vulnerable populations must be treated with special sensitivity to their restricted ability to protect themselves. The risks imposed by a proposed study involving such populations must be recognized and the benefits to be derived from participation must justify the risks. In certain instances, advocates must be appointed to protect the subjects. Such populations include fetuses (and by extension pregnant women), patients, prisoners or parolees, minors (less than 18 years old), mentally retarded, and mentally disabled people. In addition, the Board may require special measures to preserve the rights of subjects whose circumstances may make them vulnerable to undue influence to participate in research. These may include, for example, students and employees of the University. State which, if any, of the above groups may be represented in your subject population, and justify their inclusion.

- 4. Informed consent.** (See Policies and Procedures Section III D.) Describe the type of consent (oral or written) to be obtained and the means of obtaining it. If the subjects are minors or mentally incompetent, describe the means of obtaining both the subjects' assent (if feasible) and the consent of parents or legal guardians. **Attach** a copy of the consent form(s). **FOLLOW THE INFORMATION AND SAMPLE FOUND AT:** <http://www.umaine.edu/research/ethical/informedconsent.pdf>. **Please note:** The **documentation** (signature) of informed consent is not necessary for a project in one of the exempt categories, **but exempt studies still require informed consent** (unless the research falls under exemption category 4). **Consent forms should be written at an 8<sup>th</sup> grade reading level.**

- 5. Confidentiality.** Describe the precautions that will be taken to ensure confidentiality of the subjects and the confidentiality of the data, both in your possession and in reports and publications. Describe the disposition of the research data, including any audio, video, or film recordings, when the research is completed. Assurance must be provided that all identifiable data will be secured under conditions that limit their access to the investigator(s) only. Include information on how long data will be kept – x years, indefinitely, etc. If the data are published, care must be taken to remove identifying references, which would violate the intent of the preservation of privacy. Don't confuse anonymity with confidentiality. If it is possible for the investigators to determine the identity of the subject, they should tell subjects they will keep their identity confidential. Anonymity means that no one, even the investigator, can ever link the data to the subject.
- 6. Risks to subjects.** Describe in detail any possible physical, psychological, social, legal, economic, or other risks to the subjects, either immediate or long range. If the subjects will be exposed to greater than minimal risk, justify the use of the procedures and state reasons for not using a procedure that would entail a lesser risk. Estimate the magnitude and probability of the risks. Describe procedures used to minimize risk.
- 7. Benefits.** Assess the benefits of the research to the subjects and to others. Explain how the benefits outweigh the risks involved.

**RETURN TO: 114 ALUMNI HALL (OFFICE OF THE VICE PRESIDENT FOR RESEARCH)**