

IRB APPLICATION FORM INSTRUCTIONS
DO NOT SUBMIT WITH APPLICATION

Things to remember when completing the application cover page:

- **The principal investigator must have a UMaine affiliation.**
- **Faculty sponsor required if the principal investigator is a student.**
- **The title should describe the specific subject matter to be researched. If the study is funded, the title must match the grant/proposal.**
- **The start date refers to when the research with human subjects proposes to begin, and should not be earlier than ten days from the date the application is submitted.**
- **Submit as WORD DOCUMENT (not a PDF).**

Please note:

- **Please read and follow instructions; incomplete applications will be returned.**
- **FACULTY SPONSORS: you are responsible for the quality of the application; do not approve an application that is incomplete or does not follow the instructions – it will be returned to you.**
- **For undergraduate students, the application MUST BE SUBMITTED (EMAILED) BY THE FACULTY SPONSOR.**
- Type responses to points below; **please include the nine major headings** detailed below (e.g., Funding, Summary, Personnel, Participant Recruitment), but do not include the application instructions.
- Page number **entire** document. PLEASE SUBMIT AS ONE DOCUMENT. The Cover page should be submitted separately (and kept as Word document), but the narrative of the application (items 1-9 below), with appendices (measures, recruitment materials, consent forms, etc.) should be one document.
- Please submit the document as **ONLY** a Word document (not a PDF).

Application Narrative:

1. **Funding: if the proposed study has been submitted for funding or is funded, please list funding agency and grant/proposal number, if known. Note that the title of the IRB application should match the title of the grant. If the study is not funded, state N/A**

2. **Summary:**
Describe the rationale of the study in concise, non-technical language.
 - Although the IRB does not wish to receive grant/dissertation proposals, this section should include a description of the scientific significance and goals of the study, including background information and citations, to justify conducting the study. The background information should also explain the rationale for the choice of the particular participant population, as well as the use of specific measures and procedures.

- Include a methods section (with “Methods” heading). This section need not be long, but the IRB wants to understand early on how the study will be conducted. Some can be as brief as: “This study will involve face-to-face interviews at a location of the participant’s choosing. The interviews may take 45-60 minutes and will be recorded.” This section would be longer if there are many components of your study.
- Include a reference page for the citations (we expect to see citations!).
- Include questionnaires, interview questions, measures, etc., as appendices.

2. Personnel:

- Identify the person(s) named on the cover page (including the faculty sponsor, if applicable), as well as others who will have contact with the participants and/or with identifiable data. (NOTE: Make sure principal investigator is named; do not state: “I will be the principal investigator.” Be sure to define the roles that the named personnel will have in the research project.
- Specify the affiliation/qualifications of everyone listed, e.g., “Jane Doe, Graduate student in the Department of Psychology, College of Liberal Arts and Sciences.” Briefly explain each person’s experience with research with human participants. Include the years of human subjects research experience for all personnel listed.
- Everyone named in this section is required to have completed the [human subjects training](#).

3. Participant recruitment:

- Describe the characteristics of the participant population. Describe the expected number of participants or the expected response rate (e.g., plan to send out 500 surveys and expect 20% response rate). Include the age range of the participants and whether particular demographics and characteristics (e.g., state of health) are sought. If you are recruiting only one gender, explain why. (NOTE: if you are specifically recruiting members/citizens of the Penobscot Nation, please be sure to state they are your targeted population.)
- Describe how the proposed number of participants was determined.
- Describe participant identification and recruitment procedures, e.g., email (explain how are email addresses obtained), post flyers, etc. If you plan to recruit participants from another institution, please be aware that you may need to get permission from that institution to access participants and, if applicable, get approval from that institution's review board. Please note that if you are seeking participants with a specific physical or mental health condition, you CANNOT ask a professional services provider to give you a list of names of individuals who fit your criteria. However, these service providers may share your recruitment materials with those who appear to be eligible for your study, and interested individuals can contact you directly. Include (as appendices) recruitment letters, phone/email scripts, flyers, advertisements, postings, etc., that may be used to recruit participants (see [samples on the IRB website](#)). Reference the appendix number/letter.

Please note: The IRB requires special measures of protection for participants of diminished autonomy. (See Sections II, III, and/or IV from Policy.) 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 participants. Such populations include fetuses (and by extension pregnant women), patients, prisoners or parolees, minors (less than 18 years old), and mentally or physically challenged people. In addition, the IRB may require special measures to preserve the rights of participants 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 participant population, and justify their inclusion.

4. Informed consent (See Sections I.K. and I.L. of Policy):

- Describe the type of consent (oral or written) to be used and the means of obtaining it. Describe how and when potential participants will get the consent form.
- If the participants are minors or mentally incompetent, describe the means of obtaining both the participants' assent (if feasible) and the consent of parents or legal guardians.
- Include a copy (**in an appendix at the end of the application**) of the consent form(s) and assent scripts (if applicable). Consent forms should be written no higher than an 8th grade reading level.
- Review the [informed consent checklist](#) and **FOLLOW THE [SAMPLE\(s\)](#) FOUND on the IRB website Please note: The documentation (signature) of informed consent is not necessary for a project in one of the exemption categories. **THE SAMPLE FORMAT, WITH HEADINGS, MUST BE FOLLOWED OR THE APPLICATION WILL BE RETURNED.****

5. Confidentiality:

- Describe the precautions that will be taken to ensure privacy of the participants and the confidentiality of the data, both in your possession and in reports and publications (e.g., are responses anonymous, are responses coded with identification numbers and a key used to link names to identification numbers).
- If data collection will occur on-line, state the program that will be used (e.g., Qualtrics, Skype, etc.). If applicable, state whether IP addresses will be collected (preferable that they are not collected!). State whether data will be downloaded off program to researcher's computer, as well as the expected date data will be deleted off the program site.
- State the location where data will be stored. Describe the disposition of the research data, including any audio, video, or film recordings, when the research is completed (define as expected date to be destroyed or kept indefinitely). If not keeping indefinitely, don't say "kept until study completed," or "when analysis completed," etc. State an approximate date (month/year) of those occurrences, e.g., January 2024. **If you are not keeping data indefinitely, be sure to be generous with a destruction date, so you don't end up in a situation where you are not ready to destroy the data, but must because that is what you told the participant – NOTE: if you say you will keep the data indefinitely, you can destroy it at any time—but if you give an actual date, you must adhere to it!**

- If recording, state whether a transcription service will be used or if named investigator(s) will transcribe.
- If applicable, state whether the key is paper or electronic and where and how long the key will be kept (key should be kept separate from data). Keys are typically kept for a lesser amount of time than data are kept. Use a date for destroying the key, but give yourself plenty of leeway with the timing in case your project gets delayed. If you wish to keep the key indefinitely, please explain why, as it impacts participant confidentiality. If the key will be stored electronically, it must be encrypted. [Please see information on encrypting electronic, identifiable data](#) (the key linking names to data or entire dataset).
- Assurance must be provided that all identifiable data will be secured under conditions that limit their access to the investigator(s) only.
- If focus groups are used to collect data, the researcher should acknowledge that he/she cannot guarantee confidentiality of participants' responses, but will encourage participants to not discuss responses outside of the focus group.
- If the data are published, care must be taken to remove identifying references in order to preserve privacy.
- The IRB recognizes that some studies, such as oral histories, do not require confidentiality of data. The regulations and the IRB are flexible – explain what will happen with the data. If applicable, explain why data will not be confidential.

6. **Risks to participants:**

- Describe in detail any possible physical, psychological, social, legal, economic, or other risks (including a risk of identification) to the participants, either immediate or long range. **Do not state that there are no risks.** All studies have risks (e.g., time and inconvenience).
- If the participants 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.
- Describe procedures used to minimize risk (e.g., assuring participants that they may skip questions they prefer not to answer). If applicable, include referrals to relevant resources from which participants could seek support. Use the [Referral Handout Template](#) and edit as necessary.
- Describe what procedures will be followed if research procedures reveal that participants are at elevated risk (e.g., high blood pressure, clinical levels of depressive symptoms). See [Guidance for Researchers – Depression and Suicidality in Human Research](#).

7. **Benefits:**

- The description is two parts. (1) Describe the benefits of the research to the participants, if any (if no direct benefit to the participants, so state). **NOTE:** Money, course credit, gifts, etc., are not benefits; they are compensation. (2) Describe the overall potential benefit of the research.

8. **Compensation:**

- If applicable, list any compensation for participation (money, course extra credit, raffle, etc.). Also indicate how compensation will be handled if a participant

withdraws from the study (e.g., no compensation, prorated compensation, or full compensation; must reach end of survey to enter raffle; must complete survey, except for the occasional skipped question, to enter the raffle, etc.). Regarding extra credit: if extra credit is offered, the course instructor must offer other methods of earning extra credit such that participating in the research is not the only way a student can earn extra credit. If a study involves several classes with different instructors, all must agree to grant extra credit and all must offer other methods of earning extra credit. Compensation shouldn't just be for some of the participants.

- For raffle/compensation for on-line studies (where the link to the raffle/compensation takes the participant to a new page to enter their contact information), include the text of that page as part of your application. It need not be long – thanking them for taking the survey, reminding them that their contact information is not linked to their survey responses, along with place for name/email/phone, etc.
- If the value of a one-time payment **exceeds \$75.00**, subject data must be reported to other offices within the University of Maine and University of Maine System, as follows:
 - If the human subject is an employee of the University of Maine, the researcher must report any such payments to the Department of Human Resources. The Department of Human Resources will determine whether the value of the reported incentive needs to be added to the employee's gross wages, and whether the payment will be subject to taxation and withholding.
 - If the human subject is not an employee of the University of Maine, the researcher shall report any such payments to the Department of Purchasing. The researcher will work with the Department of Purchasing to comply with IRS regulations that require the University of Maine System to issue a Form 1099 when cumulative payments to a non-employee reach \$600 in a calendar year.

SEE [Consent Guidelines](#) for the wording to be used in the consent form.

SEE [Human Subjects Payment Guidelines](#) for additional information.

Submission Instructions:

- Email complete application and cover page to umric@maine.edu).
- **REMEMBER – If an undergraduate is the principal investigator, the faculty sponsor must submit the application.**
- **The submission email should have two attachments:**
 - 1) **The completed cover page as Word document.**
 - 2) **The narrative of the application (items 1-9 above) along with the appendices -- consent form(s), recruitment materials, measures, etc. as ONE document – PAGINATED.**
- Please note that the IRB expedites many applications (reviews outside of a full board meeting). The IRB will expedite applications when possible, typically within ten business days. The IRB will make the final determination of whether your study is eligible for expedited review.
- If your study involves sensitive topics, protected populations, and/or more than minimal risk, the application may require full board review. In those cases, the application is **due by the first Friday of the month** for inclusion on the agenda for that month.

Please contact the IRB if you have questions – 207-581-2657 or e-mail umric@maine.edu.