

**PROPOSAL FORM FOR RESEARCH INVOLVING HUMAN SUBJECTS**

Title of Proposed Research Project: \_\_\_\_\_

Date submitted: \_\_\_\_\_

Proposed starting date of project: \_\_\_\_\_

Date the collection of data is to end (anticipated): \_\_\_\_\_ (Note: Approvals are granted for no more than 1 year from the date of review)

Principal Investigator's name (print): \_\_\_\_\_ As this signature below testifies, the principal investigator pledges to conform to the following: As one engaged in investigation utilizing human subjects, I acknowledge the rights and welfare of the participants involved. I acknowledge my responsibility as an investigator to secure the informed consent of the participants by explaining the procedures, in so far as possible, and by describing the risks as weighted against the potential benefits of the investigation. I assure the Committee that all procedures performed under the project will be conducted in accordance with those Federal regulations and College policies which govern research involving human subjects. Any deviation from the project (e.g., change in principal investigator, research methodology, subject recruitment procedures, etc.) will be submitted to the ERRB Committee, for its approval prior to implementation. The P.I. agrees to report all protocol deviations or adverse events immediately to the ERRB.

PRINCIPAL INVESTIGATOR: \_\_\_\_\_  
(signature) (date)

(For Student Researchers) Faculty Adviser name (print):

\_\_\_\_\_

The Faculty Adviser's signature on the Research Proposal confirms that they have supervised the composition of the proposal and they approve of the research proposal as submitted.

FACULTY ADVISER: \_\_\_\_\_  
(signature) (date)

Has this proposal been subject to review by another ERRB/IRB? Yes No

If "Yes", please attach copies of all documentation submitted for that review, along with the written response (approval, approval with modification, disapproval) from the other IRB.

Please answer the below six questions on an attached page. Include the corresponding numbers and titles listed below (in order) on your page.

**1) SUMMARY OF THE PROPOSED PROJECT:** Provide a brief (100 words) summary of the project. This summary should state the research objectives, the purpose of pursuing these objectives, and the context in which the work is to be done (e.g. name where the work will take place and the disciplines or interdisciplinary fields that will inform the work).

**2) RESEARCH QUESTION:** State in a single sentence what the central research question of your proposed project is.

**3) BACKGROUND FOR THE PROJECT:** Summarize (250 words) already existing scholarship that provides context for the proposed research, and that supports the expectation of obtaining useful results that would contribute to this field without undue risk to human subjects. Note: Include appropriate citations to relevant scholarship or attach a copy of a literature review.

**4) RESEARCHER'S RELEVANT BACKGROUND:** Summarize any experience or training you have had that prepares you to conduct the proposed research (e.g. courses, internships, volunteer work, language proficiencies, employment experience).

## **5) METHODS**

- a) Describe in detail the research procedures to be used (e.g. Who will you be researching? When, where, and for how long? In what kinds of contexts will you be interacting with the people you are researching? What will participants be asked to do? What will you do in order to obtain the information you seek? If you will be observing participants, explain in what context you will be observing them. If you will be participating in activities with them, explain what kind of activities. If you will be interviewing people, explain in what kind of a context (e.g. specify public or private settings such as homes, schools, restaurants, individually or in focus groups). If you will be conducting surveys or formal interviews, please attach a copy of the survey or interview schedule and examples of the kinds of questions you plan to ask.

b) What is the anticipated number of participants to be included in the project?

c) List specific eligibility requirements for participants, including those criteria that would exclude otherwise acceptable participants. For example, if your study uses only male or female participants, explain why.

d) How will participants be recruited? (Attach any flyers, letters, announcements, etc. that will be used to recruit participants.)

e) Is there any formal relationship between researcher and participant(s)? (e.g. teacher/student, employer/employee, etc.) that might lead to the perception of coercion? If so, please explain how you will address this.

f) Does your research focus specifically on any of the following “vulnerable populations”? If so, please indicate below:

Minors (under age 18 – specify the age range) (Note: Participants under age 18 require the participant’s assent and written consent from a parent or legal guardian.)   
 Prisoners  Pregnant Women & Fetuses  Decisionally impaired individuals   
 College of the Atlantic Students or Employees as Research Subjects  Institutionalized individuals   
 Economically or Educationally Disadvantaged Persons  HIV-positive individuals   
 Non or Limited English Speaking Persons  People living outside the US   
 Other, please specify: \_\_\_\_\_

Note: this is a partial list. Please consult with your project director if you are unsure if your proposed research involves “vulnerable populations.”

If vulnerable populations are to be the primary participants in this research project, please state the justification for their inclusion.

g) Will your research involve asking people about sensitive topics? If so, please indicate below.

Sexual orientation, incest, rape, sexual molestation, deviant sexual behavior, or attitudes regarding sexual conduct (pedophilia, bestiality, etc), practices of contraception, abortion, and/or pregnancy  Substance use and/or abuse (including but not limited to: alcohol, marijuana, steroids, amphetamines, narcotics, and any prescription medication legally or illegally obtained)  Illegal or taboo behavior  Questions about mental

health (e.g. suicide, depression, obsessive compulsive behaviors like smoking, gambling, etc.) \_\_\_ Traumatic experiences of an individual, including war or combat experiences of veterans. \_\_\_ Other (please specify)

## **6) RISK**

a) Risk to participants: Given the fact that in any study it is possible for participants to experience some degree of discomfort (including for example, anxiety, concern about failure) what will you do to minimize the possibility that this will occur, and how will you address or reduce it if it does occur? What other risks to your research subjects might your project present? Please name possible risks to participants that your research might involve, and explain how you anticipate addressing such risks.

b) How will you obtain informed consent? (How and where will the consent process take place? How will it be structured to enhance independent and thoughtful decision-making? What steps will be taken to avoid coercion or undue influence?)

c) Will any information about the research purpose and design be withheld from potential or participating subjects? If so, please justify this, and describe plans for post-study debriefing.

Note: Any non-disclosure must be approved by the ERRB and may not exclude information that a reasonable person would want to know in deciding whether to participate in the research. In addition, the alteration in the consent procedure must be approvable under 45 CFR 46.116(d): (1) the research involves no more than minimal risk to the subjects; (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) the research could not practicably be carried out without the waiver or alternation; and (4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

d) How will confidentiality or anonymity (whichever is appropriate) be guaranteed? (Include a description of how data will be handled to insure confidentiality or anonymity)

e) How will participants' rights to terminate or refuse participation be ensured?