INSTITUTIONAL REVIEW BOARD

INITIAL APPLICATION FORM

Date Received: (For IRB office use)	IRB protocol #: (For IRB office use)	Version Date (date you last saved this form):
Title of Proposed Study:		
Name and Title of Principal Investigator:		
Department:		
Telephone #		
Email:		
List All Co-Investigators: (or Sponsor if Principal Investigator is a research fellow or student):		

Application Checklist:

Complete submissions should include:

- ☐ Complete Application Form
- ☐ Research instruments (e.g., surveys, interview guides, focus group guides)
- ☐ Consent forms (if applicable)
- ☐ Recruitment materials (if applicable)
- ☐ Other Institutions' IRB approvals (if applicable - only for studies taking place in another institution or country)
- ☐ Research Financial Conflict of Interest Forms
- ☐ Training Certificates

SITES AT WHICH STUDY/PROCEDURES WILL BE CONDUCTED:
FUNDING INFORMATION:
☐ Grant Grant name and grant number:
☐ Contract Organization:
☐ Other Please Specify:
☐ No External Funding

RESEARCH PERSONNEL

List all research personnel involved in the study, including principal investigator, co-investigators, research assistants, persons obtaining consent, and entering data, and indicate whether they have completed training in the protection of human subjects, and whether they have signed conflict of interest forms. **Please note, for approval, all research personnel must have completed training and signed conflict of interest forms. These forms must be submitted with your application.**

Name	Training	Conflict of Interest

I. SIGNIFICANCE OF PROJECT
1. Describe concisely the study objectives and research questions:
2. What are the anticipated study contributions, and how does it relate to previous research in this area? (Include a brief review of the relevant literature).

II. STUDY PROCEDURES
1. Describe the study design, procedures, data sources (flow charts may be used for complex procedures):
2. List measures and instruments to be used, including tests and interviews and the time required for the completion of each. Attach copies unless standard instruments are used.

III. POPULATION AND SAMPLE

1. This study includes the following groups (check all that apply):

☐ Children
☐ Prisoners
☐ Pregnant Women
☐ Persons with mental disabilities
☐ Economically or educationally disadvantaged people

If you checked any of the above, please include additional safeguards that will be used to protect the rights and welfare of study participants in the appropriate sections of this application.

2. Describe the population to be studied:

3. Provide an estimate of the number of participants and characteristics (i.e., age, gender, racial and ethnic background, and other applicable characteristics). If one gender and/or minorities are excluded or inadequately represented, a rationale should be provided:

4. List study inclusion and exclusion criteria (i.e., is there special criteria for including or excluding participants)?

5. Describe methods of recruitment:

6. Will participants be compensated? Please describe compensation.

IV. RISKS AND BENEFITS	
1.	Describe risks of participation (including physical, psychological, social/economic, or legal):
2.	If there are risks to participation, what measures will be put in place to minimize risks?
3.	What alternative procedure could be considered to conduct this study which would reduce the physical, psychological, or social risk factors (explain why they were not proposed or included for this study):
4.	Potential benefits to the human subjects (if any):
5.	Potential benefits of the study to the general public:
6.	Give your evaluation of the extent to which the possible benefits to be derived outweigh the likelihood of injury and risk to which the human subject is exposed:

V. CONFIDENTIALITY	
1.	Describe means by which privacy will be protected and confidentiality of data maintained. Include procedures for the storage and protection of electronic data. NOTE: If a Certificate of Confidentiality will be obtained for this study, please indicate so here.

VI. INFORMED CONSENT

If you are seeking to waive the requirement to obtain informed consent, or signed consent, please justify is here.

Consent may be modified or waived if ALL of the following are true:

- ☐ The research involves no more than minimal risk to the subjects
- ☐ The waiver or alteration will not adversely affect the rights and welfare of the subjects
- ☐ The research could not practicably be carried out without the waiver or alteration

Requirement for signed consent may be waived if:

- ☐ The consent document is the only record linking the subject with the research and the principal risk is associated with a breach of confidentiality concerning the subject's participation, or
- ☐ The study involves less than minimal risk to subjects. Minimal risk is defined as "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." [CFR title 45 part 46.102(i)] AND involves no procedures for which written consent is normally required outside of the research context.

1. Describe consent process (when, where and by whom consent will be obtained):

2. Describe steps taken to ensure consent is given freely:

3. If the subjects are minors, how will assent be secured?

VII. STATEMENT OF AGREEMENT

I, the Principal Investigator, agree to the following:

1. I have carefully prepared and reviewed this application for completeness and for compliance with local and federal regulatory requirements related to the protection of human research subjects.
2. All listed co-investigators have agreed to their involvement in the study.
3. I will submit continuations and modifications as described in the IRB policies and procedures;
4. I will retain copies of approved documents, including
    i. Signed consent forms for three years after project completion;
    ii. Data collected for three years after project completion, ensuring participant confidentiality.
5. Any financial interests that study investigators and those documenting consent have in relation to the study sponsor and/or any products under study have been disclosed and forwarded to the IRB for review under separate cover.
6. All study staff with a significant role in the design or implementation of the human subject components of this protocol have completed training in human research subject protections (Associated documentation in my files) and are appropriately qualified to carry out their roles.
7. I will notify the IRB of any serious and/or unexpected adverse events and any other events that occur during the course of study participation that have or might have significant impact on the rights, welfare, or safety of study participants.
8. No changes will be made to the protocol without the prior written approval of the Northland College IRB. Any deviations from the approved protocol or consent procedure will be reported promptly to the IRB.

By signing below the Principal Investigator assures agreement with the statements above:

_____	_____	_____
Principal Investigator (printed)	Signature/Date	Department

Principal Investigator Status: ☐ Faculty Member ☐ Administrator/Staff ☐ Student ☐ Other (Specify_____)

Faculty Sponsors complete this section (for all student led research projects):

Course_____

_____	_____
Faculty Sponsor (printed)	Signature/Date