INSTITUTIONAL REVIEW BOARD

ANNUAL REVIEW FORM

Date Received: (For IRB office use)	IRB protocol #: (For IRB office use)	Version Date (date of the most updated protocol):

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):
Study Status: _____Participant recruitment and enrollment are ongoing _____Participant recruitment and enrollment are complete, but data collection will continue _____Participant recruitment, enrollment and data collection are complete, but data analysis is ongoing _____Study is concluded, study closure is requested
Application for: _____Renewal without modifications _____Renewal with modifications (A detailed description of proposed modifications must be included as described in the IRB policies and procedures, including changes to recruitment materials and instruments) _____Study Closure (A study may be closed if: a) All interventions or interactions with participants is concluded, and no further data will be obtained, and b) Analysis of identifiable private information is concluded (investigators are only conducting analysis of aggregate data sets without individual identifiers or identifiable private information). Exempt studies do not require closure.

SAMPLE

Approved sample size	
Number of participants who completed the study to date	
Number of total participants enrolled to date	
Number of participants enrolled during the last IRB approval period	
Number of participants who withdrew consent during the last IRB approval period	
Number of participants removed from the study by investigators during the last IRB approval period	

STUDY UPDATES

Have there been any significant deviations from the anticipated study recruitment, retention or completion estimates? If so, please describe.
Describe actions taken or planned to address these problems.
Have there been any personnel changes, and if so, are all research personnel trained in the protection of human subjects, and have signed conflict of interest forms? (research personnel include the principal investigator, co-investigators, research assistants, and persons obtaining consent and entering data).

Have there been any changes in funding status since the prior approval? Please describe.
Have there been any study findings, recent literature, or events occurring here or at other sites in the past year which might affect the analysis of the safety, risks or benefits of study participation? If so, describe.
Have there been any serious adverse events (serious and/or unanticipated problems involving risks to subjects or others at this site which occurred in the past year)?
Is the study covered by a certificate of confidentiality?
Investigators must submit a signed research financial conflict of interest form with each annual review.

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 ☐ Administrator/Staff ☐ Student Other ☐

(Please specify_____)

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

Course_____

_____ _____

Faculty Sponsor (printed) Signature/Date