INSTITUTIONAL REVIEW BOARD

MODIFICATION FORM

This form may be submitted as a standalone form if the modification proposed will occur prior to the annual renewal due date. If the proposed modification is being submitted with a renewal, complete both the modification and renewal forms.

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

Please update your protocol as described in the "Initial Application Form" with all changes indicated in bold. Changes to recruitment materials and instruments should be made directly on those documents, also in bold. All changes should be described here with corresponding document names and page numbers. Use additional pages if necessary.
Has there been a change in research personnel? If so, list new personnel here, and include a human subjects training certificate and research conflict of interest disclosure form with this application.
If you have obtained a Certificate of Confidentiality and you are proposing major modifications, you must submit an amendment to the appropriate federal agency. Do you have a Certificate of Confidentiality for this study? YES ☐ NO ☐

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