Northland College Institutional Review Board

Policies and Procedures

Contents

A. Overview

The Institutional Review Board (IRB) reviews research studies to protect the rights of participants. The IRB applies ethical principles to research oversight, and ensures compliance with the U.S. Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP) regulations (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html). All research involving human subjects is subject to IRB review.

The Northland College IRB is a special committee that adopts the OHRP federal regulations governing research with human participants. All research with human participants conducted under the auspices of the Northland College IRB will be guided by the three ethical principles set forth in the Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (the "Belmont Report"): respect for persons, beneficence and justice. All persons involved in conducting and reviewing research with human subjects, regardless of whether or how the project is funded, have an obligation to apply the principles set forth in the "Belmont Report" (http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html):

1. Respect for persons: Individuals should be treated as autonomous agents and persons with diminished autonomy are entitled to extra protections. In application, researchers must ensure that participants are informed about the research procedures and enter the research voluntarily.
2. Beneficence: Individuals should be protected from harm, and the benefits of participation will be maximized while any potential harm will be minimized. In application, researchers must take steps to minimize risk, ensure that risks are reasonable in relation to benefits, and maintain confidentiality.
3. Justice: This principle requires an equitable distribution of benefits and burden. In application, researchers must ensure participants are selected equitably, and that vulnerable populations are not exploited.

Research is defined as "the systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" [CFR title 45 part 46.102(d)].

Human Subject is defined as "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with an individual, or (2) Identifiable private information" [CFR title 45 part 46.102(f)].

For the purposes of this policy, a project is considered research if the investigator intends to publish or otherwise disseminate the results of the study to the public, or plans to submit it as part of a capstone or degree requirement.

1. **Is my project considered research?**
   - **i.** Do you plan to publish the results of your study?
   - **ii.** Do you plan to present the results of your study in a public setting, such as a conference, or poster session?
   - **iii.** Are you completing this project as part of a capstone or other degree requirement?

If you answers "YES" to any of the questions i-iii, your study is considered research. Move on to question 2) below.

If you answered "NO" to all three questions, the IRB application is waived and you are free to begin your study.

2. **Is my study considered research on human subjects?**
   - **i.** Are people the subjects of study (If you interview geoscientists to learn about stream hydrology, they are not human subjects, but if you interview them about their experiences as geoscientists, they are human subjects.)?
   - **ii.** Does the study involves interacting with living people?
   - **iii.** Is the information individually identifiable (i.e. the identity of the subject may readily be ascertained by the investigator or associated with the information collected?)
   - **iv.** Will you collect information that would ordinarily be private?
   - **v.** Will you observe behavior where the subjects would reasonably expect privacy?

If you answered “YES” to i. and to one or more of questions ii. To v. your study involves human subjects, and you need to apply for IRB approval of your research.

If you answered “NO” to all five questions, you do not need to apply for IRB approval of your research.

B. Levels of Review

When an application is submitted, the Primary Reviewer will review the application and supporting materials, and make a decision about the level of approval necessary:

1. Full Board Review
2. Expedited Review
3. Exempt Research Status. Only the IRB can make a determination of exempt status.

The Primary Reviewer will inform the Chairperson if a full board review is recommended. To support IRB operations, the IRB Chairperson will assign a Primary Reviewer and protocol number to each submitted application. The Chairperson will keep an electronic record documenting Primary Reviewer assignments and protocol numbers. The role of Primary Reviewer will rotate among board members. The Chairperson will keep an electronic record documenting protocol numbers, submission, approval and renewal due dates. All communications will be filed with the corresponding protocol documents, including approval notices, modifications, renewals, terminations and adverse events.

B.1. Full Board Review

If the research study warrants a full board review, the IRB will convene within one month of receiving the application, and the Principal Investigator will be notified of a final decision within one week of the review.

Upon receipt of a complete application, the Primary Reviewer will distribute copies to members of the IRB. A complete application is one that includes all pertinent materials as described in the *Submissions* section of this document.

To consider a proposal, a majority of the total membership must be present at the review meeting, including a member whose primary concern is in a non-scientific area. HHS provides the following description of scientific and non-scientific members: “members whose training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline should be considered a scientist, while members whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline should be considered a nonscientist” (http://www.hhs.gov/ohrp/sachrp/20110124attchmentblettertosec.html#_ftnref2). A majority vote is needed for approval. IRB members who have a conflict of interest or direct role in the project being reviewed must be excused from the review proceedings (i.e., they will not participate in deliberation or voting, but may be asked to provide information on the protocol).

The final determination by the Board may be any one of the following:

1. Approval
2. Approval with restrictions or conditions
3. Request for modifications or additional information
4. Disapprove

If modifications or additional information are requested, the IRB Chairperson and Primary Reviewer will review all changes submitted. If further modifications are needed, the communication will continue between the Principal Investigator and assigned member of the IRB until a final determination is made. Appeals can be made to the full IRB membership by emailing the IRB Chairperson. All communications will be filed with the corresponding protocol documents, including approval notices, modifications, renewals, terminations and adverse events. If the IRB decides to disapprove a research activity, it must include a statement of the reasons for its decision in a written notification and give the investigator an opportunity to respond in person or in writing.

B.2. Expedited Review

Expedited review is conducted by the Primary Reviewer in consultation with one or more Board members and the IRB Chairperson within two weeks of receiving an application. Communications will be done over email. The Principal Investigator will be notified of a decision within one week of review.

Research may receive expedited review in accordance to Title 45 Code of Federal Regulations Part 46 (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html) if it involves no more than minimal risk to participants. 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)].

Expedited review may also be used for minor changes in previously approved research during the period (of one year or less) for which approval was granted.

Reviewers may exercise full IRB authority in expedited review processes except disapproving the research. Research may only be disapproved if reviewed in accordance to the *Full Board Review* described in this document.

B.3. Exempt Research

Research activities in which the only involvement of human subjects will be in one or more of the listed categories below are exempt from review by the IRB, unless otherwise required by a federal department or federal agency heads. Investigators will be notified of exempt status within two weeks of submitting an application.

1. Research conducted in established educational settings involving standard practices, on strategies or the effectiveness of techniques, curricula or management methods.
2. Research on educational tests, survey or interview procedures, or observation of public behavior, except when human subjects can be identified, or data disclosure could place the subjects at risk of criminal or civil liability, or damage the subjects' financial standing, employability, or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt, where the human subjects are candidates for public office, or elected or appointed public officials; where identifiable information is kept confidential.
4. Research involving publicly available or anonymous existing data, documents, records, pathological specimens, or diagnostic specimens.
5. Research and demonstration projects on a public benefit or service program, procedures for obtaining benefits or services under those programs, changes to these programs or procedures and changes to payments for benefits or services.
6. Taste and food quality evaluation and consumer studies where subjects consume wholesome foods free of additives or with food ingredients at or below established safety levels, or agricultural chemical or environmental contaminant at or below established safety levels as determined by the Food and Drug Administration or the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

If the project fits any one of these criteria, the IRB will also consider whether the study involves vulnerable participants (e.g. prisoners), if the investigator is collecting identifiable information, if the information being gathered is private or sensitive in nature, and if there is a risk to participants. The IRB may decide the study warrants expedited review.

C. Conditions of Approval

The IRB will approve projects for one year. After one year, investigators should request a continuation.

A continuation can be granted each year for three years, after which time the study must be resubmitted for re-approval, except when all data collection is completed and only data analysis is ongoing, in which case a continuation may be requested beyond the three year period.

For complex projects involving unusual levels of risk or for projects conducted by investigators with a history of non-compliance with IRB guidelines, the IRB may 1) require verification from sources other than the Principal Investigator that no material changes have occurred since the previous IRB review as part of each request for continuation, and/or 2) Additional reviews throughout the year.

Studies must meet the following criteria to be approved:

1. The study procedures do not expose participants to unnecessary risk and minimize risk. Whenever possible, the study utilizes procedures already in place as part of diagnostic or treatment purposes.
2. Risks of participation are reasonable in relation to anticipated benefits, and to knowledge gained as a result.
3. Participant selection is equitable and aligned with the study's purpose and setting.
4. The study obtains and documents informed consent in accordance with federal regulations.
5. When appropriate, research protocol includes a plan for monitoring data collection to ensure participant safety.
6. When appropriate, the research protocol describes a plan to protect participant privacy and confidentiality of the data.
7. When working with vulnerable populations (children, prisoners, pregnant women, people who are mentally disabled, and people who have economical or educational disadvantages) additional safeguards are included.

D. Additional Protections for Special Populations

Research with pregnant women, human fetuses, neonates of uncertain viability, or nonviable neonates, prisoners, and children warrants special considerations and protections described in subparts B, C and D, of CFR title 45 part 46. The IRB will only approve research with these special populations when the research protocol satisfies the conditions of all applicable sections in subparts B, C and D, of CFR title 45 part 46.

IRBs should identify and invite experts with specialized knowledge to assist in the review and deliberation of applications and research protocols for projects that involve issues that are beyond IRB's specific areas of expertise.

Additional protections are applicable to research involving pregnant women, human fetuses, neonates of uncertain viability, or nonviable neonates as described in CFR title 45 part 46 Subpart B (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartb).

Additional protections are applicable to research involving prisoners as described in CFR title 45 part 46 Subpart C (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartc).

Additional protections are applicable to research involving children as described in CFR title 45 part 46 Subpart D (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartd).

E. Investigator's Responsibilities

Investigators (and Faculty Sponsors when applicable) are responsible for conducting research with human subjects in compliance with federal laws and regulations described in CFR title 45 part 46, the institution's commitments and policies, and standards of professional conduct and practice. Investigators are responsible for following the IRB policies and procedures described in this document.

Investigators are expected to:

1. Submit applications, continuations and modifications as described in the IRB policies and procedures;
2. Report adverse events to IRB Chairperson and Primary Reviewer;
3. Retain copies of approved documents;
4. Retain signed consent forms for three years after project completion;
5. Retain data collected for three years after project completion, ensuring participant confidentiality.

F. Student Research

Student research projects that involve human subjects are subject to IRB review. All students must have a supervising faculty member who is ultimately responsible for compliance with human subject protections, referred to in this document as a Faculty Sponsor.

Instructors should decide whether planned activities constitute research. For example, an assignment to conduct a survey to better understand survey methodology may not be considered research. The instructor should consider whether the project fits the definition of research with human participants.

Senior thesis, capstone projects and independent research projects for academic credit or supported by internal or external funding should be submitted for review by the student to the supporting Faculty Sponsor. All students and faculty sponsors must have training in the protection of human subjects.

Complete student applications should be reviewed by the class instructor using a Class Research Project Evaluation Form. The form should be submitted by class instructors to the IRB on the students' behalf in one of the following ways:

1. If the project employs only one procedure, only one IRB application and Class Research Project Evaluation Form for the class is required (for example, the study involves only one instrument and one set of data collection procedures undertaken by all students). Faculty members may apply for approval prior to the start of the semester if the study procedures have been pre-established.
2. Students conducting investigations individually or in groups to meet class requirements will complete an IRB application and submit it to their instructor. The instructor will evaluate the application and submit a complete Class Research Project Evaluation Form to the IRB. The instructor will indicate on the form if the student' application is approved or not, or refer the project to the IRB for review. The instructor evaluating students' applications must have training in the protection of human subjects.

Instructors should submit the Class Research Project Evaluation Form, complete application and supporting materials to the IRB. The IRB will review the forms and confirm the instructor's determination within one week.

Student research is approved for one year. All data must be kept for three years after study closure, adhering to the standards of confidentiality outlined in the IRB application. After three years, data should be deleted in consultation with the Northland College I.T. department, if necessary, to ensure all electronic records are deleted. All hard copies of data files should be shredded. Graduating students should work closely with their Faculty Sponsor to follow these guidelines.

G. Submissions

Investigators conducting research with human subjects should complete an Application Form. The Application Form requires the following information:

1. Significance of the project
2. Population and sample to be included in the study
3. Sources of data and methodology
4. Measures to ensure the protection of data and confidentiality of participants
5. Risks and benefits of participation
6. Informed consent procedures

Complete submissions will include:

1. Complete Application Form. This includes a list of research personnel completing training and disclosing financial conflicts of interest.
2. Research instruments (e.g., surveys, interview guides, and focus group guides)
3. Consent forms
4. Recruitment materials

5. Other Institutions' IRB approvals (applicable only for studies taking place in another institution or country)
6. NIH Training Certificates (or equivalent human subjects protection training)
7. Research Conflict of Interest Disclosure Forms

Investigators must include steps to protect participants against the risks of participating in research, and minimizing risks as appropriate. Risks can be physical, psychological, social and legal. For health related research, investigators can apply for a Certificate of Confidentiality to protect research participants against legal risks. A Certificate of Confidentiality prevents investigators from having to release names or other identifying characteristics of research subjects in response to legal demands. For more information on Certificates of Confidentiality, see: http://grants.nih.gov/grants/policy/coc/index.htm.

H. Informed Consent

Informed consent is an integral part of the IRB application and ensures that all participants engage in the study by choice. Informed consent forms should contain simple language that matches the reading level of recruited participants, and should include:

1. A statement describing the research project, purposes and expected duration;
2. All procedures, including identification of experimental procedures;
3. Any foreseeable risks expected from the research;
4. Any benefits expected from the research;
5. A disclosure of alternatives to participation, alternative procedures or courses of treatment;
6. A statement describing how confidential data will be handled;
7. A description of compensation for participation;
8. An explanation of whom to contact about the research and participants' rights and whom to contact in the event of a research-related harm;
9. A statement that participation is voluntary, and that participants may refuse to participate, skip questions or withdraw without adverse consequences (i.e. no penalty, or loss of benefits).

The form should include contact information for the Principal Investigator and/or responsible faculty member, as well as the IRB contact information should participants have questions or concerns.

Investigators should obtain participant's signature on the informed consent, provide the participant with one copy and file one copy. A signature by at least one parent or legal guardian is required for any minors participating in research.

The following additional information should also be provided to subjects, where appropriate:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject;
6. The approximate number of subjects involved in the study.

Consent is waved for exempt status research studies – the IRB will make the determination of exempt status. Consent may also be modified or waived if the IRB determines that ALL of the following are true:

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 alteration

And, whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Informed consent will be documented by research staff trained in the protection of human subjects. The consent form may be either a written consent document with all the elements described above, or, a short form stating that the elements of consent described above were shared with the participant or their legal representative orally. When the short form is used, the IRB requires a witness to the oral presentation, and must approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds that either:

1. 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
2. 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.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide participants with a written statement about the study.

Investigators can apply for a waiver of consent or a waiver of signed consent if they believe their research project meets the above criteria.

I. Deception and Incomplete Disclosure

Investigators may plan to withhold information about the real purpose of their study or even deceive participants about some aspects of the study. In these types of studies, participants are unable to provide fully informed consent. The IRB will consider the following when reviewing deception or incomplete disclosure protocols:

1. IRBs will first decide whether the information to be withheld could influence the decision of prospective participants about participating in the research. Research should not be permitted if the subjects are not being informed of aspects they would consider material to a decision to participate.
2. If non-deceptive alternatives are available the research study will not be permitted.
3. IRBs will also apply the waiver of consent criteria:
   a) The research involves no more than minimal risk to the subjects and
   b) The waiver or alteration will not adversely affect the rights and welfare of the subjects and
   c) The research could not practicably be carried out without the waiver or alteration.

The IRB must also consider the appropriateness of debriefing participants after participation. Debriefing will be required if it contributes to the subject's welfare (e.g., corrects painful or stressful misperceptions, reduces pain, stress, or anxiety related to participation). The IRB should however take special care with cases where debriefing subjects might harm them in some way (e.g., participants' self-esteem, anxiety, guilt, hurt, etc.).

The terms "Informed Consent" or "Consent Form" should not be used in this type of study since they are not applicable.

J. Continuing Review and Study Closures

Investigators should apply for a continuation each year. Although it is the investigator's responsibility to apply for a renewal one year after approval, the Chairperson should keep an electronic record of each protocol and renewal due

dates, and support timely submissions of continuing research protocol applications. Continuation applications are due 30 days before the protocol expiration date.

The IRB Primary Reviewer will review the continuation application and approve or terminate approval in cases where the study has not been conducted in accordance with the approved protocol or has caused harm to participants.

To apply for continuation, investigators must complete an Annual Review Form, and provide the following information:

1. Number of participants completing procedures and drop outs
2. Explanation of recruitment or other deviations from protocol
3. Description of adverse events
4. Description of proposed modifications
5. List of new research personnel their training certificates and research conflict of interest disclosure forms
6. If modified, a revised protocol and study materials with changes indicated in bold

Investigators should apply for study closure after the study is concluded. A study may be closed when a) all interventions or interactions with participants are 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. If a study approval expires, the IRB will automatically assign a closed status to the study.

All data must be kept for three years after study closure, adhering to the standards of confidentiality outlined in the IRB application. After three years, data should be deleted in consultation with the Northland College I.T. department, if necessary, to ensure all electronic records are deleted. All hard copies of data files should be shredded. Graduating students should work closely with their Faculty Sponsor to follow these guidelines.

Principal Investigators will be notified of a decision within two weeks of submission if no modifications are proposed. For modification timeframes, consult *Modifications to Approved Protocols* section of this document.

For complex projects involving unusual levels of risk or for projects conducted by investigators with a history of non-compliance with IRB guidelines, the IRB may 1) require verification from sources other than the Principal Investigator that no material changes have occurred since the previous IRB review as part of each request for continuation, and/or 2) Additional reviews throughout the year.

K. Modifications to Approved Protocols

Modifications to an approved protocol can be requested in conjunction of a continuation request each year. If a modification is necessary before the continuation application is due, investigators can complete a request for modification form.

Minor modifications will be reviewed by the Primary Reviewer in consultation with another board member within two weeks of receipt (Expedited Review).

Major modifications will be submitted to the Primary Reviewer who will make a decision about the level of review necessary (Full, Expedited Review, Exempt) and inform the Chairperson if a full board review is recommended. Major modifications include changes to the research methods, population studied, risks, among others to be determined by the IRB.

Modification applications should be submitted along with a revised protocol and materials, with changes indicated in bold.

Changes in research personnel must be indicated in the application and training certificates and financial conflict of interest disclosures must be submitted with the application.

Principal Investigators will be notified of a decision within one week of review.

Modifications that are necessary to eliminate immediate hazards to participants are allowed without review, but must be reported to the IRB as described in the adverse events and unanticipated problems section.

L. Adverse Events and Unanticipated Problems

Unanticipated problems and adverse events must be reported to the IRB Chairperson and Primary Reviewer, funding agency or sponsors, and appropriate federal department or agency heads, including the Office for Human Research Protections as appropriate.

Reportable events are those that meet all of the following criteria: 1) are certainly or possibly related to participation in the study, 2) indicate the study poses an unanticipated risk of harm to people, and 3) is unexpected in terms of nature, severity or frequency given the research protocol and supporting documents, and the population studied.

After determining an event is reportable, investigators must also determine if it is an "Adverse Event" or "Unanticipated Problem."

> Adverse Events: There are two types of adverse events, serious and non-serious. Serious adverse events include those that are fatal or life threatening, disabling, leading to hospitalization, resulting in a congenital anomaly or requiring medical intervention. Serious adverse events must be reported to the IRB Chairperson and Primary Reviewer in writing within one week of the event. Adverse events that are related to participation that place participants at greater risk of physical or psychological harm than anticipated, but are not serious, should be reported within two weeks of the event.
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> Unanticipated problems: Unanticipated problems that do not constitute adverse events but meet the reportable events criteria should be reported within two weeks of the event. Unanticipated problems include, but are not limited to, protocol violations and deviations, new research that changes the risk assessment used to inform the study, breach of confidentiality, and participant complaints.

Investigators (and Faculty Sponsors, when applicable) must complete the Adverse Events/Unanticipated Problem Form, and submit it to the Primary Reviewer and the IRB Chairperson within the indicated timeframes described in this section.

External adverse events (for multicenter studies only, i.e. events experienced by subjects enrolled in other institutions) should be reported to and reviewed by the Investigator (or monitoring agency if applicable), and reported to the IRB within two weeks of receipt of the external Adverse Events/Unanticipated Problem report.

The IRB Chairperson and Primary Reviewer will review the report, confirm whether the event constitutes an adverse event or unanticipated problem, and report to the appropriate institutional officials (Northland College President, and the Dean of Faculty-VP of Academic Affairs), funding agency or sponsors, and appropriate federal department or agency heads, including the Office for Human Research Protections. The IRB will also determine if the protocol still satisfies ethical standards and re-assess risks to determine that risks are minimal and reasonable in relation to benefits to the participant or to general knowledge. If the IRB determines that the event/s warrant changes to or termination of the protocol, investigators will be notified in writing. If a modification is required, it should include a plan for corrective action.

M. Non-Compliance

Investigators are expected to follow the guidelines set forth in the Northland College IRB Policies and Procedures. Failure to comply with regulations can result in loss of funding and/or investigator's privilege to do the research. Serious or continuing non-compliance will result in the suspension or termination of previously granted IRB approvals, and will be reported to the appropriate institutional officials (Northland College President, and the Dean of Faculty-VP of Academic Affairs), funding agency or sponsors, and appropriate federal department or agency heads, including the Office for Human Research Protections.

Examples of non-compliance include:

1. Failure to obtain IRB approval or apply for continuations.
2. Failure to obtain approval for modifications.
3. Deviating from an approved protocol, including informed consent procedures, recruitment, research sites, etc.
4. Failure to file adverse event reports within the required timeframes.

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with its requirements, or that has resulted in unexpected serious harm to participants. The IRB will describe all actions taken and reasons in writing and report to the appropriate institutional officials (Northland College President, and the Dean of Faculty-VP of Academic Affairs), funding agency or sponsors, and appropriate federal department or agency heads, including the Office for Human Research Protections.

N. International Research and Research at Other Institutions

Investigators at Northland College conducting research that involves human subjects at another institution, national or international, must submit an IRB application with the Northland College IRB.

Research studies in foreign countries should follow IRB ethical standards and guidelines. Investigators are responsible for determining local practices, and adapting the protocol as needed. International studies must also be approved by a local institution or community leaders, and documentation should be submitted as part of the Northland College IRB application.

O. Training in the Protection of Human Subjects

Principal Investigators and all research personnel involved in the project, and all IRB members must complete training in the protection of human subjects with the National Institute of Health. Training modules can be accessed at https://phrp.nihtraining.com/users/login.php

Certificates of completion are a required part of the application process for all research staff involved in the study. Certificates must be submitted along with the application. The IRB may request renewal of certificates to ensure all individuals involved in research remain current on issues related to research ethics and the protection of human subjects.

The IRB may consider and accept other training in the protection of human subjects in lieu of the NIH training certificate. If using a different training, investigators must provide a certificate or a description of completed training.

P. Board Membership

In accordance with Federal Regulations [CFR title 45 part 46], the Northland College IRB has at least five members with diverse knowledge and experience to ensure adequate review of research activities. To the extent possible, Northland College promotes membership diversity with respect to race, gender, and cultural backgrounds. Members are sensitive to community attitudes, professionally competent in their respective fields, and have a basic understanding of research activities. Members are able to determine whether proposed studies are acceptable in terms of institutional commitments and regulations, applicable law and professional standards. The IRB includes at least one member whose primary concerns are in scientific areas, at least one member whose primary concerns are in nonscientific areas, and at least one member who is not otherwise affiliated with Northland College. Members of the IRB will complete training in the protection of human subjects with the National Institute of Health.

Proposed Northland College Membership List:

1. Community member (appointed by the Dean)
2. Dean's Representative (appointed by the Dean)
3. Institutional Research Office Representative (appointed by the Dean)
4. Research Centers Representative (appointed by the Dean)
5. Staff member (voted in)
6. Faculty member (voted in)

7. Faculty member (voted in)

All members serve three-year staggered and renewable terms. The Chairperson is elected by the members of the Board, serving a two-year renewable term as Chair.

A quorum will be a majority of the voting members of the IRB. For reasons other than conflict of interest, abstentions do not alter the quorum, or change the number of votes required.

IRB members' name, title, address, phone, and email contact information should be included on the Northland College website.

Q. Conflicts of Interest

Members of the IRB are responsible for disclosing conflicts of interest that would compromise the protection of research participants. Members must disclose any conflicts of interest in accordance with Northland College policies as well as at any time conflicts arise. Conflicts of interest must be reported for each protocol under review as indicated in the review document. Members disclosing conflicts of interest must be excused from deliberation of protocols in which they have an interest (i.e., they will not participate in deliberation or voting, but may be asked to provide information on the protocol).

Research personnel must also disclose conflicts of interest by completing a Research Financial Conflict of Interest Form and submit a signed form with an application. Any conflict of interest related to the research under IRB review must be disclosed in accordance with Northland College policies at the time of the initial protocol application, when continuing review or modifications are submitted, as well as at any time conflicts arise. The IRB Chair will keep copies of signed forms, monitor due dates, and support timely submission of signed forms.

If there is a conflict of interest, the IRB will determine the need for a management plan, considering the following:

1. Do the risks associated with the interest outweigh benefits?
2. Does the interest make participant selection unequitable or biased?
3. Should the conflict of interest be disclosed in the consent process?

If a management plan is needed, it can 1) limit the researcher's role in the study (recruitment or obtaining consent, data collection or analysis), 2) assign a monitor to observe the consent process, and/or data management, and 3) eliminate or minimize the interest, and 4) disclose the interest in the consent form.

If a management plan is deemed unnecessary, the IRB may still require disclosure of interest in the consent form.

R. Data Safety Monitoring for Clinical Trials

For clinical trials, including medical or behavioral interventions, IRBs must determine whether special data and safety monitoring is needed and if so, whether the research protocol makes adequate provision for monitoring the data collected to ensure the safety of participants.

Clinical trials involving more than minimal risk to subjects should include a data and safety monitoring plan (DSMPs). DSMPs may vary depending on the nature, size, and complexity of the protocol, expected risks of the research, and population studied. If the study is small in scope, the principal investigator (PI) or a group of investigators could perform the monitoring functions. However, larger, complex studies may require monitoring by a formal Data and Safety Monitoring Board (DSMB).

DSMPs should include:

1. A description of the type of data or events to be captured under the plan;
2. The name(s) and role(s) of the person(s) responsible for monitoring the data collected (i.e. study accruals, protocol deviations, protocol violations, unanticipated problems, adverse events);
3. The frequency or criteria (e.g. number of participants enrolled) of monitoring;

4. The time frame for reporting unanticipated problems, adverse events, protocol deviations, and protocol violations (at a minimum what is required for all studies in the *Adverse Events and Unanticipated Problems* section of this document);
5. If appropriate, description of events that will trigger action like suspension or termination;
6. Procedures and time frames for communicating outcomes of monitoring reviews to other sites, the IRB, study sponsor and/or indicated organizations;
7. Plans to monitor adherence to the IRB-approved protocol and assure the validity and integrity of collected data.

A DSMB may be necessary for large studies where risk may be better assessed through statistical comparisons of treatment groups, including controlled trials with mortality or major morbidity as a primary or secondary endpoint; blinded study treatment groups where the validity and integrity of the study may be adversely affected by having a break in the blind by an individual or group associated with the study; studies that utilize an external monitoring agency responsible for reporting adverse events, and high risk interventions.