OHIO NORTHERN UNIVERSITY
INSTITUTIONAL REVIEW BOARD
POLICY FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

I. Introduction

Ohio Northern University, recognizing its responsibility to provide measures to reasonably protect individuals involved as subjects of research conducted under the auspices of the university, requires that all research projects involving human subjects be reviewed by the Institutional Review Board (IRB). This review must be completed prior to the initiation of the research.

II. Policy

1. Rationale

   University policy entrusts the investigator with primary responsibility for the protection of individuals participating as human subjects. The university assumes its responsibility for meeting the conditions for the protection of human subjects as required by the National Research Act, Public Law 93-348 and implemented by the Department of Health and Human Services (Title 45 CFR 46, Protection of Human Subjects, as amended) and by other federal agencies with appropriate jurisdiction. In assuming its responsibility, the university intends to encourage the conduct of research which will benefit the human condition and, at the same time, protect the rights and welfare of human subjects participating in the research, the investigators doing the research and the university. University faculty, staff, and students conducting human subject research under this policy are responsible for compliance with all federal regulations.

2. Administration

   Executive functions to be performed by the university include the development of policy; the continuing education of personnel with respect to policy; the modification of this policy to maintain its conformity with laws and regulations; and providing appropriate administrative support and legal assistance for the Institutional Review Board. The university official responsible for carrying out or delegating these functions is the Vice President for Academic Affairs.

3. Applicability

   This policy is applicable to all research involving human subjects which is conducted under the auspices of the university.

III. Definitions of Terms and Phrases

1. “Human Subject”: means a living individual about whom an investigator (whether an employee of the university or a student) conducting research obtains: data, either through intervention or interaction with the individual, or identifiable private information.

   1.1 “Intervention”: includes both physical procedures by which data are gathered and manipulations of the subject or the subject’s environment that are performed for research purposes.
1.2 "Interaction": includes communication or interpersonal contact between investigator and subject.

1.3 "Private Information": includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Private information must be individually identifiable to an investigator through name or code in order for obtaining that information to constitute research involving human subjects.

2. "Legally Authorized Representative": means an individual, judicial, or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedures involved in the research.

3. "Minimal Risk": means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

4. "Research": means a systematic investigation designed to develop or contribute to generalizable knowledge.

5. "Research Involving Human Subjects Under the Auspices of the University": means for purposes of this policy, research involving human subjects shall be “under the auspices of the university” when:

5.1 The research is funded externally by way of grant, contract or similar agreement between the sponsor (public or private) and the university;

5.2 The research is funded internally by the university by way of grant, contract, or similar agreement;

5.3 The research is conducted upon assignment by the university; or

5.4 The research is actively assisted by the use of university facilities, resources, supplies, equipment, or personnel

6. "Consent to Participate in Research":

6.1 General Requirement

Except as otherwise permitted by this policy (See Section IV-4,3), no investigator may involve a human subject in research covered by this policy unless the investigator has obtained the informed consent of the subject or the subject’s legally authorized representative. The prospective subject or representative must have sufficient opportunity to consider whether or not to participate and there must be a minimal possibility of coercion or undue influence. The information that is given to the subject or representative shall be in language understandable to the subject or representative. No consent,
whether oral or written, may include any exculpatory language through which the subject or representative is made to waive or to appear to waive any of the subject’s legal rights, or to release the investigator, the sponsor, the university, or its agents from liability for negligence.

6.2 Elements of Consent

6.2.1 Except as provided in Section 111-6.4 of this policy and in the Federal Regulations 45 CFR 46.116, the following basic elements of information shall be provided to the subject:

6.2.1.1 A statement that the study involves research, a fair explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed and identification of any procedures which are experimental;

6.2.1.2 A description of any reasonably foreseeable discomforts and risks to the subject;

6.2.1.3 A description of any benefits to the subjects or to others which reasonably may be expected as a result of doing the study;

6.2.1.4 A disclosure of any appropriate alternative procedures or course of treatment which might be advantageous for the subject;

6.2.1.5 A statement describing the extent to which confidentiality of records identifying the subject will be maintained;

6.2.1.6 For research involving more than minimal risk, an explanation as to whether any compensation and/or any medical treatments are available if injury occurs, and if so, what they consist of, or where further information may be obtained. This information must be in the exact wording approved in advance by the Vice President for Academic Affairs, or his or her designee.

6.2.1.7 An explanation of whom to contact for answers to pertinent questions about the research, procedures and research subject’s rights, and whom to contact in the event of a research-related injury; and

6.2.1.8 A statement that participation is voluntary and that the subject is free to withdraw his or her consent and to discontinue participation in the project at any time without penalty or loss of benefits.

6.2.2 When determined to be appropriate by the investigator or the Institutional Review Board, one or more of the following optional
elements of information shall also be provided to the subject:

6.2.2.1 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;

6.2.2.2 Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent;

6.2.2.3 Any additional costs to the subject that may result from participation in the research;

6.2.2.4 The consequences of a subject’s decision to withdraw from the research, and procedures for orderly termination of participation by the subject;

6.2.2.5 A statement that the research will communicate to the subject significant new findings developed during the course of research which may affect the subject’s willingness to continue participation; and

6.2.2.6 The approximate number of subjects involved in the study.

6.3 Documentation of Informed Consent

Except as provided below, consent shall be documented by use of a written consent form approved by the Institutional Review Board and conforming to the then current requirements of the United States Department of Health and Human Services. The consent form shall be signed by the subject or the subject’s legally authorized representative and a copy shall be given to the person signing the form.

Since the original document is a university record, it is to be kept in a secure department or unit file. Copies of the proposed consent form shall accompany the protocol submitted by the investigator to the Institutional Review Board.

The principal investigator must be properly identified with a signature and the consent form must include the investigator’s name, affiliation with the university and with a department or unit of Ohio Northern University.

Except as provided below, the consent form may be either of the following as determined by the Institutional Review Board:

6.3.1 A written consent document that embodies the elements of informed consent in accordance with the provisions of Section III-6. This document may be read to the subject or his or her legally authorized representative, but in any event, the investigator shall give either the subject or his or her representative adequate opportunity to read it before it is signed. This
document shall be signed by the subject or his or her legally authorized representative; or

6.32 A “short form” written consent document stating that the elements of informed consent have been presented orally to the subject or the subject’s legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the Institutional Review Board shall 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. Copies of the summary and short form shall be given to the subject or the representative.

6.4 Waiver or Alteration of Consent Elements: Waiver of Consent

The Institutional Review Board may approve a consent procedure which waives or alters some or all of the above elements of consent provided the Institutional Review Board finds and documents any of the following:

6.4.1 The research is to be conducted for the purpose of demonstrating or evaluating:

6.4.1.1 Federal, state, or local benefit or service programs which are not themselves research programs;

6.4.1.2 Procedures for obtaining benefits or services under these programs; or

6.4.1.3 Possible changes in or alternatives to these programs or procedures; and, the research could not practicably be carried out without the waiver or alteration;

6.4.2 The only record linking the subject and the research would be the consent document and the principal risk would be the potential harm resulting from a breach of confidentiality. Each subject shall be asked whether he or she wants documentation linking himself or herself with the research and the subject’s wishes will govern; or

6.4.3 The research involves no more than minimal risk to the subjects; involves no procedures for which written consent is normally required outside the research context; the waiver or alteration will not adversely affect the rights and welfare of the subjects; the research could not practicably be carried out without waiver or alteration and, wherever appropriate, the subjects will be provided with additional pertinent information after participation.

When, for purposes of meeting the objectives of research, any degree of deception of subjects exists, the Institutional Review Board will ensure that all subjects shall have the right to withdraw their data after debriefing.
IV. Institutional Review Board

1. General
   The Institutional Review Board is responsible for the review and approval or modifications for approval or disapproval of all research subject to this policy. In applying for approval of their projects, investigators’ written protocols must be presented to the Institutional Review Board; the format for the protocols will be supplied by the Institutional Review Board.

2. Membership
   The Institutional Review Board shall be composed of six individuals, including five faculty or professional staff and one member who is not otherwise affiliated with the university and who is not part of the immediate family of a person affiliated with the university. The Institutional Review Board shall include at least one member whose primary concerns are in a non-scientific area and at least one member whose primary concerns are in a scientific area.

   Members shall have varying backgrounds to promote complete and adequate review of research activities commonly conducted under the auspices of the university. The Institutional Review Board shall be sufficiently qualified through the experience and expertise of its members and the diversity of the members’ backgrounds (including consideration of their sex, race, culture, and sensitivity to such issues as community attitudes) to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the Institutional Review Board shall be able to ascertain the acceptability of proposed research in terms of university commitments and regulations, applicable law and standards of professional conduct and practice. The Institutional Review Board shall, therefore, include persons knowledgeable in these areas.

   The Chair will vote only in the case of a tie vote.

   All members will be appointed by the President of the university for terms of no more than three (3) years. Membership of the Institutional Review Board shall be staggered so that the terms of no more than two members will expire in any given year. Members may be reappointed for no more than one additional consecutive term. In addition, the President will appoint one or more alternate members.

   No member who has a conflicting interest in particular research may participate in the Institutional Review Board’s initial or continuing review of that research except to provide information requested by the Institutional Review Board.

   The Institutional Review Board, at its discretion, may invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond, or in addition to that available on the Institutional Review Board. These individuals may not vote with the Institutional Review Board. If the individual is not an employee of the university; such an invitation may be extended only with the approval of the Vice President for Academic Affairs, or her or his designee.

2.1 Procedures for Appointment of Board Members
The procedures for the selection, nomination, and appointment of members shall be:

2.1 The Institutional Review Board members will recommend one or more potential nominee(s) for each vacancy. These names will be forwarded in writing by the Chair to the Vice President for Academic Affairs no later than February 15;

2.1.2 The Vice President for Academic Affairs will forward her or his recommendations to the President of the university for appointment no later than March 15.

2.2 Officers of the Institutional Review Board and Elections

2.2.1 The officers of the Institutional Review Board shall consist of a Chair and a Secretary.

2.2.2 Members of the Institutional Review Board will elect a Chair and Secretary no later than April 15 of the year preceding the beginning of their term (July 1 to June 30).

3. Responsibilities and Functions of the Institutional Review Board

3.1 The Institutional Review Board shall develop and follow written procedures for:

3.1.1 Conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the university;

3.1.2 Determining which projects require review more often than annually and which projects need verification, from sources other than the investigators, that no material changes have occurred since previous Institutional Review Board review.

3.1.3 Assuring prompt reporting to the Institutional Review Board of proposed changes in research activity;

3.1.4 Assuring that changes in proposed research, during the period for which approval has been given, may not be initiated without Institutional Review Board review and approval except where necessary to eliminate apparent immediate hazards to the subjects;

3.1.5 Assuring prompt reporting to the Institutional Review Board of unanticipated problems involving risks to subjects or others; and

3.1.6 Assuring compliance with then current protections for vulnerable categories of subjects (e.g., Children, 45 CFR, Part 46, Subpart D).
3.2 Functions of the Institutional Review Board

3.2.1 Be responsible for the Full, Expedited, or Exempt Review (See Section IV-4) of proposed research protocols involving human subjects, according to this policy. In order for the research protocol to be approved, it shall receive the approval of a majority of those members reviewing the protocol.

3.2.2 Review and have authority to approve, require modifications in, or disapprove all research covered by this policy.

3.2.3 Require that information given to subjects as part of consent is in accordance with this policy and applicable law. The Institutional Review Board may require that information, in addition to that specifically mentioned in Section 111-6 of this policy, be given to subjects when in the Institutional Review Board’s judgment the information would meaningfully add to the protection of the rights and welfare of the subjects.

3.2.4 Require documentation of informed consent or waive documentation in accordance with this policy.

3.2.5 Notify investigators and the Vice President for Academic Affairs, or her or his designee, in writing of its decision to approve or disapprove the proposed research, or of modifications required to secure Institutional Review Board approval. If the Institutional Review Board decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

3.2.6 Be responsible for reporting to the Vice President for Academic Affairs; or her or his designee, and to any appropriate government agency, any serious or continuing non-compliance by investigators with the requirements and determinations of the Institutional Review Board.

3.2.7 Conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

4. Types of Research Reviews by the Institutional Review Board

There are three types of review of proposed research protocols which investigators can submit to the Institutional Review Board: 1) Full Review which requires review by the Institutional Review Board at a convened meeting, 2) Expedited Review where the review is conducted by a Subcommittee of the Institutional Review Board, and 3) Exempt Review where the investigator submits a modified protocol under the exempt category which is then treated as an expedited review.

4.1 Full Review

Any member of the Institutional Review Board may request a Full Review of
a research protocol. The review must be conducted by a majority of the members present at a convened meeting. Research protocols or activities may be disapproved only after a Full Review.

4.2 Expedited Review

The Institutional Review Board may permit expedited review for:

4.2.1 Some or all of the categories of research then currently established by federal regulations as being eligible for an expedited review procedure if the research involves no more than minimal risk (e.g., 45 CFR 46, Subpart A. 46.110);

4.2.2 Minor changes in previously approved research during the period for which approval is authorized; or

4.2.3 Determination of whether research involving human subjects is exempt from this policy.

Under the Expedited Review procedure, the review may be carried out by the Institutional Review Board Chair, Secretary, and a rotating regular member(s) who will comprise a Subcommittee of the Institutional Review Board.

The reviewer(s) of the Subcommittee may exercise all of the authorities of the Institutional Review Board except they may not disapprove the research.

The Institutional Review Board shall adopt a method for keeping all members advised of research protocols which are pending, have been approved, or determined to be exempt under this expedited procedure.

4.3 Exempt Review

An investigator may submit a research protocol to the Institutional Review Board for Exempt Review if the research involving human subjects will be in one or more of the following exempt categories:

4.3.1 Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as

4.3.1.1 Research on regular and special education instructional strategies; or

4.3.1.2 Research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.

4.3.2 Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
4.3.3  Research involving survey or interview procedures, except where all of the following conditions exist:

4.3.3.1 Responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects;

4.3.3.2 Responses that, if they became known outside the research, could reasonably place the subject or respondent at risk of criminal or civil liability or be damaging to the subject’s financial standing or employability; and

4.3.3.3 The research deals with sensitive aspects of the subject’s own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.

All research involving survey or interview procedures is considered “exempt” when the respondents are elected or appointed public officials or candidates for public office.

4.3.4 Research involving the observation (including observation by participants) of public behavior, except where all of the conditions listed under IV-4.33 above exist.

4.3.5 Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

4.3.6 Any other category specifically added to this list by the Department of Health and Human Services and published in the Federal Register.

Except as may be provided by law (e.g., research funded by the United States Department of Health and Human Services), the Institutional Review Board has final authority to determine whether particular research is subject to this policy or exempt under one of the categories stated above. An investigator who believes his or her research is exempt under one of the stated categories shall submit his or her written protocol to the Institutional Review Board together with a statement that he or she believes it to be exempt and the reasons for his or her belief; the format of the protocol will be supplied by the Institutional Review Board. The determination of exempt status shall be made by means of the expedited review set forth in Section IV-4.2 of this policy.

5. **Criteria for Approval of Research**
In order to approve research covered by this policy, the Institutional Review Board shall determine that all of the following requirements are satisfied:
5.1 Risks to subjects are minimized: 1) by using procedures which have sound research design and which do not unnecessarily expose subjects to risk, and 2) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes;

5.2 Risks to subjects are reasonable in relation to anticipated benefits (e.g., importance of the knowledge that may result);

5.3 Selection of subjects is equitable. In making this assessment the Institutional Review Board should take into account the purposes of the research and the setting in which the research will be conducted;

5.4 Informed consent will be sought from each prospective subject or the subject’s legally authorized representative, in accordance with, and to the extent required by this policy;

5.5 Informed consent will be appropriately documented, in accordance with, and to the extent required by this policy;

5.6 Where appropriate, the research plan makes adequate provision for monitoring the data collected to insure the safety of subjects;

5.7 Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data;

5.8 Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate additional safeguards have been included in the study to protect the rights and welfare of these subjects;

5.9 If the research involves the fetus, pregnant women, in vitro fertilization, abortoses, prisoners or other special classes of subjects which may be in the future identified by federal regulations, the Institutional Review Board’s review shall be in accordance with any such regulations and shall determine that the requirements of any such regulations have been met (e.g., 45 CFR 46 Subpart D, Additional Protections for Children as Subjects in Research).

6. Suspension or Termination of Approval
The Institutional Review Board shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the Institutional Review Board’s requirements or that has been associated with unexpected, serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the Institutional Review Board’s action and shall be reported promptly to the investigator, and Vice President for Academic Affairs, or her or his designee, and if the research is externally funded, to the sponsor.

7. The Institutional Review Board shall prepare and maintain documentation of its activities, including the following:
7.1 Copies of all research protocols reviewed, scientific evaluations, if any, that accompany the protocols, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects;

7.2 Minutes of Institutional Review Board meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the Institutional Review Board; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution;

7.3 Records of continuing review activities;

7.4 Copies of all correspondence between the Institutional Review Board and the investigators;

7.5 A list of Institutional Review Board members as required by the United States Department of Health and Human Services;

7.6 Written procedures for the Institutional Review Board as required by paragraph 71V-3. 1 of this policy;

7.7 Statements of significant new findings provided to subjects, as required by Section 111-6 of this policy.

The records required by this policy shall be retained in the Office of the Vice President for Academic Affairs for at least six years after completion of the research.

8. Role of University Officials
Institutional Review Board approvals, actions, and recommendations are subject to review and to disapproval or further restrictions by the Vice President for Academic Affairs, or his or her designee. Such disapprovals or further restrictions shall then be returned to the Institutional Review Board for consultation among the Institutional Review Board, the investigator and Vice President for Academic Affairs, or her or his designee. However, Institutional Review Board disapprovals, restrictions or conditions cannot be rescinded or removed except by further action of the Institutional Review Board or in the case of federally funded research, by appeal to the Department of Health and Human Services or other federal agency with appropriate jurisdiction.

V. Cooperative Research
In the event of research in which the university and another institution(s) or party cooperate in the conduct of some or all of the research, the investigator shall comply with this policy. To avoid duplications of effort, the Institutional Review Board with the concurrence of the Vice President for Academic Affairs, or her or his designee, may use joint review, or reliance upon the review of another qualified Institutional Review Board.

VI. Interpretation
The provisions of the policy shall be interpreted in all respects to be consistent with the provisions of any law applicable to the research involved; in the event there should be any conflict or difference between this policy and the provisions of applicable law, the provisions of the applicable law shall control.

Because the provisions of this policy establish a high quality and standard of review for research involving human subjects, no provision of the policy shall be interpreted as establishing a minimum standard for safety, protection or due care which legally may be owed by an investigator, a member of the Institutional Review Board, the university or any university employee or agent, to a human subject.

Nothing in this policy prevents prior review by any subunit of the university of research proposals originating within that subunit, or proposing research to be conducted within that subunit. If approved by the subunit, such proposals must be forwarded to the Institutional Review Board for review. However, as provided in the last paragraph of Section IV-4.3 of this policy, the Institutional Review Board has final authority to determine whether particular research is subject to this policy and to approve, require modifications for approval or disapprove it.