Academic Affairs Policy

Volume: A2. Academics Chapter 05: Research	A2.05.2 Use of Human Subjects in Research Effective Date: mm/dd/yy Currently Under Review	Responsible Office: Academic Affairs Responsible Officer: Provost and Vice President for Academic Affairs

POLICY STATEMENT

The purpose of this policy is to outline Northeastern Illinois University's commitment to protecting human subjects in research studies and guaranteeing the authority and independence of the Institutional Review Board (IRB). It further describes the roles, responsibilities, and appointment of IRB members, and outlines the activities subject to IRB jurisdiction and review.

PURPOSE OF THE POLICY

Northeastern Illinois University ("The University") seeks to adequately protect every person who may be involved in research and training projects as part of its commitment to the pursuit of excellence in teaching, research, and public service. The University is guided by the ethical principles regarding research involving humans as subjects as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the Belmont Report). These ethical principles are: 1. Respect for Persons: Recognition of the personal dignity and autonomy of individuals and special protection of those persons with diminished autonomy; 2. Beneficence: Obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risk of harm; and 3. Justice: Fairness in the distribution of research benefits and burdens.

The University will maintain a Federal wide Assurance (FWA) on file with the federal Office for Human Research Protection (OHRP). The University assures protections for human subjects, regardless of funding source and whether the research is subject to U.S. Federal Policy for the Protection of Human Subjects (also known as the Common Rule), and gives further assurance that it will comply with the Department of Health and Human Services (DHHS) regulations for the protection of human subjects (45 Code of Federal Regulations 46) and relevant FDA regulations. The University will further comply with the policies set forth in 45 CFR 46 which provide additional protection pertaining to: 1) research, development, and related activities involving human subject fetuses, pregnant women, and in-vitro fertilization of human ova; 2) prisoners involved in research; 3) research that involves children, individuals with diminished decision-making capacity and other vulnerable groups; and 4) cooperative research projects.

The University has established and will maintain an Institutional Review Board. The IRB has the responsibility and authority to review, approve, disapprove or require changes in research activities involving human subjects. The IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's decisions, conditions, and requirements, or

research that has been associated with unexpected serious harm to subjects. The authority is absolute; however, any investigator receiving an adverse ruling shall have the right of reconsideration. A second adverse ruling will be final.

It is always the responsibility of the investigator to obtain clearance from the IRB prior to the initiation of any research activity involving the use of human subjects. Failure to do so may result in personal restrictions on the research activities of such individual, as well as potentially endanger all federal funding to the University.

All research involving human subjects must be reviewed by the IRB. The IRB has the authority to determine whether or not a research project requires IRB review; the investigator does not have this authority. Unless the IRB specifically identifies research as exempted by 45 CFR 46, all research involving human subjects will be reviewed and approved by an established Institutional Review Board.

The following principles are affirmed and apply to human subjects research, regardless of the status of the researcher, wherein any property or facility of this institution is utilized. (Property is interpreted to include any University non-public information whether this information is utilized in and of itself or is utilized for contacting subjects or prospective subjects.)

1. Since the participation of humans in research may raise fundamental ethical questions, no distinctions in the monitoring of projects will be drawn between funded and unfunded projects, sponsored and unsponsored projects, or between projects carried out by students, faculty, or other University employees, on-campus or off-campus, in the United States or overseas.

2. All activities involving humans as subjects must provide for the safety, health and welfare of every individual. Rights, including the right of privacy, must not be infringed.

3. The direct or potential benefits to the subject, or the importance of the knowledge to be gained, must outweigh the inherent risks to the individual.

4. Participation in projects must be voluntary and informed consent must be obtained from all subjects, unless this requirement is specifically waived by the IRB. Methods that are in accordance with the requirements of 45 CFR 46.116 and 45 CFR 46.117 and are adequate and appropriate to the risks of the project must be used to obtain the subject's informed consent.

5. Consent should be obtained from the participants themselves. If a subject is not legally or physically capable of giving informed consent, a legally authorized representative may do so. Careful consideration shall be given to the representative's depth of interest and concern with the subject's rights and welfare. Children, for example, may not be exposed to risk except for the child's benefit.

6. An individual does not abdicate any rights by consenting to be a research subject. A subject has the right to withdraw from a research project at any time or can refuse to participate without loss of benefits to which the subject would otherwise be entitled. Further, a subject has the right to receive appropriate professional care, to enjoy privacy and confidentiality in the use of personal information and to be free from undue embarrassment, discomfort, anxiety, and harassment.

7. Safeguarding information about an individual that has been obtained in the course of an investigation is a primary obligation of the investigator. Such information shall not be communicated to others unless the following conditions are met:

a. Explicit permission for the release of identifying data is given by the individual.

b. Information about individuals may be discussed only for professional purposes and only with persons clearly concerned with the project. Written and oral reports should present only data germane to the purposes of the project, and every effort should be made to avoid invasion of privacy.

c. Provisions must also be made for the maintenance of confidentiality in the preservation and ultimate disposition of any data collected. Adequate security measures must be described to the IRB and carried out by the principal investigator until the records are destroyed. Records which contain personal information shall be destroyed as soon as possible in keeping with the long-range goals of the project and records retention requirements.

8. Projects will be given initial and continuing review by the IRB. Projects shall have appropriate administrative overview carried out at least annually to insure that the procedures designed for the protection of the rights and welfare of human subjects are being effectively applied and are in compliance with the requirements of 45 CFR 46.

9. No individual involved in the conduct and/or supervision of a specific project shall participate in IRB review, except to provide information.

10. In all cases, the investigator should show practical regard for the Northeastern Illinois University community, recognizing that violations of the ethical and legal standards incorporated in this statement of principles could impugn the investigator's own name and the reputation of the University (e.g., concerning confidentiality, informed consent, debriefing, and regard for the health, safety, and welfare of all human subjects). The investigator does not abdicate ethical and legal responsibility merely by complying with this protocol.

After protocol approval, research investigators are responsible for complying with all IRB decisions, conditions, and requirements. Research investigators, department chairs, and any other employee directly knowledgeable of the research activities are encouraged to report to the IRB any noncompliance with the requirements of the NEIU policy on the use of human subjects in research or the determinations of the IRB. Anonymous and confidential reports will be appropriately investigated.

WHO IS AFFECTED BY THIS POLICY

All University employees and students who intend to conduct research involving human subjects, and all outside researchers who intend to conduct human subjects research on University property or involving University employees or students.

DEFINITIONS

ABBREVIATIONS:

CFR	Code of Federal Regulations
DHHS	Department of Health and Human Services
OHRP	Office for Human Research Protections
FWA	Federalwide Assurance
IRB	Institutional Review Board
NEIU	Northeastern Illinois University

- **Certification** means the official notification by the institution to the supporting Federal department or agency component, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

- **Human subject** means a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and, uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

- **Institution** means any public or private entity, or department or agency (including federal, state, and other agencies).

- Institutional Official means a high-level official within NEIU's administrative team who has the authority to represent the institution named on a Federal wide Assurance (FWA), as well as the institutional components listed in the FWA. The individual should be at a level of responsibility that would allow authorization of necessary administrative or legal action should that be required.

- **IRB** means an institutional review board established in accord with and for the purposes expressed in this policy.

- **IRB approval** means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

- **Minimal risk** means that 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.

- **Research** means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes.

- **Written, or in writing,** for purposes of this part, refers to writing on a tangible medium (e.g., paper) or in an electronic format.

PROCEDURES

1. IRB OFFICE OF RECORD AND IRB STAFF

The College of Graduate Studies and Research will serve as the Office of Record for the IRB. The IRB support staff is responsible for assisting researchers in the application process, facilitating review of submitted applications, preparing IRB meetings, documenting meeting minutes, assisting with IRB policy development, planning and conducting campus wide educational events and performing other tasks in support of the IRB operations.

The IRB staff member shall:

1. Receive all protocols, review for completeness and conformity to IRB requirements and forward to the IRB Chairperson;

2. Prepare and maintain adequate documentation of IRB activities, maintain records three to five years or as required by regulations, and have records accessible for inspection by DHHS authorized representatives when requested;

3. Notify research investigators in writing of the IRB's decisions, conditions, requirements;

4. Report information as appropriate to research investigators and other University personnel on issues dealing with changes in regulations and new requirements;

5. Establish and maintain written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, the head of any U.S. federal department or agency conducting or supporting the research, and OHRP of any (a) unanticipated problems involving risk to subjects or others; (b)

serious or continuing noncompliance with the applicable U.S. federal regulations or the requirements of determinations of the IRB; and (c) suspension or termination of IRB approval.

2. IRB MEMBERSHIP

The IRB shall be sufficiently qualified through the experience, expertise, and the diversity of the members, including consideration of race, gender, and cultural backgrounds 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 IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or persons with physical and/or mental disabilities, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

The IRB shall include:

- at least one member whose primary concerns are in scientific areas;
- at least one member whose primary concerns are in nonscientific areas;
- at least one member who is not otherwise affiliated with the University and who is not part of the immediate family of a person who is affiliated with the University.

No member of the IRB may participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

Total membership must encompass at least five members. Members shall be selected according to the University's research needs. The five members may not consist entirely of women or men or entirely of members of one profession. The university shall provide the Board with access to legal counsel as needed.

The Board may, at its discretion, invite individuals who have competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the Board. These individuals shall not have voting rights and shall receive copies of research protocols prior to the meeting of review.

Candidates for IRB membership may be nominated by the IRB Chair, the Deans, IRB staff, faculty, or academic departments. They may also be self-nominated. Unaffiliated members are identified by interest and relevance, and are recommended for appointment by members of the IRB, IRB staff, Deans, faculty, and academic departments.

The formal appointment of IRB members is made by the Institutional Official. The Dean of the College of Graduate Studies and Research, with input from the various university constituencies, will choose and forward nominees to the Institutional Official for any additional review and formal appointment.

3. IRB REVIEW AND CRITERIA FOR APPROVAL

In order to approve research the IRB shall determine that all of the following requirements are satisfied:

1. The selection of subjects is equitable and follow ethical guidelines. In making this assessment the IRB shall take into account the purposes of the research, the method of recruitment and data collection, the setting in which the research will be conducted, and the population from which the subjects will be recruited.

2. The rights and welfare of the subjects will be adequately protected. Each project shall be reviewed with the interests of the subjects foremost in consideration. No procedures shall be followed that would result in unnecessary or unacceptable risks to the subjects. Appropriate safeguards and emergency measures must be provided. The IRB is concerned with the protection of anonymity and confidentiality of all data collected. Furthermore, the IRB shall attempt to minimize personal embarrassment, mental anguish, and questions of conscience resulting from participation in a study. In short, the IRB shall make every effort to ascertain that both the mental and physical well-being of the subjects are adequately protected.

3. The risks to the subjects are reasonable in relation to anticipated benefits. The project protocol will be evaluated to determine if the risks to subjects are reasonable in relation to the anticipated benefits, if any, to the subject and the importance of the knowledge that may reasonably be expected to result. The IRB expects that human subjects will not be utilized in projects which are poorly designed. However, the responsibility for monitoring research design quality lies primarily with the appropriate college dean, department chair, director, principal investigator or faculty sponsor.

4. The informed consent of subjects will be obtained by adequate and appropriate methods. All subjects will be fully informed by the investigator of the procedures to be followed, including discomforts, risks, and possible benefits. Risks must be well defined in terms understandable by the subjects. Informed consent must be obtained from all subjects, unless specifically waived by the IRB in accordance with 45 CFR 46.117 (c) (1) or (2).

An exempt or expedited review procedure is possible for those applications which involve no more than minimal risk to subjects and either fall under one of the research categories eligible for expedited review or fall under the categories exempted by federal regulations. Final determination as to whether a specific project is exempt from IRB review or is eligible for expedited review can only be made by the IRB Chairperson or by one or more of the experienced IRB members designated by the Chairperson. For information as to whether or not a given research project falls under either of these category definitions contact the IRB staff member.

An expedited review procedure is also possible for minor changes in previously approved research during the period for which approval is authorized.

The IRB shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB'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 IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.

The IRB does not have the authority to take disciplinary action against any individual relating to noncompliance. Findings of noncompliance will be referred to appropriate administrative units.

Research that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

A certification of IRB approval, if required by an external funding agency or if requested by the investigator, shall be made in the form required by the agency and, as applicable, either submitted to the agency or returned to the investigator.

AUTHOR REFERENCE

Approved by the NEIU IRB on 11/30/2018

Administrative Memorandum No 66-A (9/15/99)

HISTORY

Administrative Memorandum No 66-A (9/15/99)

RELATED POLICIES AND OTHER INFORMATIONAL MATERIAL

45 CFR 46
21 CFR 50
IRB SOPs https://www.neiu.edu/academics/research/institutional-review-board

CONTACT INFORMATION

Please direct questions or concerns about this policy to:

Contact	Phone	Email
CGSR	(773) 442-4675	irb@neiu.edu

Academic Affairs Policy

DISCLAIMER

The University reserves the right to modify or amend sections of this policy at any time at its sole discretion. This policy remains in effect until such time as the Responsible Officer calls for review. Requests for exception to any portion of this policy, but not to the policy statement, must be presented in writing to the Responsible Officer.