NKU Institutional Review Board

IRB Internal Policy Title	IRB Overall Policy		
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A. General

The Northern Kentucky University Institutional Review Board (IRB) for the Protection of Human Subjects is appointed by the President, who has administrative responsibility for safeguarding the rights and welfare of human subjects involved in research. The board consists of at least five members with varying academic backgrounds and at least one who is not an employee or agent of the university. Membership of the board will be reviewed annually by the University Office of Research, Grants and Contracts (RGC), who will report any changes to the United States Secretary of Health and Human Services. Committee members with other than ex officio status normally shall have staggered three year appointments.

University policies and federal regulations regarding research with human subjects are implemented by the board and the RGC, which serves as the administrative arm to the board and the Provost.

The protection of human subjects from unnecessary risks can be achieved when the following conditions are met: the human subjects' participation is voluntary as reflected on the consent forms; the degree and nature of the risk have been carefully explained to the human subjects; and there is a desirable balance between the potential benefits of the research and the risks undertaken by the human subjects. The board has the sole responsibility to approve research with human subjects performed under the auspices of the University.

In reviewing all biomedical and social/behavioral research that involves human subjects conducted at Northern Kentucky University, IRB will utilize the following principles:

1. A human subject will not be exposed to unreasonable risk to health or well-being whether physical, psychological, or social.
2. Commensurate with the principle of protection of human subjects, the procedures for assessing and minimizing risk to human subjects shall respect and protect the academic freedom of the university's faculty and students in their pursuit of knowledge.
3. The risks to an individual must be outweighed by the potential benefit to him/her or by the importance of the knowledge to be gained.
4. The identity and personal privacy of human subjects and the confidentiality of information received will be protected.
5. The nature of the research, the procedures to be followed, and the possible risks involved must be carefully and fully explained to the subject, parent or guardian, as appropriate. The investigator must be satisfied that the explanation has been understood and consent in writing obtained without duress or deception.
6. Voluntary participation is essential in all projects. No information concerning a project may be withheld from a potential subject in order to increase the willingness of the subject to participate in the project.

7. A subject may request at any time that his/her participation in the experiment be terminated, and the request shall be honored promptly and without prejudice.
8. It shall be the responsibility of the individual investigator to decide when he/she does not have adequate knowledge of the possible consequences of his/her research, or of research done under his/her direction. When in doubt, he/she shall obtain the advice of others who do have the requisite knowledge.
9. Potentially hazardous research procedures must be preceded by laboratory and animal experimentation or other scientifically established procedures that offer reasonable assurance that the safety of human subjects will be preserved.
10. Remuneration may be offered to an individual for the time involved in a study, provided the investigator is satisfied that under the circumstances the remuneration is not so large as to constitute an undue or unreasonable inducement.
11. It shall be a responsibility of Northern Kentucky University to ensure that research involving human subjects conducted by faculty, students, and employees of the university shall be performed carefully and with regard to the above principles.

B. Research that involves human subjects

There is human-subject involvement when an investigator obtains:

1. Data through intervention or interaction with the individual; and/or
2. Identifiable private information.

"Intervention" includes both physical procedures from which data are gathered 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 which has been provided for specific purposes by an individual will not be made public. Private information must be individually identifiable.

All research conducted on human subjects--whether supported partly or wholly by external funds, University funds, or without funds--must have prior approval by the Institutional Review Board.

All proposals that request external support for activities involving human subjects under the auspices of the University must be submitted through the office of Research, Grants, and Contracts to the funding agency.

C. Research that involves human subjects but does not need approval from the Institutional Review Board

Federal guidelines state that only the IRB can determine the status of a proposed study. Because of this mandate, all potential research studies involving human participants or identifiable records

must be submitted to the IRB for review before being started. One narrowly defined study type is recognized as an exception to this policy. IRB review and approval is not needed for:

1. Studies in undergraduate classes or graduate seminars that involve human participants and are:
   a. conducted solely for instructional purposes, and
   b. not intended to contribute to general knowledge.

When a study is designed to provide a learning experience for students and when the instructor and student investigator(s) have no plan, intention, desire, or hope to publish, present, or report the findings of this study in any off-campus setting (e.g., journal, report, conference, other off-campus outlet, etc.), the activity will not be considered to be research, and will not require IRB review.

In this instance, faculty instructors are wholly responsible for classroom projects conducted by students in their classes, and for ensuring that these student projects treat human participants ethically.

D. Investigator's legal responsibility in research with human subjects

The investigator is legally responsible for any research or related activities that involve human subjects conducted under the auspices of the University and/or that utilize University time, facilities, resources, and/or students. The University's Legal Counsel has the responsibility for resolution of any legal questions.

E. Application Procedures

Principal investigators are required to submit a protocol describing the proposed research project to the Institutional Review Board for review and approval.

The principal investigator must submit new protocols and supporting documents (questionnaires, consent forms, etc.) through Mentor IRB. The Mentor IRB system will prompt the PI with questions to provide a thorough, ethical review.

The investigator should discuss the need for the research, its objectives, the methods to be used to accomplish the objectives, the risks involved, and the procedures used to protect the subjects from, or minimize, the risks. Risks may be classified as physical, psychological, social (individuals), social (groups), legal/criminal, economic/employment and privacy/dignity/self-respect. These are defined as follows:

- **Physical Risk:** The extent to which physical injury is a possibility from physical activity, injections, or stimuli from electrical apparatus, fumes, light, noise, etc.

- Psychological Risk: The extent to which research interrupts the normal activity of human subjects resulting from immediate or long-term stress. Stress includes any situation that threatens one's desired goals.

- Social Risk to Individuals: The extent to which a subject is deprived of formal or informal relationships within social groups.

- Social Risks to Groups: The extent to which a subject group, either formal or informal, is exposed to factors that may reduce the group's viability.

- Legal/Criminal Risk: The extent to which the research may put the subject at risk for legal consequences due to admitted law violations, past illegal behaviors, etc.

- Psychological/Emotional Risk: The extent to which a subject may feel stress, anxiety, depression, anger or painful memories due to the research study.

- Economic/Employment Risk: The extent to which job opportunities, work assignments or conditions of employment might be affected to the subject's participation in the study.
- Privacy/Dignity/Self-Respect: The extent to which control of a subject's privacy and confidentiality is maintained during and after the research study.

Any research proposing to place any individual at risk is obligated to obtain and document legally effective informed consent. Informed consent is the knowing consent of an individual, or his/her legally authorized representative, who is able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. Required components of an informed consent can be found on the IRB IRB website.

Research that has been approved by the board may be reviewed, approved, or disapproved by University officials. They may not, however, approve the research if it has not first been approved by the Institutional Review Board.

F. Review of applicants by the Institutional Review Board

All protocols are screened for completeness by the IRB administrator prior to the conduct of a formal review. A board member may not cast a vote, or be otherwise involved, in either the initial or continuing review or any activity in which he/she has any conflicting interest, or any involvement, except to provide information requested by the board. The review performed by the board will determine whether subjects will be placed at risk. The policy criteria for determining risk is defined as follows:

"Subject at risk" is any individual who may be exposed to the possibility of injury, including physical, psychological, social legal/criminal, economic/employment and privacy/dignity/self-

respect injury, as a consequence of participation as a subject in any research, development, or related activity that departs from the application of established and accepted methods necessary to meet his/her needs or that increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service.

If risk is involved, the answers to the following questions will be considered:

1. Do the benefits outweigh the risk to the subjects?
2. Are the rights and welfare of any such subjects adequately protected?
3. Is legally effective informed consent obtained by adequate and appropriate methods in accordance with the provisions of federal regulations?

The board may use expedited review procedures for certain kinds of research involving no more than minimal risk and for minor changes in research protocols having prior board approval. Under the expedited procedure, the reviewers may exercise all the authorities of the board except that of final disapproval of the research. All board members will be notified of all research approved in the expedited review procedure. Any protocol not approved under the exempt or expedited procedure will be referred to the full board for review.

Approval of research will necessitate that the board determine that the following requirements are satisfied:

1. Risks to subjects are minimized.
2. Risks to subjects are reasonable in relation to anticipated benefits.
3. Selection of subjects is equitable.
4. Informed consent will be obtained from each prospective subject or the subject's legally authorized representatives.
5. The informed consent will be appropriately documented per OHRP guidelines.
6. Data will be regularly monitored ensure subjects' safety.

G. Actions by the Institutional Review Board

After review and discussion of the protocol, the board will take one of the following actions:

1. Classify the Submission as Not Research:

   This includes quality improvement projects taking place in the classroom with no intention to present or publish collected data.

2. Classify the Research as Exempt:

   Exempt studies meet the definition of human subjects research and fall into one of the predefined OHRP exempt categories. Projects that do not involve changes in the ordinary risks of daily life or in recognized occupational risks are also considered no-risk. Written informed consent is required in exempt IRB studies unless waived per OHRP guidelines. Exempt studies do not require continuing review unless major changes are made to the protocol.

3. Approve the Research as Expedited:

Expedited studies meet the definition of human subjects research and fall into one of the predefined OHRP expedited categories. The research may involve some risk to the subjects, but is not unreasonable. The potential benefits of the research outweigh the risks, and risk-management procedures have been taken to minimize the risks. This approval requires oversight by the IRB and annual continuing reviews must be submitted if the study continues past the one year approval date.

4. Full Board Review Approval:

   A Full Board Review approval requires quorum approval of the IRB. The board may or may not request the investigator to be present to discuss the research proposal. This may occur when the IRB finds the research to have more than minimal risks and as defined by federal regulations, the elements, procedures or interventions require additional provisions or safeguards.

5. Disapprove the Research:

   The board is of the opinion that the potential benefits of the research do not outweigh the risks to the subjects.

Some revisions or clarifications might be requested of the PI in all types of research review. The revisions required by the board may include such items as revising the consent form to explain the procedures more clearly, restricting use of a certain procedure, or requiring use of specified safeguards necessary for the protection of human subjects.

H. Disposition of the recommendations

Approvals, recommendations, restrictions, conditions, or disapprovals of applications are communicated to the investigator by the IRB administrator via Mentor IRB. If an application is disapproved for nonconformity with the policies of the board and the University, the IRB administrator shall forward to the investigator a statement setting forth in detail the reasons for the nonconformity and recommendations of the board for modification of the research proposal. All communication will be documented through Mentor IRB.

I. Rights of appeal

If the investigator believes that the proposal has been disapproved because of incorrect, unfair, or improper evaluation by the board, the investigator may appeal to the appropriate dean who then may request a reconsideration and hearing of the proposal by the board. Within ten (10) days after a negative decision, the affected investigator must show cause in writing or at a designated hearing as to why the board's decision should be reversed.

J. Appeal decision

The board may take one of the following actions:

1. Approve;
2. Require modification; or
3. Disapprove.

K. Records and documentation of the investigator

The investigator is required to obtain and keep documentary evidence of informed consent of the human subjects or their legally authorized representatives. Such forms must be retained by the investigator (or faculty advisor) for a minimum of three (6) years after termination of the project.

L. Institutional review board records

The board is required to keep copies of all documents presented or required for initial and continuing review by the board. These include copies of all research proposals received, scientific evaluations (if any accompany the proposals), approved sample consent documents, progress reports submitted by investigators, reports of injuries to subjects and email and phone communications between IRB, investigator and reviewers. Minutes of board meetings shall reflect meeting attendance; actions taken by the board; votes on actions, which will show the number of members voting for, against, and abstaining; the basis for requiring changes in or for disapproving research; and written summaries of discussions about controverted issues and their resolution. Other documents will include records of continuing review activities; copies of all correspondence between the board and investigators; a list of board members; written procedures; statements of significant new findings; reports of injuries; progress reports; and unanticipated problems.

These records shall be retained for at least three (6) years after completion of the research and shall be available to authorized members of the Department of Health and Human Services at reasonable times and in a reasonable manner. These records are continually reviewed by the office of Research, Grants, and Contracts, with follow-ups concerning conditions of approvals, additional information requested, etc.

The IRB records pertaining to individual research projects are accessible only to the IRB, researchers and other designated personnel and to grant funding agencies for inspection pursuant to KRS 61.878(b).

Except as otherwise provided by law, information acquired in connection with a research, development, or related activity that refers to or can be identified with a particular subject will not be disclosed except:

1. With the consent of the subject or a legally authorized representative; or
2. As may be necessary for the Secretary of Health and Human Services to carry out his/her responsibilities under federal regulations.

M. Northern Kentucky University Policy for liability for Institutional Review Board

Due to the privilege of sovereign immunity, the University, as an institution, is protected through the State Board of Claims. In addition, the University maintains a professional liability policy covering most actions of the faculty and staff. In the event the professional liability policy should fail, the University Board of Regents, in its By Laws adopted August 27, 1976 and revised August 13, 1992, insured that if any legal action is taken or claims filed against any faculty or staff member, he/she will be provided legal defense and indemnification for any acts or actions taken while on official business of the University. (See Part Two, Section I.C., Legal Defense and Indemnification/Notice Requirement, and Appendix B, Article IV, Regents' By Laws.)

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