

HUMAN RESEARCH SUBJECTS

PROTECTION

RESP. OFFICIAL TITLE: PROVOST & EXEC. VICE PRESID. FOR ACADEMIC & STUDENT AFFAIRS

RESPONSIBLE OFFICE: RESEARCH, GRANTS & CONTRACTS

EFFECTIVE DATE: 11/2/1983

FACULTY HANDBOOK POLICY: FACULTY HANDBOOK SEC. 16.6 – HUMAN SUBJECTS POLICIES

NEXT REVIEW DATE: PREVIOUS REVIEW PLUS FOUR (4) YEARS – 03/18/2029

BD. OF REGENTS REPORTING: PRES. RECOMMENDATION (CONSENT AGENDA/VOTING ITEM)

I. POLICY STATEMENT

Northern Kentucky University (NKU) is committed to the highest ethical principles in the conduct of human subject research and specifically to its responsibility to ensure the rights and welfare of human research subjects. Though NKU Institutional Review Board (IRB) has the sole responsibility to approve research with human subjects; human subject protection is a shared responsibility involving NKU, the IRB, investigators and research staff.

II. ENTITIES AFFECTED

Faculty, staff and students conducting human subjects research at NKU.

III. AUTHORITY

[45 CFR 46](#)

[The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research](#)

IV. DEFINITIONS

- **Human Subject:** A living individual about whom an investigator (whether professional or student) conducting research obtains:
 - Data through intervention or interaction with the individual, or;
 - Identifiable private information.
- **Intervention** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment performed for research purposes.
- **Interaction** includes communication or interpersonal contact between the investigator and subject.
- **Private Information** is information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place. Private Information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).
- **Research** is a systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalizable knowledge.

V. RESPONSIBILITIES

The Office of Research, Grants and Contracts:

- Facilitates the review and approval of all projects that meet the federal definition of human subjects research;
- Maintains the IRB roster and ensures it meets the minimum regulatory requirements.

VI. COMMITTEE

The Institutional Review Board (IRB) reviews research studies to ensure that they comply with applicable regulations, meet commonly accepted ethical standards, follow institutional policies, and adequately protect research participants. IRB reviews help to ensure that research participants are protected from research-related risks; treated ethically, a necessary prerequisite for maintaining the public's trust in the research enterprise; and allowing science to advance for the common good. IRB composition, at a minimum, is dictated by the US Department of Health and Human Services (DHHS).

VII. PROCEDURES

Procedures and internal guidelines for the protection of human subjects can be found on the [Office of Research, Grants and Contracts website](#).

VIII. TRAINING

Researchers engaging in research that meets the federal definition of human subjects research are required to complete training related to the ethical conduct of research. Specific details of this training can be found on the Office of Research, Grants and Contracts website.

IX. REFERENCES AND RELATED MATERIALS

REFERENCES & FORMS

All projects that meet the federal definition of human subjects research must be submitted through the electronic IRB system accessible through [NKU's IRB website](#)

RELATED POLICIES

[Responsible Conduct of Research, Scholarship, and Creative Activity Training](#)

NKU Faculty Handbook: [Section 16.6: Human Subjects Policies](#)

REVISION HISTORY

REVISION TYPE	MONTH/YEAR APPROVED
Revision and Name Change – “Human Research Subjects Protection”	March 18, 2025
Revision and Name Change- “Protection of Human Research Subjects”	July 31, 1996
AR-II-2.0-1 “Policy and Procedures Assurance for the Protection of Human Research Subjects at Northern Kentucky University”	November 2, 1983

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PRESIDENTIAL APPROVAL

PRESIDENT	
Signature <i>Cady Short-Thompson</i>	Date <i>3-18-25</i>
Cady Short-Thompson	

BOARD OF REGENTS APPROVAL

BOARD OF REGENTS (IF FORWARDED BY PRESIDENT)	
<input type="checkbox"/> This policy was forwarded to the Board of Regents on the Presidential Report (information only) . Date of Board of Regents meeting at which this policy was reported: ____/____/____.	
<input checked="" type="checkbox"/> This policy was forwarded to the Board of Regents as a Presidential Recommendation (consent agenda/voting item) .	
<input checked="" type="checkbox"/> The Board of Regents approved this policy on <u>February 26, 2025</u> .	
<input type="checkbox"/> The Board of Regents rejected this policy on ____/____/____.	
BOARD OF REGENTS MATERIALS	
Board of Regents Meeting Date:	<i>February 26, 2025</i>
Board of Regents Materials Reference:	<i>Presidential Recommendation C-10, p. 72</i>