RESPONSIBLE CONDUCT OF RESEARCH, SCHOLARSHIP, AND CREATIVE ACTIVITY TRAINING

POLICY NUMBER: HYB-RESPCONDRES

POLICY TYPE: HYBRID

RESPONSIBLE OFFICIAL TITLE: PROVOST & EXEC. VICE PRESIDENT FOR ACADEMIC AFFAIRS

RESPONSIBLE OFFICE: OFFICE OF RESEARCH, GRANTS AND CONTRACTS

EFFECTIVE DATE: 8/21/2017

MOST RECENT REVISION:10/9/2023

NEXT REVIEW DATE: PREVIOUS REVIEW PLUS FOUR YEARS – 10/9/2027

BOARD OF REGENTS REPORTING (CHECK ONE):

☐ PRESIDENTIAL RECOMMENDATION (CONSENT AGENDA/VOTING ITEM)

☑ PRESIDENTIAL REPORT (INFORMATION ONLY)

I. POLICY STATEMENT

Northern Kentucky University (NKU) has the responsibility to ensure that faculty, students, and others conducting research, scholarship, or creative activity are adequately trained in research ethics.

II. ENTITIES AFFECTED

- **Type 1** Student/trainees, paid on all NSF-sponsored projects and those paid on select NIH-sponsored projects approved after January 4th, 2010.
- Type 2 All researchers, including students, conducting research with human subjects.
- Type 3 All researchers, including students, conducting research with vertebrate animals.
- **Type 4** All other types of faculty, students, and others conducting research, scholarship, or creative activity.
- **Type 5** Principal Investigators and senior personnel conducting research, scholarship, or creative activity on any sponsored projects.

Please note that, depending on the study, a researcher may be required to complete training in more than one research Type listed above.

III. AUTHORITY

Type 1 and Type 5 (Responsible Conduct of Research (RCR) – This training type implements federal requirements pertaining to NSF - Section 7009 of the America COMPETES Act, the NIH Update on the Requirement for Instruction in the Responsible Conduct of Research NOT-OD-10-019, and CHIPS and Science Act of 2022 (Section 10337) relating to guidance from Office of Research Integrity (ORI).

Type 2 (Research with Human Subjects) – This training type pertains to <u>45 CFR 46</u> and enforces requirements in NKU's Federal Wide Assurance filed with the Office of Human Subjects Protections (OHRP) and <u>Bloodborne</u> Pathogens 1910.1030 Occupational Safety and Health Administration (OSHA).

Type 3 (Research with Vertebrate Animals) – This training type pertains to requirements and guidance from U.S. Government Principles, Health Research Extension Act of 1985, and Bloodborne Pathogens 1910.1030 Occupational Safety and Health Administration (OSHA), and enforces requirements in NKU's Animal Welfare Assurance filed with the Office of Lab Animal Welfare (OLAW).

IV. DEFINITIONS

Principal Investigator – For the purpose of this policy, Principal Investigator is the Principal Investigator of the project for which the student/trainee is paid.

Researcher – For the purpose of this policy, Researcher is any individual, regardless of title, conducting research (recruiting, consenting, performing protocol procedures, etc.).

Student/Trainee – For the purpose of this policy, Student/Trainee is defined as all undergraduate, graduate, fellows, scholars receiving salary and/or stipends from any NSF project or select NIH funding for the programs listed below: D43, D71, F05, F30, F31, F32, F33, F34, F37, F38, K01, K02, K05, K07, K08, K12, K18, K22, K23, K24, K25, K26, K30, K99/R00, KL1, KL2, R25, R36, T15, T32, T34, T35, T36, T37, T90/R90, TL1, TU2, and U2R

V. RESPONSIBILITIES

Provost and Executive Vice President for Academic Affairs: Institutional Official responsible for maintaining University compliance.

Director of the Office of Research, Grants and Contracts (RGC), Research Compliance Manager in RGC: Responsible for enforcing NKU research policy procedures to maintain research compliance.

VI. PROCEDURES AND TRAINING

Type 1 – Per NSF and NIH policies, student/trainees must complete training in the Responsible Conduct of Research (RCR). There are two phases of RCR required training.

Phase 1 - Online RCR training identified and tracked by NKU Office of Research, Grants and Contracts. Training shall be repeated at least every four (4) years for the student/trainee's tenure on the project, or when (a) the regulation is substantially revised; (b) a student/trainee is new to the University; or (c) if a student/trainee is determined to not be in compliance with this regulation.

The Manager of Research Compliance or designee will be responsible for tracking this training requirement.

Phase 2 – Ongoing training including, but not limited to, face-to-face instruction, reading assignments, etc., identified and tracked by each Principal Investigator or designee.

Each Principal Investigator or designee will be responsible for recording this ongoing training requirement.

Type 2 – All researchers conducting research with human subjects must complete training in basic Human Subjects research prior to submitting an application to the Institutional Review Board (IRB) and every three (3) years thereafter for the life of the project or tenure on the project ends. Additional training in Bloodborne Pathogens may be required annually depending on study type.

The Manager of Research Compliance or designee will be responsible for tracking this training requirement.

Type 3 – All researchers conducting research with vertebrate animals must complete training in Animal Research prior to submitting an application to the Institutional Animal Care and Use Committee (IACUC) and every three (3) years thereafter for the life of the project or tenure on the project ends. Additional training in Bloodborne Pathogens may be required annually depending on study type.

The Manager of Research Compliance or designee will be responsible for tracking this training requirement for faculty and staff. Principal Investigators will be responsible for tracking training completion for students.

Type 4 – It is recommended that all Type 4 faculty, students and others conducting research, scholarship, or creative activity complete RCR training suggested by NKU Office of Research, Grants and Contracts or by their department.

Type 5 – All researchers listed as Principal Investigators or senior personnel on NSF-funded grants must complete online training identified and tracked by NKU Office of Research, Grants and Contracts. Training shall be repeated at least every four (4) years for the researcher's tenure on the project, or when (a) the regulation is substantially revised; (b) a researcher is new to the University; or (c) if a student/trainee is determined to not follow this regulation.

The Office of Research, Grants and Contracts (RGC) will be responsible for tracking this training requirement.

See the NKU RGC website for specific procedures and timelines related to training for this policy.

VII. REPORTING REQUIREMENTS

Reporting remains internal to NKU until which time the Office of Research Integrity, OHRP, or OLAW requests detailed records.

VIII. COMMUNICATIONS

Type 1 (Phase 1 and 2) – When a student/trainee is employed on any sponsored project mandated to meet these requirements, the NKU Office of Research, Grants and Contracts (RGC) communicates directly with the Principal Investigator and student to inform them of the RCR requirements and ensures the completion of Phase 1 of training per this policy.

Types 2, 3, & 4 – Information is available on the <u>NKU RGC website</u> and will be communicated as needed to researchers by RGC.

Type 5 – NKU RGC will notify any faculty or staff who meets the requirements to inform them of the training requirement and ensure the completion of this training.

This policy and detailed procedures are available on the NKU RGC website.

IX. REFERENCES AND RELATED MATERIALS

REFERENCES & FORMS

Type 1: NSF - Section 7009 of the America COMPETES Act
NIH - Update on the Requirement for Instruction in the Responsible Conduct of Research NOT-OD-10-019
Office of Research Integrity

Type 2: Office for Human Research Protections

Type 3: Office of Lab Animal Welfare

<u>U.S. Government Principles</u>, <u>Health Research Extension Act of 1985</u> <u>Bloodborne Pathogens 1910.1030 Occupational Safety and Health Administration (OSHA)</u>

Type 5: CHIPS and Science Act of 2022

REVISION HISTORY

REVISION TYPE	MONTH/YEAR APPROVED
Revision (added Type 5)	October 9, 2023
Review/Minor Edits & Formatting	August 29, 2022
Revision/Edits	May 15, 2018
New Policy	August 21, 2017

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PRESIDENTIAL APPROVAL
PRESIDENT
Signature Cardy Short-Thompson Date 10/9/23
Cady Short-Thompson
BOARD OF REGENTS APPROVAL
BOARD OF REGENTS (IF FORWARDED BY PRESIDENT)
This policy was forwarded to the Board of Regents on the <i>Presidential Report (information only)</i> . Date of Board of Regents meeting at which this policy was reported:
☐ This policy was forwarded to the Board of Regents as a <i>Presidential Recommendation</i> (consent agenda/voting item).
☐ The Board of Regents approved this policy on//(Attach a copy of Board of Regents meeting minutes showing approval of policy.)
☐ The Board of Regents rejected this policy on/ (Attach a copy of Board of Regents meeting minutes showing rejection of policy.)
SECRETARY TO THE BOARD OF REGENTS
Signature Janny Gnochelman Date 11/9/2023
Tammy Knochelmann