I. POLICY STATEMENT

Northern Kentucky University 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.

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

III. AUTHORITY

Type 1 (Responsible Conduct of Research (RCR)) – This training type implements federal requirements pertaining to NSF - Section 7009 of America COMPETES Act and the NIH - Update on the Requirement for Instruction in the Responsible Conduct of Research NOT-OD-10-019 relating to guidance from Office of Research Integrity (ORI).
Type 2 (Research with human subjects) – This training type pertains to 45 CFR 46 and enforces requirements in NKU’s Federal Wide Assurance filed with the Office of Human Subjects Protections (OHRP) and Bloodborne 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 – 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. There are two phases of RCR required training.

Phase 1 - Online RCR training identified and tracked by NKU Office of Research, Grants and Contracts. Student/trainees must complete Phase 1 of training within 90 days of joining a research project. Training shall be repeated at least every four 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 years thereafter for the life of the project or tenure on the project ends. Additional training in Blood borne 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 years thereafter for the life of the project or tenure on the project ends. Additional training in Blood borne 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 Investigator’s 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, & Contracts or by their department.

See the Northern Kentucky University Office of Research, Grants, and Contracts website for specific procedures 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) – Type 1 (Phase 1 and 2) – When a student/trainee is employed on any sponsored project mandated to meet these requirements, RGC communicates directly with the PI 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 NKU RGC website and will be communicated as needed to researchers by RGC.

This policy and detailed procedures are be available on the Northern Kentucky University Office of Research, Grants, and Contracts website.

IX. REFERENCES AND RELATED MATERIALS

REFERENCES & FORMS

Type 1 - NSF - Section 7009 of 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 of Human Research Protections

Type 3 – Office of Lab Animal Welfare
Bloodborne Pathogens 1910.1030 Occupational Safety and Health Administration (OSHA)

REVISION HISTORY

Indicate any revisions to this policy using the table below. Include the type of revision and the month & year the revision was approved.

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<th>REVISION TYPE</th>
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