

UNIVERSITY OF KENTUCKY ADMINISTRATIVE REGULATIONS	IDENTIFICATION AR III-4.0-6	PAGE 1
	DATE EFFECTIVE 2/19/07	SUPERSEDES REGULATION DATED 6/5/89 7/25/89 2/19/98

HUMAN RESEARCH SUBJECT PROTECTION AND INSTITUTIONAL REVIEW BOARDS

I. Introduction

The University is committed to the highest ethical standards in the conduct of research and specifically to its obligation to ensure the rights and welfare of human research subjects. Human research protection is a shared responsibility involving the University, the Institutional Review Boards (IRBs), investigators, and research staff.

Any undertaking, regardless of funding source, in which a University faculty member, staff member, or student conducts research involving human subjects or a clinical investigation requires IRB review and approval prior to initiation. The University applies the applicable federal definitions for “research”, “human subjects”, and “clinical investigation” in determining which activities require prior IRB review and approval.

II. Responsibilities of the Designated Human Research Protection Official

A. As authorized by the President, the Vice President for Research (VPR) is the designated human research protection official at the University and in the University’s Federalwide Assurance of Compliance with Department of Health and Human Services’ regulations for protection of human research subjects.

B. The VPR is authorized to act for the institution, specifically committing the University to compliance with all applicable state and federal regulations governing human research activity or clinical investigation.

C. The VPR is responsible for ensuring that the institution establishes and maintains an appropriate number of IRBs sufficient to meet institutional research needs.

III. Institutional Review Boards

A. The Medical IRBs have institutional responsibility for reviewing research from the Colleges of Dentistry, Health Sciences, Medicine, Nursing, Public Health, and Pharmacy.

B. The Nonmedical IRBs are responsible for research review for the Colleges of Agriculture, Arts and Sciences, Business and Economics, Communications and

Information Studies, Design, Education, Engineering, Fine Arts, Law, and Social Work, as well as for the Graduate School.

C. Depending on the nature of the research activity and the expertise of the membership, a research protocol may be transferred between Medical and Non-medical IRBs if necessary to ensure the reviewing IRB has the appropriate expertise to conduct the review.

D. The University grants the IRB the authority to act independently in conducting reviews of research. No University official, committee, or body may approve research involving human subjects or clinical investigation that has been disapproved by the appropriate IRB.

E. The IRB performs its duties as described in the University of Kentucky Human Research Protection Program Comprehensive Plan and IRB policies and procedures maintained by the Office of Research Integrity (ORI).

IV. Institutional Review Board Membership

A. After consultation with appropriate University administrators and review of scholarly, scientific, and other credentials, IRB chairs, vice chairs, and members are appointed by the VPR, as authorized by the President.

B. Membership shall be consistent with applicable federal regulations to ensure appropriate and diverse representation from multiple scientific and non-scientific professions, various ethnic backgrounds, and both genders, as well as sufficient expertise to meet institutional research needs.

C. One member, a “community member,” shall not be affiliated with the University.

D. IRB members, other than those with ex officio status, serve staggered three-year appointments.

V. ORI Responsibilities

The ORI is responsible for managing protocol review; assisting the University in responding to federal initiatives affecting the ethical conduct of research, policy development, agency liaison, education, quality improvement, federal record keeping and reporting; and handling allegations of noncompliance.

VI. Institutional Review Board Responsibilities

Within the guidelines set forth by the applicable federal granting and regulatory agencies and University IRB policy, specific responsibilities and authority of the IRB are as follows:

- A. Review, approve, require modifications to secure approval, or disapprove all University human research activity or clinical investigation;
- B. Review proposed changes in previously approved research or clinical investigation and approve, require modifications to secure approval, or disapprove proposed changes;
- C. Conduct continuing review of previously approved research or clinical investigation at intervals appropriate to the degree of risk, but not less than once per year;
- D. Monitor, when appropriate, the informed consent process and the conduct of the research or clinical investigation;
- E. Suspend or terminate approval of research or clinical investigation that is not conducted in accordance with IRB requirements or that has resulted in unexpected serious harm to subjects;
- F. Handle reports of unanticipated problems and allegations of noncompliance with human subjects regulations and, in cases where corrective action is needed, issue appropriate sanctions, including but not limited to requesting minor changes, determining data collected cannot be published, disqualifying investigators from conducting research involving human subjects or clinical investigation at the University, and recommending further administrative action to University administration.

VII. Responsibilities of Investigators and Research Personnel

- A. The investigator and research personnel engaged in human research activity or clinical investigations are directly responsible for ethical conduct of research involving human subjects and protection of human subjects. .
- B. The investigator is responsible for obtaining IRB approval prior to initiating research activity; implementing research as approved by the IRB and in compliance with all IRB decisions, conditions and requirements; implementing research within sound study designs according to the standards of the discipline; and complying with all applicable federal and state regulations and laws and all University requirements for the conduct of human research.

VIII. Cooperative Project

When University human research or clinical investigation involves a cooperative project with another entity, the VPR has the authority to enter into a joint review arrangement with another entity, rely upon the review of another qualified IRB, or make similar arrangements in accord with guidelines set forth by the applicable federal granting and regulatory agency and University IRB policy.

AR III-4.0-6

2/19/07

Page 4

References:

45 Code of Federal Regulations 46

21 Code of Federal Regulations 50

21 Code of Federal Regulations 56

38 Code of Federal Regulations 16