3361:10-17-10 Conduct and ethics: ethical conduct in research involving human subjects.

Employees and students of the university of Cincinnati conduct human subjects' research ethically and in accordance with this rule, with the ethical principles stated in the "Belmont" report and with all applicable federal, state, and local law and regulations, including regulations of the department of health and human services (DHHS) regulations for the protection of human research subjects, 45 C.F.R. part 46 subpart A, and FDA regulations governing research with drugs, devices, and biologics, C.F.R. title 21 (food and drugs), parts 50 (protection of human subjects) and 56 (institutional review boards).

(A) To assure such compliance, the university has a federal wide assurance with DHHS regulations certifying that procedures will be followed that will assure the protection of all human subjects involved in research projects. This certification applies anyone engaged in human subjects research on the premises of the university of Cincinnati, and to faculty, students, staff, or other representatives of the university engaged in human subjects research conducted elsewhere on behalf of the university of Cincinnati.

(B) The university has established institutional review boards ("IRB") to review research involving human subjects. The IRB reviews research involving investigational drugs, biologics, devices, and medical treatments and other research involving human subjects. All research to which this rule applies must be reviewed and approved by a university IRB before research begins.

(1) The IRB shall establish policies and procedures for membership, regular meetings, review and approval of protocols and consent forms, modifications to approved research, the risk/benefit ratio of the research to the subjects involved, protection of the confidentiality of the subjects' private information, and the reviews of approved research protocols at timely intervals.

(2) The IRB may suspend or terminate approved research if it is not being conducted in accordance with this policy, with IRB requirements, or if it may pose the risk of serious harm to human subjects.

(3) The IRB has authority, as a condition of approval of a protocol, to observe, or have a third party observe, the consent process; and to observe, or have a third party observe, the conduct of the research at any time.

(4) The IRB shall act independently of university officials. No university official shall attempt to influence the IRB inappropriately on any matter before the IRB or within the IRB's jurisdiction.

(C) The vice president for research or designee shall serve as the institutional official for human subjects' research and is responsible for administering this rule. Any violation of this policy should be reported to the institutional official who shall have the authority to take such action as required to bring the university into compliance.

Replaces: Former 3361:50-47-50

Effective: July 18, 2019

Certification: Nicole S. Blount

Nicole S. Blount
Executive Director of Board Relations

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