DEMONSTRATING KNOWLEDGE OF HUMAN RESEARCH PROTECTION BY RESEARCHERS

Purpose

The University of Cincinnati is committed to following the highest standards of ethical conduct in human subject research. Central to the mission of fostering excellence in research is a commitment to ensuring that all individuals responsible for the design, conduct and reporting of a research study involving human subjects demonstrate an adequate level of knowledge in the protection of those human subjects. This policy defines the University of Cincinnati requirement for demonstrating such knowledge.

Applicability

All members of the research team who have contact or interactions with research subjects or with their private, identifiable information must demonstrate their knowledge. Faculty supervisors of student research projects must also demonstrate their knowledge. This policy applies to both medical and social/behavioral researchers.

Methods for Meeting the Requirement

Methods for demonstrating knowledge of human subject’s protection will be selected by the University of Cincinnati IRB(s) in conjunction with the Office of Research Compliance Training and the Vice President for Research, who retain responsibility for assuring the protection of human research subjects at the University of Cincinnati.

Specific curriculum will be identified by the appropriate IRB, based on the type of research conducted (biomedical or social-behavioral). The currently approved methods are accessible through the Continuous Professional Development (CPD) application.

Each IRB reserves the right to require additional education as they deem appropriate for the proposed research in order to ensure research is conducted by individuals fully knowledgeable in the protection of human subjects.

There are two approved methods for demonstrating knowledge on the protection of human subjects:
Human Research Protection
Program Policy

1) Successfully complete the Collaborative IRB Training Initiative (CITI) web-based training course or;

2) Pass the Continuous Professional Development (CPD) on-line competency test.

The training course and the competency test are divided into two tracks: Biomedical Research and Social/Behavioral Research. Investigators who conduct both types of studies must successfully complete both tracks.

The IRB office staff will verify that the CITI training or CPD competency testing has been completed.

Frequency

The training course or competency test must be completed initially and the CITI refresher course completed every three years thereafter, not prior to each IRB submission.

Compliance Dates

Effective January 1, 2006, individuals participating in the conduct of research that involves human subjects must successfully complete the training or the competency test prior to initiating any new research. All individuals currently involved in approved research must successfully complete the educational requirements no later than March 31, 2006.

Failure to comply with this policy will not affect the IRB review process but will impact the final approval status. New research protocols or continuing review of on-going projects will not be approved until all key personnel have demonstrated their knowledge of human subject’s protection.