Human Research Protection Program Policy

DEMONSTRATING KNOWLEDGE OF HUMAN RESEARCH PROTECTION BY RESEARCHERS

PURPOSE

The University of Cincinnati (UC) 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 all researchers. Additional training may be required by federally funded and/or initiated research, such as the Department of Defense, Department of Justice, or Department of Education. Checklists are made available as guides on the website to support awareness and education of these other requirements.

METHODS FOR MEETING THE REQUIREMENT

Methods for demonstrating knowledge of human subjects protection will be selected by the University of Cincinnati Institutional Review Board (IRB).

Specific curriculum will be identified by the IRB, based on the type of research conducted (e.g. biomedical or social-behavioral) with additional modules assigned based on the type of research (e.g. Good Clinical Practice modules for FDA regulated research). The approved method with the exceptions described below (Sponsor Investigators and Special Circumstances) is accessible through the Collaborative Institutional Training Initiative (CITI) website.

The IRB reserves the right to require additional education to ensure research is conducted by individuals fully knowledgeable in the protection of human subjects.

In addition to the specific curriculum identified by the IRB, all UC affiliated Sponsors, Sponsor-Investigators and the Clinical Research Coordinators on those research teams are

required to take CITI Good Clinical Practice (GCP) modules and complete additional training available online or annually in person.
Verification of CITI training is part of administrative pre-review.

Special Circumstances for Personnel Not Affiliated with UC, Cincinnati Children's Hospital Medical Center, Cincinnati Veterans Administration Medical Center, or Cincinnati Shriners Hospital.

For some types of research it is necessary that personnel unaffiliated with the University of Cincinnati "engage" in research. This research usually involves (1) multiple sites within the state of Ohio, (2) sites in other states within the United States or (3) sites in countries outside the United States. For these studies the investigators will submit the training materials to the IRB for approval. Any study that involves vulnerable populations must contain content covering special provisions to protect that vulnerability.

Each protocol requesting to use something besides CITI training must designate an education facilitator. The facilitator will be responsible for presenting to the group, documenting that all persons who 'engage" in research are in attendance, and obtain assurance from those individuals that they will abide by all determinations of the IRB with regard to proper protection of human participants. This documentation must be provided to obtain IRB approval. When new personnel are added at the research site, training must be documented and submitted to the IRB office as an administrative amendment. When it is necessary to translate the training into local languages, those translations (with certifications of the translator's qualifications) must be provided.

FREQUENCY

Training must be completed initially and renewed/refreshed every three years thereafter when applicable.

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 subjects protection.

UNIVERSITY OF Cincinnati

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Adoption Date:	Created by:	Date of Revision:	Revised By:	Summary of Revision:
11/05	D. Oneill	7/08	J. Lindwall	Addition of requirement for Sponsor-Investigators to take GCP modules along with CITI training
		11/08	J. Gerlach	Removal of CPD testing. Addition of combined training applicable to all researchers conducting human subjects research.
			C. Norman	Additional text addressing special circumstances for Personnel Not Affiliated with the AHC. Additional of GCP training for Sponsor/Investigators with IND/IDEs protocols
		06/2014	A. Braggs-Brown	Revised to clarify and remove references to AAHRPP domains
		09/2014	A. Braggs-Brown	Revised to address AAHRPP recommendations
3/2015		3/2015	J. Strasser	Revisions for clarification

Date Adopted March 2015 **Signature** signed copy on file