UNIVERSITY OF Cincinnati

Human Research Protection Program Policy

POLICIES AND PROCEDURES IN HUMAN SUBJECT RESEARCH: PREPARATION, REVISION AND DISSEMINATION

POLICY

University of Cincinnati (UC) Human Research Protection Program (HRPP) policies and procedures ensure uniform protection of the rights and welfare of all human research participants who are involved in human subject research (HSR) at UC, and adequate documentation of such oversight. UC HRPP policies and procedures must be consistent with regulations and guidance of the Office of Human Research Protection (OHRP), Food and Drug Administration (FDA) and UC institutional policies and rules.

UC HRPP policies and procedures apply to all HRPP staff, IRB members, researchers, research staff and UC as an institution, as indicated. They must be made publicly available to all stakeholders in human subjects research.

RESPONSIBILITY

Institutional Official (IO)	Review, approve, and ensure implementation of new or revised HRP policies and procedures.
IO, IRB Chair or designee	Prepare new or revised HRPP policies and procedures to incorporate any new or revised knowledge, guidance or practices.
IO, IRB Chair	Maintain current knowledge of federal, state and local laws and regulations, guidance of regulatory agencies, and standards of accrediting agencies and research practices.
IO, IRB Chair	Evaluate any findings of the Quality Assurance/Quality Improvement (QA/QI) Program; and evaluate comments and complaints by researchers or the IRB as they may affect HRPP policies and procedures.
HRPP Director or designee	Post approved HRPP policies, procedures and standard operating procedures (SOPs) on the UC HRPP website and notify all researchers by email and on the HRPP's website when changes are made to an HRPP policy or procedure.
HRPP Director	Inform the IO and IRB Chair of changes in HRPP processes, comments or complaints received from any source about UC HRPP activities, and any other matters that could impact UC HRPP policies and procedures.
HRPP Director	Provide training to researchers and regulatory compliance staff if new or revised HRPP policies reflect a significant change.

HRPP Director	Monitor the application of current policies and procedures by researchers.
HRPP Director	Notify the IO and IRB Chair of possible new HRPP policies or procedures or changes in existing HRPP policies or procedures that might enhance compliance or protect human research participants

REVIEW FREQUENCY

HRPP policies and procedures will be reviewed at least annually by the IO and IRB Chair, in collaboration with the HRPP Director and any other personnel deemed appropriate. If it is determined that revisions or new HRPP policies or procedures are needed, they will be prepared and disseminated as described in this policy and Procedure 104 *Policy & Procedure Preparation & Dissemination*.

DISSEMINATION AND TRAINING

The HRPP Director or designee will make each new or revised HRPP policy or procedure publicly available.

The HRPP Director or designee will identify any significant changes reflected in a new or revised HRPP policy or procedure, and will bring those changes to the attention of IRB members, HRPP staff, and researchers.

Applicable Regulations and Documents:
21CFR56.108
45CFR46.103
Procedure 104 *Policy & Procedure Preparation & Dissemination*

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Adoption Date:	Created by:	Date of Revision:	Revised By:	Summary of Revision:
11/2005	L. Harpster	8-9-06	J. Gerlach	AAHRPP required changes: expanded definitions, clarification of posting and dissemination of policies and procedures.
		8-14-12	C. Norman	Major revision to wording and format to improve understandability and be consistent with other HRP policies. Remove language that more appropriately belongs in other documents. Replace Director of OHRP, Compliance Officer and VP for Research with IO.
		04/2014	A. Braggs-Brown	Revisions to reflect organizational changes

Date Adopted April 2014 **Signature signed copy on file**