



Human Research Protection Program Policy

Policy Number: IV.01

**Rights and Responsibilities of Principal
Investigators in Human Subjects Research**

Adopted: 11/2005

Revised: 11/2006

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RIGHTS AND RESPONSIBILITIES OF PRINCIPAL INVESTIGATORS IN HUMAN SUBJECTS RESEARCH

POLICY

Each research study will have a Principal Investigator (PI) and may have a Co-Principal Investigator (Co-PI). This individual(s) of record assumes authority and accountability for the ethical conduct of a research study in accordance with all applicable federal and state laws and regulations and with university policy.

RIGHTS AND RESPONSIBILITIES

The PI (and Co PI) is each fully responsible for:

1. Conducting the research study in a manner that will protect the safety and welfare of participants in the study and that conforms to the protocol approved by the IRB.
2. Ensuring that research studies employ a sound study design that develops or contributes to generalizable knowledge that uses research methods that minimize risks to participants, and that recruits participants in a fair and equitable manner that adequately reflects the population being studied and protects participants from coercion or undue influence.
3. Ensuring that federal (FDA and HHS), state and local laws and regulations and the policies and procedures of the University of Cincinnati are followed in the conduct of research.
4. For externally sponsored studies, reading and understanding all the information in the grant documents, the investigator's brochure, the informed consent, the protocol and all other study related materials.
5. Informing all participants of all the elements of the research and following all requirements relating to obtaining their informed consent. See Research Policy II.01, *Obtaining Informed Consent in Human Subjects Research*.
6. Preparing and submitting documents for initial review, and, timely submission of documents for continuing IRB review and approval
7. Conducting study activities only after IRB approval and in accordance with the approved protocol, and assuring that all IRB requirements are met.



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8. Implementing modifications in approved research only after review and approval of the modification by the IRB, except where necessary to eliminate apparent immediate hazards to participants.
9. Appropriate control, inventory, administration, storage, record keeping and destruction or return of test articles.
10. Reporting to the IRB unforeseen events that may present risks or affect the safety or welfare of subjects or others, or that may affect the integrity of the research. See Research Policy II.02 *Reporting Unanticipated Problems in Human Subjects Research*.
11. Reporting any interim analysis or other study findings to the IRB and study participants, when they may affect the health or welfare of study participants.
12. Formally delegating responsibilities to other members of the research team for appropriate tasks, such as delegation of obtaining informed consent. The PI will provide appropriate training to such individuals for whom the tasks have been delegated. The Delegation of Responsibilities Form (as part of the Research Review Submission Form) will indicate the delegated tasks and to whom they have been delegated.
13. Adequately supervising members of the research team and ensuring that all members of the research team have appropriate training, expertise, and any required current licenses, certifications, or other credentials, to conduct the study.
14. Assuring that the facilities and equipment for conducting the research are adequate, and that provisions exist to protect the health and safety of participants.
15. For clinical research, assuring that all study drug(s), device(s), equipment and supplies are distributed and stored in accordance with the protocol, FDA and OHRP regulations and institutional policy.
16. Ensuring that all blood, tissue and other samples are collected, processed, and stored in accordance with the protocol, Good Laboratory Practices, and Good Clinical Practices.
17. If research is conducted by a person in-training such as a student, fellow, or resident, the research protocol must have a faculty member designated as the Co-PI.



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18. Assuring that key personnel have reported any financial conflict of interest in accordance with Research Policy IV.02 *Investigator Conflict of Interest in Human Subjects Research*.
19. Maintaining adequate and accurate records.
20. Assuring full cooperation with both external and internal monitoring, reviews, investigations, and audits of the research.

The PI has the Following Rights:

1. To a review of their submissions to the IRB in a reasonably prompt manner.
2. To reasonable notice of internal monitoring reviews, investigations, or audits of the research and to actively participate during the course of any such review.
3. To receive notice of disapprovals, suspensions, or terminations of research in writing with the reason for the action.
4. To address concerns with the IRB on any matter of concern, either in person or in writing, and to have concerns addressed.
5. To a reasonably prompt rehearing by the IRB on any research proposal or modification which has been disapproved, or any research which has been suspended or terminated.
6. To bring any question or concern regarding the functioning of the IRB to the attention of the Office of Research Compliance and Regulatory Affairs, and if the concerns are not adequately addressed, to the Vice President for Research or the Institutional Official or to the Office of General Counsel.

Date Adopted _____ Signature _____