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). The (Co-) PI 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 (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, 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, understanding, and complying with all of the information in the grant or contract, 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.

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 as described in HRPP 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. An investigator shall submit progress reports on the investigation to the sponsor, the monitor, and the reviewing IRB at regular intervals, as described in HRPP Policy III.09 *Continuing Review By the IRB.*

13. Formally delegating responsibilities to other members of the research team for appropriate tasks, such as obtaining informed consent. The PI must provide appropriate training for individuals to whom the tasks have been delegated.

14. Adequately supervising members of the research team and ensuring that all have appropriate training, expertise, current licensure, and/or any certifications or other credentials required to conduct the study.

15. Assuring that the facilities and equipment for conducting the research are adequate, and that provisions exist to protect the health and safety of participants.

16. 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.

17. 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.

18. If research is conducted by a person in-training such as a student, fellow, or resident, the (co-) PI of the research protocol must be a faculty member.

19. 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*.

20. Maintaining adequate and accurate records.

21. Assuring full cooperation with both external and internal monitoring, reviews, investigations, and audits of the research.

ICH-GCP (E6) Specific Responsibilities for Investigators

A. Investigators conducting industry-sponsored studies with contract requirements for adherence to ICH-GCP are responsible for ensuring adherence to ICH-GCP specific requirements.

B. With the participant's permission the investigator shall inform the participant's primary physician (if one exists) of their participation in the trial.

C. The investigator should make a reasonable effort to ascertain the reason, while fully respecting the participant's rights to withdraw from the trial without explanation.

D. Medical care and decisions are provided by a qualified physician.

E. The investigator provides evidence of such qualifications through up-to-date curriculum vitae or other relevant documentation requested by the sponsor, the IRB, or the regulatory authority.

F. The investigator is familiar with the appropriate use of the investigational product(s), as described in the protocol, in the current Investigator's Brochure, in the product information and in other information sources provided by the sponsor.

G. The investigator is aware of and follows GCP and the applicable regulatory requirements.

H. The investigator permits monitoring and auditing by the sponsor, and inspection by the appropriate regulatory authority.

I. A qualified physician (or dentist, when appropriate), who is an investigator or a co-investigator for the clinical trial, is responsible for all trial-related medical (or dental) decisions.

J. During and following a participant's participation in a trial, the investigator ensures that adequate medical care is provided to a participant for any adverse events, including clinically significant laboratory values, related to the trial.

K. The investigator informs a participant when medical care is needed for illnesses for which the investigator becomes aware.

L. Responsibility for accountability of the investigational product at the clinical trial site rests with the investigator.

M. The investigator ensures that the investigational product is used only in accordance with the approved IRB protocol.

N. The investigator ensures the accuracy, completeness, legibility, and timeliness of the data reports to the sponsor.

O. The investigator maintains the clinical trial documents as specified in Essential Documents for the Conduct of a Clinical Trial (REF?) and as required by the applicable regulatory requirements.

P. Essential documents are retained until at least two years after the last approval of a marketing application in an ICH region and there are no pending or contemplated marketing applications in an ICH region or at least two years have elapsed since the formal discontinuation of clinical development of the investigational product.

Q. If the investigator terminates or suspends a clinical trial without prior agreement of the sponsor, the investigator must promptly inform the IRB and the sponsor.

R. If the sponsor terminates or suspends a clinical trial, the investigator must promptly inform the IRB.

S. If the IRB terminates or suspends its approval of the clinical trial, the investigator should promptly notify the sponsor.

T. Upon completion of the trial, the investigator provides the IRB with a summary of the trial's outcome, and the relevant regulatory authorities with any reports required.

U. The investigator provides written reports to the sponsor and the IRB on any changes significantly affecting the conduct of a clinical trial or increasing risk to participants.

V. The investigator maintains a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.

W. The investigator reports all serious adverse events (SAEs) to the sponsor except for those SAEs that the protocol or other document (e.g., Investigator's Brochure) identifies as not needing immediate reporting. The investigator follows regulatory requirements related to the reporting of unexpected serious adverse drug or device reactions to the regulatory authority and the IRB.

X. Investigators report adverse events or laboratory abnormalities identified in the protocol as critical to safety evaluations to the sponsor according to the reporting requirements and within the time periods specified by the sponsor in the protocol.

Y. For reports of deaths, the investigator supplies the sponsor and the IRB with any additional information (e.g., autopsy reports and terminal medical reports).

The PI has the Right to:

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 Integrity, 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.

Applicable Regulations
21 CFR 312.50
21 CFR 812.43(c)(4)
21 CFR 812.100
21 CFR 812.150 (a)(1)(2)

Guidance for Industry Investigator Responsibilities- Protecting the Rights, Safety and Welfare of Study Subjects October 2009
International Conference on Harmonisation (ICH) Guidance for Industry, E6 Good Clinical Practice; Consolidated Guidance (Good Clinical Practice Guidance).

Adoption Date:	Created by:	Date of Revision:	Revised By:	Summary of Revision:
11/2005	IRB Director	07/2009	J. Gerlach	Revision has been made to remove text regarding the Delegation of Responsibilities Form
	IRB Director	10/2009	J. Gerlach per AAHRPP	Revision adds specific ICH-GCP (E6) specific responsibilities required of investigators
		09/2010	J. Gerlach	Remove reference to Policy II.02 Add text regarding 21 CFR 812
		06/2014	A. Braggs-Brown	Revised to reflect organizational changes

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