



Human Research Protection Program Policy

Policy Number: III.03

**Review of Protocols Involving Hazardous
Materials in Human Subjects Research**

Adopted: 11/05

Revised: 10/2016

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REVIEW OF PROTOCOLS INVOLVING HAZARDOUS MATERIALS IN HUMAN SUBJECTS RESEARCH

POLICY

All protocols involving human subjects and hazardous material require review by the appropriate safety committee or office in collaboration with the IRB.

BIOHAZARDS

Protocols involving biohazardous material or recombinant material at UC sites must be reviewed by the Institutional Biosafety Committee (the “IBC”) in collaboration with the IRB. Approval by the IRB requires prior approval by the IBC.

Research that may require IBC review includes:

1. Experiments involving the deliberate transfer of recombinant DNA or RNA into human subjects (e.g. plasmids, viral vectors);
2. Experiments involving biological agents (e.g. bacteria, virus, fungus, protozoa) isolated from/administered to human subjects;
3. Experiments involving human derived materials (e.g., blood, bodily secretions, tissues, cells);
4. Research using a therapeutic agent that is derived from recombinant DNA technologies on human subjects.

The IRB Chair or designee will review all protocols and forward to the Biosafety Office those protocols that meet the criteria described above. The Biosafety Office will determine if the protocol requires review and approval by the IBC and will inform the IRB office in writing if the protocol does not need IBC review. If the protocol requires review by the IBC, the IRB will not release the formal Protocol Approval Notification Form until there is IBC approval.

If the research is conducted at a site other than UC, the site must have a mechanism to review the protocol for biohazardous agents and be capable of complying with the requirements for protection of personnel from biohazardous agents



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RADIATION EXPOSURE AND RADIOISOTOPES

The Radiation Safety Committee (RSC) reviews all human research protocols involving ionizing radiation. Ionizing radiation includes x-rays, brachytherapy sources, radiopharmaceuticals, and accelerators used for teletherapy treatments. The RSC review of human-use protocols focuses on potential radiation exposure to personnel and the public from procedures performed in the protocol. However, consideration is given to the appropriateness of the procedure; e.g., if the concern is for potential lung problems, then chest x-rays at reasonable frequencies may be appropriate.

1. These protocols are reviewed by an identified expert in clinical radiation safety procedures and issues as a consultant to, and an active member of both the IRB and RSC. If the protocol requires review by the full RSC, the IRB will not release the formal Protocol Approval Notification Form until there is RSC approval. If the protocol does not require review by the full RSC, the radiation safety expert will note this as part of his comments during the IRB protocol review process.
2. If there is no FDA approval for a radioactive drug used in human research, the Radioactive Drug Research Committee must also approve the protocol, in addition to the IRB and the RSC.
3. If the protocol involves radiation related procedures which are carried out at sites other than the University of Cincinnati, the IRB also must have an approval by the RSC or equivalent of the non-university site before the study can be evaluated for final approval.

For additional information, refer to the Radiation Safety Manual of the University of Cincinnati or contact the Radiation Safety Office.

DEPARTMENT OF ENVIRONMENTAL HEALTH AND SAFETY

The Department of Environmental Health and Safety provides technical and management support for researchers on safe laboratory practices and handling hazardous biological and chemical agents.

The Department of Environmental Health and Safety staff is available to researchers and the IRB when research poses a risk to the health or safety of university employees. The policy covering the Department of Environmental Health and Safety is set forth in University Rule 10:10-45-01 *Safety: Policy Statement on Safety and Environmental Health at the University of Cincinnati*.



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UNIVERSITY HEALTH SERVICES

University Health Services provides health care and health education to university employees for employee related accidents and illness. Employees and students who suffer illness or injury during the scope of their duties can be treated at clinic facilities on both East and West campuses.

OTHER HAZARDS

If the IRB identifies hazards other than biological or radiological and there is not appropriate expertise on the committee to determine what protections may be appropriate, it will identify an appropriate consultant and will consider the consultant’s recommendations when considering approval of the research.

Applicable Documents

University Rule 10:10-45-01 *Safety: Policy Statement on Safety and Environmental Health at the University of Cincinnati.*

Adopted Date	Created By:	Revision Date:	Revised By:	Summary of Revisions:
11/2005	M. Belskis	07/2009	J. Gerlach	Update to types of research requiring IBC review
		10/2016	M. Linke/ M. Espinola	Clarification of the types of research requiring IBC review

Date Adopted: July 2009 **Signature:** on file