

ROLES AND RESPONSIBILITIES

Office of Research Compliance and Regulatory Affairs

The Office of Research Compliance and Regulatory Affairs (“ORCRA”) provides administrative support to the Institutional Review Boards and the other research review committees and compliance functions. With respect to human subjects’ research, these committees include the Radiation Safety Committee, which reviews and provides approval for all human research protocols involving the use of ionizing radiation and the Institutional Biosafety Committee, which reviews and approves all human research protocols involving the use of infectious agents or recombinant DNA. The University’s Compliance Hotline program for anonymous reporting of allegations of non compliance in any aspect of research or physician billing is administered by ORCRA. The Quality Assurance/Quality Improvement program is also a service of ORCRA. It provides post-approval monitoring of human subjects’ research projects. The office is directed by the Research Compliance Officer, who reports to the Vice President for Research.

The Institutional Review Board

The University of Cincinnati has established three Institutional Review Board (“IRB”) panels to review all proposed research involving human subjects to ensure that the rights and welfare of participants in research are adequately protected. The University of Cincinnati IRB serves as the IRB of record for the University of Cincinnati, University Hospital, Inc., The Shriners’ Institute for Burned Children, The Cincinnati Veterans Affairs Medical Center, and The Drake Center. The IRBs are composed primarily of faculty members from disciplines in which research involving human subjects is integral to that discipline's work, as well as several members from the community whose primary interest is in non-scientific areas. The Board(s) membership, policies, and procedures are governed by an Assurance agreement with the Federal government.

Human subjects’ research means any activity intended to obtain and record information from or about individuals for research purposes. Any undertaking in which students, faculty, or staff investigate and/or collect data on human subjects or use existing data or specimens collected from living human subjects for research purposes, requires review by the Institutional Review Board prior to initiation of the project. This includes both funded and non-funded research, including dissertations, masters’ theses, pilot studies, class projects, and non-funded, faculty-directed research if the following conditions are met:

- the research is sponsored by the University, or
- the research is conducted by or under the direction of any University employee or agent of this institution in connection with his/her institutional responsibilities, or
- the research is conducted by or under the direction of any University employee or agent of this institution using any University property or facility, or
- the research involves the use of the University's non-public information to identify or contact human research subjects or prospective subjects

Studies involving drugs, devices, or other invasive interventions will be reviewed by the Medical IRBs. Those studies involving surveys, interviews and observation techniques will be reviewed by the Behavioral and Social Sciences Board. The human subjects review process is administered through the Institutional Review Board Office for the University

The Office of Research Compliance Training

The Office of Research Compliance Training is responsible for developing and delivering workshops and training classes, as well as designing computer-based training courses on research regulatory compliance issues. In addition to delivering training that meets the needs of the research investigators, courses are developed in response to changing regulatory and accreditation requirements, e.g., HIPAA. Efforts are coordinated with the Regulatory Compliance Officer, the multiple Institutional Review Boards and IRB support staff, the Institutional Animal Care and Use Committee and IACUC support staff, the Institutional Biosafety Committee and IBC support staff, and others, as needed. Many programs are eligible for continuing education credits.

The Office of Sponsored Programs

Institutional Commitment

All members of the University community involved in research will take personal responsibility for their actions in pursuit of individual and organizational excellence. Each individual will uphold the highest standards of ethical and professional conduct in accordance with the University Rules, sponsoring agency policies and regulations and all other University policies governing research.

Unit Role

The Office of Sponsored Programs reviews, approves, and provides the institutional signature for proposals, awards, and all contracts, and is responsible for the dissemination and monitoring of Federal regulations and University policies and procedures regarding the management of sponsored programs. The Office of Sponsored Programs functions as a liaison between sponsors and University investigators in matters of policy, procedures, and regulations. The Office provides communication, education, and training on proposals, awards, and contracts to the University-wide research community.

The Office of Sponsored Programs reports to the Associate Senior Vice President, a report to the Vice President for Research.

Sponsored Program Administration

General Administrative

- Serves as liaison with sponsors, Sponsored Program Accounting to ensure appropriate interpretation of agency policies, guidelines, and award terms.
- Responsibility to review and approve contract budgets and proposals.
- Verifies that appropriate regulatory approvals and assurances are in place, as required by the sponsoring agency.
- Endorses proposals and other documents requiring an authorized institutional official to approve plan and certify compliance.
- Confirms appropriate regulatory approvals and assurances, as required by the sponsoring agency.
- Communicates information about sponsors and funding opportunities to faculty and deans to support faculty research interests and institutional goals.

Provides reports, as requested, regarding research proposals, awards, and other key statistics.

Proposal Budget

Reviews and approves proposal budgets to certify compliance with Federal regulations and sponsor and University policies and procedures for budget preparation.

Award Acceptance (Terms and Conditions)

- Reviews all incoming awards for accuracy and acceptability of terms.
- Verifies compliance prior to establishing award.
- Negotiates acceptable terms and conditions with sponsors who have contracts with the University.
- Establishes accounts for all awards.

Prepares and issues sponsored research award subcontracts, as necessary.

Facilities and Administrative Cost Rate

Verifies that the appropriate facilities and administrative cost rates are being requested and used.

Equipment Management

Reviews list of equipment to be transferred to another institution after department review and approval.

Reporting

- Notifies Principal Investigators of imminent (30-day) project end date as reminder of technical report requirement. (Electronic – COEUS)
- Serves as authorized institutional contact for late technical reports notices.
- Monitors web sites of agencies with technical report tracking databases.

Notifies appropriate officials of non-compliance.

Project Closure and Reporting

Provides institutional signature when required by sponsoring agency, (e.g., transfer reports, patent reports, and relinquishing statements).

Financial Management

Management of Project Funds

- Partners with the Sponsored Program Accounting to formulate, implement, and interpret policies for allowable costs and cost sharing according to Federal regulations and sponsor and University policies and procedures.
- Partners with Sponsored Program Accounting in providing training to researchers and staff on the appropriate stewardship of all project-related funds.
- Interacts with funding agencies on award management issues.
- Reviews and processes forms for the advance expenditure of funds and other account actions requiring University prior approval.
- Reviews and approves account actions as required by award terms and conditions.

Assists in resolving instances of discovered non-compliance.

Financial Conflicts of Interest

- Verifies disclosures at proposal submission.
- Verifies disclosures and coordinates successful management, reduction, or elimination of any financial conflicts with VP for Research prior to award set-up.

Reports, as the designated Institutional Official, any conflict disclosures and their resolution to the appropriate governmental agency.

Human Subjects Protection

General Administrative

- Verifies that the appropriate human studies regulatory approvals and assurances are current prior to submitting proposal (if applicable) and prior to establishment of account.

Animal Welfare

General Administrative

- Verifies that the appropriate animal studies regulatory approvals and assurances are current prior to submitting proposal (if applicable) and prior to establishment of account.

Institutional Biosafety

General Administrative

- Verifies that appropriate regulatory approvals and assurances for activities that involve the use of biohazardous agents and recombinant DNA molecules are current prior to submitting proposal (if applicable) and prior to establishment of account.

Environmental Health and Safety

General Administrative

- Verifies the accuracy of all environmental approval information included on grant applications with the Environmental Health and Safety Office.

Patents and Inventions

General Administrative

- Verifies the acceptability of patent and invention policies as written in proposal guidelines with the Intellectual Property Office.
- Reviews and processes non-Edison patent and invention reports required by sponsoring agencies.

The Biosafety Committee

The Institutional Biosafety Committee (IBC) reviews all those University research and teaching activities involving the use of biohazardous agents and recombinant DNA molecules as described in the NIH Guidelines, and the Centers for Disease Control and Prevention (CDC) Guidelines. It reviews human research protocols as requested by researchers or by the IRB.

All activities involving the use of Biolevel 2 or Biolevel 3 agents, certain activities involving Biolevel 1 agents, or non-exempt recombinant DNA molecules as defined by NIH, are reviewed by the IBC regardless of the source of funding for the project. Research using Risk Group 4 is not carried out at the University of Cincinnati. The IBC may approve research protocols with or without modifications, or withhold approval of all or any portion of a protocol.

The Radiation Safety Committee

The mission of the University of Cincinnati Radiation Safety Committee (RSC) is to develop a Radiation Control and Safety Program that complies with the requirements of applicable regulatory agencies, licenses, permits and registrations and ensures personnel, their coworkers, the general public, and the environment are protected from detrimental effects of radioactive materials and radiation producing devices used under the program. One of the roles of the RSC is to review Human-Use Research Protocols as necessary for radiation safety issues.

All Human-Use Research Protocols must be reviewed and approved by the Institutional Review Board (IRB), and, when applicable, the Radioactive Drug Research Committee (RDRC). Those protocols involving the use of ionizing radiation in any form must also be reviewed and, when applicable, approved by the full Radiation Safety Committee (RSC). The RSC shall appoint a Human Research Subcommittee consisting of at least the following individuals.

- Two Radiation Oncology physicians
- Two Nuclear Medicine physicians
- Two Medical Physicists

The Human-use Subcommittee of the RSC reviews IRB protocols. The review and approval is limited to radiation safety issues only and does not constitute approval of the protocol. The Chair of the Human-use subcommittee of the RSC must also be a member of the both medical IRBs. This individual serves as the IRB/RSC liaison reviews and classifies each protocol based on the radiation exposure involved and the extent of review

required. Protocols that require full RSC approval are forwarded to the Radiation Safety Officer (“RSO”) for review and distribution to the RSC. The full RSC approves a protocol after any questions or problems are addressed with the PI through the UC IRB/RSC liaison.

The Standing Committee on Conflicts of Interest

The Standing Committee on Conflicts of Interest provides guidance in the management of conflicts of interest arising from the activities of the University and its employees, and helps to ensure that relationships between the University, its employees and outside entities have been examined and will be conducted in a manner consistent with institutional guidelines and all applicable law. Three members of the Standing Committee are appointed by the President of the University and two members are selected by the Faculty Senate.

The Office of General Counsel

The Office of General Counsel (“OGC”) provides legal support and advice to the Institutional Review Boards, including providing interpretations of all relevant federal, state, and local regulatory and statutory materials governing the performance of human subjects’ research. OGC also takes responsibility for the University’s response to requests for information and investigations by external regulatory and funding agencies arising from human research activities. In cooperation with the Vice President for Research, the OGC also oversees conflict management plans and provides support for the activities of the University’s Standing Committee on Conflicts of Interest. OGC also performs legal review on behalf of the University for all contracts for the performance of human subjects research, whether funded by public or private sources. OGC is directed by the Vice President for Legal Affairs and University Counsel.