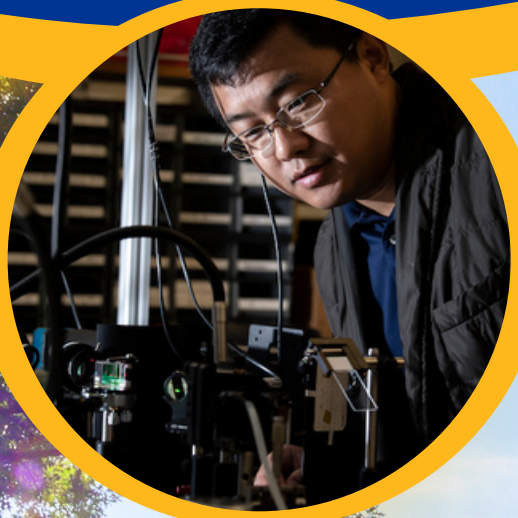
A Guide to the

OFFICE OF RESEARCH PROTECTIONS



University of Pittsburgh

Office of the Senior Vice Chancellor for Research

University of Pittsburgh

Office of Research Protections

Overview

MISSION:

The Office of Research Protections (ORP) is a unit within the Office of the Senior Vice Chancellor for Research. The mission of ORP is to aid investigators in designing and performing research studies so they meet current ethical standards and conform to all applicable laws and regulations.

The divisions that comprise ORP accomplish this goal through education, prospective review of research protocols, consultations with investigators, and monitoring of ongoing studies. The activities of most of our divisions are defined by federal laws and regulations, as well as University policies stemming from these regulations.

HISTORY

Originally known as the Research Conduct and Compliance Office, ORP was created in 1999 to house the University's units responsible for ensuring ethical and regulation-compliant research practices at the University: Animal Research Protection (affiliated with the Institutional Animal Care and Use Committee), Human Research Protection (affiliated with the Institutional Review Board), Education and Compliance Support for Human Subject Research, and Radiation Safety.

Over time, other divisions were added to offer more comprehensive support to investigators, and to ensure compliance with evolving laws and regulations, including Institutional Biosafety (2001), Conflict of Interest (2004), Research Integrity (2015), and Trade Compliance (2021).

CURRENT OPERATION

Today, ORP is staffed by more than 80 dedicated staff members across all divisions. Additionally, ORP supports 16 committees made up of more than 200 University members and community stakeholders.

Visit our site to learn more

orp@pitt.edu

Office of Research Protections

Pitt Research

Bill Yates
Vice Chancellor

Susan Sesack
Research Integrity Officer

Mara Horwitz
Assistant Vice Chancellor

Jean Barone, Director
Human Research Protection

- Associate Director

Full Board Team
- Team Manager
- Research Review Team (5)

Exempt/Expedited Team
- Team Manager
- Research Review Team (8)

Reliance Team
- Associate Director
- Reliance Specialists (5)

Admin. Team
- Program Manager
- Education Coordinator
- Regulatory Specialist

Jeremy DeRicco, Director
Animal Research Protection

- Director of Regulatory Affairs
- Manager
- Regulatory Coordinators (2)
- Risk Assessment Officer
- Compliance Coordinators (3)
- Training & Compliance Coordinator

Christina Gasdia, Director
Conflict of Interest (COI)

- COI Program Manager
- Senior COI Analysts (2)
- COI Analysts (2)
- COI Coordinator

Beverly Harding, Director
Institutional Biosafety

- Compliance Coordinator
- Biosecurity & Compliance Specialist

Kelly Dornin-Koss, Director
Education & Compliance Support - Human Subject Research

- Associate Director
- Education & Compliance Coordinators (6)
- Information Disclosure Specialist
- IIS Program Manager
- IIS Coordinator

Lara Paciello, Director
Radiation Safety

- Associate Radiation Safety Officer
- Diagnostic Medical Physicist
- Diagnostic Medical Physicist/Associate Professor of Radiology
- Medical Health Physicists (2)
- Health Physicists (2)
- Assistant Health Physicists (4)
- Radiation Safety Technologists (2)
- X-Ray Tech

Allen DiPalma, Executive Director
Research Security & Trade Compliance

- Assistant Director
- Assistant to the Director
- Manager
- Biosecuirty & Compliance Specialist
- Research Security Manager

Stephen Korbich, Director
Administrative Support

- Office Administrator
- Financial Analyst
- Senior Communications Specialist
- HR Administrator
- Compliance & Validation Manager

Data Analytics & IT Team
- Director
- Systems Administrator
- Systems Programmer
- Project Manager
- Business Analyst

Committees Supported by ORP

Human Research Protection

Institutional Review Board
Chair: Margaret Hsieh, MD
83 Total Members

Committee A
Vice-Chair: Judith Martin, MD
12 Members

Committee B
Vice-Chair: Beatrice Chen, MD
13 Members

Committee C
Vice-Chair: James Castellano, MD
14 Members

Committee D
Vice-Chair: Adam Frisch, MD
13 Members

Committee E
Chair: Margaret Hsieh, MD
8 Members

Committee F
Chair: Margaret Hsieh, MD
10 Members

Committee G
Vice-Chair: Jamie Zelazny, PhD
12 Members

Committee H
Vice-Chair: Timothy Corcoran, PhD
13 Members

Committee I
Vice-Chairs: Jamie Zelazny, PhD and Tim Corcoran, PhD
5 Members

Animal Research Protection

Institutional Animal Care and Use Committee
Chair: Deborah Chapman, PhD
43 Members

Conflict of Interest

Conflict of Interest Committee
Chair: John S. Maier, PhD, MD
26 Members

Institutional Conflict of Interest Committee
Co-Chairs: Lisa Parker, PhD
Sunil Saxena, PhD
15 Members

Institutional Biosafety

Institutional Biosafety Committee
Chair: William Walker, PhD
21 Members

Human Stem Cell Research Oversight Committee
Chair: Eric Lagasse, PhD
7 Members

Radiation Safety

Radiation Safety Committee
Chair: Margarita Zuley, MD, FACR
18 Members

Radioactive Drug Research Committee
Chair: Kenneth G. Bennet, MD
8 Members

Human Use Subcommittee
Chair: Kenneth G. Bennet, MD
13 Members

University of Pittsburgh

Office of Research Protections

Human Research Protection

ABOUT US:

Pitt's Human Research Protection (HRP) Division supports the Institutional Review Board (IRB) in protecting human research subjects by:

- Promoting a culture of compliance throughout all academic departments
- Serving as the resource to navigate the complex regulatory landscape
- Facilitating the prospective review of research protocols by the IRB to assure that studies on humans are conducted ethically

INSTITUTIONAL REVIEW BOARD (IRB)

In accordance with federal regulations, Pitt's IRB is empowered to review and monitor research involving human subjects. The IRB has the authority to approve, require modifications in (to secure approval), or disapprove human subject research.

SERVICES WE OFFER:

- **One-on-one consultations:** Discuss the details of your project with an IRB Specialist. Learn what type of submission you need and how to submit to the IRB.
- **Classroom and department presentations:** From undergraudates submitting their first project to post-graduates submitting a clinical trial, we can tailor a presentation to meet your needs.
- **Coordinator training:** Whether you are a new research coordinator or just need a refresher, we can advise you.
- **Virtual PittPRO training:** Learn how to navigate the platform for IRB submissions. Individual or group sessions are available.
- **General education sessions:** HRP offers continuing education on a variety of topics.

To arrange for our services, contact us at askirb@pitt.edu

HRP TEAMS:

- **Exempt/Expedited Team**
  - Conducts administrative reviews of minimal risk research in qualifying categories
- **Full Board Team**
  - Manages reviews of greater than minimal risk studies and other types of studies requiring convened IRB review
- **Reliance Team**
  - Facilitates management of all aspects of multi-center studies requiring review by a single IRB
- **Leadership Team**
  - Oversees daily operations of the HRP

Visit our site to learn more

@ askirb@pitt.edu

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Office of Research Protections

EDUCATION & COMPLIANCE SUPPORT

For Human Subject Research

ABOUT US:

The Education and Compliance Support for Human Subject Research (ECS-HSR) Division aims to protect the rights and safety of research participants and support investigators in the conduct of quality research by providing regulatory education and assistance to the University research community.

The ECS-HSR offers support in three main areas:

- IND and IDE Support (IIS)
- Monitoring & Compliance Support
- Clinical Trial Registration & Transparency Support

The ECS-HSR Division serves as a resource to educate and assist University investigators and study staff in the conduct of research in compliance with federal regulations and Good Clinical Practices (GCP), which are the recognized standards for conducting a clinical trial. We also offer departmental presentations on GCP requirements, study documentation, and regulatory file maintenance.

Our dedicated staff are available for individual consultations by appointment.

IND & IDE SUPPORT (IIS)

Provides education and support to faculty who will serve as the Sponsor of an Investigational New Drug Application (IND) or Investigational Device Exemption (IDE). Services are offered throughout the entire process including planning, development, maintenance, and closure.

Contact IIS@pitt.edu for assistance.

MONITORING & COMPLIANCE SUPPORT

Provides local monitoring services and education to sponsors of clinical investigations involving an IND or IDE under the jurisdiction of the University. Support is also available to biomedical and social and behavioral researchers through Educational Outreach Programs such as Research Investigator Startup Education (RISE) reviews and Quality Assistance Reviews (QAR)

Contact ecs-hsr@pitt.edu for assistance.

CLINICAL TRIAL REGISTRATION & TRANSPARENCY SUPPORT

Provides training and resources on the disclosure and sharing of information, documents, and data for clinical studies, including submitting clinical study registration and summary results to ClinicalTrials.gov.

Contact CTgov@pitt.edu for assistance.

Visit our site to learn more

@ ECS-HSR@pitt.edu

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Animal Research Protection

ABOUT US:

The Animal Research Protection (ARP) Division supports the Institutional Animal Care and Use Committee in ensuring the appropriate care, use, and humane treatment of animals used for research and education at the University.

We serve as a resource to the University community by providing guidance to ensure that all animal use is in accordance with the highest scientific, humane, and ethical principles.

EDUCATION & TRAINING

The ARP provides mandatory training required for working with animals and offers monthly educational presentations and individualized training upon request.

REVIEW & APPROVAL

ARP staff provide support to investigators in the preparation and submission of protocols to the IACUC, and also aid IACUC members in completing protocol reviews.

POST-APPROVAL MONITORING

Ongoing monitoring of animal activities is essential to uphold the highest standards in scientific rigor and animal care. ARP maintains a post-approval monitoring program, investigates concerns regarding animal use, and provides support to investigators in maintaining the highest standards for animal research.

INSTITUTIONAL ANIMAL CARE & USE COMMITTEE (IACUC)

The IACUC is a University committee mandated by federal laws and regulations to prospectively review all proposals for the use of vertebrate animals in teaching and research. In addition, the IACUC is empowered to provide oversight for the animal care and use program.

WE ARE HERE TO HELP!

We are available to help you write your IACUC protocol, provide information about regulatory requirements, and aid you in managing animal care and use in you laboratory.

Click to Contact ARP

Visit our site to learn more

iacuc@pitt.edu

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INSTITUTIONAL BIOSAFETY

ABOUT US:

The Institutional Biosafety Division supports three different committees that oversee research compliance for research projects involving recombinant or synthetic nucleic acid molecules, human stem cells, or Select Agent materials. These committees are:

- Institutional Biosafety Committee
- Human Stem Cell Research Oversight
- Dual Use Research of Concern

The Institutional Biosafety Division serves as a resource for the University research community, other administrative divisions within Pitt Research, and offices or departments that support related research efforts at the University. The Division staff provide information and can assist researchers in submitting research proposals for review.

For assistance in preparing submissions for the committees we support, or if you need more information, contact us at: ibc_support@pitt.edu.

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

The IBC is a University committee mandated by the National Institutes of Health (NIH) to review and approve all research involving recombinant or synthetic nucleic acid molecules in accordance with NIH Guidelines.

HUMAN STEM CELL RESEARCH OVERSIGHT (HSCRO)

The hSCRO committee reviews research involving human embryonic stem cells, as well as studies utilizing certain other types of human stem cells, to ensure the work is compliant with both federal and Commonwealth of Pennsylvania laws and regulations.

DUAL USE RESEARCH OF CONCERN (DURC)

DURC is life sciences research that can be reasonably anticipated to provide knowledge, information, products, or technologies that could be misapplied to pose a threat to public health and safety, the environment, or national security. The DURC Committee evaluates research that may be classified as DURC in accordance with federal policies.

Visit our site to learn more

@ ibc_support@pitt.edu

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Radiation Safety

ABOUT US:

The Radiation Safety Division manages the University's radiation safety program, which ensures the safe and optimal use of radioactive material and ionizing radiation-producing equipment in compliance with applicable federal and state regulations and institutional licenses.

The program covers all main and regional campuses as well as some UPMC facilities: UPMC Presbyterian/Shadyside, UPMC Children's Hospital, and UPMC Magee-Women's Hospital.

For information or support, contact us at: radsafe@pitt.edu.

WHAT WE DO:

We manage and execute the policies and procedures approved by the University's Radiation Safety Committee.

Our responsibilities include:

- Maintenance of radioactive materials and accelerator licenses and X-Ray machine registrations
- Providing radiation safety training
- Monitoring personnel radiation exposures
- Receipt and inventory of radioactive materials
- Radiation surveys and compliance audits
- Clinical radiation physics support
- Radiation safety procedure design and review
- Radioactive waste disposal
- Support for radiation safety committee and subcommittees

RADIATION SAFETY COMMITTEE

Our division supports the University's Radiation Safety Committee and two subcommittees that review and approve experimental uses of radiation:

- **Radiation Safety Committee:** establishes policies and standards for the radiation safety program; approves new radiation workers (authorized users); approves new modalities and uses of radiation; reviews incidents and corrective actions.
- **Human Use Subcommittee**: has the authority and responsibility to review and approve all proposed human research uses of radioactive material and X-Ray producing equipment.
- **Radioactive Drug Research Committee**: has the authority and responsibility to review and approve the research use of radioactive drugs in accordance with Food and Drug Administration (FDA) regulations.

Visit our site to learn more

@ radsafe@pitt.edu

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Office of Research Protections

CONFLICT OF INTEREST

ABOUT US:

The Conflict of Interest Division (COID) supports the Conflict of Interest (COI) and Institutional Conflict of Interest (ICOI) Committees in reviewing and managing potential financial conflicts of interest. We also educate the University community about the University's COI and ICOI policies and related federal regulations.

The COID maintains the University's online disclosure system, *My*Disclosures.

CONFLICT OF INTEREST COMMITTEE (COIC)

The COIC is responsible for the oversight and management of potential financial COIs, including those that involve University licensed start-up companies, to ensure they do not bias the conduct of research.

INSTITUTIONAL CONFLICT OF INTEREST COMMITTEE (ICOIC)

The ICOIC is responsible for ensuring that the financial interests of the University or the external engagements of its senior officials do not influence the University's business decisions or integrity of its academic and research missions. The ICOIC formulates management plans to address actual or perceived incidents of ICOI by the University or senior University officials.

COI POLICIES

The activities of the COI and ICOI committees and the COI Division are guided by two University policies:

- RI-01: Conflict of Interest
- RI-11: Institutional Conflict of Interest

*MY*DISCLOSURES

Disclosure of outside activities is essential to identifying and managing potential conflicts of interest. Mandatory disclosers are required to report their outside interests, activities, and relationships related to their institutional responsibilities in MyDisclosures. Disclosures are then reviewed by the discloser's supervisor and the COID to identify and manage potential conflicts.

Visit our site to learn more

@ coi@pitt.edu

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Research Security & Trade Compliance

ABOUT US

The Office of Research Security and Trade Compliance is responsible for managing regulatory programs related to federal export controls, biological imports, academic visitor vetting and management, drones compliance, and research security.

ACADEMIC VISITOR VETTING

Academic Visitors include graduate students, post-docs, fellows, scientists, researchers, scholars and other individuals from industry, universities, government, or other institutions who come to campus for academic or research purposes for more than a short stay. We manage a five-step process spanning the lifecycle of a visit which includes research security reviews and agreement sourcing.

Learn more about hosting Academic Visitors

EXPORT CONTROLS

The U.S. export control regulations are a series of laws and regulations that control specific commodities, technologies, software, and services for reasons of national security, economic interest, foreign policy, and human rights purposes. We offer training, best practices and hands on support for the University community for compliance with these regulations.

DRONES

We manage the University's Drones Policy which covers the safe operations of drones over University owned or leased property. The policy requires outdoor flight notifications in some cases along with an approval process for proposed indoor flights.

Learn more about the Drone Policy

BIOLOGICAL IMPORTS

Certain biological materials are regulated by federal agencies for international importation and interstate transfer. We offer training and other direct assistance to the University community on this topic and work with other central offices to identify and manage research that may invoke these regulations.

RESEARCH SECURITY

The U.S. government has in recent years raised awareness of how foreign governments have disregarded research integrity principles through Malign Foreign Talent Recruitment Programs and other methods to acquire U.S. technologies for purposes of advancing their economic and military ambitions. We assist the community with understanding current and future federal rules on this topic including federal disclosure requirements, restricted party lists, data safety, and travel considerations.

Learn more about Research Security

Visit our site to learn more

tradecompliance@pitt.edu

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Research Integrity

ABOUT US:

The Research Integrity Division is responsible for the implementation of the University's Research Integrity Policy (RI-07), and is empowered to investigate concerns of research misconduct. We also provide training to the University community about the responsible conduct of research.

Research Misconduct is defined as fabrication, falsification, or plagiarism, in proposing, performing, or reviewing research, or in reporting research results. Research Misconduct does not include honest error or differences of opinion, or disputes over authorship or credit.

Plagiarism is the unattributed copying or appropriation of another person's ideas, unique processes, results, or words without giving appropriate credit.

Should the conduct of research or the collection or reporting of research data and information be challenged in good faith on grounds of Research Misconduct, the Research Integrity Policy provides the framework for resolution of the grievance through a process of peer and administrative review. Principles of basic fairness and confidentiality are observed in these procedures.

REPORTING RESEARCH MISCONDUCT

- Contact the Research Integrity Officer at 412-624-8270 or by emailing research.integrity@pitt.edu

RESPONSIBLE CONDUCT OF RESEARCH

Learn more about the responsible conduct of research by visiting our website:

- Responsible conduct of research website

RESEARCH INTEGRITY POLICY

- Policy RI-07, Research Integrity

Visit our site to learn more

@ research.integrity@pitt.edu

University of Pittsburgh

Office of Research Protections

Guidance & Resources

The Office of Research Protections provides these additional resources and guidance for the University community:

GUIDANCE

Controlled Drugs. ORP is committed to ensuring compliance with government regulations pertaining to the use of controlled substances.

Link to Controlled Drug Guidance

Departing Investigators. When faculty leave the University, it is critical that ongoing research be closed appropriately. ORP maintains a checklist of closeout activities for departing investigators.

Link to Departing Investigator Checklist

Onboarding. ORP provides a customized onboarding process for new investigators. Onboarding sessions offer individualized assistance in protocol writing and regulatory compliance, while also establishing a point-of-contact that is helpful in addressing questions in the future.

Request ORP Onboarding

OTHER RESOURCES

CLINICAL TRIAL REGISTRATION & TRANSPARENCY SUPPORT

Through its Education & Compliance for Human Subject Research division, ORP provides support and guidance for every step of the clinical trial life cycle.

Visit our Website

DUAL USE RESEARCH OF CONCERN

Dual Use Research of Concern (DURC) is life science research whose findings can be misused to cause harm. Policies are in place to minimize the risk of misuse.

Learn More about DURC

DATA GOVERNANCE

Effective data management is critical to protecting the security and integrity of Pitt's research enterprise.

Review the University's Data Management Policy

ORP SUPPORT SERVICE

Need help in ensuring that your research meets regulatory requirements and ethical standards? Complete this short survey and relevant ORP staff will contact you.

Request ORP Support

@ orp@pitt.edu

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University of Pittsburgh
Office of Research
Protections
Hieber Building, Suite 401
3500 Fifth Avenue
Pittsburgh, PA 15213

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