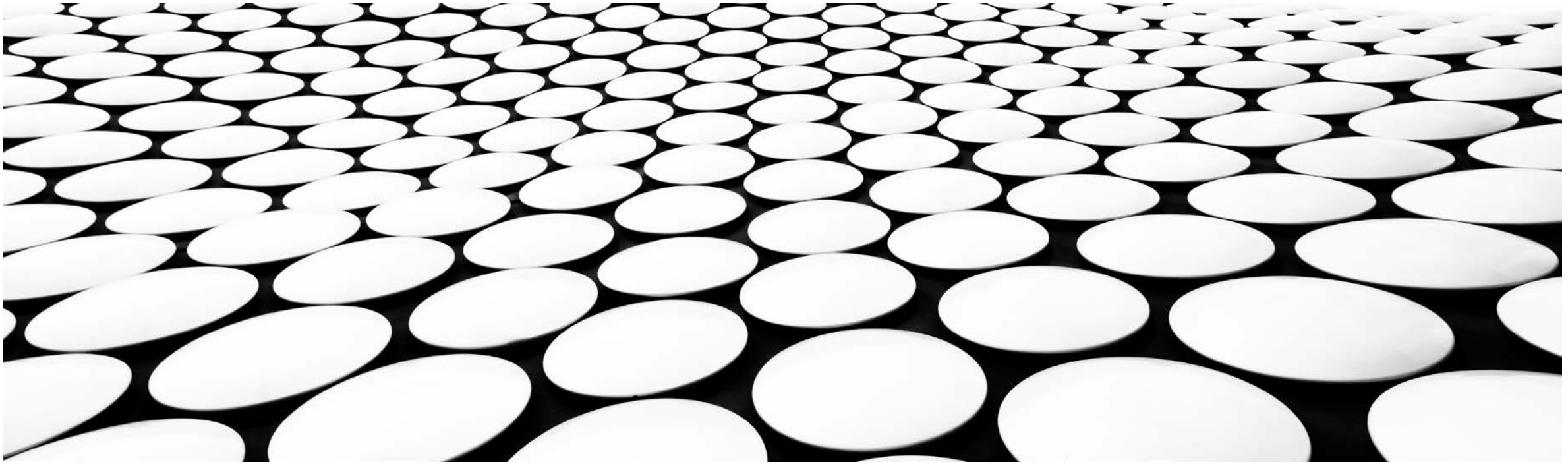
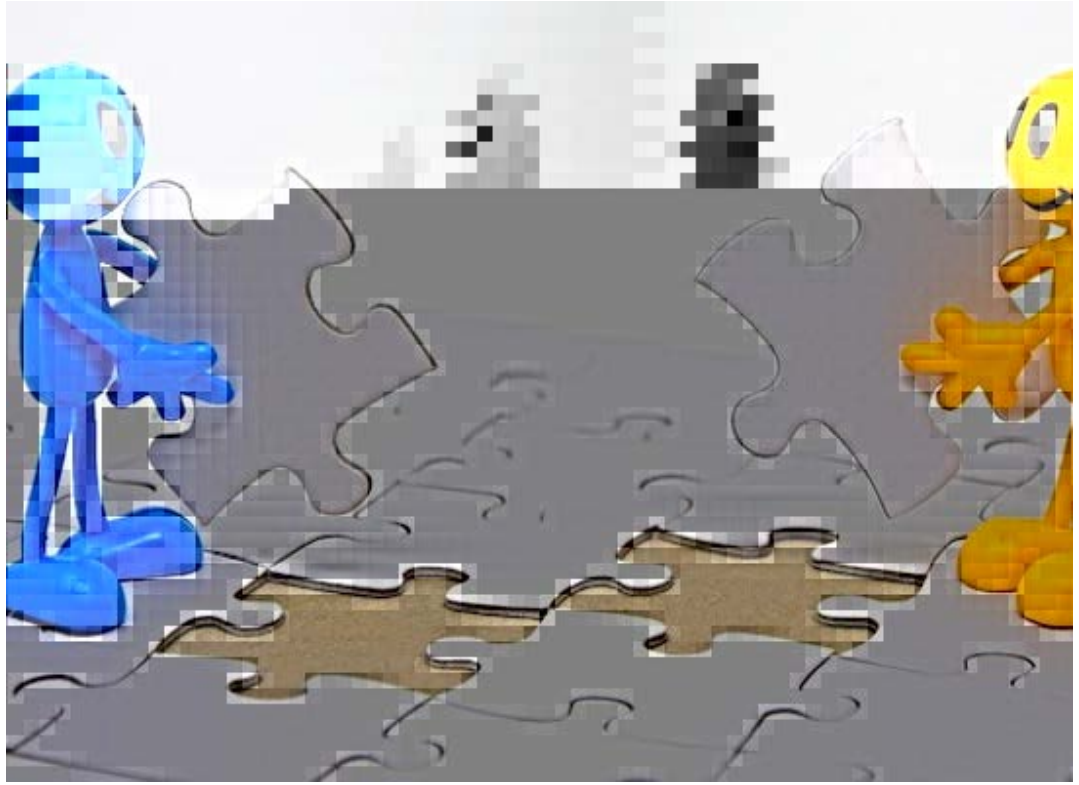
UNIVERSITY OF PITTSBURGH HUMAN RESEARCH PROTECTION PROGRAM (HRPP)

STRUCTURE, JURISDICTION AND CONFLICT OF INTEREST



UNIVERSITY OF PITTSBURGH HRPP – A SHARED RESPONSIBILITY



Pitt Leadership
Deans & Department Chairs
Investigators
Scientific Reviewers
Research Teams

Institutional Official
IRB Chair
IRB Vice Chairs
IRB Committees
Human Research Protection

Human Research Participants

Research Support Offices
Clinical and Translational Science Institute
Investigational Drug Service
University Counsel
Office of Sponsored Programs
Research Centers

Office of Research Protections:
COI and Committee
Education and Compliance Support
Institutional Biosafety
Research Integrity
Radiation Safety

Pitt Research

ROB RUTENBAR – SENIOR VICE CHANCELLOR FOR RESEARCH

Office of Research Protections

Office of Innovation and Entrepreneurship

Office of Economic Partnerships

Office of Sponsored Programs

Office of Research Computing

Pitt Research, led by the Senior Vice Chancellor for Research, is the core unit at the University of Pittsburgh with responsibility to:

- Facilitate research of impact
- Identify and catalyze strategic opportunities
- Position the University to lead large research collaborations
- Translate scholarly excellence into commercial innovation and economic partnership
- Maintain the highest standards of research integrity

https://research.pitt.edu/

Pitt Research
LEADERSHIP

Rob Rutenbar, Senior Vice Chancellor for Research

Bill Yates, PhD
Vice Chancellor of Research Protections
University of Pittsburgh Institutional Official

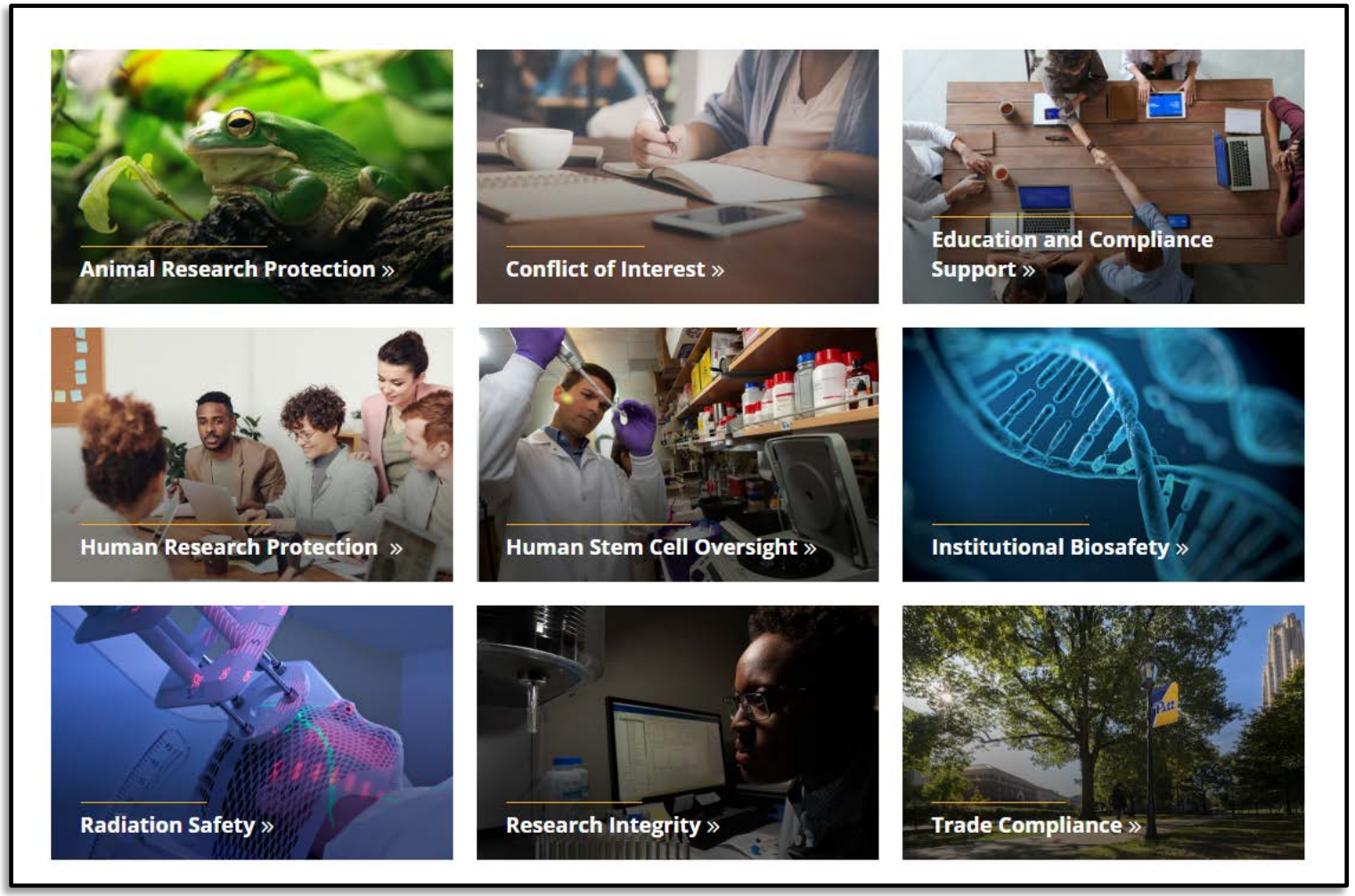
Margaret Hsieh, MD
Chair, Institutional Review Board

OFFICE OF RESEARCH PROTECTIONS (ORP)

Bill Yates, PhD
Vice Chancellor of Research Protections

ORP aids investigators in designing and performing research to meet current ethical standards and conform to all applicable laws and regulations.

The units that comprise the ORP accomplish this goal through education, prospective review of research protocols, consultations with investigators, and monitoring of ongoing studies.



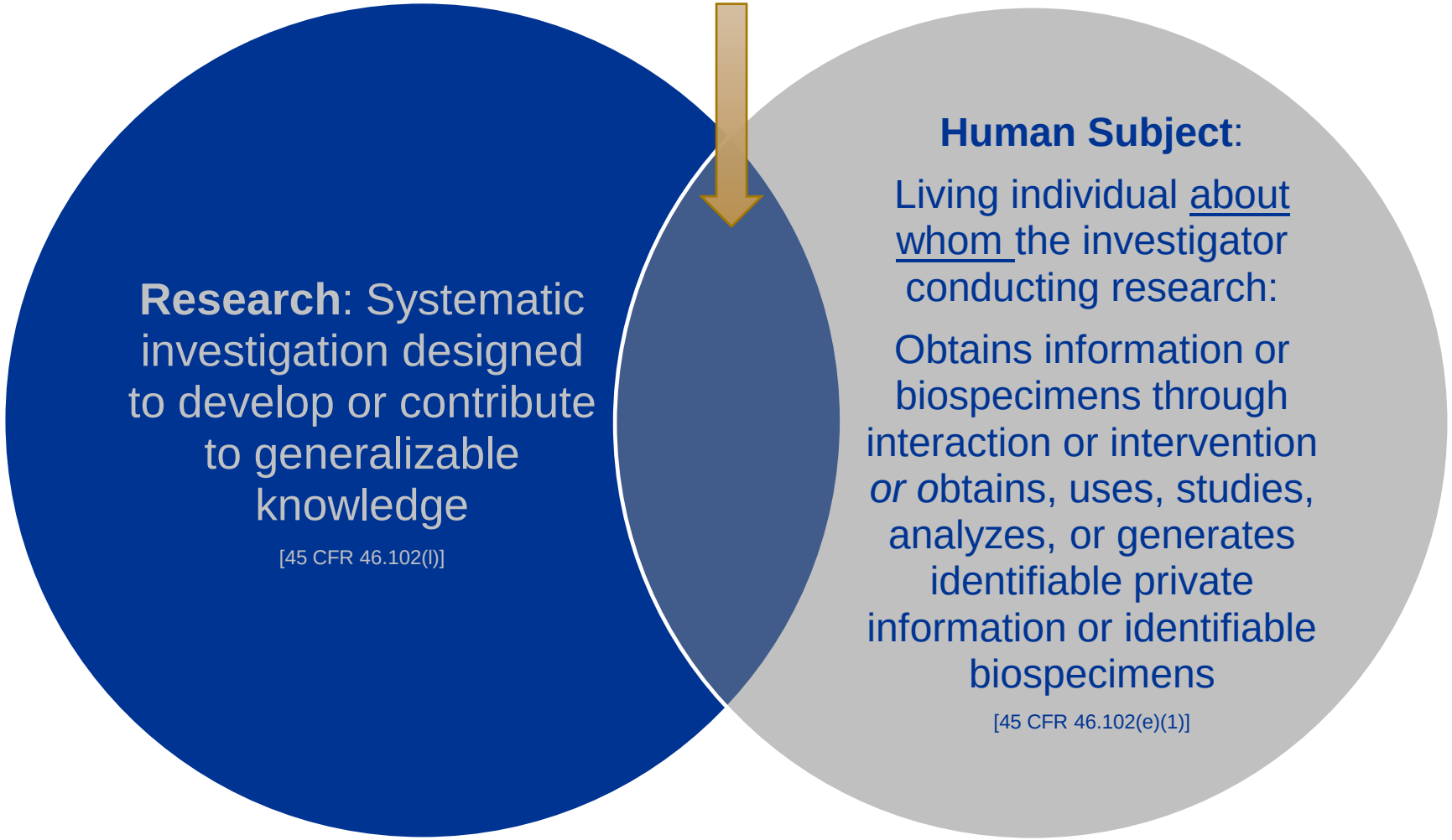
https://www.orp.pitt.edu/

HRP PURPOSE

PROTECT THE RIGHTS AND WELFARE OF HUMAN SUBJECTS INVOLVED IN RESEARCH ACTIVITIES

WHEN DO I NEED IRB REVIEW?

Human Subject Research



The IRB has the authority to approve, require modifications in (in order to approve), or disapprove all research activities involving human subjects when

Pitt/UPMC faculty, staff or students are engaged in human subject research

It takes place in Pitt/UPMC facilities

It is conducted using the private records of Pitt/UPMC

Single IRB Review (sIRB)

Legal arrangement that allows one IRB to review the research on behalf of other engaged institutions

NIH Policy:

- Effective January 25, 2018
- Applies to NIH funded new grant, renewal, revision or resubmission
- Multi-site
- Non-exempt
- Domestic

DHHS Policy:

- Effective January 18, 2020
- Applies to ANY federally funded new grant, renewal, revision or resubmission
- Multi-site
- Non-exempt
- Domestic

IRB.reliance@pitt.edu

When is reliance appropriate?

In an effort to reduce duplicate submission and oversight by multiple IRBs for the same protocol, the University of Pittsburgh IRB offers reliance agreement opportunities.

Reliance agreements are arrangements between institutions allowing the IRB of one institution to rely on the IRB of another institution for review of human subjects research.

Required

- NIH
- DHHS
- Consortium or Network

Optional

- Engaged collaborator conducting subcontract
- Investigator relocating with previous IRB approval
- Engaged investigator(s) with no IRB

Pitt Research

OSPARS:

UPMC Office of Sponsored Programs and Research Support

Purview: Facilitate industry-initiated and sponsored clinical trials of drugs and devices

- Conducted within a UPMC or UPP facility

  or

- Conducted under the direction of a UPMC or UPP staff member in connection with UPMC and/or UPP responsibilities, appointments and clinical privileges

OSPARS@upmc.edu

Pitt IRB or OSPARS Checklist

- ✓ Was any University of Pittsburgh faculty or staff member involved substantially in the development of the clinical trial protocol?
- ✓ Does any University of Pittsburgh faculty or staff member serve as the investigator-sponsor of an Investigational New Drug (IND) or Investigational Device Exemption (IDE) for the experimental drug or device being evaluated in the clinical trial?
- ✓ Is the conduct of this clinical trial being financially supported by any entity other than the industry sponsor and, possibly, the clinical department/division to whom the principal investigator reports?
- ✓ Will the clinical trial procedures be performed exclusively within a University facility without any use of UPMC patients, records, or facilities (i.e., this does not apply to University-owned buildings leased by UPMC)?
- ✓ Does the experimental drug or device being evaluated in the clinical trial 1) emit ionizing radiation; 2) involve a gene transfer intervention; or 3) involve a transgenic xenotransplant?

"NO" to ALL is submitted to OSPARS for processing

WHAT IS A FEDERAL-WIDE ASSURANCE?

- Each institution **engaged** in federally funded research must provide written **assurance** that it will comply with human subject protections regulations (45 CFR 46)
  - Names IRB of Record
  - Signed by **Institutional Official** (I/O)

WHAT IS AN INSTITUTIONAL OFFICIAL (I/O)?

- An individual who is legally authorized to act for the institution and can assure the institution will act according to the terms of the FWA
- Ensures that the HRPP has the resources and support essential to function in compliance with all requirements of human subject research
- Sufficient authority to allow authorization of necessary administrative or legal action should that be required
- Draft Guidance for Institutional Official Responsibilities

Institution	University of Pittsburgh	UPMC	MWRI	UPMC Cancer Centers
FWA #	FWA00006790	FWA00006735	FWA00003567	FWA00003338
Institutional Official	Bill Yates, PhD	Barbara Barnes, MD	Yoel Sadovsky, MD	Charles Bogosta
Title	Vice Chancellor for Research Protections	Vice President for Sponsored Programs, for Research Support, and for Continuing Medical Education, UPMC	Executive Director, Magee-Womens Research Institute	Executive Vice President President, UPMC International President, UPMC Hillman Cancer Center

REGULATORY ADHERENCE

The University complies with the following regulations as appropriate for the research being conducted

Establishes regulations that govern FDA materials in research

21 CFR 50
21 CFR 56
Other parts of 21 CFR depending on the research

Regulates research involving human subjects in order to protect the rights and safety of subjects

45 CFR 46 (Common Rule)

Enforces HIPAA: provides data privacy and security for medical information

45 CFR 160
45 CFR 164(A)(E)

Other regulations pertaining to specific scenarios:
types of records, locations (state & local laws), populations

CONFLICT OF INTEREST

The Conflict of Interest Committee and the Conflict of Interest Division play an important role in assisting the University community with understanding federal regulations and implementing best practices for managing potential conflicts arising from interactions with industry partners and engagement in entrepreneurial activities.

Conflicts of interest, especially those of a financial nature, have the potential to threaten the integrity of a university's research, scholarship, instruction, evaluation, and administrative functions.

Resources and notes:

COI Philosophy – purpose, definitions, disclosures

About the Conflict of Interest Committee

Examples of COIs

COI Management Plans for Research

Researchers must complete COI CITI Training and complete a *My*Disclosures form

IRB Members cannot participate in the discussion or voting on protocols when there is an actual or perceived conflict of interest

https://www.coi.pitt.edu/

POSSIBLE INTERVIEW QUESTIONS

- Who is the Institutional Official?
- What is the role of the Institutional Official?
- When does the University of Pittsburgh HRP have jurisdiction for review?
- What is a conflict of interest?
- How are conflicts of interest managed?

Resources:

HRP Policies and Procedures

Chapter 1 - Ethical and Regulatory Mandates to Protect Human Research Participants
Chapter 2 - Purpose of the Human Research Protection Office and Institutional Review Board
Chapter 3 - Human Subject Research and the Authority and Jurisdiction of the University of Pittsburgh Human Research Protection Office and IRB

Guidance: Activities Not Under the Pitt IRB Jurisdiction

QUESTIONS?

SPECIALIZED EDUCATION AVAILABLE UPON REQUEST: ASKIRB@PITT.EDU