Human Research Protection Program (HRPP) Structure and Jurisdiction
Research Conduct and Compliance Office

- Human Research Protection Office (HRPO)
- Office for Investigator Initiated IND/IDE Support (O3IS)
- Radioactive Drug Research Committee/Human Use Subcommittee (RDRC/HUSC)
- Education and Compliance Office (ECO)
- Stem Cell Research Oversight Committee (SCRO)
- Institutional Bio-Safety Committee (IBC)
- Conflict of Interest (COI)
- Office for Investigator Initiated IND/IDE Support (O3IS)

George Huber, JD: Vice Provost, Research Conduct and Compliance
IRB Office is now HRPO

- Education
- IRB Committees
- Human Research Protection Office (HRPO)
- Exempt, Expedited & other determinations
- Regulatory assurance
Leadership

George Huber, JD: Vice Provost for Research Conduct & Compliance

Kelly Dornin-Koss, MPPM, RN: Co-Director, Research Conduct & Compliance Office

Richard Guido, MD: HRPO Chair
HRPO Purpose

Protect the rights and welfare of human subjects involved in research activities
When is IRB review needed?

**Research**: Systematic investigation designed to develop or contribute to generalizable knowledge

[45 CFR 46.102(d)]

**Human Subject**:
Living individual about whom the investigator obtains:

Data through interaction or intervention *or* identifiable private info

[45 CFR 46.102(f)]
Jurisdiction of Pitt IRB

- Pitt faculty, staff or students engaged in research (at any site)
- Research conducted at Pitt facilities
- Research using the private records of the University
Jurisdiction Related to UPMC

Research conducted in any UPMC owned, operated, controlled DOMESTIC facility or program

Research conducted by any UPP member and/or any UPMC Employee

Does NOT cover UPMC Hamot, or UPMC Altoona
Industry sponsored research conducted entirely in a UPMC facility
- The University of Pittsburgh IRB is **NOT** permitted to be the IRB–of–Record
- May use an accredited national IRB
Pitt IRB or OSPARS?

Is it an investigator-initiated study?

Does it require any Pitt ancillary reviews (e.g. RDRC)?

Yes = PITT

Is the contract being processed through the Pitt Office of Research?
Federal–Wide Assurances

Each institution engaged in federally funded research provides written assurance that it will comply with human subject protections regulations (45 CFR 46)

- Names IRB of Record
- Signed by Institutional Official (I/O)
The 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

# Institutional Officials

<table>
<thead>
<tr>
<th>Pitt</th>
<th>UPMC</th>
<th>MWRI</th>
<th>CHP</th>
<th>UPMC Cancer Centers</th>
</tr>
</thead>
<tbody>
<tr>
<td>FWA00006790</td>
<td>FWA00006735</td>
<td>FWA00003567</td>
<td>FWA00000600</td>
<td>FWA00003338</td>
</tr>
<tr>
<td>George Huber, JD</td>
<td>Barbara Barnes, MD</td>
<td>John Worth, CPA</td>
<td>Terence Dermody, MD</td>
<td>Chuck Bogosta</td>
</tr>
<tr>
<td>Vice Provost, Research Conduct and Compliance</td>
<td>Vice President, Sponsored Programs, Research Support &amp; CME</td>
<td>Executive Director</td>
<td>Chairman of Pediatrics</td>
<td>Executive Vice President, UPMC Cancer Center</td>
</tr>
</tbody>
</table>
Possible Questions

- Who is the Institutional Official?
- What is the role of the Institutional Official?
- When does the Pitt HRPO have jurisdiction for review?

- Review HRPO Policies and Procedures: http://www.irb.pitt.edu/content/policies-and-procedures
Conflict of Interest

- Any interest of the investigator that may compete with the investigator’s obligation to protect the rights and welfare of research participants

- Investigators:
  - COI module
  - OSIRIS questions

- Board Members: cannot participate in discussion or voting
Possible Questions

- What is a conflict of interest?
- Are you as a member able to review a protocol if you have a conflict of interest?
- How do the members get information about an investigator’s conflict of interest and how is it managed?

COI Office: [http://www.coi.pitt.edu/](http://www.coi.pitt.edu/)
Questions?

Specialized education available upon request: askirb@pitt.edu