IRB RESPONSIBILITIES

- Ensure that research activities are consistent with the established ethical principles of the Belmont Report
  http://www.irb.pitt.edu/regulate.htm
- Ensure that subjects are adequately informed about study requirements and risks and benefits, so that they can make an informed decision about participating;
- Ensure that investigators conduct scientifically sound human subject research;
- Ensure that research activities are fully compliant with the federal regulations, including FDA requirements (if appropriate), as well as with state laws and university policies.

IRB MANAGEMENT

- Richard Guido, MD, CIP
  IRB Chair
  rguido@upmc.edu
- Christopher Ryan, PhD, CIP
  IRB Director
  ryancm@upmc.edu
- Margaret Hsieh, MD, CIP
  IRB Medical Director
  hsiehm@upmc.edu
- Jean Barone, CIP
  IRB Assistant Director
  baronej2@upmc.edu



FOR MORE INFORMATION
General Questions

- Information about submissions, review, and regulatory issues, contact the IRB office or IRB staff at
  http://www.irb.pitt.edu/irbstaff.htm

IRB or OSIRIS Training

- Patty Orndoff, RN, MEd, CIP
  IRB Education Coordinator
  orndoffpa@upmc.edu

Getting Started

- Investigators: detailed submission information available on the IRB website at
  http://www.irb.pitt.edu
- Student researchers: Student Research Guide at http://www.irb.pitt.edu

Consultation on Research Projects (in person or by phone)

- Nicholas Landolina, MPM, MEd
  IRB Office Manager
  landna@upmc.edu

Technical Support for OSIRIS

- Send e-mail to irb@pitt.edu

INSTITUTIONAL REVIEW BOARD

3500 Fifth Avenue
First Floor, Room 106
Pittsburgh, PA 15213
Phone: 412-383-1480
Fax: 412-383-1508

University of Pittsburgh

University of Pittsburgh

Institutional Review Board (IRB)

Investigators' Guide for Human Subject Protections & Institutional Review Processes

MISSION STATEMENT

It is the mission of the University of Pittsburgh's IRB to protect the rights and welfare of individuals who participate in research studies in a way that is consistent with both ethical principles and federal, state and local regulations.

DEFINITIONS

What is Research?

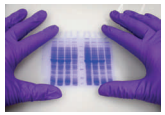
Research is defined as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

What is a Human Subject?

A human subject is a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual; or (2) identifiable private information.

What Projects Require IRB Oversight?

All research involving human subjects that is conducted 1) by University of Pittsburgh faculty, staff, or students; 2) at University or UPMC facilities; or that 3) involves the private records of the University of Pittsburgh.



FOR INVESTIGATORS

Requirements for IRB Submission

- Completion of web-based training modules on (1) research integrity and (2) human subjects research (biomedical or psychosocial); available at http://cme.hs.pitt.edu;
- Completion of 'smart forms' to prepare and submit an IRB protocol. Log on to OSIRIS (**O**nline **S**ubmission for **I**nstitutional **R**ev**I**ew**S**) at http://www.osiris.pitt.edu

Other Important Information

- Most research protocols are approved for one year; investigators should submit renewal applications at least six weeks prior to approval expiration;
- Any modifications to a study protocol and/or consent form must be submitted for approval prior to implementation of those changes

Responsibilities of Student Researchers

- Visit the IRB Student research web page;
- Identify a Faculty mentor who agrees to provide oversight and guidance for the conduct of the research project;
- Obtain IRB approval if this project meets the criteria for human subjects research

Responsibilities of Faculty Mentors

- Review student's project and provide advice about IRB requirements;
- Ensure that the student provides the IRB with all necessary materials (protocol, reports, modifications, etc.) in a timely fashion

ORGANIZATION OF THE UNIVERSITY OF PITTSBURGH IRB

- The IRB has several committees comprised of more than 200 scientists and lay people from the University and the community at large.
- These members volunteer their time to attend one 2-3 hour meeting each month to review protocols and related consent forms for research that may potentially expose subjects to more than minimal risk.
- In addition, a specialized group of IRB staff members conducts administrative reviews of research protocols that pose minimal risks and qualify for "expedited" or "exempt" review. Determination that a project is either 'not research' or does not 'involve human subjects' is also made by this review group.

BECOMING AN IRB MEMBER

- For information about serving on the IRB or to learn more about membership, contact the IRB office.