Institutional Review Board (IRB)

Melissa Miklos
Program Manager
miklosm@upmc.edu
Institutional Review Board

• What is the IRB?
• Why does the IRB exist?
• Where is the IRB?
• Who is the IRB?
• When do you need the IRB?
• How do you submit to the IRB?
What is the IRB?

- A committee that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans.

- Empowered by the FDA, DHHS/OHRP and the University to ensure compliance

- Scientific, ethical, and regulatory oversight
IRB Purpose

• Protect the rights and welfare of human subjects involved in research activities
  – IRB determines that risk/benefit ratio associated with study participation is appropriate
  – IRB ensures that investigators fully inform subjects about the study and study-related risks & benefits, so subjects can make an informed decision to participate
University of Pittsburgh IRB Jurisdiction

• Research conducted where University of Pittsburgh faculty, staff or students are engaged
  – Regardless of where the research is conducted

• Research conducted in University of Pittsburgh facilities

• Research conducted using the private records of the University of Pittsburgh
Why does the IRB exist?
Nuremberg Code - 1947

- Voluntary Consent is Essential
- Capacity to Consent
- Freedom from Coercion
- Comprehension of Potential Risks/Benefits
- Freedom to Withdraw At Any Time
- Minimization of Potential Risks/Harm
- Favorable Benefit/Risk Ratio
- Qualified Investigators/Appropriate Research Design
Historical Points

- **Willowbrook Hepatitis Studies- 1950s:** studies of natural history of infectious hepatitis

- **Jewish Chronic Disease Hospital Studies – 1960s:** Determine whether cancer cells lived longer in debilitated non-cancer patients than in those with cancer

- **Milgram Research on Obedience - 1960s:** Experiment on obedience to and defiance of authority
The Tuskegee Syphilis Study

- Conducted from 1932-1972
- Study to evaluate untreated syphilis in humans
- African-American sharecroppers in Alabama
- Perceived that they were receiving care
- Subjects were neither informed nor given penicillin when it became available
Belmont Report

- Written in 1978 by the National Commission for Protection of Human Subjects of Biomedical and Behavioral Research
  - Respect for Persons = voluntary consent
  - Beneficence = minimizing risk/maximizing benefit
  - Justice = equitable selection of subjects
FDA Halts Gene Experiments at University of Pennsylvania

By Rick Weiss and Deborah Nelson
Washington Post Staff Writers
Saturday, January 22, 2000; Page A1

The federal government yesterday halted all human gene therapy experiments involving a prominent researcher at the University of Pennsylvania, saying an investigation into the September death of a teenager there found the school's prestigious program in serious disarray.
Duke University – Research Misconduct

- 2007 – Duke announces DNA matched tumor treatments
- Others studied data to verify results
- 2010 – Duke announces failure of methods
- Further investigation revealed data manipulation and falsification
Where is the IRB?

- Hieber Pharmacy Building
- 5th Avenue and McKee Place – Oakland
- 412-383-1480
- askirb@pitt.edu
Who is the IRB?

- Exempt/Expedited Team
- Full Board Team
- Made up of nurses, social workers, and staff with previous research experience
IRB Committees

- 7 IRB Committees
- Each committee has at least 10 members to include at least one of each of the following:
  - A biomedical scientist
  - A psychosocial scientist
  - A non-scientist
  - A person who is not otherwise affiliated with the University of Pittsburgh, UPMC, CHP, UPMC Cancer Centers, or Magee, and who is not part of the immediate family an affiliated person
IRB Administration

- Richard Guido, MD – Chairman
- Chris Ryan, PhD – Director
- Jean Barone – Assistant Director
- Margaret Hsieh, MD – Medical Director
- Melissa Miklos – Program Manager
When do you need the IRB?

When you’re doing human subject research, of course
What is ‘research’

“A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge”

– Example: Testing a hypothesis or attempting to answer a question that has relevance beyond the specific data collection site
What is a ‘human subject’

- *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains
  
  (1) Data through intervention or interaction with the individual, or
  
  (2) Identifiable private information.
Does it meet the definition of research?

- Case reports – information was not collected to test hypotheses or produce generalizable knowledge
- Innovative practice – designed solely to enhance the well-being of a patient (diagnosis, treatment and/or therapy)
- QA/QI – focus on improving patient care within a patient care environment
- Research involving deceased individuals
How do you submit to the IRB?

**OSIRIS: Online Submission for Institutional Reviews**
Submission of New Studies

- **OSIRIS** (electronic submission process)
  - Pre IRB reviews
  - Series of questions and answers to build application
  - All attachments (grant, consent form, multi-center protocol) included in one online location
Requirement for all Investigators

- Internet Based Studies in Education and Research (ISER) [https://cme.hs.pitt.edu](https://cme.hs.pitt.edu)
  - Human Subject Research
  - Research Integrity
  - HIPAA – if research involves protected health information (PHI)
  - Good Clinical Practice – if research involves FDA regulated products
OSIRIS Application

• **Triage section**
  – Once completed, all names listed in the application will have access to the study

• **Cover sheet section**
  – Demographic and site information

• **Protocol section**
  – Protocol development
New Study Created

OSIRIS

demo study  PRO10080004

Study Title: 
PI: Patricia Orndoff
IRB Staff:
Mentor Required:

Study Coordinator:
Review Type:
Special Population:

Categories
There are no items to display

Pending Scientific Review Approval
Department Name
There are no items to display

Received Scientific Review Approval
Department Name
There are no items to display

Pending Ancillary approvals
ID
There are no items to display

Received Ancillary Approvals
ID
There are no items to display
Ancillary Reviews

- Fiscal Review
- Scientific Review
- Research Protocols Involving Human Subject or Patient Exposure to Ionizing Radiation: Radioactive Drug Research Committee
- Gene Transfer Research: University of Pittsburgh Institutional Biosafety (rDNA) Committee (IBC-rDNA)
- Conflict of Interest
Creating a new study

• Any member of the research team can start developing the application

• The person who initiates the study is automatically listed as the Primary Investigator

• If you are not the PI
  – Assign yourself a role as coordinator or co-investigator
  – Go directly to the section CS3.0 and correctly identify the PI

• **ONLY** the PI can hit the “submit” button
What does the IRB review?
Types of Review

- **Exempt (determination made by IRB)**
  - Limited, very restricted categories of research that are exempt from many of the Federal research regulations

- **Expedited ("Administrative") Review**
  - Minimal risk research that falls into certain categories

- **Full Board Review**
  - More than minimal risk research, or research that cannot be expedited
Risk Definition

- Risk is defined as the probability of harm or injury occurring as a result of study participation.
  - Physical
  - Psychological
  - Social
  - Economic
Minimal Risk

• The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
IRB Review

• Risks are minimized

• Risks are reasonable in relation to anticipated benefit (if any) and importance of knowledge that may be expected to result

• Selection of subjects is equitable

• Subjects are adequately informed of risks/benefits
IRB Review

• Recruitment and Informed consent processes are appropriate

• Research plan makes adequate provisions for monitoring (DSMP or DSMB)

• Adequate provisions to protect privacy and confidentiality

• Additional safeguards for vulnerable subjects
Informed Consent

- Written informed consent must be obtained from all subjects unless the IRB has approved a waiver.

- Types of waivers
  - waiver of informed consent
  - waiver of the requirement to obtain a signed informed consent document
Full Board Actions

- Full Approval
- Approval Subject to Minor Modifications
- Reconsideration
- Disapproval
Protocol Renewals

- Investigator is responsible for ensuring that the study is submitted for renewal prior to the expiration date.

- Submit for review at least five weeks before the expiration date in the event that the reviewers have comments or concerns that need to be addressed before final approval can be granted.
Renewals

• My IRB approval expired:
  – Can I continue with research procedures?
    • Enrollment of new subjects?
    • Continuation of previously enrolled subjects?
    • Data analysis?
  – How do I obtain re-approval to continue?
Modifications

All modifications must IRB approved prior to implementation

- **Minor mod**: does not materially affect the risks/benefit of the study or does not substantially change the specific aims or design of the study

- **Major mod**: doesn’t meet the definition of a minor mod
Reportable Events

- Adverse events
- Unanticipated problems involving risk to subjects or others
- Deviations or non-compliance
- Questions? Jamie Zelazny, RN, Adverse Events Coordinator
  zelaznyjh@upmc.edu
Other things to consider
Vulnerable Populations

- Pregnant Women, Fetuses, and In-Vito Fertilization (Subpart B)
- Prisoners (Subpart C)
- Children (Subpart D)
- Decisionally impaired
- Traumatized or comatose
- Terminally ill
All subjects need to provide informed consent to participate

• Unless otherwise waived

• Who should provide it?
  – Subject
  – Subject’s parent or guardian (1 vs. 2)
  – Subject’s proxy

• Reconsent
Every study has a beginning...and an end

- Submit a final progress report
- Do not terminate until final study visit conducted by sponsor
- The IRB strongly encourages investigators to keep a protocol active (e.g., ‘data analysis only’) as long as investigators are currently using or planning to utilize identifiable data
Resources

- IRB website: www.irb.pitt.edu
  - Policies and Procedures Manual
  - IRB forms
  - Staff listing
  - Meeting/deadline dates
Contact Information

- IRB office hours: landna@upmc.edu
- Melissa Miklos: miklosm@upmc.edu
- OSIRIS Training: Patty Orndoff orndoffpa@upmc.edu
- General Questions: askirb@pitt.edu
Data Security Awareness for Researchers

Date: Wednesday, March 14, 2012
Time: 12pm to 1pm
Location: O’Hara Student Center, Ballroom
Speaker: John Hudson, Pitt Information Security Officer

The goal of this interactive program is review current data security practices, identify potential weaknesses, and learn what resources Pitt has available to decrease potential risks.

Registration is free and available online at www.irb.pitt.edu/event/dsar.aspx.