The IRB and the Ethical Conduct of Research

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IRB Review Perspectives

Well, I know we *can*

But I don't know if we *should*

Legalities:

Ensure compliance with the laws, regulations, and policies

Ethics:

Protect the rights and welfare of human subjects involved in research activities

Jurisdiction of the Pitt IRB

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

The Belmont Report - 1979

Cornerstone of the ethical principles upon which the federal regulations for the protection of human subjects are based

The Belmont Ethical Principles

- Respect for Persons
- Beneficence
- Justice

https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html

Federal Regulations

Establishes regulations that govern FDA materials in research

21 CFR 50
21 CFR 56

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

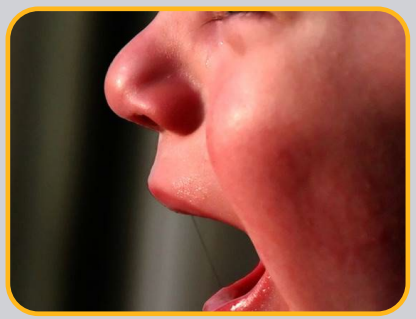
45 CFR 46 (Common Rule)

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

45 CFR 46: Protection of Human Subjects



Subpart A: The Common Rule – Basic Protections

Subpart B: Pregnant Women, Fetuses & Neonates

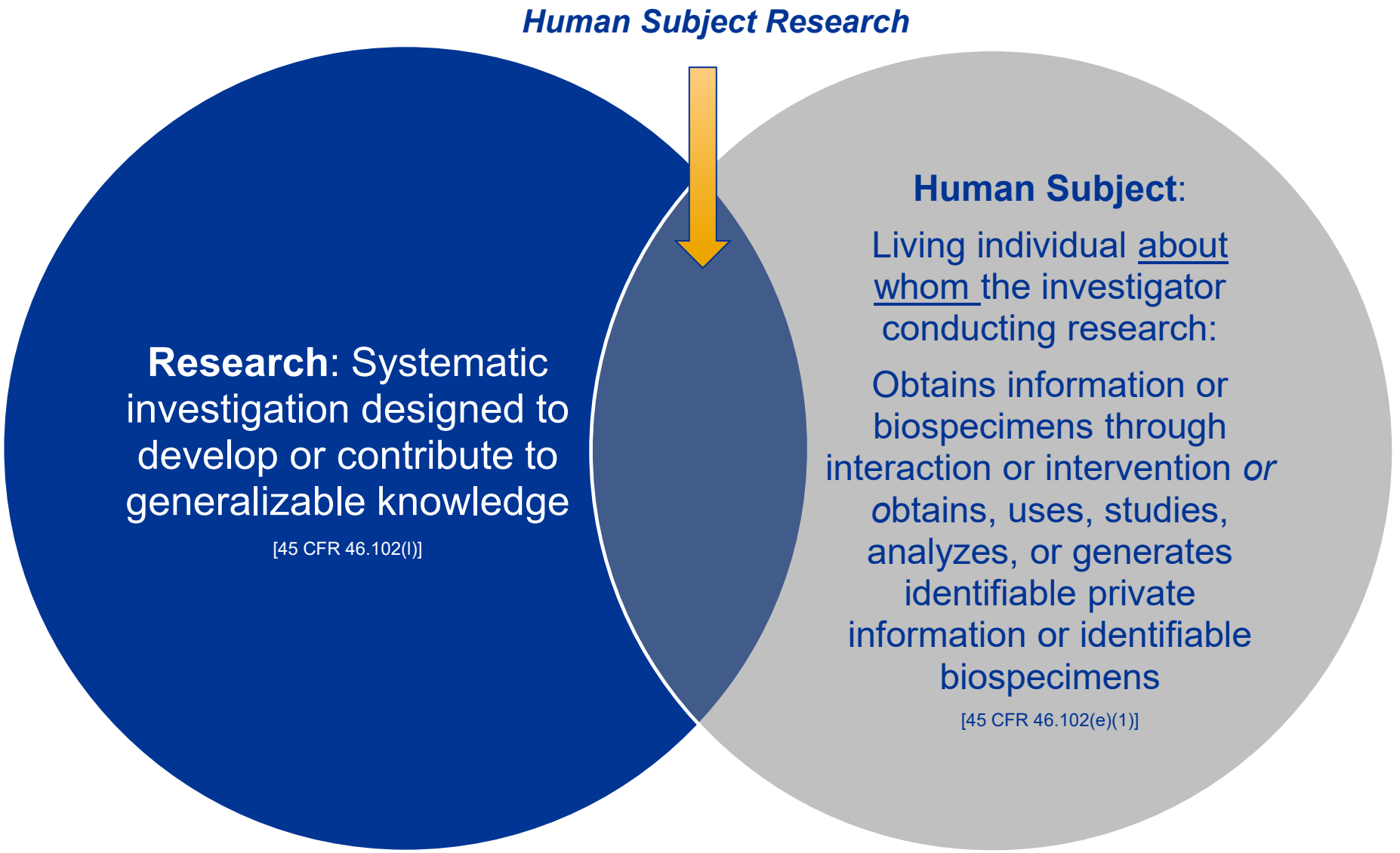
Subpart C: Prisoners

Subpart D: Children

When is IRB approval needed?

When you’re doing human subject research, of course

When do I need IRB Review?



Is it human subject research?

Other institutional permissions/approval may be necessary even if IRB oversight is not required

	Project	Other institutional offices
	QA/QI: Focuses on improving patient care or experience	***UPMC Quality Improvement Review Committee*** *– accessed through UPMC InfoNet.* *Contact: Mary Hilmes hilmesmk@upmc.edu*
	Innovative Practice: Designed to enhance the well-being of a patient (diagnosis, treatment, and/or therapy)	***UPMC Innovative Practice Committee*** ***UPMC Pharmacy and Therapeutics Committee*** ***UPMC Surgical Services Oversight Committee***
	Case Reports: Information was not collected to test hypotheses or produce generalizable knowledge	• Does not require IRB approval but use of identifiable info requires authorization • Case series might require IRB approval
	Utilizes data or specimens from deceased individuals	***Committee for Oversight in Research Involving Decedents (CORID)*** *https://ooas.pitt.edu/corid*

Minimal Risk 45 CFR 46.102(J)

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**

But nobody will get hurt

Physical risks aren't the only risks

- Physical
- Social
- Economic
- Psychological

What are the Types of IRB Review?

Not Research/No Human Subjects

Letter may be necessary at sponsor's request or for journal publication

Exempt

Limited, restricted categories of research that are exempt from regulation

Examples:

- Anonymous surveys
- Non-sensitive surveys
- Observation of public behavior
- Secondary data analysis
- Some classroom research

Expedited

Minimal risk research that falls into certain categories

Examples:

- MRI without contrast,
- limited blood draw by venipuncture
- non-invasive collection of data or biological specimens
- Studies of individual or group characteristics or behavior

Full Board

Greater than minimal risk research or research that cannot be expedited

Categories for Exempt Review

1. Educational Strategies, curricula, or classroom management methods
2. Tests, surveys, interviews or passive observations of public behavior
3. Data collection with benign behavioral interventions
4. Secondary research with data and/or specimens
5. Research and demonstration projects conducted by or for a federal department or agency

Categories for Exempt Review

Educational strategies, curricula, or classroom management methods

Tests, surveys, interviews or passive observations of public behavior

Data collection with benign behavioral interventions

Secondary research with data and/or specimens

Research and demonstration projects conducted by or for a federal department or agency

Tests, Surveys, Interviews, Passive Observation of Public Behavior

Basic Criteria:

- Limited to the procedures listed above
- Recorded anonymously or non-sensitive nature
- Passive observation of public behavior
- Tests and surveys with children don’t qualify for exemption

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Secondary research when consent is not required

Must meet one of these four options:

1. Identifiable private info is publicly available, or
2. Information is recorded in a de-identified manner, no contact can be made and no reidentification will occur, or
3. Identifiable health info is used only for “health care operations” or “research” or “public health activities and purposes” as defined by HIPAA, or
4. Uses government generated or collected info with restrictions

Expedited

- Materials collected for non-research purposes
- Medical, employee or school records
- Data from audio/video files for research purposes
- Interviews, focus groups, surveys
- Non-invasive data collection
- MRI, Ultrasound, EEG, (no x-rays or CT)
- Collection of blood samples, non-invasive biological specimens

Full Board

- Greater than minimal risk research
- Research that cannot be expedited
- Research sent by IRB discretion

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Planning your study

Who CAN serve as PI

Appropriately Qualified:

- Faculty (compensated)
- Pitt Students
- Residents
- Fellows
- Post Docs

Mentor approval required

- Pitt Staff
- UPMC Staff
- UPP Staff

Supervisor approval required

- Adjunct Faculty
- Visiting Professor
- Clinical Instructor
- Lecturers & Instructors
- Non-Pitt individuals
- Non-UPMC individuals

*Who CANNOT serve as PI

**may be exceptions granted based on contract*

General Points to Consider

Write broadly, provide flexibility

IRB needs to be able to determine risk/benefit, not be able to conduct the studies

Consent forms are not required to follow a particular format. Templates are recommendations

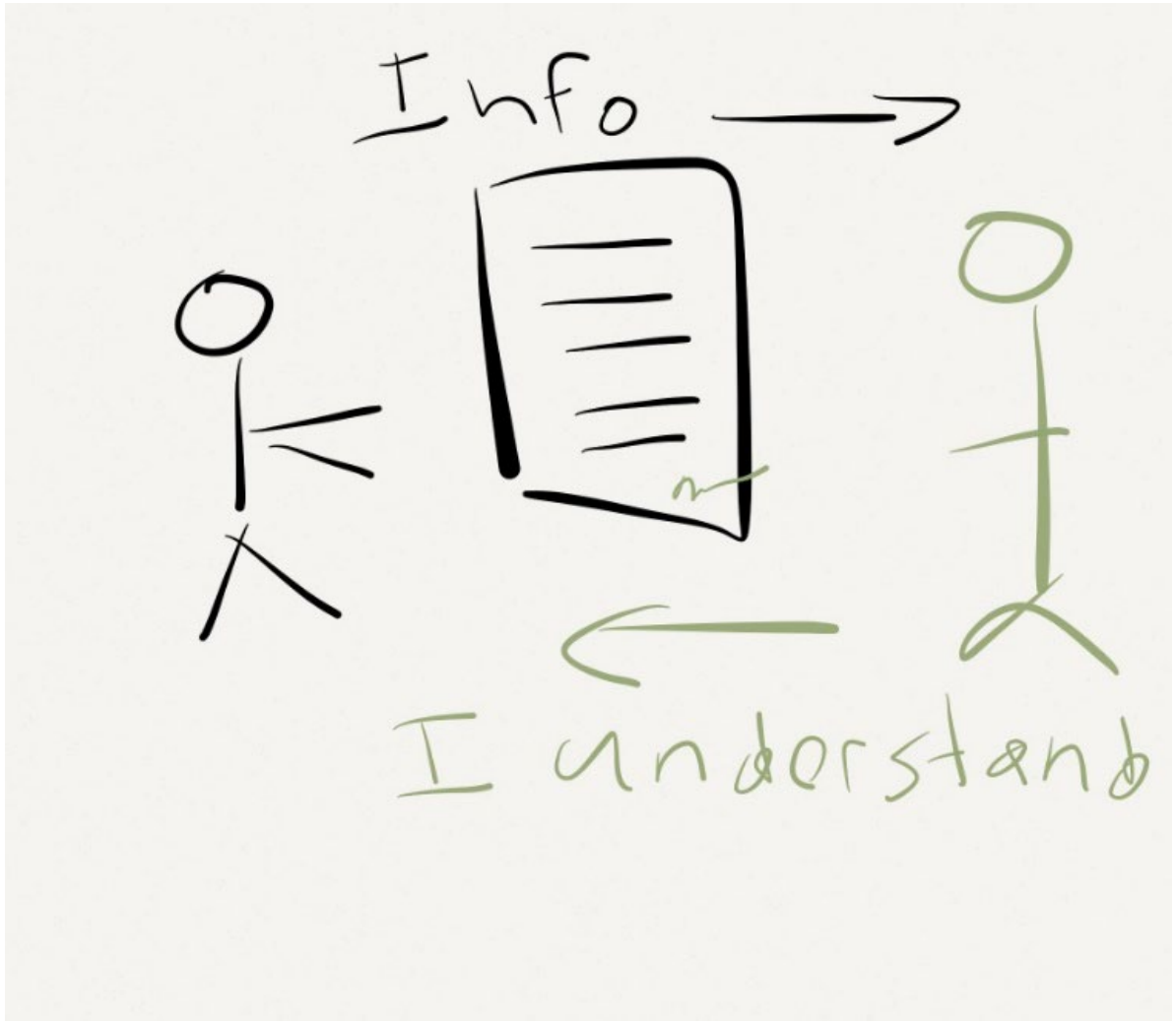
WHAT IS NEEDED FOR IRB APPROVAL?

- Risks to study participants are minimized
- Risks are reasonable in relation to anticipated benefits
- Selection of subjects is equitable
- Informed Consent is obtained and appropriately documented
- Adequate provisions for monitoring collected data to ensure safety
- Privacy of participants and confidentiality of data are protected

-45 CFR 46.111, 21 CFR 56.111

Think About Consent Process

Written Informed Consent	Traditional consent form • Must obtain the written informed consent of the subject or the subject's legally authorized representative • Signature can be electronic
Waiver to Document Consent	Written informed consent is not obtained • Verbal consent process takes place • May include scripts or other visual aids • Researcher documents subject's willingness in research record
Full Waiver of Informed Consent	Consent is not obtained from any subjects in the study • Researcher must justify criteria



Elements of Informed Consent

1. A clear statement of research, purpose, duration, and procedures;
2. A description of any risks or discomforts to the subject;
3. A description of any benefits to the subject or to others;
4. Alternative procedures;
5. A statement describing how confidentiality will be maintained;
6. Compensation for injury (> min risk);
7. Research subjects' rights, and whom to contact in the event of a research-related injury;
8. A statement that participation is voluntary
9. Whether or not identifiable private information or biospecimens will be used in future studies

Data Security

- What data is involved (MR data is sensitive)
- Where is the data coming from?
- How will it be transmitted?
- Who will need access to the data?
- Where can I store the data?
- What do I do with it when I'm done?

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Student Researchers

- Must have a research mentor
- Mentor must approve study in PittPRO prior to IRB review
- Mentor should provide guidance, support and responsibility for the study

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How Do I Get Started?

University of Pittsburgh HSConnect

Set up HSConnect account with Pitt credentials when possible
(DO NOT use Gmail, etc. if you need to switch your account, contact HSConnect)

University of Pittsburgh CITI Access Portal

Complete CITI training or link completed CITI training from another institution to Pitt account (https://www.citi.pitt.edu/)

- Responsible Conduct of Research
- Human Subjects Protection
- Good Clinical Practice

PittPRO | Pitt Protocol Review Online

Build submission in PittPRO and submit for approval
(same username and password as HSConnect and CITI)

The PittPRO Getting Started Guide is available at https://www.hrpo.pitt.edu/applications-training/pittpro

When can I get started?

- After **FINAL** approval is granted by IRB
- A formal letter is generated by PittPRO

Call us early and often

412-383-1480
Main IRB number

askirb@pitt.edu
General IRB questions

Irb.reliance@pitt.edu
Central IRB questions (aka sIRB)

Orp_support@pitt.edu
Technical Issues