CONDUCTING HUMAN SUBJECTS RESEARCH

Responsible Conduct of Research

August 2015

Overview

- Definition and Authority
- Background / Ethical foundations
- What requires IRB review
- Tips

What is an IRB?

IRB = Institutional Review Board

A group registered with the federal government that is formally designated to review and monitor research involving human subjects.

IRB Authority

Federal regulations

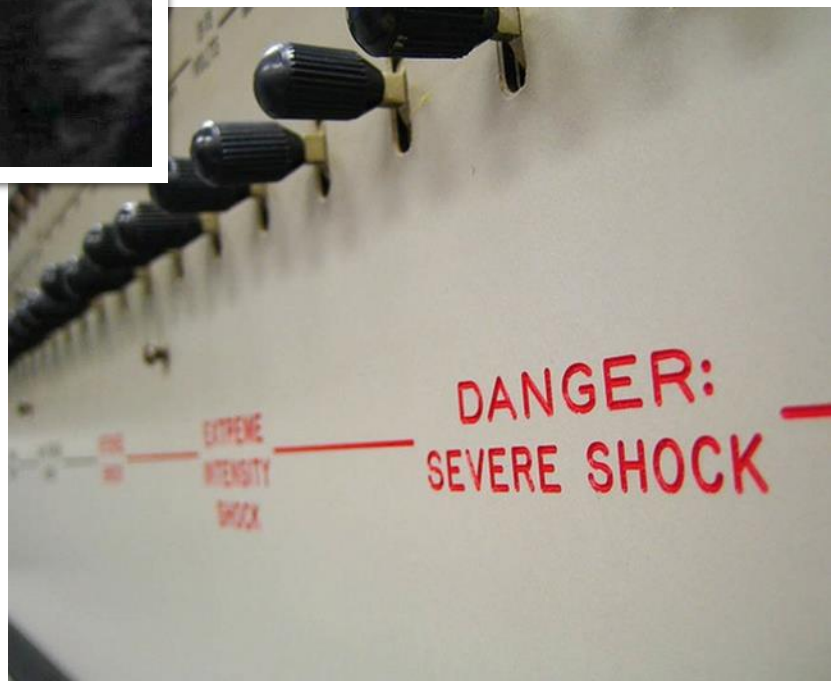
- FDA: 21 CFR 56
- Federally-funded research: 45 CFR 46 (the Common Rule)

An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities.

21 CFR 56.109(a), 45 CFR 46.109(a)

Background

- Mostly reactive
- Nuremberg; Tuskegee syphilis study

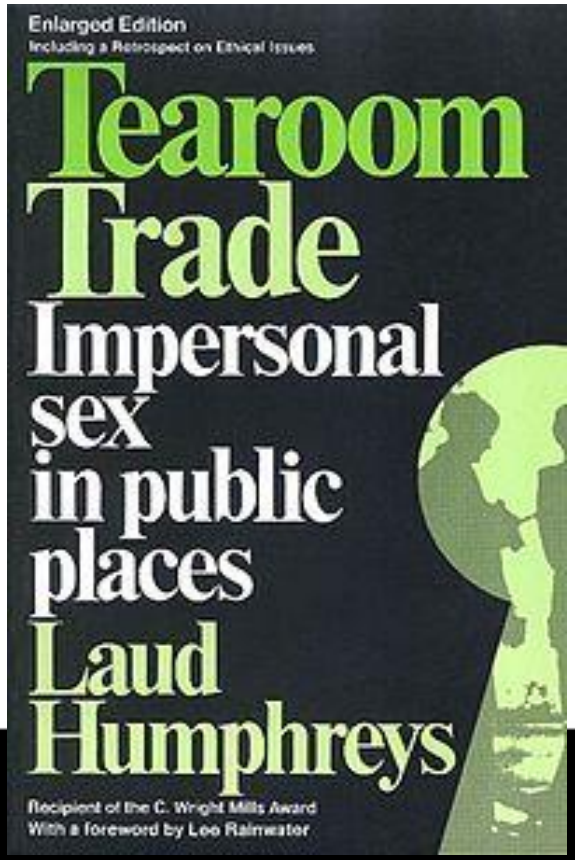


Obedience to Authority

Stanley Milgram

Tea Room Trade Study

Laud Humphreys



Ethical and Regulatory Foundations

OHRP

OFFICE FOR HUMAN RESEARCH PROTECTIONS

FDA

What requires IRB review?

Designed, Systematic Investigation

Contribute to GENERALIZABLE knowledge

What requires IRB review?

Human Subject

A living individual about whom an investigator obtains: (1) data through intervention or interaction with the individual OR (2) private, identifiable information

IRB Criteria for Approval

- Risks are reasonable relative to benefits
- Risks to subjects are minimized
- Privacy & confidentiality protected
- Adequate safety monitoring plan
- Written informed consent obtained
- Consent process provides all required info
- Subject selection is equitable
- Additional safeguards for protected & vulnerable populations

Not always easy…

Tip #1

Records and specimens can be “human subjects”, even if you are not obtaining them directly from the individuals.

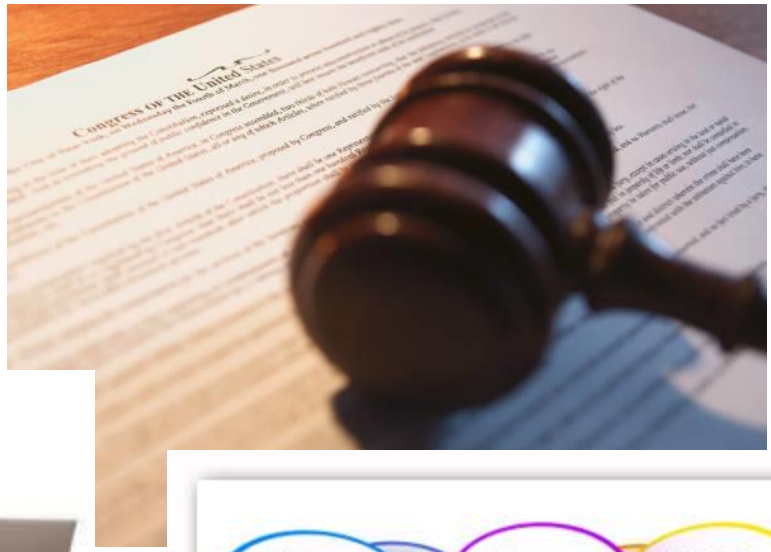
Tip #2

Consent is not just a document….

It is a process.

Tip #3

"Risk" does not only mean physical risk



Tip #4

Vulnerable Populations = additional requirements

Tip #5

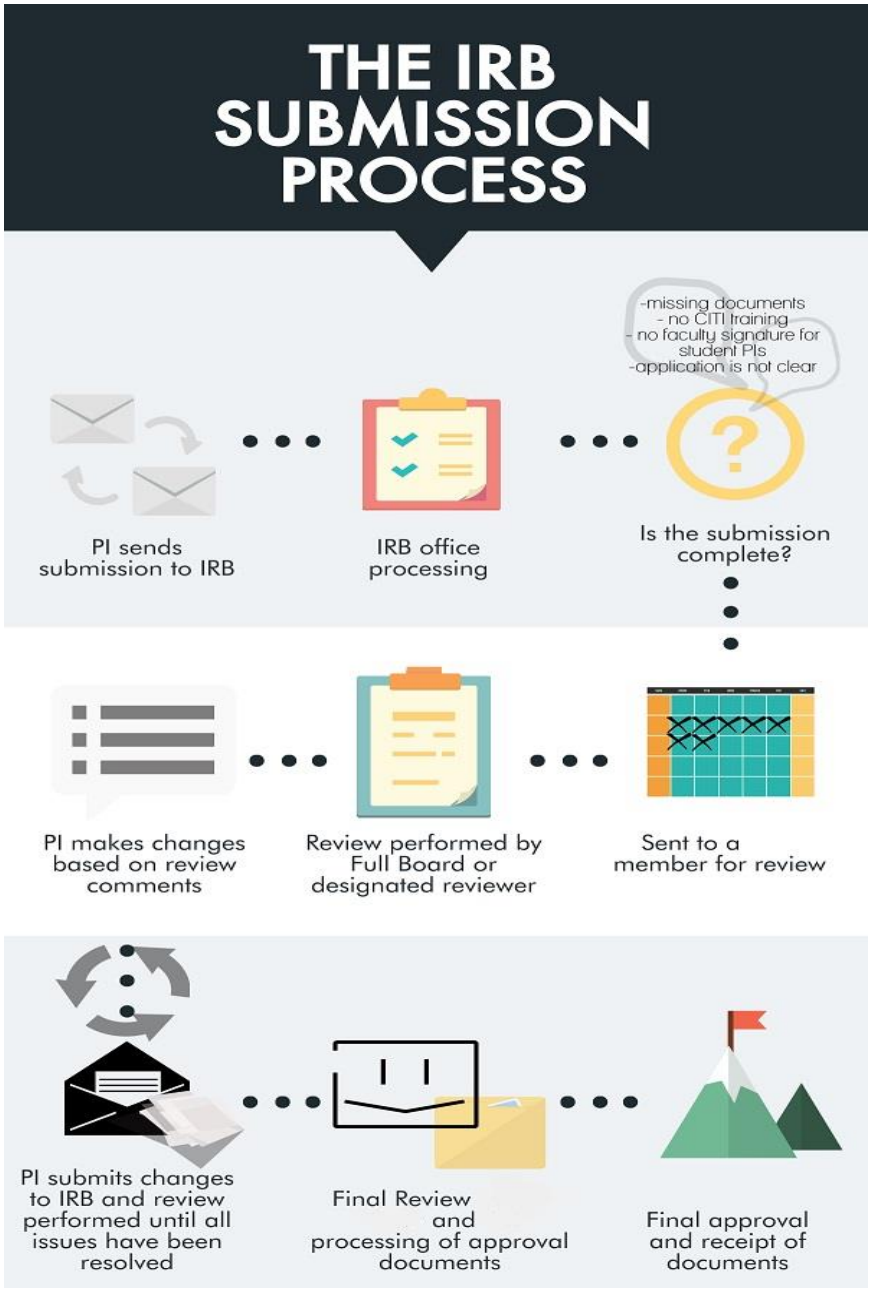
Multiple IRB Involvement

Each institution involved in the research must obtain IRB approval, from

- Its own IRB
- A commercial IRB
- The IRB of one of the other institutions

Tip #6

IRB review takes time – plan ahead



Tip #7

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