

# Protecting Human Subjects and IRBs: An Overview

Presented by  
Justice Research and Statistics Association

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# Research with Human subjects



# What is Research?

- “A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” 45 CFR §46.102

# What is a Human Subject?

- “A living individual(s) about whom an investigator conducting research obtains:
- (a) data through intervention or interaction with the individual, or
- (b) identifiable private information.” 45 CFR §46.102



# What is a Human Subject? (New Revision)

- Human subject means a living individual about whom an investigator (whether professional or student) conducting research:
- (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.”



# What is an IRB?

- An independent committee that reviews and approves all research involving human subjects to ensure that it is conducted in accordance with all federal, institutional, and ethical guidelines

# IRBs in General

- At least 5 members
- Varied professions, scientific, nonscientific
- Member not otherwise affiliated with USM
- Experience, Expertise, Diversity
- Sensitivity to community attitudes
- Knowledgeable in institutional commitments and regulations, applicable laws, etc.



# Research Outside the Purview of the IRB

- Research funding through a “Non-Common Rule” agency
- Industry sponsored research not covered under FDA regulations, such as marketing research
- Human Subject Research in another country not funded through a “Common Rule” agency



# Ethical Considerations

When there are ethical considerations, but the protocol is not covered under regulations:

- What is the role of the IRB?
- Who is responsible for addressing ethics?
- What options do institutions have to protect participants without succumbing to “mission creep”?

# Why do we have IRBs?

## Nazi Concentration Camps Research WWII



### What were the ethical issues?

No Consent

Risks > Benefits

Vulnerable Participants

### What was the follow-up?

Nuremberg Trials

Nuremberg Code

# Why do we have IRBs?

**Tuskegee Syphilis Study  
1932 – 1972 (penicillin treatment 1947)**



## **What were the ethical issues?**

No Informed Consent

Risks > Benefits

Vulnerable Participants

## **What was the follow-up?**

1972 NY Times Story

Congressional Hearing

Belmont Commission

National Research Act

## Macon County Health Department

ALABAMA STATE BOARD OF HEALTH AND U. S. PUBLIC HEALTH  
SERVICE COOPERATING WITH TUSKEGEE INSTITUTE

Dear Sir:

Some time ago you were given a thorough examination and since that time we hope you have gotten a great deal of treatment for bad blood. You will now be given your last chance to get a second examination. This examination is a very special one and after it is finished you will be given a special treatment if it is believed you are in a condition to stand it.

If you want this special examination and treatment you must meet the nurse at \_\_\_\_\_ on

\_\_\_\_\_ at \_\_\_\_\_ M. She will bring you to the Tuskegee Institute Hospital for this free treatment. We will be very busy when these examinations and treatments are being given, and will have lots of people to wait on. You will remember that you had to wait for some time when you had your last good examination, and we wish to let you know that because we expect to be so busy it may be necessary for you to remain in the hospital over one night. If this is necessary you will be furnished your meals and a bed, as well as the examination and treatment without cost.

**REMEMBER THIS IS YOUR LAST CHANCE FOR SPECIAL FREE TREATMENT. BE SURE TO MEET THE NURSE.**

Macon County Health Department

# Why do we have IRB's?

## Stanley Milgram's Obedience to Authority Study



### What were the ethical issues?

Deception -> Emotional Stress

Informed Consent?

### What was the follow-up?

Ethics of social behavioral research questioned.

# What is IRB Approval?



# IRB Submission

- Investigators
- Funding
- Research Protocol
- Participant Information
- Risks & Benefits
- Privacy & Confidentiality
- Consent Process
- Conflicts of Interest
- Obligations

# HIPAA

- Covered entities
- PHI
- Individual Authorization
- Without Authorization
  - IRB or Privacy Board Approval
  - Preparatory
  - Decedents
  - Limited Data Sets



# IRB Review Categories

- Student Classroom Projects
- Not Human Subject Research
- Exempt
- Expedited
- Full Board



# Criteria for Review

- Risks are minimized
- Benefits outweigh risks
- Equitable selection of subjects
- Informed Consent obtained
- Informed Consent documented
- Privacy/confidentiality is protected
- Safeguards for vulnerable populations

# Vulnerable Populations

- What are vulnerable populations?
- Specified by Regulation
  - Fetuses
  - Pregnant Women
  - Prisoners
  - Children
- Not Specified

# Researcher Responsibilities - Once protocol is approved

1. Conduct the research during the study period;
2. Conduct the research according to the plans and protocol submitted;
3. Inform immediately the IRB of any injuries or adverse research events involving subjects;

# Researcher Responsibilities - Once protocol is approved (cont.)

4. Request approval from the IRB of any proposed changes in your research, and do not initiate any changes until they have been reviewed and approved;
5. Conform to any security and protected information policies/standards your agency may have in place;

# Researcher Responsibilities - Once protocol is approved (cont.)

6. Request a continuing review at least 60 days prior to the IRB approval expiration if you anticipate your research going beyond the original end date; and
7. Close the project upon completion (or discontinued) and submit final report.

# Unanticipated Problems/Adverse Events

1. Unexpected given (a) the research procedures that are described in the protocol-related documents; and (b) the characteristics of the subject population being studied;
2. Related or possibly related to participation in the research (*possibly related* means there is a reasonable possibility that the incident, may have been caused by the procedures involved in the research); and
3. Suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized.

# Unanticipated Problems - Remedies

1. modification of inclusion or exclusion criteria to mitigate the newly identified risks;
2. implementation of additional procedures for monitoring subjects;
3. suspension of enrollment of new subjects;
4. suspension of research procedures in currently enrolled subjects;
5. modification of informed consent documents to include a description of newly recognized risks; and
6. provision of additional information about newly recognized risks to previously enrolled subjects.

*Source:OHRP*



# Choosing an IRB

- Responsiveness - level of detail, service
- Timeliness - turnaround time
- Cost - breakdowns for various type of reviews
- Reputation
- Expertise - do IRB members know the subject and methodology(ies)
- Convenience

# Moving the approval process along

- Follow protocol submission instructions
- Answer the questions completely
- Refrain from using such expressions as N/A when the instructions ask for detail
- Include attachments (CVs, consent, project proposals)
- Respond to IRB questions promptly

# Questions?

