“ETHICALLY IMPOSSIBLE”
STD Research in Guatemala
from 1946 to 1948
STD Inoculation Study
Session Objectives

• Explain the oversight requirements for research involving human subjects

• Provide regulatory background and definitions

• Discuss basic Buck-IRB navigation/submission components

• Identify available resources
Session Overview

**Regulatory Framework**
- Ethical principles
- Regulations
- Definitions

**Pre-Submission**
- CITI/COI
- Buck-IRB application
- Supporting documents

**Review Process**
- Exempt
- Expedited
- Convened

**Resources**
- Submission Assistance
- Website
- OR Help Desk
Ethical Principles

National Research Act of 1974

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
Ethical Principles

Belmont Report

- Respect for persons
  Autonomy, right to choose
- Beneficence
  Maximize benefits and reduce risks
- Justice
  Equitable selection of subjects
Federal Regulations

Department of Health and Human Services (DHHS)

• 45 CFR 46 (Common Rule)
• Subpart B: Pregnant women, fetuses, neonates
• Subpart C: Prisoners
• Subpart D: Children

Food and Drug Administration

• 21 CFR 50 (Informed Consent)
• 21 CFR 56 (IRBs)
Regulatory Definitions

**Research**
A systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge

**Human subject**
Living individual about whom an investigator obtains:
- **Data** through intervention or interaction
- Identifiable **private information**
Regulatory Definitions (cont.)

**Private information**

- Individually identifiable information about behavior with reasonable expectation that no observation or recording is taking place.

- Identifiable information provided for specific purposes with reasonable expectation will not be made public (e.g., academic records).
Regulatory Definitions (cont.)

**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.
Review Algorithm

Questions

- Is the project research?
- If research, does it involve human subjects?
- If human subjects research, what type of review is required?

ORRPDeterminations@osu.edu
Human Research Examples

- Record review
- Educational research
- Surveys, focus groups, interviews
- Blood draws
- Tissue collection and analysis
- Clinical trials
- Exercise studies
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Next Steps...

Complete institutional requirements

• Collaborative Institutional Training Initiative (CITI)
  Basic Human Research Course

• Conflict of Interest (COI)
  Electronic Conflict of Interest Disclosure
Complete Buck-IRB application

Buck-IRB

going.osu.edu/buck-irb
Submission Components

• Completed Buck-IRB application with study personnel listed
• Research protocol
• Recruitment materials
• Consent form or waiver request
• Surveys, interview/focus group questions
• Data collection forms
• External funding proposals
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Types of Review

- Exempt
- Expedited IRB
- Convened IRB
Exempt Research

- Minimal risk
- Six categories (exceptions)
- ORRP review
- Category 4 (existing specimens/data) may require Privacy Board review
Exempt Categories

Category 1: Classroom research
Category 2: Surveys, observational studies, interviews, focus groups
Category 3: Category 2 with elected officials
Category 4: Existing data/materials
Category 5: Federal Agency initiated programs
Category 6: Food quality and taste
Exceptions

- Greater than minimal risk
- Prisoners
- Involves deception
- Surveys or interviews with children
  Unless observation of public behavior
- FDA-regulated research
  Category 6 (food taste studies) only
ORRP Actions

- Exempt
- Not exempt
- Not human subject research
IRB Review Objectives

- Determining risks are reasonable in relation to benefits
- Assuring accurate description of risks and benefits (informed consent)
IRB Review

- **Expedited**
  - Minimal risk
  - Seven categories
  - Reviewed by IRB Chair or designee

- **Convened**
  - Greater than minimal risk
  - Outside expedited categories
Expedited Categories

Category 1: Marketed drugs/devices

Category 2: Blood collection

Category 3: Non-invasive specimen collection

Category 4: Non-invasive clinical data collection
Expedited Categories (cont.)

Category 5: Materials collected for non-research purposes

Category 6: Audio and video recordings

Category 7: Characteristics/behavior or survey, interview, etc. methods
Board Actions

- Approved
- Modifications required
- Deferred
- Disapproved

**Note:** No research activities, including recruitment or data collection, may occur prior to final approval.
Review Timelines

Median review Turnaround Times are posted on the ORRP website, currently:

- Expedited Behavioral IRB review – 35 days
- Expedited Biomedical Sciences IRB review – 33 days
- Expedited Cancer IRB review – 23 days
- Exempt determinations – four days
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Submission Assistance

Behavioral Office Hours

- 3rd floor Research Commons
- Tuesdays/Thursdays - 9am to 11am
- Wednesdays - 1pm to 3pm
- Call 292-8412 for appointment

Biomedical Assistance

- Call 688-8457 for appointment
Office of Responsible Research Practices

Contact Us

Protecting Human Subjects in Research at Ohio State

Human Subjects

The Human Research Protection Program is responsible for all Ohio State research involving human subjects. The HRPP's primary responsibility is to protect the rights and welfare of human research.

orrp.osu.edu
614-688-8457
Information Technology Help

- 614.688.8288
- ORhelpdesk@osu.edu
- https://orhelp.osu.edu/support/
Summary Overview

- Provide all requested information
- Upload needed documents
- Use available resources/call ORRP with questions
- Obtain approval before beginning activity
Questions?

"We've considered every potential risk except the risks of avoiding all risks."

HARDIN