THE OHIO STATE UNIVERSITY

IRB Submission and Review Processes

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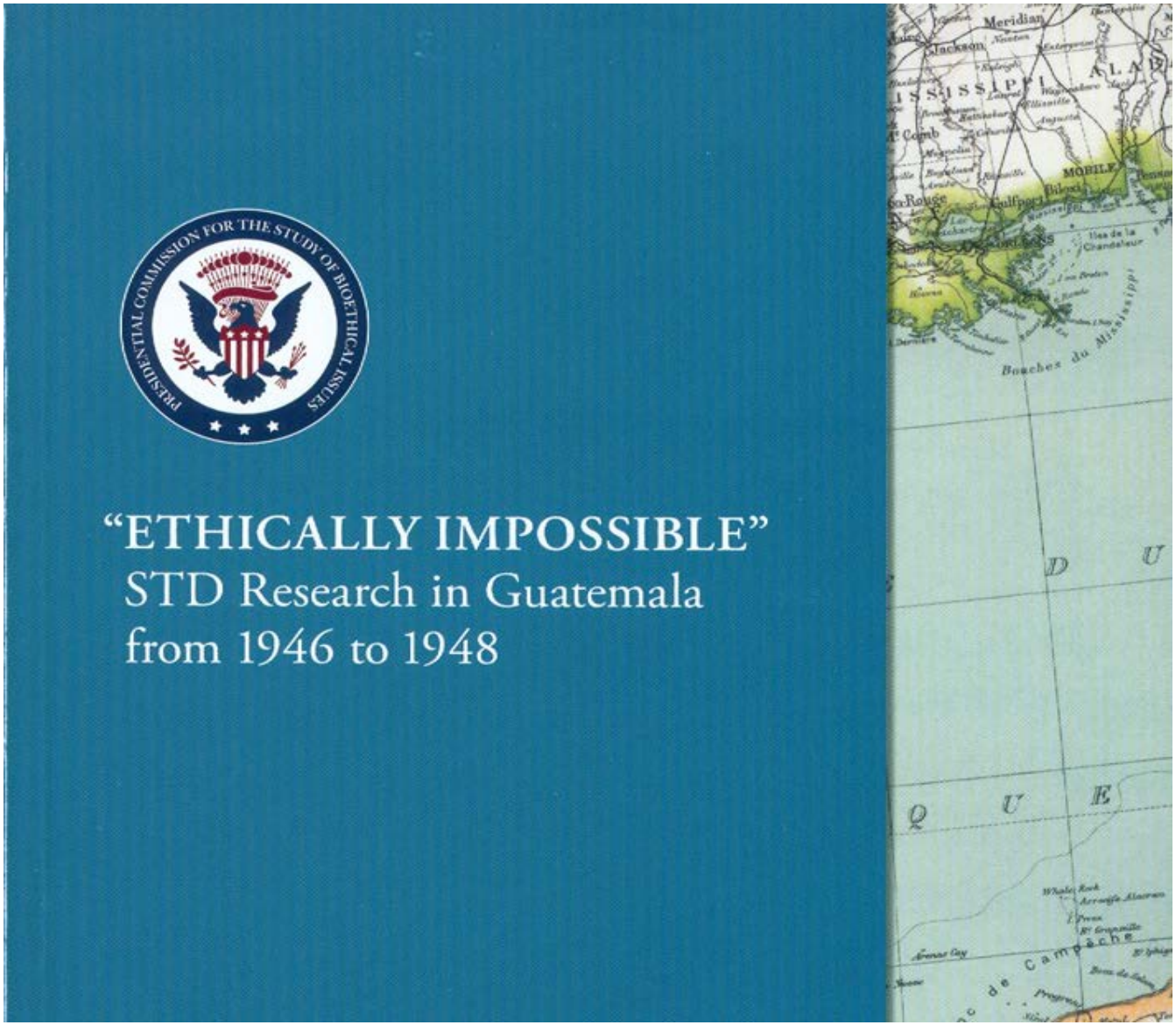

PRESIDENTIAL COMMISSION FOR THE STUDY OF BIOETHICAL ISSUES
"ETHICALLY IMPOSSIBLE"
STD Research in Guatemala
from 1946 to 1948
Meridian
Jackson
MOBILE
Bouches du Mississippi
de Campêche

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

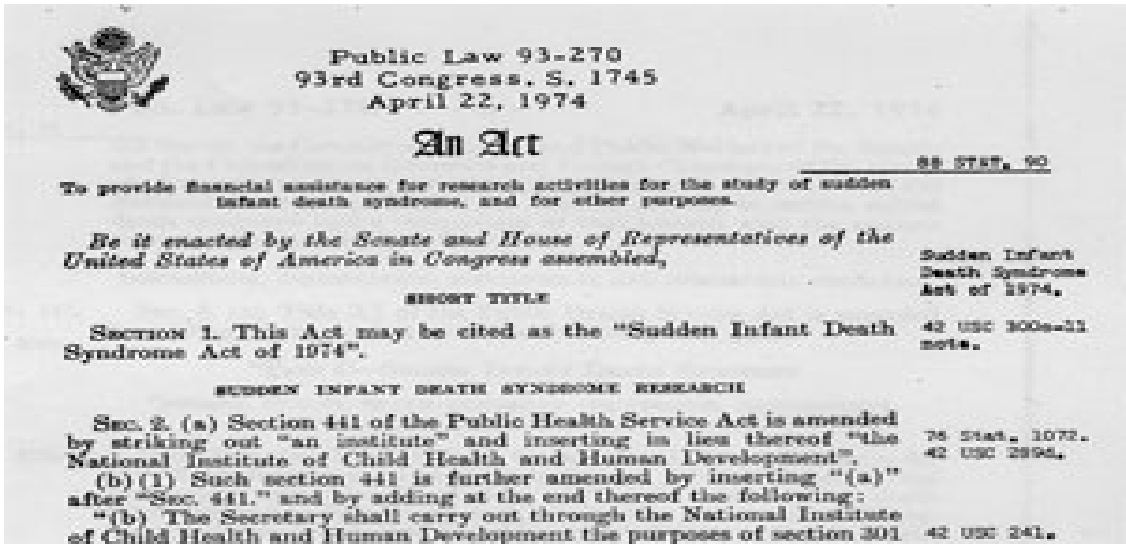
- Submission Assistance
- Website
- OR Help Desk

Regulatory Framework

Ethical Principles

National Research Act of 1974

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



Public Law 93-270
93rd Congress, S. 1745
April 22, 1974

An Act

88 STAT. 90

To provide financial assistance for research activities for the study of sudden infant death syndrome, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Sudden Infant Death Syndrome Act of 1974.

SHORT TITLE

SECTION 1. This Act may be cited as the "Sudden Infant Death Syndrome Act of 1974".

42 USC 300a-33 note.

SUDDEN INFANT DEATH SYNDROME RESEARCH

SEC. 2. (a) Section 441 of the Public Health Service Act is amended by striking out "an institute" and inserting in lieu thereof "the National Institute of Child Health and Human Development".

(b)(1) Such section 441 is further amended by inserting "(a)" after "SEC. 441." and by adding at the end thereof the following:

"(b) The Secretary shall carry out through the National Institute of Child Health and Human Development the purposes of section 301

75 Stat. 1072.
42 USC 289a.

42 USC 241.

Ethical Principles

Belmont Report

- Respect for persons

  Autonomy, right to choose

- Beneficence

  Maximize benefits and reduce risks

- Justice

  Equitable selection of subjects

Federal Regulations

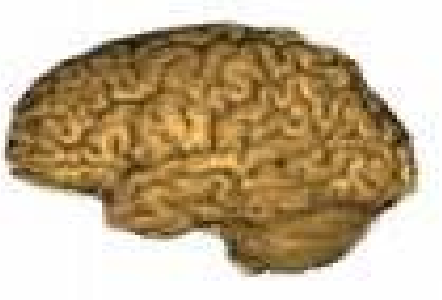
Department of Health and Human Services (DHHS)

- 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.)

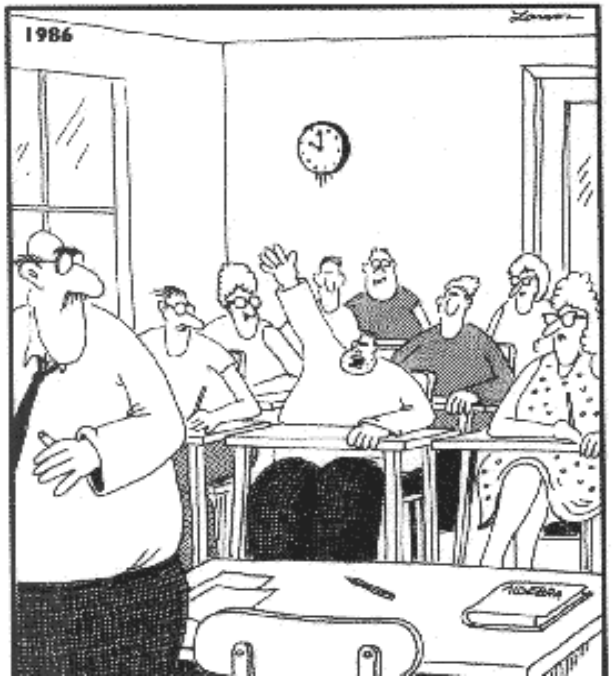
Minimal Risk

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

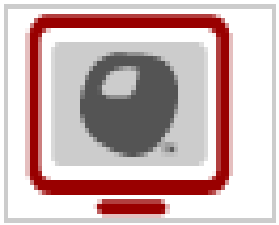
- Collaborative Institutional Training Initiative (CITI)

  Basic Human Research Course

- Conflict of Interest (COI)

  Electronic Conflict of Interest Disclosure

Complete Buck-IRB application



Buck-IRB

go.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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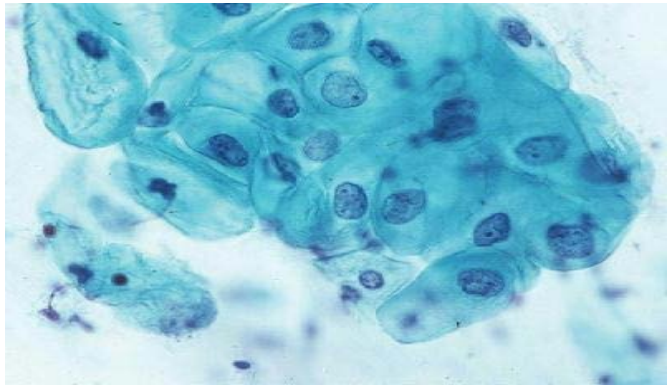
Types of Review

- 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)

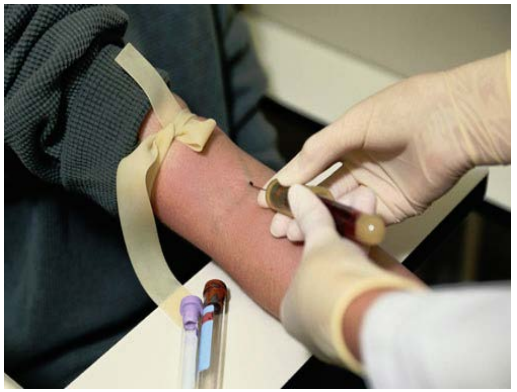
IRB Review

- **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

Contact Us

orrp.osu.edu
614-688-8457

Resources

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?


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