

SUNY STONY BROOK EDUCATIONAL PROGRAM FOR RESEARCH INVOLVING HUMAN SUBJECTS

PART I

(Note: Depending on the lecturer, discussion of Utilitarianism, Kantianism, ethical issues involving the media may also be covered)

1. The NIH Requirement
NIH Notice OD-00-039
2. Historical Developments Which Led to the Current Legislation
3. OHRP/FDA Shutdowns of Major Research Programs

PART II

I. Definitions

- What is research?
- What is clinical research?

II. Belmont Report

- A . Beneficence
 1. Do not harm
 2. Minimize risk, maximize benefit
 - a. What's a benefit?
 - b. What's a risk? How do you minimize it?
- B. Justice
 1. inclusion/exclusion criteria
 2. women, minorities, minors
 3. social justice
 4. justifiable exclusions
 5. inclusion of women of child-bearing potential
- C. Respect for persons:
 1. treat people as individuals; general consent discussion
 2. protection of vulnerable populations, e.g., minors, populations with diminished capacity
 3. Deception: Ethical?

III. CORIHS Jurisdiction: 45CFR46

- A. Assurance of Compliance: M1036-01
- B. FDA Regulations (general discussion):
21 CFR 50, 56, 312, 600, 812

C. Subparts

1. Subpart A: Federal Common Rule
2. Subpart B: : Additional Protections: Fetuses, Pregnant Women, and Human In Vitro Fertilization
3. Subpart C: Additional protections pertaining to prisoners
4. Subpart D: Additional protections pertaining to use of children as subjects

IV. CORIHS Submission Requirements

V. Review Categories

- A. Exempt Review Category 45CFR46.101
 1. Exempt Review Procedure

- B. Expedited Review Category 45 CFR 46 110
 1. Expedited Review Procedure

- C. Full Committee Review and Procedure

VI. Criteria for IRB Approval 45 CFR 46.111

VII. Responsibilities of CORIHS-approved Investigators

VIII. Continuing Review

- A. Renewal of Approval
- B. Amendments
- C. Adverse Events

IX. Consent

- A. Mandated Elements of Informed Consent 45CFR46.116,7
- B. Waiver/alterations of informed consent , OHRP. FDA
- C. Waivers of documentation of informed consent , OHRP, FDA
- D. Role of the Person Obtaining Consent
- E. The Consent Process
- F. Capacity to Consent
 1. criteria for capacity

2. characteristics of diminished capacity
3. independent assessment of capacity
4. Confirmed diminished capacity and Surrogate consent
 - a. allowable types of research
 - b. allowable surrogates

X. Biological Specimens

- A. Moore Case
- B. Retrospective vs. prospective collections
- C. Anonymous vs. Identifiable/Coded
- D. Risks in research involving biological specimens
- E. Rights of subjects who are the sources of tissue

XI. Conflict of Interest

- A. The ethics of 'Per patient' \$\$ from drug companies
 1. USB 'checks and balances'
- C. Financial interests of the Investigator
 1. 'SUNY -2' process