

Ascertainment, Recruitment & Respect for Subjects

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Objectives

- Review research history
- Belmont Report
- Define who are “vulnerable” subjects
- How we recruit?

History

- 1747- Lind conducts first documented comparative study on people with scurvy
- 1800s-Drugs and vaccines to treat smallpox, diphtheria, and cholera were developed and tested
- 1887- National Institute of Health (NIH) founded to provide funding for research on prevention, detection and treatment of disease

History (cont)

- 1990s-Research on infection diseases begins
- 1937- National Cancer Institute Act established the National Cancer Institute (NCI)
- 1947- Nuremberg Code established basic code of ethics for experimentation on human subjects
- 1964- Helsinki Declaration established specific guidelines for physicians conducting research

History (cont)

- 1978- Belmont Report outlines ethical principles and guidelines for protection of human subjects
- 1986- NIH established policies for the inclusion of women in clinical trials

Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research

- Part A: Boundaries between practice and research
- Part B: Basic Ethical Principles
- Part C: Applications

Belmont Report: Part A

- Practice: Interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success

Belmont Report: Part A

- Research: To test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge.

Belmont Report: Part B

■ Basic Ethical Principles

- Respect for Persons: Individuals should be treated as autonomous agents and persons with diminished autonomy are entitled to protection

Belmont Report: Part B

- Basic Ethical Principles
 - Beneficence: an obligation of beneficence affect individuals, investigators and society to maximize benefits and reduce risk

Belmont Report: Part B

■ Basic Ethical Principles

- Justice: Fairness in distribution. Groups should not be unfairly targeted due to easy availability or being easily manipulated.

Belmont Report: Part C

- Applications:
 - Informed Consent
 - Information
 - Comprehension
 - Voluntaries
 - Assessment of Risks and Benefits
 - Nature and Scope of Risk and Benefits
 - Systematic Assessment of Risks and Benefits
 - Selection of Subjects

Vulnerable Populations

- 45 CFR 46.102: Human Subject: a living individual about whom an investigator obtains data through intervention or interaction with the individual or the individual's identifiable private information
- 45 CFR 46.111: IRB must assure that selection of subject is equitable

Vulnerable Populations

- IRBs must be cognizant of special populations
 - Children
 - Prisoners
 - Pregnant women
 - Persons with impaired decisional capacity
 - Economically disadvantaged persons
- Informed consent must be sought by the subject of subject's legally authorized representative.

Vulnerable Populations

- 45 CFR 46 Subpart B: Research may pose additional risk/unknown risk to pregnant women, human fetuses and neonates.
- 45 CFR 46 Subpart C: Prisoners “may be” under constraints because of being in prison which may effect their ability to volunteer without Coercion.

Vulnerable Populations

- 45 CFR 46 Subpart D: additional protections for children
 - Minimal risk or
 - Research greater than minimal risk with the potential for benefit
 - Assent from minors- if minor is old enough and competent to comprehend- - obtain assent along with parental consent

Vulnerable Populations

SAMPLE

PEDIATRIC RISK ASSESSMENT FORM- required for all IRB protocols involving subjects less than 18 years of age -
Study Title: _____

Principal Investigator/Faculty Sponsor: _____
Risk Assessment by Chairman, Department of Pediatrics:

Minimal Risk. Not involving risk (physical or emotional) greater than that ordinarily encountered in _____ daily life or during the performance of routine physical or psychological examinations or tests.
Both parents must give permission unless the IRB approves one.

Greater than Minimal Risk but presenting the prospect of **direct benefit** to the individual _____ subject. Both parents must give permission unless the IRB approves one.

Greater than Minimal Risk and **no** reasonable prospect of **direct benefit** to the individual subject, but _____ likely to yield generalizable knowledge about the subject's disorder or condition.
Both parents must give permission unless one parent is deceased, unknown, incompetent, not reasonably available, or does not have legal responsibility for the custody of the minor.

Research not otherwise approvable which presents an opportunity to understand, prevent, or _____ alleviate serious problems affecting the health or welfare of children. Requires approval by the _____ Secretary of Health and Human Services. Requires permission of both parents unless one parent _____ is deceased, unknown, incompetent, not reasonably available, or does not have legal _____ responsibility for the custody of the minor.

Chairman, Department of Pediatrics Date

Vulnerable Populations

- Special Consideration

- Those subjects who become prisoners

- Decide whether it is reasonable to request that the subject remain on study during the incarceration or should be withdrawn from the study since continued participation would be too risky for the subject

Vulnerable Populations

- Special Considerations (cont)
 - When research subject becomes a prisoner and the relevant research protocol was NOT reviewed and approved by the IRB in accordance with 45 CFR part 46, subpart C- - a prisoner representative was present- the PI needs to notify the IRB of this event. All research activity with, the now-incarcerated prisoner-subject must **STOP** until the requirements of subpart C have been satisfied.

Vulnerable Populations

- Special Considerations (cont)
 - OHRP has allowed one important exception. IF the PI notes that the subject is best served on the study while incarcerated, the IRB Chairperson may determine that the subject may continue to participate in the research until the requirements of subpart C are satisfied.
 - Upon receipt of notification that a previously enrolled research subject has become a prisoner, the IRB will promptly re-review the protocol with the prison representative.

Vulnerable Populations

- Special Consideration (cont)
 - The PI must remember that, except in special circumstances, research activities with the now-incarcerated prisoner/subject must cease until all of the requirements of subpart C have been satisfied with respect to the relevant protocol

Vulnerable Populations

- Fetuses
- Human in vitro fertilization
- Women
- Children & minors
- Cognitively impaired persons
- Prisoners
- Traumatized and comatose people

Any special population OHRP defines as whom special considerations may apply

http://www.hhs.gov/ohrp/irb/irb_chapter6.htm

Recruitment

- Items which need IRB approval
 - Ads
 - Phone scripts
 - E-mails
 - Web links

Recruitment

- Items which need IRB approval
 - No Cold Calls: Those who know the patient need to introduce the research.
 - Subject to subject referral
 - Waiver of Consent

How To Do Research at DUHS

- Use IRB as resource
- Consult with IRB Specialist- - YOUR BEST FRIEND!
- Partner with Chairs and Vice-Chairs
- Clarify with primary reviewer to help with the approval process