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HST 502 - Survival Skills for Researchers  
Spring 2003

## Human Subjects in Research

I. Key issues and concerns are embodied in the continuum from research subject >> participant >> volunteer >> partner.

II. Human experimentation is thought provoking concept

A. Negative images: eg., Frankenstein, Nazi experiments

B. Positive qualities:

- Curiosity & interest in the world
- thirst for knowledge
- Altruism & generosity of spirit of research subjects
- desire that good can & should come from suffering

C. Examples:

- Barney Clark
- Anencephalic baby as organ donor

D. Major issues raised by clinical research:

- a. For what purpose will research be allowed?
- b. Under what conditions?
- c. How will this be decided?
- d. Who will decide?

III. Historically

A. "Above all, do no harm" - *Primum non nocere*

1. "Do nothing not intended for the direct benefit of the patient."
2. Implies a dichotomy between therapeutic & non-therapeutic res.

B. Claude Bernard - French physiologist, father of experimental medicine

"... among the experiments that may be tried on man those that can only harm are forbidden, those that are innocent are permissible, and those that may do good are obligatory." (1865)

- C. Justice Benjamin Cardozo (1914) NY State Supreme Court
  - 1. "Every human being of adult years and sound mind has a right to determine what shall be done with his own body."
- D. Nazi research (WW II)
  - 1. High altitude experiments
  - 2. Freezing
  - 3. Starvation or sea water as primary liquid
  - 4. Infectious organisms - malaria, typhoid, strep, tetanus
- E. Led to Nuremberg Code (1946), and others with recurring themes:
  - 1. Informed decision not coerced
  - 2. Subject's welfare is primary
  - 3. Risks as well as benefits considered
  - 4. Ultimate responsibility is the investigator's
- F. Tuskegee syphilis study (1932-1972) - disadvantaged, rural black males used to study untreated course of disease

#### IV. Ethical Principles

- A. Belmont Report (1978): Ethical Principles and Guidelines for the Protection of Human Subjects of Research
  - 1. Respect for persons
    - a. Autonomy
    - b. Protection for those with diminished capacity
  - 2. Beneficence
    - a. Do no harm
    - b. Maximize possible benefits & minimize possible harms
  - 3. Justice - fair distribution of benefits & burdens
- B. Greg Koski, former Director of Office for Human Research Protections added:
  - 1. Responsibility
  - 2. Caring (from Ethics of Care)
- C. Goal: "Culture of Conscience"

V. IRBs charged with the responsibility of implementing the regulations that are designed to put ethical theory into practice; PI has primary responsibility.

- A. Informed decision making has become Informed Consent
- B. Surrogate/Proxy consent
- C. Voluntary
- D. Research partner
- E. Assessing benefits - "In the eye of the beholder"
- F. Selection of vulnerable populations justified - Fernald School

VI. Case discussion

- A. The Coronary Artery Bypass Patient
- [B. A Cognitive Enhancing Drug Requiring Blood Draws (?)]