Current Human Subject Regulations (Part 1)

US275 Scientific Ethics
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Nuremberg Code

- Developed for the Nuremberg Trials
  - standards by which to judge the human experimentation conducted by the Nazi government

The Military Tribunal I judges hearing the Doctors Trial.
From left to right are Harold L. Sebring, Walter B. Beals, Johnson T. Crawford, and Victor C. Swearingen. USHMM [Photograph #82957]

Nuremberg Code Principles

- Voluntary consent of subject
  - freely given consent
  - capacity to consent
    - comprehension of risks and benefits
  - freedom from coercion
  - freedom to withdraw at any time

Declaration of Helsinki

- Similar to Nuremberg Code
- World Medical Association
  - not binding international law,
    - but influences national laws and regulations
  - 1964, subsequent revisions in 1975, 1983, 1989, 2000, 2008
- further distinguishes between medical treatment and medical research

Signing of the 1975 revision to the Declaration of Helsinki. Chancellor of Federal Republic of Germany (West Germany) Helmut Schmidt, Chairman of the Council of State of the German Democratic Republic (East Germany) Erich Honecker, U.S. president Gerald Ford and Austrian chancellor Bruno Kreisky.

United States Regulations

- Department of Health, Education and Welfare
  - NIH Policies for the Protection of Human Subjects, 1966
  - enforced as regulatory standard effective May 30, 1974
  - now regulated by the Department of Health and Human Services

National Research Act

- National Commission for the Protection of Human Subjects on Biomedical and Behavioral Research (July 1974)
  - 1974 - 1978
  - issued *The Belmont Report*

The New York Times

Syphilis Victims in U.S. Study Went Untreated for 40 Years

By JEAN HELLER
The Associated Press

WASHINGTON, July 25—For 40 years the United States Public Health Service has conducted a study in which human beings with syphilis, who were induced to serve as guinea pigs, have gone without medical treatment for the disease and a few have died of its late effects, even though an effective therapy was eventually discovered.

The study was conducted to determine from autopsies what the disease does to the human body.

Officials of the health service who initiated the experiment have long since retired. Current officials, who say they have serious doubts about the morality of the study, also say that it is too late to treat the syphilis in any surviving participants.

Doctors in the service say they are now rendering whatever other medical services they can give to the survivors while the study of the disease's effects continues.

Dr. Merlin K. DuVal, Assistant Secretary of Health, Education and Welfare for Health and Scientific Affairs, expressed shock on learning of the study. He said that he was making an immediate investigation.

The experiment, called the Tuskegee Study, began in 1932 with about 600 black men.

The Belmont Report

- Established 3 basic ethical principles for biomedical and behavioral research involving human subjects
  - Respect for persons
  - Beneficence
  - Justice

Belmont Report: Respect for Persons

- Emphasizes the need to obtain informed consent
  - recognition of personal dignity
  - autonomy of individuals
  - special protection of those persons with diminished autonomy
    - children, patients with mental illness, prisoners

Belmont Report: Beneficence

- importance of risk/benefit analysis in order to minimize risks
- protect persons from harm by
  - maximizing anticipated benefits
  - minimizing possible risks of harm

Belmont Report: Justice

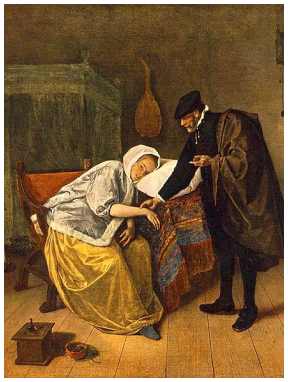
- benefits and burdens of research should be fairly distributed
- individual justice
  - not offer potentially beneficial research to preferred subjects
  - risky research on "undesirable" persons
- social justice
  - affect of benefits and burdens of research on groups of subjects

Belmont Report: Defined boundaries between clinical treatment and research

- Clinical Therapy
  - standard of care
- Clinical Research
  - determining better treatment protocols
- often occur simultaneously

Belmont Report: Clinical Practice

- Therapeutic Practice
  - enhance well-being of an individual patient
  - using interventions with reasonable expectation of success
- Purpose
  - provide diagnosis
  - preventative treatment
  - therapy to particular individuals



The doctor and His Patient.
Jan Steen, 17th century

Belmont Report: Research

- activity designed to test hypothesis
  - permit conclusions to be drawn
  - develop or contribute to generalizable knowledge
- often with formal protocols and procedures to test objective

Common Rule

- Federal Policy for the Protection of Human Subjects (1991)
  - covers research in 16 departments and agencies
    - including NSF, NASA, EPA, CIA, Veterans Affairs, Education, Justice
- Food and Drug Administration (FDA)
  - adopted certain provisions

Food and Drug Administration Regulations

- separate set of regulations, but basic requirements are the same
  - Institutional Review Board
  - Informed Consent
- Differences based on applicability
  - Common Rule- federal funding
  - FDA - use of FDA regulated products
    - Drugs, devices, or biologics.

FDA Approved

FDA

FDA Approved

Current Human Subject Regulations (Part 2)

- continued in next video...

Any Questions?

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