Ethics in Research

Overview and History
Human Experimentation

- Devaluing of groups of humans by experimenting ‘ON’ them without their fully informed consent.

- Historical evidence of human experimentation.
The Study of Untreated Syphilis in the Negro Male

- 400 Black men in south with syphilis
- Treated for ‘bad blood’
- Long term follow up to see effects of syphilis even after cure found
Tuskegee Study

- Presidential apology in 1997
- Long term impact - lack of trust in medical research by minorities
- Resulted in formation of research ethics
Nuremberg Code

- Developed for the Nuremberg Military Tribunal
- Standards by which to judge the human experimentation conducted by the Nazis
- Developed the basic principles governing the ethical conduct of research involving humans
Nuremberg Code

Principles of Nuremberg Code

- Voluntary consent
- Capacity to consent
- Freedom from coercion
- Comprehension of the risks and benefits
Human Radiation Experiments

- Government sponsored exposed subjects (frequently children) to radioisotopes without disclosure to them or their parents

- The Advisory Committee on Human Radiation Experiments (ACHRE) was formed in January 1994
Willowbrook State School

- During the period of 1955 – 1970’s newly-admitted mentally retarded children were deliberately infected with hepatitis in order to study the natural history of the disease under controlled circumstances.

- Parents were offered admission to the study after receiving notification of being placed on a waiting list because of the crowded condition.
The Thalidomide Study

- Thalidomide was approved as a sedative in Europe in the late 1950’s.

- The FDA never approved the drug, but samples were sent to US doctors.

- By 1961 thalidomide was shown to be very harmful to the fetus, interfering with the normal development of arms and legs.
Milgram Experiment

The shock generator, showing the switched ranging from 15 to 400 volts
Declaration of Helsinki

- Recommendations guiding medical doctors in biomedical research involving human subjects
- Adopted in 1964 at the 18th World Medical Assembly
- Distinguishes between therapeutic research “in which the aim is essentially diagnostic or therapeutic for a patient” and research “which is purely scientific”.
The Belmont Report

- Set forth 3 principles required to ethically engage in research involving humans
  - Respect for persons
  - Beneficence
  - Justice
Respect for Persons

- Treat participants as autonomous individuals
- Obtain their informed consent prior to participation
- People are participants, partners, or collaborators, rather than ‘subjects’
Beneficence

- Requires investigators to design protocols that will provide valid and generalizable knowledge

- Requires investigators to ensure that the benefits of the research are proportionate to the risk assumed by the participants
Justice

- Requires that the benefits and burdens of research be distributed fairly
- No group of people should bear a disproportionate share of risk