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Examples of Unethical Studies

- Nazi medical experiments
- Tuskegee syphilis study
- Willowbrook study
  - Hepatitis and retarded children
- Jewish chronic disease
  - Injecting cancer cells into patients
Ethical Codes and Regulations (1)

• Nuremberg Code (1949)
  ○ Voluntary consent
  ○ Withdrawal of subjects from studies
  ○ Protection of subjects from physical and mental suffering
  ○ Balance of benefits and risks
• Declaration of Helsinki (1964): Therapeutic and non-therapeutic research
  ○ Differentiated therapeutic from non-therapeutic research

• Department of Health, Education, & Welfare (DHEW) Regulations
  ○ National Research Act 1974
Ethical Codes and Regulations (3)

- Department of Health & Human Services (DHHS)
  - Published Regulations in 1981
  - Revised in 1983, 1991

Ethical Principles

- **Respect for persons**
  - Right to self-determination
  - Right to refuse

- **Beneficence**
  - Do no harm

- **Justice**
  - Fair treatment

- **Use of principles to guide a study**
Human Rights

- Right to self-determination
- Right to anonymity and confidentiality
- Right to privacy
- HIPPA
Self-Determination

- Self-determination
  - Participation and withdrawing
- No coercion
- Full disclosure, no deception
- Voluntary consent
Vulnerable Populations

- Old, young
- Mentally or physically disabled
- Institutionalized persons
- Pregnant women
- Homeless
Justice

- Right to fair treatment
- Right to protection from discomfort and harm
  - No anticipated effects
  - Temporary discomfort
  - Unusual levels of temporary discomfort
  - Risk of permanent damage
  - Certainty of permanent damage
Informed Consent Elements (1)

- Essential information for consent
- Comprehension of consent information
- Competency to give consent
- Voluntary consent
Informed Consent Elements (2)

- Assent versus consent
- Who signs for whom?
- Can the language be understood?
- Documentation of consent: Written, taped, or video
- Completion of the questionnaire indicates comprehension of consent
Ethical Issues Related to Research

- Scientific misconduct in the conduct of research
- Use of animals in research
Critiquing the Ethics of a Study

- Was the study approved by the appropriate IRB?
- Was informed consent obtained from the subjects?
- If the subjects were incompetent to give consent, did their legally authorized representative give consent?
- Were the subjects’ rights protected during sampling, data collection and analyses?
- Was the privacy of subjects protected during the study and in the final report?
- Was the benefit risk ratio of the study acceptable?