Ethics and Scientific Integrity

Contributors
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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

Ethical Codes and Regulations (2)

- 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
- National Commission for the Protection of Human Subjects of Biomedical & Behavioral Research (1978): Ethical Principles

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?