

NURSING RESEARCH 2

NCMB315

Ethical Principles

ETHICS

- A declaration of right or wrong; reflects the "should" of human behavior
- Science of ideals - guides our judgment concerning morality of human acts
- Study of moral conduct or principles of underlying desirable types of human conduct.
- Ethics determines:
 - Why one act is better than the other
 - To have an orderly social life

UNETHICAL RESEARCHES: HUMAN SUBJECTS

NAZI MEDICAL EXPERIMENTS

- The Nazi Medical Experiments were conducted on prisoner of war and racially "valueless" people who were confined to concentration camps by the Third Reich.

TUSKEGEE SYPHILIS STUDY

- The Tuskegee Syphilis Study was conducted to determine the natural course of syphilis in the adult black man.
- By the end of the study, only 74 of the test subjects were still alive. Twenty-eight of the men had died directly of syphilis, 100 were dead of related complications, 40 of their wives had been infected, and 19 of their children had been born with congenital syphilis.

WILLOWBROOK STUDY

- The Willowbrook Study involved deliberately infecting children with the hepatitis virus.

JEWISH CHRONIC DISEASE HOSPITAL STUDY

- The Jewish Chronic Disease Hospital Study involved injecting patients with live cancer cells to determine the patients' rejection response to these cells.

HISTORICAL DOCUMENTS ON RESEARCH

NUREMBERG CODE (1949)

- Consent process
- Protection of subjects from harm
- Balance of benefits and risks in a study

DECLARATION OF HELSINKI (1964)

- Differentiated therapeutic from non-therapeutic research
 - Investigator should protect life
 - Investigator should exercise greater care to protect subjects from harm in non-therapeutic research
 - Investigator should conduct research only when the importance of the objective outweighs the inherent risks and burdens to the subjects

BENEFICENCE

- Beneficence encompasses the maxim: Above all, do no harm.
 - Freedom from harm
 - Freedom from exploitation
 - Benefits from research
 - Risk/ benefit ratio



JUSTICE

- Justice includes participants' right to fair treatment and their right to privacy
 - The right to fair treatment
 - The right to privacy
 - Anonymity
 - Confidentiality

RESPECT FOR HUMAN DIGNITY

- Respect for human dignity includes participants' right to self-determination and their right to full disclosure
 - The right to self-determination
 - The right to full disclosure

INFORMED CONSENT

- Means that participants have adequate information regarding the research, are capable of comprehending the information, and have the power of free choice, enabling them to consent to or decline participation voluntarily.



VULNERABLE SUBJECTS

- Special groups of people whose rights in research studies need special protection because of their inability to provide meaningful informed consent or because their circumstances place them at higher than-average-risk of adverse effects; examples include young children, the mentally retarded, and unconscious patients.

BUILDING ETHICS INTO THE DESIGN OF THE STUDY

- RESEARCH DESIGN
 - Will the setting for the study be selected to protect against participant discomfort?
- INTERVENTION
 - Is the intervention designed to maximize good and minimize harm?
- SAMPLE
 - Will potential participants be recruited into the study equitably?
- DATA COLLECTION
 - Will data be collected in such a way as to minimize respondent burden?
- REPORTING
 - Will participants' identities be adequately protected?

INSTITUTIONAL REVIEW BOARDS

- IRBs are responsible for reviewing in universities, clinical agencies, and managed care centers involving human subjects for the express purpose of determining if potential benefits of the investigation outweigh any risk that may be present to the subject.

TYPES OF REVIEW

- EXEMPT FROM REVIEW
 - No apparent risk or harm to the subjects
- EXPEDITED REVIEW
 - Minimal risk or harm to the subjects
- COMPLETE REVIEW
 - Greater than minimal risk or harm to the subjects

SCIENTIFIC MISCONDUCT**RANKIN AND ESTEVEZ, 1997**

- Scientific misconduct in research includes fraudulent practices as fabrication, falsification, or forging of data, dishonest manipulations of the study designs or methods with protocol violations; misrepresentations of findings, and plagiarism

TYPES OF SCIENTIFIC MISCONDUCT

- FABRICATION
 - Deliberate invention of nonexistent information
- IRRESPONSIBLE COLLABORATION
 - Failure to participate appropriately in an investigation team
- PLAGIARISM
 - The intentional representation of the work or ideas of others as one's own
- MANIPULATION OF DATA
 - Choosing only data that are consistent with the research hypothesis