Ethics in Nursing Research

Dr. Sahar Hassan

Definitions

- Ethics: refers to the study and evaluation of human conduct.
- Deception: The deliberate withholding of information, or the provision of false information, to research subjects, usually used to reduce potential biases.
- Institutional Review Board (IRB): A group of people who convene to review proposed and on-going studies with respect to ethical consideration.

Ethical Dilemma in Conducting Research

- A situation in which the rights of study participants are in direct conflict with requirements for a rigorous study

Code of Ethics

- Nuremberg Code (1949)
- Belmont Report: Ethical Principles & Guidelines for the Protection of Human Subjects of Research (1979)
- Declaration of Helsinki (since 1964 & updated regularly) Ethical Principles for Medical Research Involving Human Subjects
- Codes for professional disciplines (e.g., by the American Nurses' Association, American Psychological Association)

Declaration of Helsinki

Declaration of Helsinki

World Medical Association Declaration of Helsinki

Ethical Principles for Medical Research Involving Human Subjects

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964; amended by the 29th WMA General Assembly, Tokyo, Japan, October 1975; 35th WMA General Assembly, Venice, Italy, October 1983; 41st WMA General Assembly, Hong Kong, September 1989; 48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996, and the 52nd WMA General Assembly, Edinburgh, Scotland, October 2000

A. Introduction

1. The World Medical Association has developed the Declaration of Helsinki as a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects. Medical research involving human subjects includes research on identifiable human material or identifiable data.

2. It is the duty of the physician to promote and safeguard the health of the people. The physician's knowledge and conscience are dedicated to the fulfillment of this duty.

3. The Declaration of Geneva of the World Medical Association binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient."

4. Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects in their own countries as well as applicable international requirements. No national ethical, legal or regulatory requirement should be allowed to reduce or eliminate any of the protections for human subjects set forth in this Declaration.

B. Basic principles for all medical research

10. It is the duty of the physician in medical research to protect the life, health, privacy, and dignity of the human subject.

11. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and on adequate laboratory and, where appropriate, animal experimentation.

12. Appropriate caution must be exercised in the conduct of research which may affect the environment, and the

Code of Ethics

- The fundamental ethical principles that are established by a discipline of institution to guide researchers' conduct in research with humans.
- The Belmont Report is one of the famous reports that included three ethical principles and these are:

Code of Ethics

I. Principle of Beneficence: A fundamental ethical principle that seeks to prevent harm & exploitation of, & maximize benefits for, human subjects.

- Freedom from harm
- Freedom from exploitation
- Risk/benefit ratio: the relative costs & benefits, to an individual subject & to society at large, or participation in a scientific study.

Codes of Ethics

Potential benefits:

- Access to an intervention to which they might otherwise not have access
- Comfort in being able to discuss their situation or problem with an objective and non-judgmental researcher.
- Increased knowledge about themselves or their conditions, either through opportunity for introspection or through direct interaction with the researcher
- Enhanced self-esteem resulting from special attention or treatment.

Codes of Ethics

Potential Risks:

- Physical harm, including unanticipated side effects
- Physical discomfort, fatigue, or boredom
- Psychological or emotional distress resulting from self-disclosure, fear of the unknown or interacting with strangers, anger at the type of questions being asked, and so on.
- Loss of privacy

Codes of Ethics

II. Principle of Respect for Human dignity

- Right to self-determination:

✓ Self-determination is a person's ability to decide voluntarily whether or not to participate as a subject in a study.

✓ It includes freedom from coercion of any type.

✓ Coercion involves explicit or implicit threats of penalty for falling to participate in a study or excessive rewards form agreeing to participate.

- Right to Full disclosure: the researcher has fully described the nature of the study.

Informed Consent

Informed Consent: A written agreement signed by a subject & researcher concerning the terms & conditions of a subject's voluntary participation in a study.

Informed consent means that participants:

- Have adequate information about the research
- Can comprehend that information
- Have free choice in deciding whether to participate in or withdraw from the study

Informed Consent

Informed Consent includes the following information:

1. The fact that the data provided by or obtained from the subjects will be used in a scientific study.

2. The purpose of the study.

3. The type of data to be collected

4. The nature & extent of the subjects' time commitment

5. The procedures to be followed in collecting the research data.

Informed Consent (Cont.)

6. How subjects came to be selected

7. Potential physical or emotional discomforts or sides effects.

8. If injury is possible, an explanation of any medical treatments that might be available.

9. If relevant, alternative treatments available that might be advantageous to subjects.

Informed Consent (cont.)

10. Potential benefits to subjects (including whether or not a stipend) & potential benefits to others.

11. A description of the voluntary nature of participation and the right to withdraw at any time without penalty

12. A pledge that the subjects' privacy will at all times be protected.

13. The names of people to contact for information or complaints about the study.

Codes of Ethics

III. Principle of Justice:

Right to fair treatment**:**

- Fair & non-discriminatory selection of subjects such that any risks & benefits will be equitably shared (e.g. subjects' selection).
- The non-prejudicial treatment of peoples who decline to participate or who withdraw from the study after agreeing to participate.
- Honoring of all agreements made between the researcher & the subject, including adherence to the procedures outline in advance & the payment of any promised stipends

Codes of Ethics

III. Principle of Justice: (cont.)

- Subjects' access to research personnel at any point in the study to clarify information
- Subjects' access to appropriate professional assistance if there is any physical or psychological damage.
- Debriefing is communication with research subjects, generally after their participation has been completed regarding various aspects of the study.
- Respectful & courteous treatment at all times.

Codes of Ethics

Right to Privacy:

- Anonymity: Protection of the participant in a study such that even the researcher cannot link him or her with the information provided

- Confidentiality: An element of ethical research, it is the researcher's ability to keep data sources protected by using numbers instead of names and by using locked records that reveal code names/numbers.

Vulnerable Subjects

- Special groups of people whose rights in research studies need to be protected through additional procedures because of their inability to provide meaningful informed consent or because their circumstances place them at higher than average risk or deleterious effects.

Vulnerable Subjects

Those subjects are:

- Children
- Mentally ill or mentally retarded subjects
- Aged subjects
- Captive persons
- The poor people
- The dying or the unconscious person