HSM 470
Research Methods and Data Analysis in Health Sciences

Ethics in Research

Unit Objectives

- Upon completion of this unit, the student will be able to:
  - Define ethical dilemma.
  - Describe the Nuremberg Code.
  - Discuss the limitations of the Nuremberg Code.
  - Describe the need for informed consent of research participants.
  - Describe the procedure for obtaining informed consent.
  - Discuss the dimensions of privacy.
  - Compare and contrast anonymity and confidentiality.

Ethical Dilemma

Conflict between the right to research and to acquire knowledge and the right of individual research participants to self-determination, privacy, and dignity.

The Nuremberg Code

- Voluntary consent of the participant is absolutely essential. The subject must be capable of giving consent without coercion and full responsibility rests with the principal investigator.
- The experiment must be designed to bring forth results that will benefit society and cannot be obtained in any other manner.
- Human experimentation should be based on animal research results as well as knowledge of the natural course of events, disease, or problem.

Nuremberg Code continued

- All unnecessary mental or physical harm should be avoided.
- When there is reason to believe that death or disabling injury may occur, no experiment should be conducted except perhaps when the experimenting physicians also serve as subjects.
- The degree of risk should never exceed the humanitarian importance of the problem to be solved.
- All precautions should be taken to protect subjects from even remote possibilities of injury or death.

Nuremberg Code continued

- Only qualified personnel should be allowed to conduct experiments.
- The subject must be able to withdraw from the experiment at any time if a point is reached which may bring about physical or mental harm.
- The principal investigator must be ready to terminate the experiment at any stage if it appears that injury or death will result.

Flaws of the Nuremberg Code

- Too much latitude given to principal investigators to apply these principles.
- Justification
  - Interests of health sciences
  - Interests of the subjects
  - Interests of the community

Informed Consent

- There is wide consensus among scientists that research involving human participants should be performed with the informed consent of the participants.
- Informed consent is absolutely essential whenever participants are exposed to substantial risks or are asked to forfeit personal rights.
- Most funding agencies (especially governmental agencies) require that a signed consent form be completed if research participants are placed "at risk."

Informed Consent continued

Major universities have voluntarily agreed to comply with federal guidelines in reviewing all research conducted in their institutions, whether funded by the federal government or not.

Reasons for Informed consent

- The need for informed consent is rooted in the high value we attach to freedom and self-determination.
- Individuals are best able to promote their own well-being.
- Limits the legal liability of the researcher.
- Most scientific journals will not publish results of studies that do not adhere to ethical standards.

The Meaning of Informed Consent

The procedure in which individuals choose whether to participate in an investigation after being informed of facts that would be likely to influence their decision. This definition involves 4 components:

Components of Informed Consent

- Competence – Requires that individual be capable of making the decision to participate.
- Voluntarism-Freedom of individual to choose whether to participate

Components of Informed Consent continued

- Full Information (Federal Guidelines)
  - Fair explanation of the procedure to be followed, including identification of experimental methods.
  - Description of any attendant discomforts and risks reasonably expected.
  - Description of any benefits reasonably expected.
  - Disclosure of any appropriate alternative that might be advantageous for the subject.
  - An offer to answer any inquiries concerning the procedure.
  - Instruction that the person is free to withdraw consent and to discontinue participation in the project or activity at any time without prejudice to the subject.

Components of Informed Consent continued

Comprehension – Confidence that the participant has provided knowing consent when the research is associated with complex or subtle risks.

Privacy

Right to Privacy

- The freedom of the individual to pick and choose for himself the time and circumstances under which, and most importantly, the extent to which, his attitudes, beliefs, behavior, and opinions are to be shared with or withheld from others.

Privacy continued

- Dimensions of Privacy
  - Sensitivity of Information – The degree of personal threat of information release; examples – sexual preference, health status, religious beliefs
  - Settings being Observed – public vs. private
  - Dissemination of Information – The ability to match personal information with the identity of research participants

Anonymity and Confidentiality

- Anonymity
  - Requires the identity of individuals be separated from the information they give.
    - No names, aliases, transformations, or codes
    - Cannot be traced
- Confidentiality
  - Information provided my identify a particular individual, but the information will not be revealed publicly. Data may be subpoenaed and can be used to trace individuals.

Anonymity and Confidentiality continued

- Techniques for Maintaining Confidentiality
  - Deletion of identifiers
  - Crude report categories
    - Examples: year of birth instead of date, county data instead of city or census tract data, shift data instead of individual paramedic data
    - Microaggregation – release data on "average respondent" instead of individual information
    - Error inoculation – deliberately introducing "fudge factor"