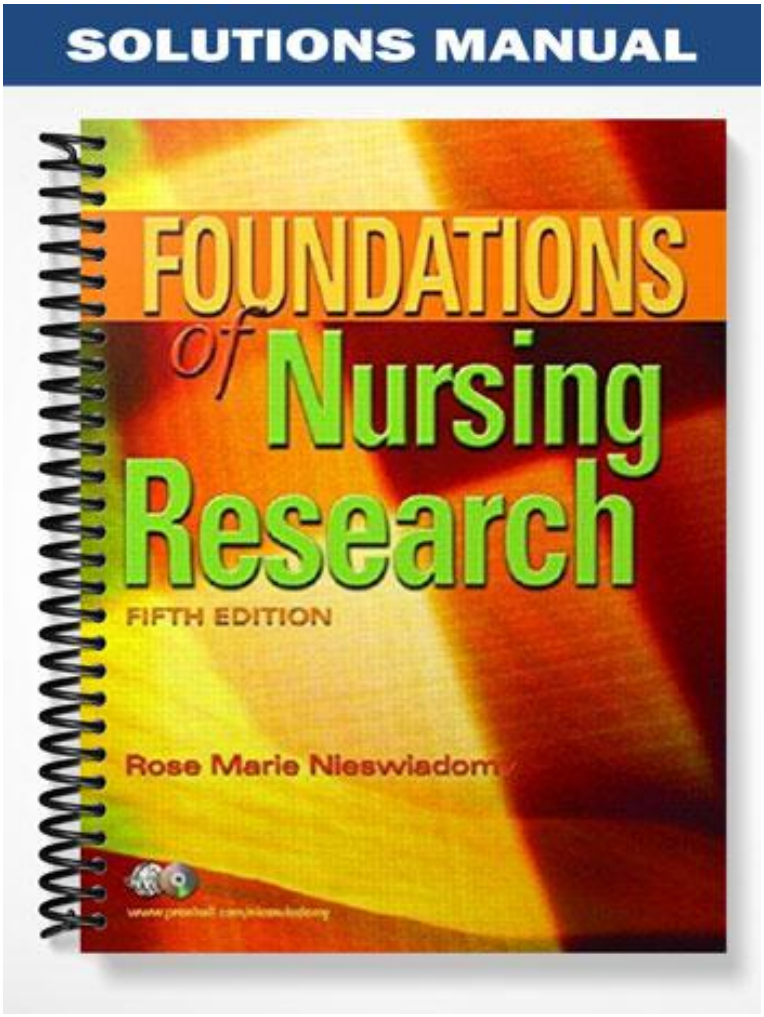
SOLUTIONS MANUAL



Chapter Number 2: Ethical Issues in Nursing Research

LEARNING OBJECTIVE 1
Discuss some of the unethical studies that have been documented in the literature

Concepts for Lecture

1. There were numerous unethical research studies performed throughout the world on a variety of populations.
2. These populations were never informed of the purpose of the research.
3. The United States was also not immune to these unethical research practices.
4. Since human beings are used as subjects for research studies, advocates for their safety and health issues are critical.

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1. Unethical Research Studies
   - Examples of how prisoners were used
   - Drug effectiveness on wounds
   - The prediction of skeletal size
   - Freedom of Information Act
2. Informed Consent not an option
   - Are prisoners "real people"?
   - Nurses expected to participate
   - Atrocities surfaced in 1940s
   - *The Truth about Unit 731*
3. Unethical Studies in the United States
   - Mentally retarded children and infectious hepatitis
   - Elderly patients and their ability to fight cancer cells
   - Experimental measles vaccine to black and Hispanic children
   - American Indian children and hepatitis A vaccine
   - Tuskegee study of untreated syphilis
4. Advocates for "at risk" populations
   - Children
   - Poor populations
   - Minority Groups

LEARNING OBJECTIVE 2
Trace the development of ethical codes and guidelines

Concepts for Lecture

1. Populations are protected by rules and ethical standards.
2. The atrocities that occurred during the 1940s resulted in the establishment of the 1947 Nuremberg Code.
3. Many other ethical codes quickly followed to protect human beings from unethical situations.

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1. Codes of Conducts
   - The role of ethics
   - The Ten Commandments
   - Rules to govern actions must be considered
2. The Nuremberg Code, 1947
   - A result of prisoner research
   - Criteria for research identified
     - Researcher must inform subjects
     - Research for the good of society
     - Research based on animal experiments
     - Researcher must avoid injury to subjects
     - Researcher must be qualified to do research
     - Subjects or researcher can stop study if problems occur
3. Other Ethical Codes
   - Universal Declaration of Human Rights, 1948
   - *The Belmont Report* – 1979
     - Respect for Persons
     - Beneficence
     - Justice
   - The Department of Health and Human Services (DHHS)

LEARNING OBJECTIVE 3
Appreciate the role of institutional review boards

Concepts for Lecture

1. The federal government (DHHS) established the creation of Institutional Review Boards (IRBs).
2. The Health Insurance Portability and Accountability Act (HIPAA, 2003) protects an individual's health information.
3. Nurses Organizations have also established guidelines for nursing research.

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1. Institutional Review Boards (IRBs)
   - In 1981, DHHS published guidelines
   - These guidelines led to the IRBs

- The federal government oversees IRBs
- Human research needs IRB approval

2. HIPAA and its implications
   - The Privacy Rule
   - Protection for person's health information
   - Written permission must be obtained
   - HIPAA covers health care and research
3. Research Guidelines for Nurses
   - *Human Rights Guidelines for Nurses in Clinical and Other Research*
   - General principles
   - *Ethical Guidelines in the Conduct, Dissemination, and Implementation of Nursing Research*

LEARNING OBECTIVE 4
Identify the elements of informed consent

Concepts for Lecture

1. The principal way of assuring that the rights of research subjects are protected is through informed consent.
2. There are 12 major elements that need to be addressed in the informed consent.

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1. Informed Consent
   - Protects rights of research subjects
   - Receives full explanation of the study
   - Allows time for clarification
   - Submits permission by signed name
2. Major Elements of Informed Consent
   - Researcher and Credentials
   - Subject Selection Process
   - Study Purpose
   - Study Procedures
   - Potential Risks
   - Potential Benefits
   - Compensation, if any
   - Alternative procedures, if any
   - Anonymity or confidentiality
   - Right to refuse or withdraw
   - Questions addressed
   - Means of getting study feedback

2.1 Research Identification
   - Research name and qualifications

- Sponsor or sponsoring agency
- Confusion if nurse caregiver is also researcher

2.2 Subject Selection Process
- Other names for "subject"
- Selection goal—unbiased sample
- Subjects told how they are selected
- Women, men, ethnic, and cultural groups
- NINR and funding opportunities

2.3 Study Purpose
- Language and reading level
- Open and honest with explanation
- Enough information for informed consent

2.4 Study Procedures
- Place
- Time commitments
- Procedure format
- Debriefing if necessary

2.5 Potential Risks
- Physical
- Psychological
- Privacy issues

2.6 Potential Benefits
- Nuremberg Code
- Society benefits
- Subjects plus others

2.7 Compensation
- Monetary incentives
- Examples of other types
    - Tests
    - Travel
- Compensation and biases

2.8 Alternative Procedures
- Treatment
- Control Group
- Hawthorne Effect

2.9 Anonymity or Confidentiality
- Definitions
- Procedures to help assure
- Deletion of identification information
- Data reported in aggregate
- Clear instructions to help process

2.10 Right to Refuse/Withdraw

- Re-explain the voluntary aspect
- No penalty for withdrawal
- Always able to drop at any time

2.11 Question Opportunities

- At time of informed consent
- Available by phone or email
- Always there to answer questions

2.12 Final Results

- Subjects may receive study results
- How to obtain these results
- Publication plans must be given
- Date when results are available

LEARNING OBJECTIVE 5
Recognize unethical research

Concepts for Lecture

1. Office of Research Integrity (ORI) in the Department of Health and Human Services investigates cases suspected of misconduct by researchers who have federal funding.
2. Nurse researchers need to be especially attentive to issues of coercions, deceptive language on informed consent forms, the falsification of documents, and "conflicts of interest".

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1. Misconduct in Research
   - Federal Government's Office of Research Integrity
   - Tracking started in 1989
   - ORI investigates only federal funded studies
   - Nursing research studies cited in 1993
2. Citations for misconduct
   - Issues of coercions
   - Deceptive language on consent forms
   - Falsification of documents
   - Conflict of interest issues

LEARNING OBJECTIVE 6
Act as a patient advocate during research investigations

Concepts for Lecture

1. The researcher must protect the privacy and dignity of all subjects.

2. The researcher must protect the subjects from physical or psychological harm.
3. The researcher must be aware of subjects that are “vulnerable”.

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1. Patient Advocate Role
   - Protect privacy and dignity of subjects
   - Clinical Trial questions
     - Purpose
     - Work setting
     - Available brochures
2. Do No Harm
   - Physical Harm
   - Psychological Harm
3. Vulnerable Populations
   - Children
   - Geriatric clients
   - Prisoners
   - Homeless
   - AIDS
   - Unconscious
   - Sedated
   - Assent considerations

LEARNING OBJECTIVE 7
Critique the ethical aspects of a study

Concepts for Lecture

1. Subjects enrolled in research must be protected by federal and state guidelines identified in the document titled *Ethical Guidelines in the Conduct, Dissemination, and Implementation of Nursing Research, the Belmont Report* and associated Institutional Reviews Boards.

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1. Ethical Aspects of Study
   - Institutional Review Board Guidelines
   - The Belmont Report
   - Other Ethical Guidelines
     - Association Guidelines (ANA)
     - Department of Health and Human Services
     - Health Insurance Portability and Accountability Act

Suggestions for Classroom Activities

1. Go to the ORI website (http://ori.dhhs.gov/misconduct/cases/index.shtml) and discuss briefly the cases of misconduct currently under investigation.
2. Go to a National Nursing Association and review their research guidelines.
3. Review the document used by an Institutional Review Board and determine how unethical behaviors are prevented.
4. Obtain an informed consent form from a nursing research study and see if all the elements are present.
5. Discuss whether you believe the issue of "euthanasia" lends itself to a research study.
6. Interview a nurse researcher at an acute care institution and identify the various ways that they act as a patient advocate for their research studies.
7. Critique the ethical aspects of the study article presented in this course of study.