Nursing Research Series
Essentials of Science: Methods, Appraisal and Utilization

Objectives

By the completion of this presentation the participant will be able to:

1. **Describe fraudulent practices in the conduct, reporting and publication of health care research.**
2. **Understand the historical events influencing the development of ethical codes and regulations in research.**
3. **Identify the ethical principles that are important in conducting research on human participants.**
4. **Describe the human rights that require protection in research.**
5. **Critique the informed consent and institutional review processes in published studies.**

Ethics of Research

- **What do we mean by ethics of research?**
  - **Ethics of research is defined as what one morally ought to do in conducting, disseminating, and implementing the results from a systematic investigation.**
  - **The ethics of research are determined by both traditional and changing social values, which vary within and between cultures.**
    - **All researchers must carefully avoid ethnocentrism and cultural imposition (Anderson, 2006).**
    - **What is ethnocentrism?**
    - **Ethnocentric individuals will judge other groups relative to their own particular ethnic group or culture, especially with concern to language, behavior, customs, and religion.**

Ethics of Research

- **All research has ethical dimensions**
- **All research must be ethical**

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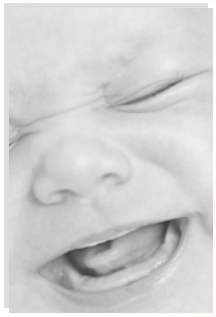
Misconduct in Research



- **Scientific misconduct is a major ethical problem**
- **Over 50% of the top U.S. research institutions have been investigated for fraud.**
- **Misconduct in research includes:**
  - Fabrication, falsification, or forging of data.
  - Dishonest manipulation of the study design or methods with protocol violations.
  - Misrepresentation of findings.
  - Plagiarism (copying someone else's, including your own, published work)

(Rankin & Esteves, 1997; Dellavalle, Banks, and Ellis, 2007)

Historical Perspective

- **Codes of Ethics have been developed in response to human rights violations**
- **Blatant violations of human rights occurred during the 1930's to the early 1970's, including:**
  - Nazi Medical Experiments, 1933-1945 (Berger, 1990; Steinfels & Levine, 1976)
  - Tuskegee Syphilis Study, 1932-1972 (Levine, 1986; Rothman, 1982)
  - Willowbrook Study, 1955-1970's (Levine, 1986; Rothman, 1982)
  - Jewish Chronic Disease Hospital Study, 1960's (Levine, 1986; Hershey & Miller, 1976)

Historical Perspective

- **Those human rights violations led to the establishment major codes of conduct for ethical research:**
  - Nuremberg Code, 1949 (Levine, 1986)
  - Declaration of Helsinki, 1964 (http://www.wma.net/e/policy/b3.htm)
- **Despite these, harmful and unethical research continued.**
- **In 1973, the Department of Health, Education, and Welfare (DHEW) published its first regulations for the protection of human research participants (Levine, 1986).**
- **These regulations required all research involving humans to undergo a full Institutional Review Board (IRB) review.**

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Belmont Report

- **Despite the DHEW regulations, research misconduct continued.**
- **In 1974, the National Research Act was passed. (Public Law 93-348).**
- **Resulting in the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research**
- **In 1978, the Commission published the Belmont Report.**
  - The Belmont Report identified three ethical principles on which standards of ethical conduct in research are based:
    - Principle of Respect for Persons
    - Principle of Beneficence
    - Principle of Justice

Respect for Persons

- **The principle of *Respect for Persons* indicates that people should be treated as autonomous agents with the right to self determination and the freedom to participate or not participate in research.**
- **Those persons with diminished autonomy, such as children, people who are terminally or mentally ill, and prisoners are entitled to additional protection.**

Beneficence

- **The Principle of Beneficence encourages the researcher to do good and "above all, do no harm."**
  - Freedom from Exploitation
  - Is the Risk/Benefit Ratio Acceptable?
  - Such an assessment is designed to determine whether the benefits of participating in a study balance with the costs, be they financial, physical, emotional, or social.

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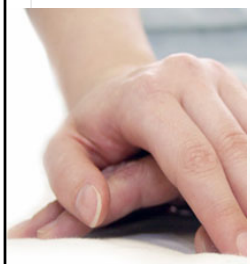
Justice



- **Right to Fair Treatment**
  - Research participants have the right to fair and equitable treatment in terms of the benefits and the risks of research before, during, and after their participation in the study.
- **Right to Privacy**
  - Virtually all research with humans constitutes some type of intrusion into their personal lives.
  - Researchers should ensure that their research is not more intrusive than it needs to be and that the participants' privacy is maintained throughout the study.

Human Rights

- **The ethical principles of Respect for Persons, Beneficence, and Justice provide research participants with human rights.**
- **Human rights are claims and demands that have been justified in the eyes of an individual or by the consensus of a group of people.**
- **Nurses who critique published studies, review research to be conducted in their agencies, *or assist with data collection for a study,* have an ethical responsibility to determine whether the rights of the research participants are protected.**

Human Rights

- **The Human Rights that require protection in research are the rights to:**
  - Self-Determination
  - Privacy
  - Anonymity
  - Confidentiality
  - Fair Treatment

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Right to Self-Determination

- The Right to Self-Determination is based on the ethical principle of Respect for Persons, and it indicates that humans are capable of controlling their own destiny.
- Therefore, research participants should be treated as autonomous agents, who have the freedom to conduct their lives as they choose without external controls.
- Participants are treated as autonomous agents in a study if the researcher has:
  - Informed them about the study
  - Allowed them to choose whether to participate, and
  - Allowed them to withdraw from the study at any time without penalty (Levine, 1986)

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Informed Consent

- *Informed consent* is an especially important procedure for protecting self determination
- Informed consent means participants have adequate information; and have the power of free choice; enabling them to consent voluntarily to participate in the research or decline participation.
- Minors (neonates and children), pregnant women, fetuses, mentally impaired persons, unconscious patients, and employees, *including RNs*, are considered vulnerable.
- Additional safeguards are included to protect vulnerable participants rights and welfare.

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HIPPA: The Privacy Rule

- **In 2003, the Health Insurance Portability and Accountability Act (HIPPA) was enacted to protect the privacy of health information (Olsen, 2003).**
- **HIPPA calls this information "protected health information" or 'PHI'.**
- **Implications for the Consumer:**
  - Most of us believe that our medical and other health information is private and should be protected, and we want to know who has this information.
  - HIPPA, The Privacy Rule, a Federal law, gives you rights over your health information and sets rules and limits on who can look at and receive your health information.
  - The Privacy Rule applies to all forms of individuals' PHI, whether electronic, written, or oral.

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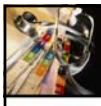
HIPPA: Implications for RNs

- **RNs are accustomed to having access to their patients' PHI.**
- **Accessing PHI for research or quality improvement may require a review by the IRB to meet HIPPA federal regulations.**
- **When PHI is accessed outside of routine patient care in the conduct, reporting, and publication of health care research, the IRB is responsible for determining if the methodology or protocol meets HIPPA regulations for privacy protection.**
  - Often, the IRB will determine a study is *exempt* or eligible for an *expedited review*, in which case a full IRB review is not necessary to access protected information for an investigation or selected quality improvement projects.
  - In addition to research, HIPPA applies to employees who participate in surveys, questionnaires and interviews as well.

PHI Identifiers

- **18 Identifiers Constitute PHI – *Note: If all of the following 18 identifiers are removed, then the data is considered de-identified and may be used/disclosed without restriction.***
  1. **Names**
  2. **All geographic subdivisions smaller than a state, including street address, city, county, precinct, and ZIP Code**
  3. **Except year, all of dates directly related to an individual, including birth date, admission date, discharge date, date of death; as well as all ages over 89, except that such ages and elements may be aggregated into a single category of age 90 or older.**
  4. **Telephone Number**
  5. **FAX Number**
  6. **E-Mail Address**



PHI Identifiers Continued

7. **Social Security number**
8. **Medical Record number**
9. **Health Plan Beneficiary number**
10. **Account numbers**
11. **Certificate/License number**
12. **Vehicle Identifiers & Serial numbers (including license plates)**
13. **Device identifiers and Serial numbers**
14. **URL Address**
15. **IP Address**
16. **Biometric identifiers, like fingerprints and voiceprints**
17. **Full-face Photos and comparable Images**
18. **Any other unique identifying number, characteristic or code**

http://www.hhs.gov/ocr/privacy/hipaa/understanding/consumers/index.html

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Implications for Patient Care

- **Revealing patient or employee information, e.g. a private conversation between two RNs overheard by someone else on an elevator violates HIPPA.**
- **Recording patient information on facebook, a blog, or other electronic means violates HIPPA.**
- **These violations of HIPPA are punishable by a fine and termination of employment**.

Institutional Review Board (IRB)

- **IRBs in academic institutions and clinical agencies, have been organized to examine the ethical aspects of studies *before they are conducted*.**
  - Because of the risk of a biased evaluation, the ethical dimensions of a study normally should be subjected to an IRB or other external review.
  - Studies supported with federal funds are subject to strict guidelines with respect to treatment of humans and animals used in research.
  - There is a separate and independent IRB for each KP Regional Division: KPNC-IRB & KPSC-IRB.
  - Researchers have a responsibility to ensure that their research plans are ethically acceptable *before* the study starts.

IRB continued

- **The IRB is responsible for protecting research participants by determining:**
  - Risks to participants are minimized
  - Risks to participants are reasonable in relation to anticipated benefits, if any, and the importance of the knowledge that may be reasonably be expected to result
  - Selection of participants is equitable
  - Informed consent is sought, as required, and appropriately documented
  - Adequate provision is made for monitoring the research to ensure the safety of participants
  - Appropriate provisions are made to protect the privacy of participants and the confidentiality of data (Code of Federal Regulations, 1983, revised 2009)

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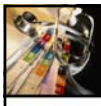
Educational Requirements To Conduct Research

- ***Before submitting an application to the IRB,*** **investigators are required to obtain certificates of completion for:**
  1. **HIPPA Privacy Rule Training for Researchers**
  2. **Protecting Human Research Participants KP RNs can obtain Certificates of Completion through the Pathways Nursing Research Web Sites:**
     - **SCAL http://nursingpathways.kp.org/scal/**
     - **NCAL http://nursingpathways.kp.org/ncal/**
     - **Protecting Human Research Participants may also be obtained online for free through the National Institutes for Health (NIH) at http://phrp.nihtraining.com/users/login.php**

Informed Consent: Example Quantitative Research

- **An MSN student proposes to survey RNs to assess their knowledge of analgesic medications.**
- **The IRB will examine the proposal for the following:**
  - Is the study survey valid and reliable? Has it been tested before?
  - Could the Kaiser RNs feel coerced to participate?
    - Is the MSN student in a managerial position?
    - Could the content of the RNs responses affect their employment?
    - Will the surveys be distributed and returned anonymously?
    - Will the participants' names be used on any study materials, except on the consent forms and a master list of names and code numbers?
    - Will the consent forms and the master list of names be filed in a locked cabinet in a separate office on the hospital premises?
    - Is there a plan to destroy the consent forms and master list of names at the completion of the study?



Privacy Protection: Example Qualitative Research

- **Example of confidentiality procedures in a qualitative study:**
  - Spiers (2002) described interpersonal contexts in which care was negotiated between home care nurses and their patients.
  - Her qualitative study was based on an analysis of 31 videotaped home visits.
  - The video portion of the tapes was not altered, inasmuch as the researcher wanted to analyze facial expressions.
  - However, any audio containing names or other identifying information was removed in dubbed tapes.
  - Pseudonyms were used in the transcripts.

Putting it All Together

Guidelines of critiquing the ethical aspects of a study:

1. Were the study participants subjected to any physical harm, discomfort, or psychological distress? Did the researchers take appropriate steps to remove or prevent harm?
2. Did the benefits to participants outweigh any potential risks or actual discomfort they experienced? Did the benefits to society outweigh the costs to participants?
3. Was any type of coercion or undue influence used in recruiting participants? Were vulnerable participants used?

Putting it All Together Continued

- **Guidelines of critiquing ethical aspects of a study continued**
  3. Were participants deceived in any way? Were they fully aware of participating in a study and did they understand the purpose of the research? Were appropriate consent procedures implemented?
  4. Were appropriate steps taken to safeguard the privacy of participants?
  5. Was the research approved and monitored by an IRB or other similar ethics review committee?

American Nurses Association

- **Clinical and research nurses are guided by:**
  - The 1980 and 1995 American Nurses Association's (ANA) *Nursing Social Policy Statement* (ANA, 1995)
  - The ANA-sponsored monograph, *Ethical Guidelines in the Conduct, Dissemination, and Implementation of Nursing Research* (Silva, 1995).

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In Conclusion

- In conclusion, we will review the key concepts of this presentation, which can be found on page 233 of Chapter 7, Examining Ethics in Nursing Research (Burns & Grove, 2007).

Key Concepts

- Four experimental projects have been highly publicized for their unethical treatment of human subjects:
  - 1. The Nazi medical experiments
  - 2. The Tuskegee Syphilis Study
  - 3. The Willowbrook Study
  - 4. The Jewish Chronic Disease Study
- Two historical documents, the Nuremberg Code and the Declaration of Helsinki, have had a strong impact on the conduct of research

Key Concepts

- The DHHS (1981, 1983, 1991, 2001, 2005) and the FDA (1988a, 1988b, 2002) passed regulations to promote ethical conduct in research, including:
  - General requirements for informed consent
  - Guidelines for IRB review of research and some quality improvement projects
- The HIPPA was enacted in 2003 to protect the privacy of PHI
- The human rights that require protection in research are:
  - Self Determination
  - Privacy
  - Anonymity and confidentiality
  - Fair Treatment
  - Protection from discomfort and harm

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Key Concepts

- **Informed consent involves:**
  - **1. Transmission of essential study information to the potential subject/participant,**
  - **2. Comprehension of that information by the potential subject**
  - **3. Competence of the potential subject to give consent**
  - **4. Voluntary consent by the potential subject to participate in the study**

Key Concepts

- **An IRB consists of a committee of peers who examine studies for ethical concerns with three levels of review:**
  - **Exempt**
  - **Expedited**
  - **Complete**
- **To balance the benefits and risks of a study, the type, degree and number of risks are examined, and the potential benefits are identified**
- **Scientific misconduct is a serious ethical problem of the last few decades, with the conducting, reporting, and publication of fraudulent research.**

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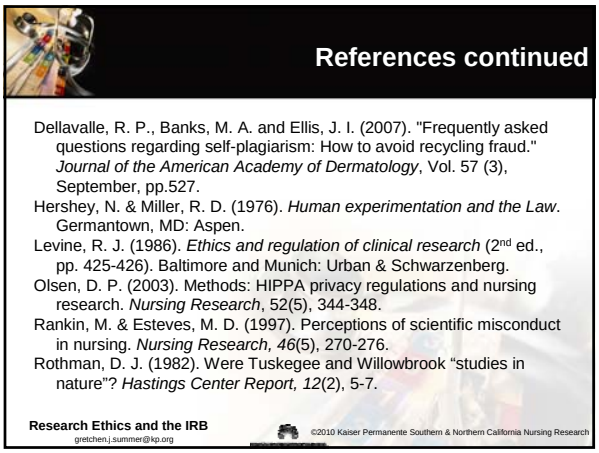

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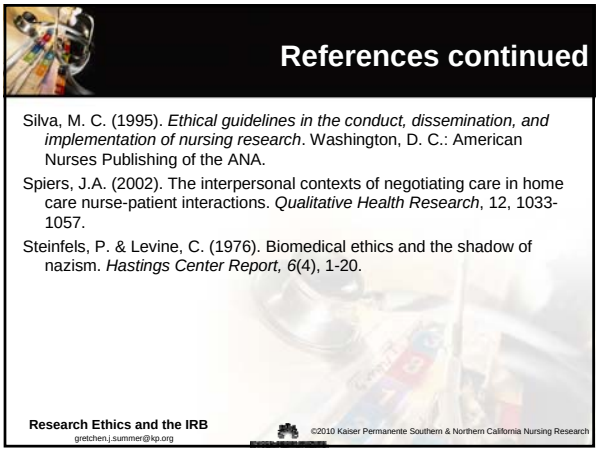

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