Ethics in Clinical Research
(including transcript of audio)

NUR 720

Events That Shaped Modern-Day Research Ethics Rules

- Tuskegee Syphilis Study 1932–1972
- WW II—Nazi medical experiments early 1940s
- New York City—Cancer Experiments—1963
- Jenner's Smallpox vaccine—1979
- Los Angeles EZ me3asles vaccine—1989–1991

Transcript of audio:

During the **Tuskegee Syphilis Study,** more than 400 poor black men with advanced syphilis were recruited and not treated to determine the long-term effects of syphilis. This continued even after the discovery of penicillin for the successful treatment of syphilis.

During **WW II, Nazi medical experiments on prisoners of war (POW)** were performed to determine the effects of cold on German pilots. POWs were left naked in cold or submerged in cold ice water for a minimum of 3 hours to see how long it took for body parts to freeze. To identify the effects of Sulfa drugs, POWs' wounds were deliberately infected with bacteria, then given varying doses of the drug; German doctors performed many bizarre studies involving twins, including surgeries, injections, blood tests, and autopsies.

To determine the body's ability to reject foreign cells, 22 elderly patients were injected with live cancer cells in **New York City** in 1963 but were told they were being given a skin test.

Eight-year-old children were exposed to cowpox to test the efficacy of the new vaccine during the testing of Jenner's Smallpox Vaccine in 1979.

Then, during the trial of the **Los Angeles EZ measles vaccine**, 900 black and Hispanic children were given the new unlicensed EZ measles vaccine without parents' knowledge.

These are just a few example of research studies carried out with total disregard for human rights.

Nuremberg Code of Ethics—1947

1. Informed consent
2. Research must be for the good of society
3. Research must be based on animal experiments, when possible
4. Researcher must avoid injury to subjects
5. No research if death or disabling injury is possible

6. Degree of risk can never exceed expected benefit
7. Preparations must protect subjects
8. Researcher must be qualified to conduct research
9. Subjects can stop study if problems occur
10. Researcher should stop study if problems occur

Adapted from:
Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10, Vol. 2, pp. 181-182. Washington, D.C.: U.S. Government Printing Office, 1949.

Transcript of audio:

As a reaction to the Nazi medical experiments during WW II, the war crimes tribunal at Nuremberg laid down 10 standards to which physicians must conform when carrying out experiments on human subjects in a new code that is now accepted worldwide. This judgment established a new standard of ethical medical behavior for the post–World War II human rights era. This document introduces the requirement of ***voluntary informed consent*** of the human subject meant to protect the right of the individual to control his own body. This code also recognizes risk must be weighed against expected benefit, and that unnecessary pain and suffering must be avoided.

Ethical Principles—Belmont Report

- Respect for persons—autonomy and self-determination.
- Beneficence—protect from harm.
- Justice—fair treatment.

Transcript of audio:

In 1979, the **Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research** was published in the United States to provide a succinct description of the mandate for review of research involving human research participants. Regulations and guidelines concerning the use of human subjects in research are based on the fundamental from the Belmont Report.

Respect for Persons—People have the right to decide for themselves whether to participate in research. You may not use information about people without first getting their informed consent. Special care must be taken with people who are unable to understand or who are particularly susceptible to coercion.

Beneficence—Researchers must maximize possible benefits and minimize possible harms. It is not OK to use people for research unless the research is likely to have some benefit. Furthermore, this benefit must outweigh the risks.

Justice—People must be treated fairly. Researchers should not take from research participants without giving back. Selection of research participants must be constantly monitored to determine whether some pools of participants are being systematically selected from simply because they are easily available or vulnerable or easy to manipulate, rather than chosen for reasons directly related to the research problem being studied.

Institutional Review Board (IRB)

- Ensure protection of health, well-being, and rights of human subjects involved in research.
- Bradley—Committee on the Use of Human Subjects in Research (CIHSR).
    - Reviews all research conducted at BU.
    - Determines if research is exempt, expeditable, or requires a full review.
    - Guidelines for informed consent.

Elements of Informed Consent

- Researcher ID and credentials
- Purpose of the study
- Selection process described
- Study procedures discussed
- Potential risks described
- Potential benefits described
- Compensation discussed (*if applicable)
- Alternative procedures (*if applicable)
- Anonymity of confidentiality assured
- Right to refuse or to withdraw without penalty
- Contact information for questions
- Means of obtaining study results

Transcript of audio:

Informed Consent is a voluntary agreement to participate in research. The subject acknowledges that he/she has an understanding of the research and its risks. Informed consent must be obtained prior to enrolling a participant and ongoing once enrolled. Informed consent must be obtained for all types of human subjects research. Vulnerable populations (i.e. prisoners, children, pregnant women, etc.) must receive extra protections. The legal rights of subjects may not be waived and subjects may not be asked to release or appear to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Vulnerable Populations

- Children (over age of 7—must get assent from child along with parental consent)
- Geriatric patients
- Prisoners
- Persons with AIDS
- Homeless
- Unconscious
- Sedated patients
- Pregnant women, human fetuses, neonates

Transcript of audio:

Subjects can be considered vulnerable if subjected to:

- **Physical Control**—The use of physical force to make subjects participate in research.
- **Coercion**—The use of credible threat of harm or force to control another person.
- **Undue Influence**—The misuse of a position of confidence or power to get participants to participate in research.
- **Manipulation**—Deliberate management of conditions or information to lead participants to participate in research.

When dealing with vulnerable populations the researcher must do the following:

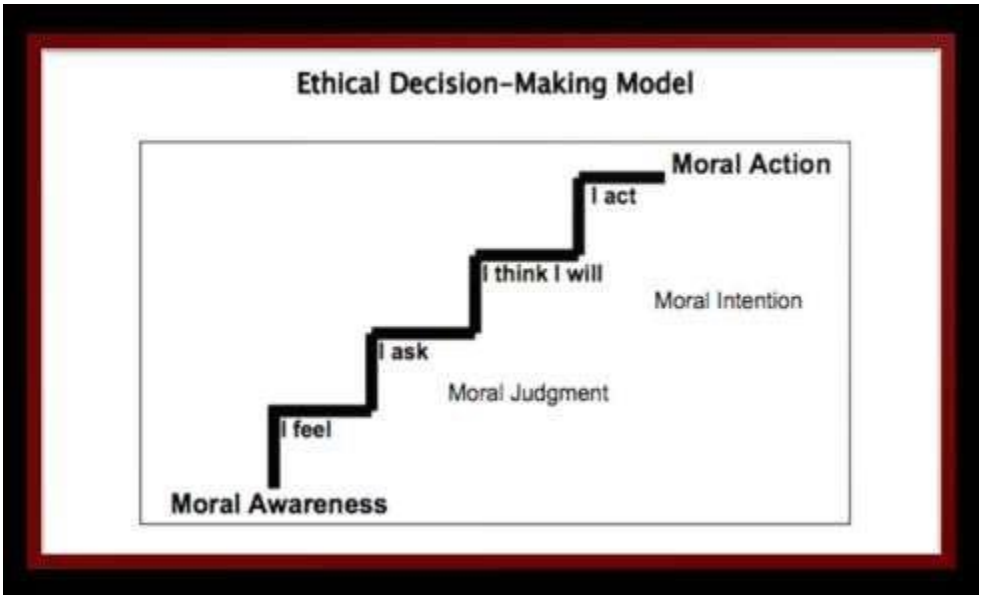
- Identify additional procedures that will be utilized to protect and respect subjects' rights.
- Describe how subjects' disadvantages will be accommodated (including language barriers) in terms of recruitment, informed consent, questions during research, early withdrawal and research procedures.
- Identify steps that will be taken to minimize the possibility of coercion or undue influence being imposed on the individual.

Research Integrity

Transcript of audio:

Research Integrity involves the use of honest and verifiable methods in proposing, performing, and evaluating research. Failure to uphold research integrity undermines confidence and trust.

Ethical Decision-Making Model



Transcript of audio:

The Ethical Decision-Making Model helps to determine whether a decision that needs to be made is being upheld to the most ethical standard. The following are the components of the Ethical Decision-Making Model.

- **Moral Awareness, or "I feel"—**The ability to recognize the presence of a moral issue and realize that actions have the potential to harm and/or benefit others.
- **Moral Judgment, or –"I ask"**—Formulating & evaluating possible solutions to the moral issue, looking at consequences vs benefits
- **Moral Intention, or "I think"—**Committing to choose the morally right action over another solution.
- **Moral Action**—An individual's action Involves courage, determination, and ability to follow through with moral decision.

Research Misconduct

- Fabrication—reporting nonexistent data.
- Falsification—misrepresentation of data.
- Plagiarism—misrepresenting another person's words or ideas as your own.
- Abuse of confidentiality—misuse of confidential information.
- Exploitation/coercion—forcing involvement.

Transcript of audio:

Research misconduct can distort scientific knowledge, mislead the scientific community, and/or be harmful to human subjects.

Examples of Research Misconduct

- National Institutes of Health (NIH)
- Office of Research Integrity

Transcript of audio:

Research misconduct is a reportable offense, especially if federal grant money is involved. The National Institute of Health as well as the Office of Research integrity offer valuable information about actual cases of research misconduct.

Use of Electronic Health Record Data

- Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule
- IRB and HIPAA Privacy Rule

Transcript of audio:

The advent of electronic health records brings with it new challenges for maintaining the privacy and confidentiality of human subjects in research. The Health Insurance Portability and Accountability Act (HIPAA) privacy rule and institutional review boards (or IRBs) offer more information about special considerations for the use of patient information from electronic health records.

Critiquing Ethical Aspects of a Study

- IRB Approval?
- Informed consent?
- Anonymity or confidentiality?
- Vulnerable groups?
- Coercion or undue influence?
- Inclusion/exclusion justified?
- Benefits? > risks?

Transcript of audio:

To assure the reader that proper ethical considerations were followed, the researcher must share how each of these aspects was addressed in the research methodology plan and implementation.