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N 536 - Utilization of Nursing Research in Advanced Practice, Summer 2008

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Ethics and Scientific Integrity



Contributors

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Examples of Unethical Studies



- Nazi medical experiments
- Tuskegee syphilis study
- Willowbrook study
 - Hepatitis and retarded children
- Jewish chronic disease
 - Injecting cancer cells into patients

Ethical Codes and Regulations (1)



- **Nuremberg Code (1949)**
 - Voluntary consent
 - Withdrawal of subjects from studies
 - Protection of subjects from physical and mental suffering
 - Balance of benefits and risks

Ethical Codes and Regulations (2)



- Declaration of Helsinki (1964):
Therapeutic and non-therapeutic research
 - Differentiated therapeutic from non-therapeutic research
- Department of Health, Education, & Welfare (DHEW) Regulations
 - National Research Act 1974

Ethical Codes and Regulations (3)



- Department of Health & Human Services (DHHS)
 - Published Regulations in 1981
 - Revised in 1983, 1991
- National Commission for the Protection of Human Subjects of Biomedical & Behavioral Research (1978): Ethical Principles

Ethical Principles



- **Respect for persons**
 - Right to self-determination
 - Right to refuse
- **Beneficence**
 - Do no harm
- **Justice**
 - Fair treatment
- **Use of principles to guide a study**

Human Rights



- Right to self-determination
- Right to anonymity and confidentiality
- Right to privacy
- HIPPA



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Self-Determination



- **Self-determination**
 - Participation and withdrawing
- **No coercion**
- **Full disclosure, no deception**
- **Voluntary consent**

Vulnerable Populations



- Old, young
- Mentally or physically disabled
- Institutionalized persons
- Pregnant women
- Homeless

Justice



- Right to fair treatment
- Right to protection from discomfort and harm
 - No anticipated effects
 - Temporary discomfort
 - Unusual levels of temporary discomfort
 - Risk of permanent damage
 - Certainty of permanent damage

Informed Consent Elements (1)



- Essential information for consent
- Comprehension of consent information
- Competency to give consent
- Voluntary consent

Informed Consent Elements (2)



- Assent versus consent
- Who signs for whom?
- Can the language be understood?
- Documentation of consent: Written, taped, or video
- Completion of the questionnaire indicates comprehension of consent

Ethical Issues Related to Research



- **Scientific misconduct in the conduct of research**
- **Use of animals in research**

Critiquing the Ethics of a Study



- Was the study approved by the appropriate IRB?
- Was informed consent obtained from the subjects?
- If the subjects were incompetent to give consent, did their legally authorized representative give consent?
- Were the subjects' rights protected during sampling, data collection and analyses?
- Was the privacy of subjects protected during the study and in the final report?
- Was the benefit risk ratio of the study acceptable?