

Unless otherwise noted, the content of this course material is licensed under a Creative Commons 3.0 License.
<http://creativecommons.org/licenses/by/3.0/>

Copyright 2008, Huey-Ming Tzeng, Sonia A. Duffy, Lisa Kane Low.

The following information is intended to inform and educate and is not a tool for self-diagnosis or a replacement for medical evaluation, advice, diagnosis or treatment by a healthcare professional. You should speak to your physician or make an appointment to be seen if you have questions or concerns about this information or your medical condition. You assume all responsibility for use and potential liability associated with any use of the material.

Material contains copyrighted content, used in accordance with U.S. law. Copyright holders of content included in this material should contact open.michigan@umich.edu with any questions, corrections, or clarifications regarding the use of content. The Regents of the University of Michigan do not license the use of third party content posted to this site unless such a license is specifically granted in connection with particular content objects. Users of content are responsible for their compliance with applicable law. Mention of specific products in this recording solely represents the opinion of the speaker and does not represent an endorsement by the University of Michigan.

Ethics and Scientific Integrity



Contributors

Sonia A. Duffy, PhD, RN

Lisa Kane Low, PhD, CNM, FACNM

Huey-Ming Tzeng, PhD, RN

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



BY: victoriapeckham (flickr)
<http://creativecommons.org/licenses/by/2.0/deed.en>



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?