Young Adult Series

Course #7: Informed Consent

Guided Notes

Remember: You can pause the video for extra time on any section.

Informed Consent CDC: https://wwwnc.cdc.gov/eid/page/informed-consent

"In brief, when studies involve human participants, authors are responsible for including a statement that those studies have been approved by an appropriate institution or national research ethics committee and have been performed in accordance with the ethical standards noted in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards."

Declaration of Helsinki: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

"Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees."

Informed Consent HHS:
https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html

- *"A description of any reasonable foreseeable risks or discomforts to the subject."*
- *"A description of any benefits to the subject or to others which may reasonable be expected from the research."*
- *"A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject."*
- *"A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled."*

Informed Consent FDA:

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/informed-consent#genrequirments

"Informed consent is required for participation in FDA-regulated clinical investigations except under limited circumstances as described in 21 CFR 50.23 (involving certain life-threatening situations, military operations, or public health emergencies) and 21 CFR 50.24 (involving emergency research)."

Exceptions: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.23
Cambridge University: https://www.cambridge.org/core/journals/cambridge-quarterly-of-healthcare-ethics/article/abs/informed-consent-its-history-meaning-and-present-challenges/27E8171706F09D53D5702137B3DEA168

"The term "informed consent" emerged only in the 1950s, and serious discussion of the meaning and ethics of informed consent began in medicine, research, law, and philosophy only around 1972."

PBS Nazi Germany Medical Experiments:
WARNING: If you are under 18, show this link to your parent or guardian first and check that it is okay with them for you to read it. This link contains detailed descriptions of horrific medical experiments performed without consent of the victims, and may be disturbing to readers.
https://www.pbs.org/wgbh/nova/holocaust/experiside.html

Nuremberg Trials:

https://www.britannica.com/event/Nurnberg-trials

"Nürnberg trials, Nürnberg also spelled Nuremberg were a series of trials held in Nuremberg, Germany, in 1945 through 1946, in which former Nazi leaders were indicted and tried as war criminals by the International Military Tribunal."

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2352998/

"The issue of ethics with respect to medical experimentation in Germany during the 1930s and 1940s was crucial at the Nuremberg trials and related trials of doctors and public health officials. Those involved in horrible crimes attempted to excuse themselves by arguing that there were no explicit rules governing medical research on human beings in Germany during the period and that research practices in Germany were not different from those in allied countries. In this context the Nuremberg code of 1947 is generally regarded as the first document to set out ethical regulations in human experimentation based on informed consent. New research, however, indicates that ethical issues of informed consent in guidelines for human experimentation were recognised as early as the nineteenth century. These guidelines shed light on the still contentious issue of when the concepts of autonomy, informed consent, and therapeutic and non-therapeutic research first emerged."

Tuskegee: https://www.cdc.gov/tuskegee/timeline.htm

- **1932**: U.S. Public Health Service engaged the Tuskegee Institute in Alabama in a Syphilis Study.
    - 600 black men, 399 with syphilis and 201 without syphilis.
    - No informed consent.
- **1943**: Penicillin was a known treatment for syphilis, but participants in the study were not offered treatment, depriving them of care that could have saved their health and lives.
- **1972**: Associated Press broke story. Assistant Secretary for Health and Scientific Affairs appointed an Advisory Panel to review the study. The panel found that the study was "ethically unjustifiable."
- **1973**: The panel advised the Department to instruct the US Public Health Service to provide all necessary medical care to survivors of the study.

Nuremberg Code 10 Standards:
https://media.tghn.org/medialibrary/2011/04/BMJ_No_7070_Volume_313_The_Nuremberg_Code.pdf

Harvard University – History of Informed Consent Requirements in US Federal Policy:
https://dash.harvard.edu/bitstream/handle/1/8852197/Wandler.pdf?sequence=1

- Page 7 has the 1957 Case: Salgo vs. Leland Stanford Jr. University Board of Trustees.

"Mr. Salgo brought a malpractice suit against his physicians alleging negligence when he became permanently paralyzed after having undergone a translumbar aortography. Mr. Salgo's doctor had recommended the surgery, but Mr. Salgo claimed that the doctor had never… warned him about the risk of potential paralysis. A California Court of Appeals decided that the physician was liable for not disclosing relevant information to the patient. Although the consent issue in the case was not the main grounds for appeal, the court nonetheless set an important precedent when it created a heightened duty to disclose on the part of doctors. The court determined that "a physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment."