

**WEO research workshop in conjunction with Jakarta International GI
Endoscopy symposium & Live demonstration**

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Research Ethics

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Disclosure

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- Olympus
- Pentax
- Cook
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- Covidien
- CDX Diagnostics
- Astra Zeneca



What is Ethics?

- The study of what is morally right and wrong, or a set of beliefs about what is morally right and wrong.
- Moral principles that govern a person's behaviour or the conducting of an activity.

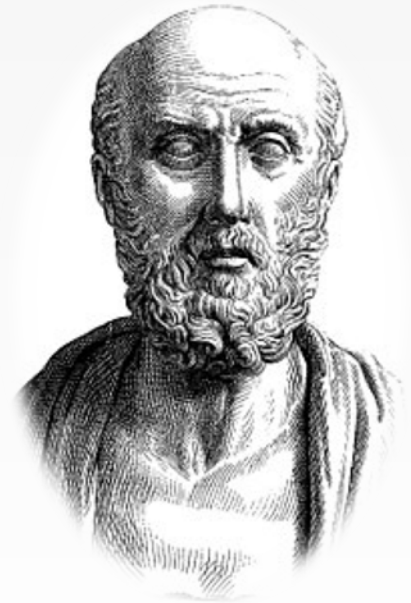
Cambridge dictionary



Research Ethics

- The Hipocratic oath is the oldest expression of medical ethics

“Primum non nocere: First do no harm”



The “Doctors Trial”



Nuremberg code, August 1947



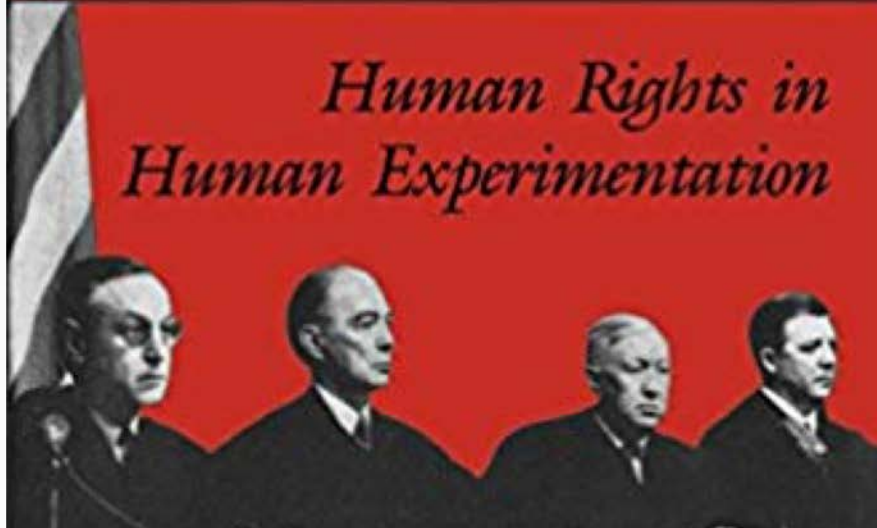
Nuremberg Code

- Post WWII, the American military tribunal opened criminal proceedings against German Physicians for crimes against humanity- 16 doctors found guilty.
- Medical experiments were conducted on thousands of prisoners without consent- died or permanently crippled.



The Nazi Doctors and the Nuremberg Code

*Human Rights in
Human Experimentation*



The Nuremberg code was established in 1948
“voluntary participation and informed consent- core principles”

George J. Annas Michael A. Grodin



Basic principles of research ethics

- Do good 'beneficence' and do no harm non-maleficance
 - Clear written protocol- minimise risk of harm
 - Informed written consent
 - Protect confidentiality & anonymity
 - Option and liberty to withdraw
 - Avoid deceptive practice- conflict of interest



Thalidomide disaster 1962

“darkest moment in pharma research”



- Thalidomide was developed in the 1950s by a German Pharma “Chemie Grünenthal GmbH”
- Marketed in Europe as morning sickness pill to pregnant women without any safety testing
- Resulted in >20,000 babies born with limb deformities
- FDA did not approve it in USA



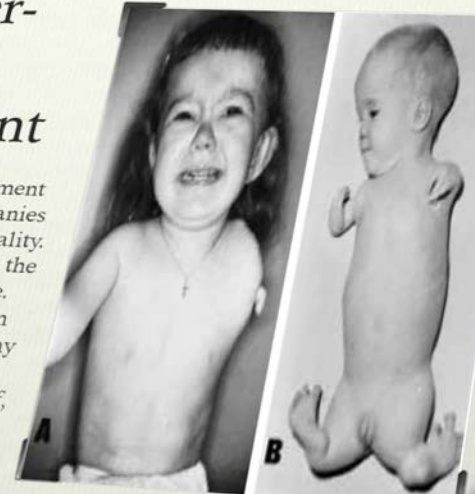
FDA did not approve thalidomide

Dr Frances Kelsey receives the pen from President JFK



Kefauver- Harris Amendment

The Kefauver- Harris Amendment required pharmaceutical companies to test for safety, efficacy and quality. This amendment was spurred by the Thalidomide tragedy in Europe. Thalidomide was marketed as an anti-nausea drug and given to many pregnant women for morning sickness. The drug did provide relief, however, it also caused significant birth defects.



Declaration of Helsinki 1964



Declaration of Helsinki: principles

World Medical Association recommendation

- Human Research should be based on lab /animal research findings
- Risk should not exceed benefit
- Research protocols, should be reviewed by an independent committee
- Informed consent necessary
- Should be conducted by scientific qualified researchers
- Several Revisions, current version 2013



Tuskegee study 1932-72

The New York Times

Syphilis Victims in U.S. Study Went Untreated for 40 Years

By JEAN HELLER
The Associated Press

WASHINGTON, July 25—For 40 years the United States Public Health Service has conducted a study in which human beings with syphilis, who were induced to serve as guinea pigs, have gone without medical treatment for the disease and a few have died of its late effects, even though an effective therapy was eventually discovered.

The study was conducted to determine from autopsies what the disease does to the human body.

Officials of the health service who initiated the experiment have long since retired. Current officials, who say they

have serious doubts about the morality of the study, also say that it is too late to treat the syphilis in any surviving participants.

Doctors in the service say they are now rendering whatever other medical services they can give to the survivors while the study of the disease's effects continues.

Dr. Merlin K. DuVal, Assistant Secretary of Health, Education and Welfare for Health and Scientific Affairs, expressed shock on learning of the study. He said that he was making an immediate investigation.

The experiment, called the Tuskegee Study, began in 1932 with about 600 black men,



Conducted by US Public Health

- Tuskegee University, Macon County, Alabama
- 600 impoverished African-American men
- 399 infected and 201 controls
- Natural history of Syphilis in spite of Penicillin proven to work half way in to the study
- Diagnosis was not told nor informed consent
- Provided free medical care & meals



Belmont Report 1979

- Basic ethical principles
 - Autonomy (research subjects empowered)
 - Beneficence (minimize risk)
 - Justice (benefits and risk of research fairly distributed)



International Council for Harmonization

“Good Clinical Practice”

- Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects.
- Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.



Principles of GCP

- Conducted in accordance with Helsinki declaration
- Risk & benefit weighed whilst writing protocol
- The participants rights, safety and well being should prevail over science and society
- Qualified researchers to conduct trials with IRB approval
- Informed consent and liberty to withdraw
- Confidentiality protected at all times
- Investigational products should be manufactured, handled and stored in accordance with “Good Manufacturing Practices” (GMP)
- Accurate data entry & Quality assurance



CONCLUSION

- Research is essential for the advancement of science and medicine
- It is a privilege for us as doctors that our patients and fellow human beings trust us
- Research should be conducted with utmost integrity and ethics





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