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JOHNS HOPKINS
BLOOMBERG
SCHOOL *of* PUBLIC HEALTH

History of Research Ethics: U.S. and South Asia

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Challenges in Global Health Initiative



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Section A: Background

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Beginning of the 20th Century

- Limited amount of research conducted
 - Pre-World War II experimentation on self or one's own patients
 - Larger studies mostly through defense efforts
 - ▶ Some evidence of consent requirements
 - World War II led to broader government interests in science and research
 - Larger, systematic clinical investigations initiated to gain knowledge for sake of others, not for subjects themselves

Nuremberg Code: 1948

- As a result of World War II Nazi experiments
- First international code
- Voluntary consent essential
 - Legal capacity required
 - Able to exercise free choice
 - Duty and responsibility for ascertaining the quality of consent rests with investigator

The 23 Defendants at the Doctors Trial



Source: National Holocaust Museum photo archives. Public domain.

Dr. Hans Kurt Eisele—Medical Researcher at Dachau



Source: National Holocaust Museum photo archives. Public domain.

Survivor of Experiments at a Concentration Camp



Source: National Holocaust Museum photo archives. Public domain.

Declaration of Helsinki: 1964

- International code by and for physicians who conduct research
- Emphasized potential conflict physician-researchers have
- “It is the mission of the physician to safeguard the health of the people”
- “The health of my patient will be my first consideration”

Declaration of Helsinki

- Based on good science
- Reviewed by independent committee
- Importance in proportion to risk
- Interest of subjects “must always prevail over interests of science and society”
- Intervention should be tested against “best current prophylactic, diagnostic, and therapeutic methods”; then revised again
- Can’t publish if not compliant with code
- Informed consent (Provision #9)

- First code to consider less developed communities
- Individual informed consent
- Investigator's duties regarding consent
- Appropriate inducements
- Special populations
- Privacy
- Independent committee review

CIOMS: Strong Emphasis on Justice

- Responsive to health needs of host country
- Agree in advance that products will be made reasonably available afterward