History of Human Subject Protection

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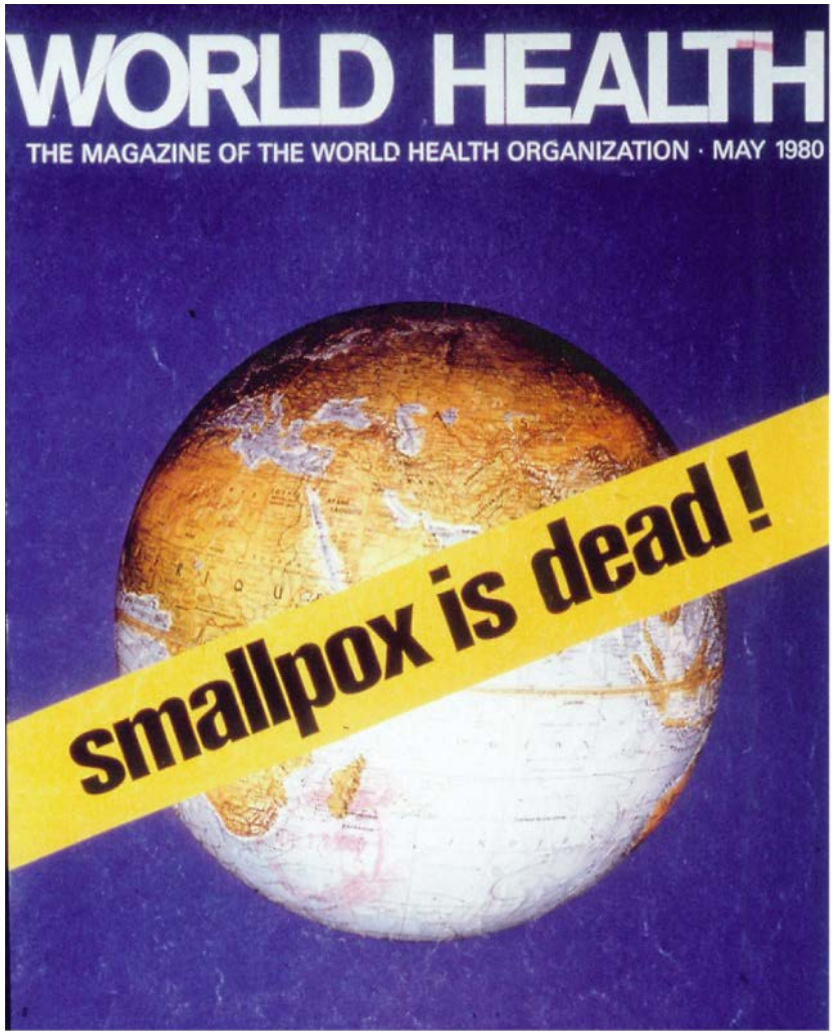
Globalizing Ethics for Health Research



=> Researchers must be ethical to ensure the validity and integrity of their research

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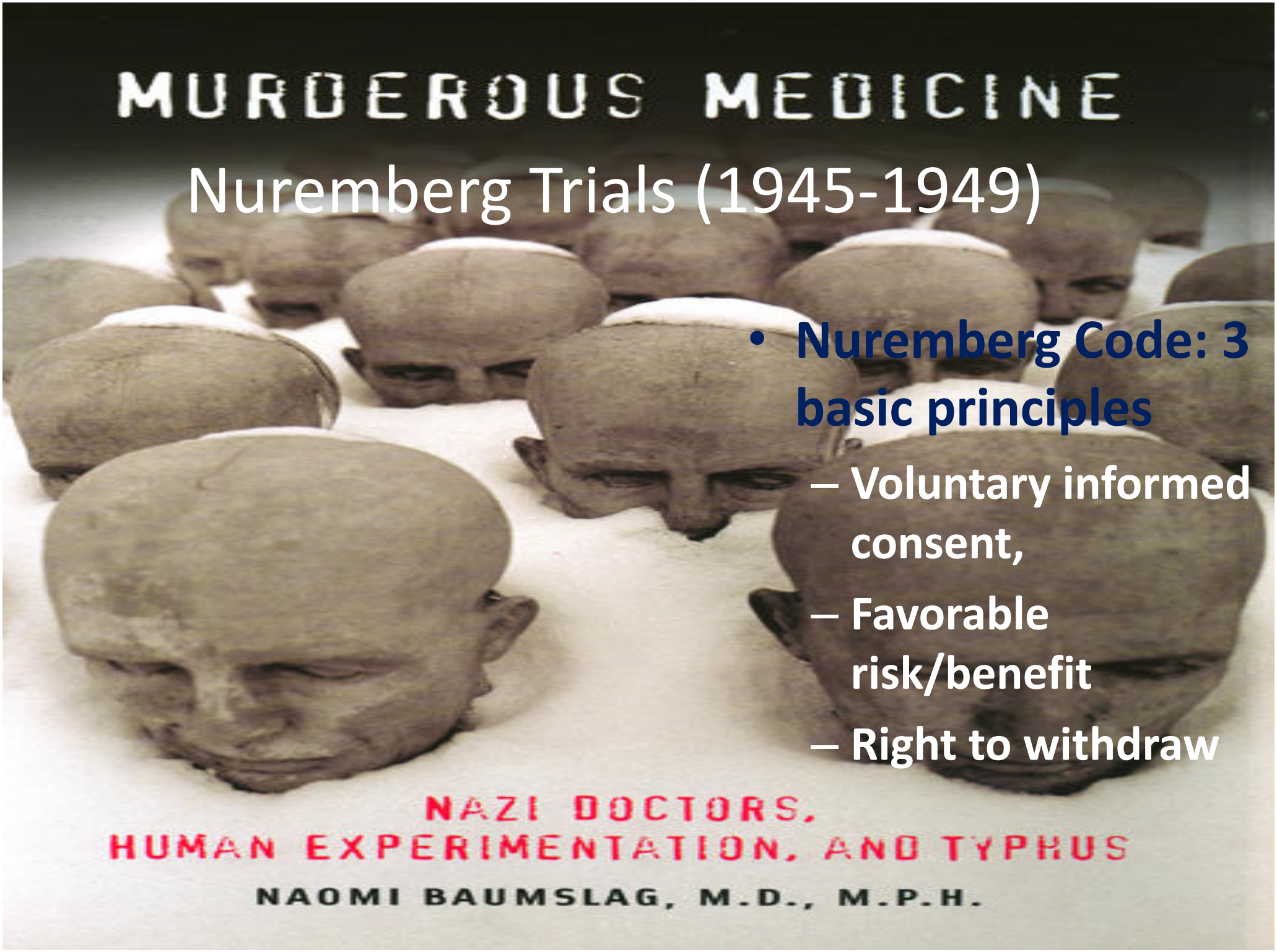
Nuremberg Trials (1945-1949)



- **Nuremberg Code: 3 basic principles**
  - **Voluntary informed consent,**
  - **Favorable risk/benefit**
  - **Right to withdraw**

Declaration of Helsinki

- First version in 1964: no statement on Ethics committee
- DoH 1975: …. protocol should be transmitted to a specially appointed independent committee for consideration, comment and guidance.
- DOH 1989: ….an independent of the investigator and the sponsor provided that committee is in conformity with the laws and regulations
- DoH 2000: Research Ethics Committee has the right to monitor ongoing trials, review SAE, sponsor, Affiliation, COI
- DoH 2008: review Amendment
- DoH 2013: review Final report, ERC must be duly qualified

Mechanism of Protections

Belmont Report 1979

- **3 basic principles**
  - Respect for persons
    - informed consent, respect privacy, confidentiality
  - Beneficence
    - Use best possible research design to maximize benefits and minimize harms
    - Researcher competence to perform procedures and handle risk
    - Prohibition of research with unfavorable risk/benefit
  - Justice
    - Select subjects equitable
    - Avoid exploitation of vulnerable or pop of convenience

Ethics Committee

- On March 31, 1996, a 19-year-old Asian American student at the University of Rochester responded to an advertisement for study subjects to undergo bronchoscopy for the harvest of alveolar macrophages.
- The bronchoscopy was difficult and required numerous doses of topical lidocaine. The investigator repeatedly asked the subject if she wanted to continue and the subject nodded her head "yes".
- The study was completed, but the subject returned to the hospital in cardiac arrest from an overdose of lidocaine and died April 2, 1996.

Ethics Committee

- An investigation into this death revealed that the protocol did not limit lidocaine doses, that the subject was not observed after the bronchoscopy, and that the concentrations of lidocaine were increased without EC approval.

Competent Research Ethics Committee

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Thank you for your Attention

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