

# Vulnerability in Clinical Research

AHS Course Capstone Presentation

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# Overview

- Human Rights
- Vulnerability
- Creating policy
  - After Nazi experiments
  - After Tuskegee
- Current case
  - Response



# Human Rights

What are they?

- Universalism vs relativism

Who gets them?

- Equality

Who decides?

- Power, majority



Source: <http://www.hrproject.org/>

# Vulnerability

- Humans are ‘embodied,’ able to be wounded
- Specific groups
  - Poor
  - Women
  - Children
- Two responses:
  - Exploit
  - Aid



Source: <http://www.unep.org/dewa/Africa/publications/aeo-1/242.htm>

# Framework

- How do we protect the vulnerable?
  - Organize
  - Create policy



# Nazi Experiments

- Tested extreme conditions
  - Freezing experiments
  - High altitude
- Racial experiments
  - Led by Dr. Josef Mengele
  - Twins and Gypsies



Source: <http://www.ushmm.org/>

# Response to Nazi Experiments

Nuremberg Code – 1947

- Outlined policies for human experimentation
- Informed consent essential
- Well-designed, necessary experiment
- Beneficence towards subjects



Source: <http://www.ushmm.org/>

# Tuskegee Syphilis Study

- 1932-1972 in Macon County, AL
- 600 black men, 399 with syphilis
- Lied to: “bad blood”
- Lack of informed consent
- No proper treatment

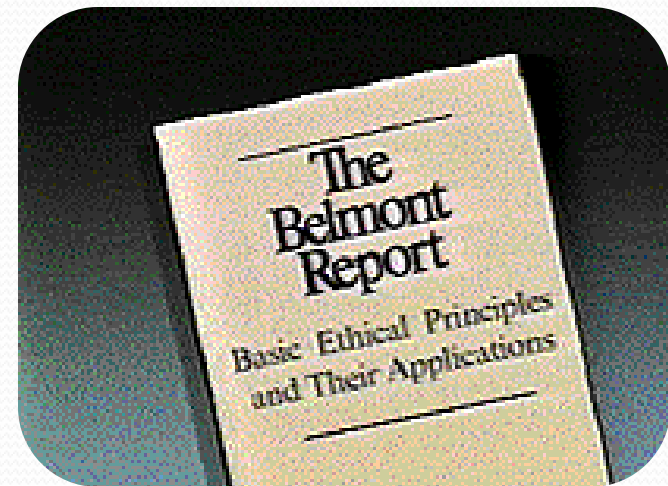


Source: <http://www.archives.gov/southeast/exhibit/6.php>



# Response to Tuskegee

- Establishment of US commission, 1974-1978
  - Identify ethical principles for research
- Result: Belmont Report, 1979
- Three basic principles:
  - Respect for Persons
  - Beneficence
  - Justice



Source: <http://www.mcmaster.ca>

# Continued Policymaking

Declaration of Helsinki – 1964 WMA

- Less-restrictive informed consent
- 1975 – added IRB requirement

Other policies

- Council for International Organizations of Medical Sciences (CIOMS)
- Title 45 CFR 46 – “Common Rule”

# Important Ethical Concepts

- Informed consent
- Approval by IRB
- Safety of patient
- Benefit to patient
- Authors and publishers
  
- Not defined:
  - Placebos/standard of care



<http://www.cancerboard.ab.ca/polyomx/faqs.htm>

# Recent Cases

HIV in Africa – vulnerable populations

One study published NEJM 2000:

- Uganda: 415 couples
- Followed for 30 months
- Viral load in relation to infection
- Not offered anti-retrovirals

# Concern

Declaration of Helsinki, Article 19:

*Medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research.*

- HIV particularly 'relevant' to sub-Saharan Africa?
- Who will benefit from the study?

# Questions?

- When giving consent, did subjects understand the lack of treatment?
- Are drug prices fair?
- Profit motive for studying vulnerable populations?
- Is it acceptable to infringe upon one person's rights if it benefits humanity?



Source: <http://www.onlinedrugnews.com/2007/10/08/>

# Take Home Messages

- Conceptions of rights/ethics are not static
- Ethics and related policies protect the vulnerable
- Change inequalities to reduce vulnerability
- Compassion fatigue



Questions or Comments?