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JOHNS HOPKINS
BLOOMBERG
SCHOOL *of* PUBLIC HEALTH

Section B: Landmark Cases in Research Ethics: U.S. History

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Controversial Cases in the U.S.

- Controversial cases in the United States led to the need for regulations
- Cases were funded or conducted by the U.S. government
- Most of these cases involved vulnerable populations
- All cases involved either harm to those enrolled, non-disclosure that the activity was research, or both

Willowbrook Experiments

- Conducted at a State institution in New York from 1956 to 1972
- Institution for mentally retarded children
- Vastly overcrowded
- “Infectious hepatitis” (hepatitis A) a large problem

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Series of Experiments Conducted

- Immune globulin to determine if hepatitis could be prevented
- “Challenge studies” to see if immune globulin would be protective in children never exposed to the virus

Jewish Chronic Disease Hospital Study, 1963

- To determine if cancer cells act the same way in healthy persons as in persons who have cancer
- Injections of live cancer cells into 22 elderly persons who were institutionalized
- Led NIH in 1963 to create a panel to examine human subjects research

Jewish Chronic Disease Hospital Study

- 1966 Henry Beecher article

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Henry Beecher 1966 Article

- Henry Beecher—Harvard physician
- Article published in *New England Journal of Medicine*
- Discussed standards for “normal” medical research
- Do our standards need to be changed?

Tuskegee Syphilis Study

- 1932-1972
- 400 poor, African American men with syphilis
- 200 poor, African American men without syphilis (controls)
- Misled about purpose
- Denied treatment and forced to stay in “natural history” study
- Ad Hoc Tuskegee panel formed 1972

Tuskegee Syphilis Study



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National Commission

- National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1974-1978
- Wrote *The Belmont Report*
- Laid the foundation for U.S. regulations regarding ethics and human subjects research