

Ethics in Epidemiology

E2040

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Tuskegee Syphilis Study (1932-1972)

- To observe the effect of untreated syphilis
- 600 poor African Americans enrolled (399 cases, 201 controls)
 - Never informed about the purpose of the study
 - Deception – “treated for bad blood”
- No treatment offered (penicillin available since 1943)
- 1972: study was stopped after media coverage
 - 28 died directly from s., 100 from complications due to s.
 - 40 wives infected with s., 19 children born with s.



The Belmont Report (1978)

- Reaction to ethical problems in research, especially the Tuskegee Study
- It defined basic ethical principles and guidelines for human subject research

Declaration of Helsinki (1964)

- Developed by World Medical Association
- Revised 7 times since
- Ethical principles for medical research involving human subjects
- Respect for individual, their right of self-determination, their right to make informed decisions, their welfare

Basic ethical principles by the BR

1. **Respect for persons**
 - Autonomy of individuals should be respected
 - Extra protection for children, people with illness or mental disability
2. **Beneficence**
 - Protecting subjects from harm
 - Maximizing possible benefits and minimizing possible harms
3. **Justice**
 - Fair treatment and fair distribution of risk and benefits of research



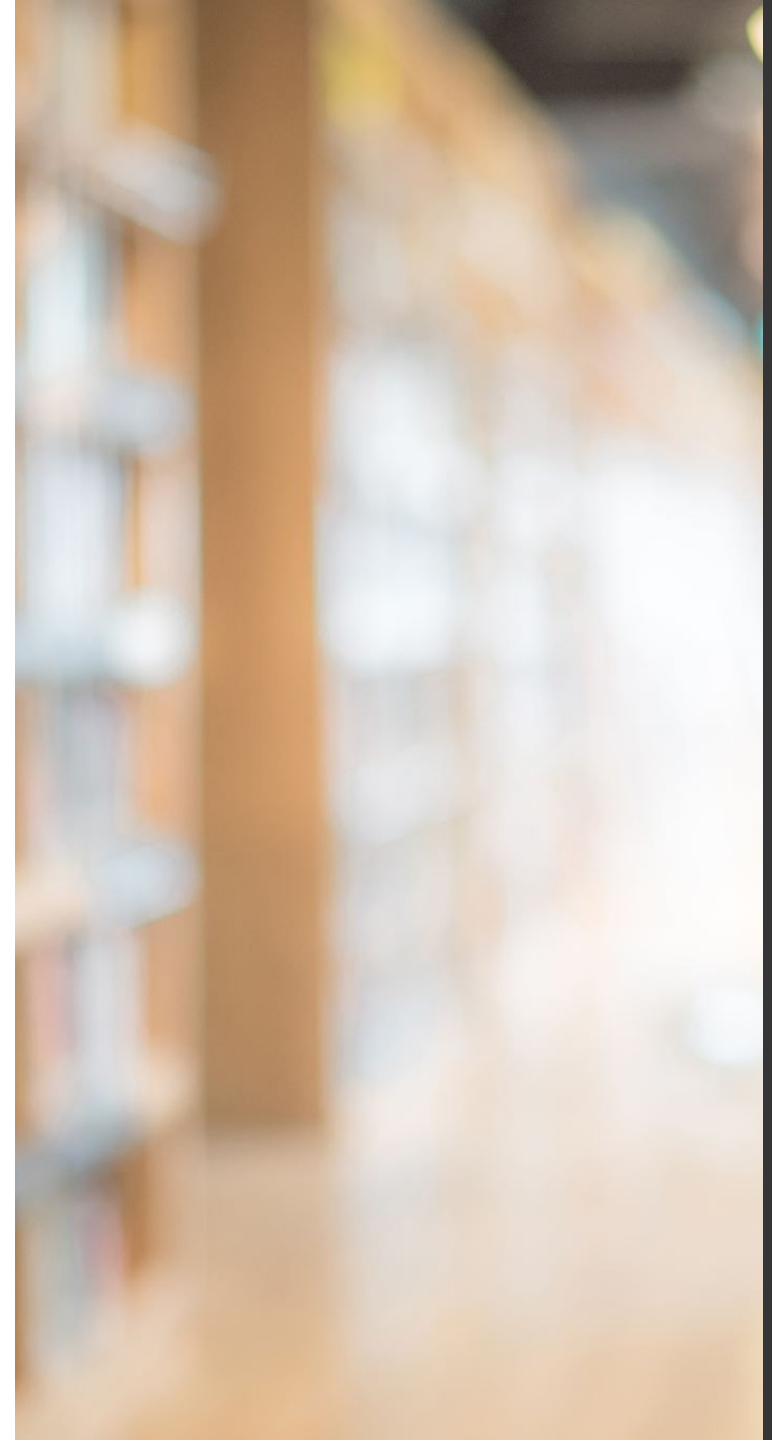
Informed consent

Necessary part of every study with human subjects

1. Information – ensure that all information is provided to participants
2. Comprehension – ensure that participants can fully understand the information
3. Voluntariness – ensure that participation is voluntary

Institutional Review Board (IRB) or Ethics Committee

- Every research institution needs to have a board for evaluating research with regards to ethics
- Every study needs to be approved by the committee before conducted
- The submission to IRB/EC needs to describe the study, the benefits and risks for participants, how informed consent is obtained, what steps are taken to protect subjects from harm etc.



Research ethics more broadly

1. Conducting research
 - Respect, Beneficence, Justice
 - Confidentiality and Privacy
2. Research integrity
 - Data accuracy
 - No fabrication or falsification of data
 - Transparent reporting of results
 - Avoiding bias
3. Ethics in Publishing
 - Authorship
 - Conflict of Interest
 - Plagiarism
 - Peer review