

Human Subjects Research

Principles and landmark cases

Evaluation Lab - ECHO

Claudia Díaz Fuentes, PhD. claudiadf@unm.edu

November 19, 2019

Historical Lessons and Physician's Code of Ethics

- Ethical principles governing human subjects research in the US go back to the Nuremberg code on ethical medical research and revisions that followed in the 1960s.
 - These gave rise to the Declaration of Geneva which outlines the key ethical principles for medical practice (available [here](#))
- In the US, principles were officially adopted by federal agencies until 1974 with the Belmont Report.

What is the Belmont Report?

- The report's goal was written by the National Commission in order to
 - “identify the **basic ethical principles** that should underlie the conduct of biomedical and behavioral research involving human subjects and
 - to **develop guidelines** which should be followed to assure that such research is conducted in accordance with those principles”

What led to it?

It began with the Tuskegee Study in 1932

- 399 men told they were being treated for bad blood (they had syphilis)
- Lasted for 40 years when it was meant to last 6 months, and men not receive treatment even when it became available
- Participants did not know what the researchers were doing, and had no choice to stay or leave the program.
- It was until 1972, when an AP article denounced the study that it came to an end.
- Class action lawsuit won and a fund was set to cover medical care of survivors, spouses and children ([here's a timeline](#))

Three Ethical Principles

- **Respect for persons**
 - Individuals are autonomous
 - Persons with diminished autonomy are entitled to protection
- **Beneficence.** Two general rules have been formulated as complementary expressions of beneficent actions in this sense:
 - do not harm and
 - maximize possible benefits and minimize possible harms.
- **Justice.** An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly.
 - Addresses the practice of using a group as test subjects to benefit another group

Principles (not) in practice:

Justice

- Tuskegee
- Studies of men and women
 - Most studies have historically used men to defined standard of care and diagnosis criteria for women
 - Heart disease (took a while to figure out women's heart attack symptoms were different)
 - Insulin treatment
- [This paper](#) is an interesting read on ethical and legal issues

Principles (not) in practice:

Respect for persons

- Tearoom Trade study (1970): the researcher observed men meeting other men for casual sexual encounters in public restrooms. Pretended to be a participant and act as a lookout
 - He disclosed to some men he was a researcher
 - Collected license plates and other identifiable information to follow up with interviews
- The Tastes, Ties, and Time study (2006-2009)
 - Collected FB data from undergraduate students. Data included gender, major, state of origin, tastes in books and music, pictures, etc.
 - Data was made publicly available without direct identifiers (name) but a 2010 study (and another one in 2011) showed that the data available were enough for re-identification.

Principles (not) in practice:

Beneficence

- The Stanford Prison Experiment (1971) Philip Zimbardo's psychological study of the human response to prison life (physical and psychological risk)
 - Distress and physical abuse within 36 hours of the beginning of the study, but took 6 days to stop it
- "Boston College Oral History Archive of the Troubles in Northern Ireland" (2011) Interviewed former IRA members (reputational and legal risk of harm).
 - Researchers committed to keep data sealed until subjects' deaths.
 - The British government subpoenaed researchers in an unsolved murder investigation