Lecture 10, Part I: Protecting Human Subjects

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14.310x

Protecting Human Subjects

The research governing human subjects is regulated, to ensure the protection of the participants.

The background, Nazi research, Tuskegee Syphilis trials

- American medical research project conducted by the U.S. Public Health Service from 1932 to 1972, examined the natural course of untreated syphilis in black American men.
- The subjects, all impoverished sharecroppers from Macon county, Alabama, were unknowing participants in the study; they were not told that they had syphilis, nor were they offered effective treatment.
- By the end of the experiment, 28 of the men had died directly of syphilis, 100 were dead of related complications, 40 of their wives had been infected, and 19 of their children had been born with congenital syphilis.
- People were also lured to come for tests with publicity of free treatment.

- In 1972 the whistle was blown, and the men finally won a $10 million class action trial against the PHS. The scientific merit of the study was also shoddy: apparently not much was ever learnt from it about how to treat the disease
- President Clinton apologized in the name of the Nation in 1997.

What is wrong here?

Protection of Human Subject

The research involving human subjects is governed by federal regulation . HHS Regulations for the Protection of Human Subjects at Title 45 Code of Federal Regulations Part 46.
The HHS regulations are intended to implement the basic ethical principles governing the conduct of human subjects research.
These ethical principles are set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the "Belmont Report").

Human subject research

Research - A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of the HHS regulations, whether or not they are conducted or supported under a program, which is considered research for other purposes. For example, some demonstration and service programs may include research activities.
Human Subject - A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

Human subject research

Research - A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. **This means that Facebook or Amazon can experiment as much as they want on you unless they publish; but if you are working with them with the goal of publishing you need to go through an IRB**
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Key principles of the Belmont report

1. Respect for persons
   - Respect individual autonomy
   - Protect individuals with reduced autonomy
2. Beneficence
   - Maximize benefits and minimize harms
3. Justice
   - Equitable distribution of research burdens and benefits

Related requirements

Application of the general ethical principles to the conduct of human subjects research leads to the following requirements:

- Respect for Persons
  - Informed consent
  - Protecting privacy and maintaining confidentiality
  - Additional safeguards for protection of subjects likely to be vulnerable to coercion or undue influence
- Beneficence
  - Assessment of risk/benefit analysis including study design
  - Ensure that risks to subjects are minimized
  - Risk justified by benefits of the research
- Justice
  - Ensure that selection of subjects is equitable.

How this works in practice

- For any research by an MIT, you need to be trained in human subject
- You need to submit to MIT COUHES a form describing your research.
- You need to follow the appropriate deadlines; and get the authorization BEFORE you start.
- You need to submit your informed consent forms as well, unless you request a waiver
- The form is used to asses if there is risk to the subjects or others.
- A committee assess the risks and the benefits, and if necessary asks you for changes to protect the subjects better.
- When work is conducted abroad, typically you also need to obtain human subject permission from that country.
- Some research which has minimum risk and does not involve individually linked data is considered exempt.