Research Ethics I

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Learning Outcomes

- To learn about the History of Research Ethics
- To Explore the cases of Scientific misconducts
- To figureout the Policy makers
- To know about various code of conduct on Research Ethics
- To know the current regulations on Research Ethics

Tuskegee Study of Untreated Syphilis

- *Tuskegee Study of Untreated Syphilis in the Negro Male, the study was sponsored by the United States Public Health Service and was conducted between 1932 and 1972. As the title suggests, the study aimed to follow the* ***progression of untreated syphilis in the human body*** *with a target study population of black males.*
- *The research was intended to test whether syphilis caused* ***cardiovascular*** *damage more often than* ***neurological*** *damage and to determine if the natural course of syphilis in black men was significantly different from that in whites. In order to recruit participants for its study, the PHS enlisted the support of the prestigious Tuskegee Institute (now Tuskegee University), located in Macon county, Alabama. A group of 399 infected patients and 201 uninfected control patients were recruited for the program.*
- *The subjects were not told that they had syphilis or that the disease could be transmitted through sexual intercourse. Instead, they were told that they suffered from "bad blood," a local term used to refer to a range of ills. Treatment was initially part of the study, and some patients were administered arsenic, bismuth, and mercury. But after the original study failed to produce any useful data, it was decided to follow the subjects until their deaths, and all treatment was halted. Penicillin was denied to the infected men after that drug became available in the mid-1940s, and it was still being withheld from them 25 years later, in direct violation of government legislation that mandated the treatment of venereal disease. It is estimated that more than 100 of the subjects died of tertiary syphilis.*

Unethical Research in Concentration Camps

- Nazis conducting medical experiments on adults and children detained at Sachsenhausen, Dachau, Auschwitz, and Buchenwald concentration camps during World War II.
- The horrific tales of maltreatment, disfigurement, hunger, and torture read like a gruesome synopsis of the nine circles of hell.
- Under the pretences of racial and demographic expansion, medical and pharmaceutical progress, and military advancement, prisoners in these death camps were subjected to horrible crimes.

Watson's 'Little Albert' Experiment

- To test their idea that all humans are initially blank slates that can be fashioned, John Watson and graduate student Rosalie Rayner performed an emotional-conditioning experiment at Johns Hopkins University on a nine-month-old baby they dubbed "Albert B" in 1920.

James Watson and Francis Crick 1962

- In 1962, James Watson and Francis Crick jointly won the Nobel Prize for their model of the DNA structure, which included Maurice Wilkins. Watson and Crick's concept was confirmed by Rosalind Franklin (1920–1958), whose X-ray diffraction image of DNA, known as Photo 51, was essential. Without Franklin's consent, Wilkins displayed Photo 51 to Watson and Crick.
- In 1953, Watson and Crick as well as Wilkins and Franklin released their research in the same issue of the magazine Nature. On the Watson/Crick publication, neither Wilkins nor Franklin had their names listed as authors (and vice versa). Franklin passed away at the age of 37 from ovarian cancer in 1958, and the Nobel Prize is not given out posthumously. For this reason, Franklin was not given the prize.

History of Unethical Practices in Research

- History is full of Unethical cases of Research, exposed time to time, led the need for some code of conduct for research and publication.
- 1947- Nuremberg Code of Conduct
- 1964- Declaration of Helsinki
- 1960-70- Laws of Protection of Animals Right
- 1979- The Belmont Report
- 1989- NIH mendates Resposible conduct of Research

1947- Nuremberg Code of Conduct

- The Nuremberg Code is a 10-point set of rules for the conduct of human experiments articulated in 1947 in the trials of Nazi doctors and bureaucrats convicted of crimes against humanity for their roles in concentration camp experiments.
- https://media.tghn.org/medialibrary/2011/04/BMJ_No_7070_Volume_313_The_Nuremberg_Code.pdf

1964- Declaration of Helsinki

- The "Declaration of Helsinki," which was formed by the World Medical Association in 1964, offers guidelines for physicians doing biomedical research on human beings. The statement establishes guidelines for "research combined with clinical care" and "non-therapeutic research," as well as governing international research ethics. Revised in 1975, 1983, 1989, and 1996, the Declaration of Helsinki serves as the foundation for modern, successful healthcare procedures.
- https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

1960- Animals Protection Laws

- **India 1960**
- https://www.indiacode.nic.in/bitstream/123456789/11237/1/the_prevention_of_cruelty_to_animals_act%2C_1960.pdf

- **World 2005**
- https://www.wellbeingintlstudiesrepository.org/cgi/viewcontent.cgi?article=1005&context=sota_2005

1979- The Belmont Report

- Established by the National Research Act of 1974 ,the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research authored the Belmont Report.
- The report outlines fundamental ethical principles and guidelines that address ethical issues arising from the conduct of research involving human subjects.
- https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html#:~:text=Informed%20by%20monthly%20discussions%20that,of%20research%20with%20human%20subjects.

Current Regulations

The main elements of the Common Rules;

- Requirements for research institutions to ensure compliance;
- Requirements for researchers to get informed consent and record it;
- Requirements for membership, function, and operations of the Institutional Review Board (IRB)
- Additional protections for specific vulnerable research subjects (children, pregnant women, and prisoners).
- https://www.hhs.gov/ohrp/education-and-outreach/about-research-participation/index.html

Policy Makers

- WHO
- NIH
- ICMJE
- EU
- NSF
- FDA
- COPE

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Thanks