**Ethical Research**

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In the early history of empirical research, the ethical code of conduct was only loosely followed and not well regulated. Now, following a proper code of ethics is expected in research with committees from the institutional to the international level strictly regulating and holding researchers accountable for their work. Research ethics address questions, such as whether a study will produce the greatest good; who is intended to benefit from a study at the expense of others; and how research participants, especially those from vulnerable populations (e.g., pregnant women; minors; people in impoverished circumstances, with disabilities, or from minority groups), should be protected.

The Nuremberg Code, established in 1948, was the first international document on ethics advocating for the need to protect human subjects in research. It was the direct result of the Nuremberg Trails in 1945, wherein Nazi physicians and scientists were convicted of experimenting on thousands of concentration camp prisoners against their will. The experiments were often horrifically and unnecessarily inhumane, which caused either deaths or severe impairments. As a result, the Nuremberg Code emphasized the essential need for human participants’ voluntary and informed consent as well as the requirement for researchers to provide justification for the scientiﬁc and social contribution of a study, to avoid unnecessary physical and psychological harms, and to put in place adequate protections against harm.

Almost two decades later in 1964, the World Medical Association published the Declaration of Helsinki—an international set of ethical guidelines for biomedical, clinical, and non-therapeutic research involving human subjects. The Declaration of Helsinki forms the foundation of the currently used Good Clinical Practices with emphasis on the physician and scientist’s primary obligation to promote health, wellbeing, and rights of participants.

Despite the creation of these two major documents on research ethics, medical/clinical and social research was still heavily unregulated. It was not until the public exposure of hugely unethical studies that enforcement and strict regulation of the code of ethics became pressing. For example, from 1932 to 1972, the U.S. Public Health Service conducted the Tuskegee Syphilis Study, wherein the effects of untreated syphilis were monitored among 399 African American males. First, these individuals were unaware of their participation in this study and was under the false pretense of receiving free health care. Second, the experiments actively kept their participants unaware of their diseases and purposely withheld penicillin from these participants, which was known at the time to be a cure for syphilis. These actions taken by the researchers grossly violated the basic and fundamental rights of participants for voluntary and informed consent. The ethical practice of protecting human participants from unnecessary harm was also entirely disregarded.

Due to the public outcry over the unethical practices in the Tuskegee Syphilis Study, the National Research Act was passed in 1974 and resulted in the formation of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The National Commission was the first U.S. national entity tasked to identify basic bioethical principles of scientific research on human subjects and to ensure that researchers abide by these guidelines, outlined within the Belmont Report published in 1979. The Belmont Report established three basic ethical principles that regulate research involving human subjects: respect for persons, beneficence, and justice. Respect for persons ensures that individuals be informed of the study truthfully, treated as autonomous, and afforded protection (particularly if they are members of vulnerable populations described earlier). Beneficence refers to the cost-benefit ratio of a study whereby the study’s benefits exceed potential harm to participants. The principle of justice addresses the fair distribution of costs and benefits of a study among all participants. For example, in the selection of participants, no one within a target population should be denied a chance at receiving a treatment or procedure.

The American Psychological Association (APA) originally drafted a code of ethics for social science research in 1953, but like the Nuremberg Code and Declaration of Helsinki, it was neither well specified nor well enforced. For example, both the Milgram obedience experiment and the Stanford prison experiment were conducted in 1970s and have been criticized for their ethical violations, particularly psychological harm to participants. The APA Ethics Code has been revised multiple times since its conception. Most recently revised in 2010, it includes the demand for reduced harm due to deception, confidentiality of data, and the existence of an Institutional Review Board (IRB) to ensure that the rights and welfare of research participants are protected.

Further reading:

American Psychological Association. (2017, December 15). Ethical principles of psychologists and code of conduct. Retrieved from http://www.apa.org/ethics/code/

Burger, J. M. (2009). Replicating Milgram: Would people still obey today? *American Psychologist, 64*(1), 1-11. doi: 10.1037/a0010932

Office of History, National Institutes of Health. (2017, December 15). The Nuremberg Code. Retrieved from https://history.nih.gov/research/downloads/nuremberg.pdf

Office for Human Research Protections, U.S. Department of Health & Human Services. (2017, December 15). The Belmont Report. Retrieved from https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html

Reverby, S. M. (2011). “Normal exposure” and inoculation syphilis: A PHS “Tuskegee” doctor in Guatemala, 1946-1948. *Journal of Policy History, 23*(1), 6-28. doi: 10.1017/S0898030610000291

World Medical Association (2017, December 15). Declaration of Helsinki - Ethical principles for medical research involving human subjects. Retrieved from https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/