



Research Regulations

...and the Helsinki Declaration

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Research Regulations are a code of ethics that governs how research should be conducted.

Research is conducted across many disciplines. It is used to define public policy, treatment protocol even for marketing products.

Research uses different populations and species to gain a broader knowledge of a particular subject. Each institution sets their own research regulations [1]. Typically there are universal regulations whether they are legally required or not, than there are cultural mores and rules and there may also be local rules governing a specific research activity.

Laws governing research are related to safety concerns and handling concerns. Ethical codes are more in depth codes that scientists are bound ethically to uphold.

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- Quiz: Psychology 101 Part 2
- Quiz: Psychology 101 Part 2
- Quiz: Flags in Europe

[See all quizzes =>](#)

Declaration of Helsinki

The Declaration of Helsinki was created by the World Medical Association to set a standard for the way human subjects [2] are to be treated in experimentation [3].

This document lays out the requirements for ethical treatment of human subjects, and was drawn up as an attempt to self-regulate science. It is not a legally binding document but widely

accepted as the ethical cornerstone for the treatment of human subjects.

The inception of the document was in the early 1960's and started as an 11 paragraph directive, the first ever of its kind. Since its inception it has had six revisions and an additional 21 paragraphs added.

The Declaration of Helsinki is named after the geographic location where the document was drawn up, Helsinki Finland. Prior to this document the premier code of ethics was the Nuremburg Code.

The basic principles of the Declaration of Helsinki are:

- Respect for the individual
- Respect for the individuals right to make determinations and make informed decisions regarding participation in the research both before and during the research
- The individuals welfare always takes precedence over society or scientific needs
- Ethical considerations must always take precedence over laws and regulations
- If an individual is not able to grant consent or is a minor, than consent for participation should be sought from the guardian who is acting in the individuals best interest.

Basic principles regarding research in general:

- Research should be based on a through knowledge of the scientific background
- Research should offer a reasonable benefit to the population involved in the research
- Risks and benefits of the research should be carefully analyzed and should not cause further harm
- Research should be conducted by suitably trained investigators
- Research findings should be shared and made publicly accessible

Examples

There are other guidelines but the above are the basic principles. Prior to the 1940's there were no universal guidelines in place for research practices. Some of the research that took place then would never be permitted today. Take a look!

One of the most famous is the Tuskegee Study [4].

And this one is clearly not ethical:

Project MKULTRA, or MK-ULTRA, was the code name for a CIA mind-control research program, run by the Office of Scientific Intelligence, that began in the early 1950s and continued at least through the late 1960s. There is much published evidence that the project involved the surreptitious use of many types of drugs, as well as other methodologies, to manipulate individual mental states and to alter brain function.

Experiments included administering LSD to CIA employees, military personnel, doctors, other government agents, prostitutes, mentally ill patients, and members of the general public in order to study their reactions. LSD and other drugs were usually administered without the subject's knowledge and informed consent, a violation of the Nuremberg Code that the U.S. agreed to follow after WWII.

Source:

"Top 10 Evil Human Experiments" [5]

Two other prime examples are Project 4.1 [6] and the Monster Study [7].

These studies now seem archaic, and impossible that they could have occurred, but they did and they took place in the name of science. These examples are prime examples of the need for a code of ethics that goes beyond what the law lays out. Even with the codes in place there are still instances where unethical experimentation continues:

From 1990 to 1991 the Center for Disease Control (CDC) conducted a study of an experimental measles vaccine in Los Angeles, California involving 1200 children whose parents had not given informed consent for their children's participation.

Reference:

Bibliotecapleyades.net [8]

It is incredible that we still have cases of unethical testing even today, but with the research regulations in place we have a point of reference to recognize a deficiency in the treatment of research participants. Without a point of reference there would be nothing to compare to.

Source URL: <https://explorable.com/research-regulations>

Links:

[1] <http://www.adelaide.edu.au/ethics/animal/>, [2] <https://explorable.com/social-science-subjects>, [3] <https://explorable.com/conducting-an-experiment>, [4] <https://explorable.com/tuskegee-syphilis-study>, [5] <http://listverse.com/2008/03/14/top-10-evil-human-experiments/>, [6] http://en.wikipedia.org/wiki/Project_4.1, [7] http://en.wikipedia.org/wiki/The_Monster_Study, [8] http://www.bibliotecapleyades.net/sociopolitica/esp_sociopol_mindcon17.htm, [9] <https://explorable.com/>, [10] <https://explorable.com/research-regulations>