

The belmont report essay sample

[Health & Medicine](#), [Disease](#)



The “ Ethical Principles and Guidelines for the Protection of Human Subjects of Research”, otherwise known as the “ Belmont Report”, was published back in 1979 but to this day continues to be the basis for regulating human research in the U. S., ensuring that biomedical and behavioral studies are conducted in accordance with the ethical principles of *respect for persons* , *beneficence* and *justice* (U. S. Department of Health and Human Services [HSS], 2006).

The Report was produced by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research which was created to address grave ethical concerns in research, of which the most flagrant example would probably be the Nazi wartime experiments involving unwilling concentration camp prisoners. However, what made those concerns more alarming and pressing then was that similarly unethical studies had been likewise taking place in the US (Office for Human Research Protections [OHRP], 2004). One particular research is the Tuskegee Syphilis Study which was started in 1932 by the Public Health Service (PHS). This was undertaken to document the natural progression of the disease and involved 600 black men who were never informed that they had syphilis (Centers for Disease Control and Prevention [CDC], 2007), a sexually transmitted disease which when left untreated, may damage vital internal organs in its late stages (CDC, 2004). Participation was “ rewarded” with free medical exams, free meals and burial insurance but none of the patients received proper treatment for their disease, not even when penicillin became available (CDC, 2007). In fact, the PHS actively sought to prevent the patients from receiving treatment up until the project’s end in 1972 (Tuskegee University, 2007).

Such wanton disregard for ethical principles spurred the creation of the Belmont Report. The Report identified *respect for persons*, *beneficence* and *justice* as the relevant ethical principles that will serve as guidelines for resolving ethical problems that may arise from human research. Respect for persons holds that individuals “ should be treated as autonomous agents” who are capable of making their own choices and whose judgments should be respected unless these would cause harm to others. It is also recognized under this principle that some individuals might have a diminished capacity for self-determination due to immaturity or disability, and as such should be given protection. Beneficence on the other hand, refers to promoting the good of individuals and thus carries with it the aim of maximizing possible benefits as well as avoiding or minimizing possible harms. Lastly, justice pertains to “ fairness in distribution” so that no individual is unreasonably denied what he/she is entitled to or given an undue burden (The National Commission, 1979).

The implications of these principles and the protections they afford are better understood in the applications section of the Belmont Report (Vanderpool, 2004), which cites the following requirements for the conduct of research: *informed consent*, *risk/benefit assessment* and the *selection of subjects of research*. Informed consent follows from the principle of respect for persons, which recognizes the capability of individuals to decide “ what shall or shall not happen to them” and entails three elements: 1) information, in that subjects should be sufficiently informed about research procedures and their purposes, known risks and expected benefits, and be given answers to questions they may have as well as the choice to withdraw

from the study at any time; 2) comprehension, in that information should be presented in a clear and organized manner that is suited to the subject's capacity to understand, thus ensuring that they completely comprehend the nature and risks of participating in the study; and 3) voluntariness, in that an informed consent is only considered valid when it is " given voluntarily... [and] without coercion or undue influence". A special provision exists however, for those with diminished autonomy. Though these individuals may be considered incompetent, their decisions (in as much as they are capable of) should be respected and third parties deemed most likely to act in their best interests should likewise be consulted for their permission (The National Commission, 1979).

The assessment of risks and benefits follows from the principle of beneficence and aims to systematically weigh the benefits versus the risks so that the acceptability of the latter may be better judged. The Report specifically saw this requirement as a means for the researcher to examine the soundness of the research design, for the prospective subject to make an informed decision, and for the review board to assess the justifiability of the risks involved (The National Commission, 1979).

The last requirement on the other hand, follows from the principle of justice. Fairness in the selection of subjects involves both individual and social justice. Individual justice requires that selection should be unbiased so that no particular individuals are exclusively benefited while others deemed " undesirable" are relegated to studies that carry greater risks, while social justice calls for an " order of preference in the selection of classes of

subjects” which takes into account differences between classes, particularly, their different capacities to bear burdens as they may already be disadvantaged to start with (The National Commission, 1979).

The Belmont Report served as the basis for the HHS (2006) Code of Federal Regulations which contains the policies governing human research. Prior to the report and federal regulations, researchers independently decided on the nature and conduct of their studies (OHRP, 2004), thus leaving adequate room for ethically questionable research. With the establishment of the regulations however, human subjects were provided protection as researchers now work following set guidelines, having Institutional Review Boards (IRBs) to assess whether these studies will be or are being conducted according to the principles set forth by the Report (Vanderpool, 2004).

Thus, the Belmont Report is an invaluable document that serves to ensure the protection of human subjects in biomedical and behavioral studies. Although it recognizes the benefits that such research brings to society (The National Commission, 1979), it still places the highest value on human dignity and aims to give human subjects the respect and protection that they deserve.

References:

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