Merits of the Belmont Report

Author
Enago Academy

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What is the Belmont Report?

In July 1974, the National Research Act was signed into law, creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The creation of the Commission was prompted by a National Institutes of Health study that tracked the long-term health of a group of black males with untreated syphilis. The subsequent outcry over the allowance of such clear human suffering prompted a charge to the Commission to develop guidelines that would protect an agreed set of ethical principles that should underlie any research involving human subjects.

After an intensive four-day meeting at the Smithsonian Institution's Belmont Conference Center, followed by many months of additional deliberation, the Belmont Report was presented to the Commission in April 1979.

Basic Principles

The report was designed to offer clear guidance to any scientists and members of Institutional Review Boards (IRB) as to the basic ethical principles that should be followed in any biomedical and behavioral research involving human subjects. The acceptable code of conduct was stipulated in three categories:

- ***Respect for Persons*** – recognition of the personal dignity and autonomy of individuals, especially those in need of special protection as a result of diminished autonomy. In practice, this introduced the requirement of *informed consent*, based on the provision of complete information that is fully comprehensible by the research subject, with complete confirmation that participation is voluntary.
- ***Beneficence*** – protecting research subjects from potential harm by designing research protocols so as to maximize anticipated benefits and minimize possible risks of harm. In practice, it falls to the IRB to accept or challenge all assessments of potential risk in the research design.
- ***Justice*** – the selection of research subjects must be fair and equitable. In practice, their selection cannot be influenced by favor (as friends or colleagues of the researcher) or "disdain" (responding to the historical practice of subjecting

"undesirable" persons to high risk research).

The Hippocratic Oath

The basic principles of the Belmont Report closely reflect the professional oath that medical school graduates take when they enter the professions of medicine and medical research. Just as patients should be able to trust that their doctor has their best interests at heart and that he or she is providing them with all relevant information in relation to their diagnosis or condition, research subjects have the right to expect the same from the researchers conducting the study in which those subjects have volunteered to participate.

Gaps in the Safety Net

The guidelines offered by the Belmont Report give clear directions to IRBs as to the areas of proposed research studies that should be closely examined to ensure that human subjects are protected. However, the larger the study, and the more research personnel involved in that study, the greater the risk that IRBs will not be able to monitor all potential interactions between researchers and subjects. In pharmaceutical research, for example, clinical research trials operate under scrutiny from the Federal Drug Administration (FDA), who oversees the actions of the researchers. However, most clinical trials involve direct interaction between physicians and patients (the research subjects). Patients that enroll in the studies are typically given information on the nature of the drug being tested and are usually compensated in some way for time and travel. However, the financial relationship between the physician and the drug company is not disclosed. Since some prospective participants might perceive such compensation as a conflict of interest (the more patients enrolled from that physician's practice, the more that physician will earn), failure to disclose the amount of compensation constitutes misconduct.

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