

In the 1970s, in the immediate aftermath of the Tuskegee Syphilis Experiment, the US Department of Health, Education, and Welfare—today the Department of Health and Human Services—formed a special commission to focus on bioethics policy. Between 1974 and 1978, this commission issued numerous reports and recommendations, including a summary of principles and guidelines to govern human subject research and the work of institutional review boards throughout the United States. That summary, published in 1979 and to this day a cornerstone document in human subject research ethics, was the Belmont Report.

The report begins by defining research and distinguishing it from clinical practice. “The purpose of medical or behavioral practice,” says the report, “is to provide diagnosis, preventive treatment, or therapy to particular individuals. By contrast, the term ‘research’ designates an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge.”

Next, the Belmont Report identifies three basic ethical principles that should guide researchers and IRBs in making the best ethical judgments in human subject research. Those three principles are respect for persons, beneficence, and justice.

Respect for persons involves not only recognition of individuals’ autonomy, but also protection of those individuals whose autonomy is limited, such as children or the cognitively impaired.

Sometimes, ethical conduct involves balancing the recognition of an individual’s autonomy and the protection of someone with limited autonomy. The Belmont Report presents the example of prisoners. As autonomous persons, prisoners may be entitled to participate in certain studies; as inmates, however, they may also face unusual kinds and degrees of influence. Researchers and IRBs must work diligently to ensure that the principle of respect for persons applies in just these sorts of special circumstances.

The Belmont Report’s second basic ethical principle is that of beneficence. In the report’s use of the term, beneficence refers to every researcher’s obligation to maximize benefits while minimizing risks.

To illustrate the complexity of this obligation, the report offers the example of research involving children. By enrolling children in research, and thereby exposing them to some risks, researchers learn new and valuable treatments that will help other children in the future. The more significant the risk to subjects, however, the harder it becomes to measure that risk against the prospect of future benefit. This means that researchers and IRBs sometimes have to make intricate ethical decisions.

## U-MIC TRANSCRIPT

### The Belmont Report (Part One)

The last of the Belmont Report's three basic ethical principles is justice. Justice involves fair distribution of both the benefits and the burdens of research. The report offers five "formulations of just ways to distribute burdens and benefits." They are: "to each person an equal share, to each person according to individual need, to each person according to individual effort, to each person according to societal contribution, and to each person according to merit."

The report highlights some historical instances of unjust distribution of benefits and burdens. It cites a 19<sup>th</sup>- and early 20<sup>th</sup>-century pattern of conducting experiments on the poor for the sake of improved medical treatment for the wealthy. Additionally, the report mentions the non-consensual experimentation on prisoners in Nazi concentration camps, as well as the Tuskegee syphilis experiment, a study sponsored by the US Public Health Service, in which, over the course of decades, researchers deprived hundreds of poor, black men of effective treatment for syphilis, in order to analyze the natural progression of the disease.

The Belmont Report's three basic ethical principles—respect for persons, beneficence, and justice—represent three major categories of ethical decision-making in human subject research.

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