

Having established the basic ethical principles—respect for persons, beneficence, and justice—the Belmont Report examines three areas in which researchers and IRBs should apply those principles: the informed consent process, the assessment of risk and benefit, and the selection of human subjects.

The report states: “Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them.” It then isolates three elements that it considers crucial to an effective and appropriate consent process: information, comprehension, and voluntariness. Researchers have a duty to ensure that they inform individuals about what their participation would involve, that those individuals understand the information, and, if they then decide to participate, that it is of their own free will, without undue influence or coercion.

But even before researchers have begun obtaining subjects’ consent, they will already have given careful thought to an assessment of the risk and benefits of the proposed research. This assessment is central to a complete grasp of a study’s justification on ethical grounds. As the Belmont Report states: “For the investigator, [an assessment of risks and benefits] is a means to examine whether the proposed research is properly designed. For a review committee, it is a method for determining whether the risks that will be presented to subjects are justified. For prospective subjects, the assessment will assist the determination whether or not to participate.”

The report goes on to discuss some of the difficulties of achieving a truly reliable assessment. Proceeding from a desire for what the report refers to as “a favorable ratio,” researchers and IRBs may struggle to find quantifiable ways to measure risk and benefit. “Thus,” says the report, “there should first be a determination of the validity of the presuppositions of the research; then the nature, probability and magnitude of risk should be distinguished with as much clarity as possible.”

Finally, the report demands that research reflect at least five specific considerations: 1. Brutal or inhumane treatment of human subjects is never morally justified. 2. Risks should be reduced to those necessary to achieve the research objective. 3. When research involves significant risk of serious impairment, review committees should be extraordinarily insistent on the justification of the risk. 4. When vulnerable populations are involved in research, the appropriateness of involving them should itself be demonstrated. 5. Relevant risks and benefits must be thoroughly arrayed in documents and procedures used in the informed consent process.

## **U-MIC TRANSCRIPT**

### **The Belmont Report (Part Two)**

The Belmont Report concludes by outlining the ethical considerations that researchers should apply in the selection of research participants. “Justice,” according to the report, “is relevant to the selection of subjects of research at two levels: the societal and the individual.” Individual justice refers to every researcher’s obligation to ignore personal biases in the selection of particular subjects. Societal justice is similar, but applies to broad categories of subjects, and involves factors such as economics, sex, or culture.

In the decades since the Belmont Report’s original publication, US agencies have enacted many detailed policies to ensure the highest possible standard of ethical research. The Belmont Report, however, is more than historic. It remains a concise, reliable summary of some of the basic priorities that continue to guide the work of researchers, institutional review boards, and all of those committed to ethics in research involving human subjects.

*Posted: 10/11/2011*