



Ethical and Policy Issues in Research Involving Human Participants (Report and Recommendations of the National Bioethics Advisory Commission) (Volume 1)

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Protecting the rights and welfare of those who volunteer to participate in research is a fundamental tenet of ethical research. A great deal of progress has been made in recent decades in changing the culture of research to incorporate more fully this ethical responsibility into protocol design and implementation. In the 1960s and 1970s, a series of scandals concerning social science research and medical research conducted with the sick and the illiterate underlined the need to systematically and rigorously protect individuals in research (Beecher 1966; Faden and Beauchamp 1986; Jones 1981; Katz 1972; Tuskegee Syphilis Study Ad Hoc Advisory Panel 1973). However, the resulting system of protections that evolved out of these rising concerns—although an improvement over past practices—is no longer sufficient. It is a patchwork arrangement associated with the receipt of federal research funding or the regulatory review and approval of new drugs and devices. In addition, it depends on the voluntary cooperation of investigators, research institutions, and professional societies across a wide array of research disciplines. Increasingly, the current system is being viewed as uneven in its ability to simultaneously protect the rights and welfare of research participants and promote ethically responsible research.

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