



President's Bioethics Commission Releases Report on Human Subjects Protection

Current regulations are robust, but should be improved

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WASHINGTON, D.C. – The Presidential Commission for the Study of Bioethical Issues today issued its report concerning federally-sponsored research involving human volunteers, concluding that current rules and regulations provide adequate safeguards to mitigate risk. In its report, “*Moral Science: Protecting Participants in Human Subjects Research*,” the Commission also recommended 14 changes to current practices to better protect research subjects, and called on the federal government to improve its tracking of research programs supported with taxpayer dollars.

President Obama requested that the Commission undertake an assessment of research standards following the October 2010 revelation that the U.S. Public Health Service supported unethical research in Guatemala from 1946 to 1948 that involved intentionally exposing thousands of Guatemalans to sexually transmitted diseases without their consent. The President gave the Bioethics Commission two assignments: to oversee a thorough fact-finding investigation into the specifics of the studies (released September 13, 2011); and to assure that current rules for research participants protect people from harm or unethical treatment, domestically as well as internationally.

“The Commission is confident that what happened in Guatemala in the 1940s could not happen today,” Commission Chair, Amy Gutmann, Ph.D. said. “However, it is also clear that improvements can be made to protect human subjects going forward. With the Commission’s recommendations, society will continue to benefit from advances in quality of life made possible by human subjects research and ensure respect for the inherent dignity of individual research volunteers.”

“Many of the most important advances today are driven by research that involves human participants,” Commission Vice Chair, James W. Wagner, Ph.D. said. “We must ensure that the way we conduct research involving human subjects protects, encourages, and makes fruitful the selfless practice of allowing oneself to become the subject of a medical or social study intended for the benefit of another.”

Key Findings:

In the report's central finding, the Commission found that the "U.S. system provides substantial protections for the health, rights, and welfare of research subjects."

In assessing the current regulations that protect human subjects, the Commission learned that there is no central source with information about the overall size, scope, and cost of the government's research involving human subjects. The Commission requested information from 18 individual agencies that conduct most federal human subjects research, but discovered that many federal offices could not provide basic data about the research they support. The Pentagon, for example, required more than seven months to prepare information on specific studies supported by the Department of Defense. In its report, the Commission found that the federal government supported more than 55,000 projects involving human subjects around the globe in Fiscal Year 2010, mostly in health-related research, but also in other fields such as education, engineering and social science.

Recommendations:

The Commission recommended several areas where improvements could be made to current rules and procedures. "Immediate changes can be made to increase accountability and thereby reduce the likelihood of harm or unethical treatment," Gutmann said.

The Commission recommends that each federal department or agency supporting research with human subjects maintain a core set of data for their research programs that includes the title and lead investigator of each project, the location of each study, and the amount appropriated for the research. Each office should aid the public in learning more about the government's research efforts by developing or improving publicly available electronic systems or releasing information through a government-wide system. To support these efforts, the Commission suggested that the Office for Human Research Protections or another office should administer a central web-based portal that links to each individual department or agency system. In addition, the government should consider developing a unified federal research database, which may ultimately be more cost-effective and efficient.

"When federal agencies lack the internal mechanisms to provide needed data about research they fund, you have a limited basis on which to answer the President's charge about research protections," Gutmann said. "It is clear that nothing like what happened in Guatemala would be permitted under today's robust system for human subjects protection—the system today is vastly improved from what it was—but there still is a need for more transparency and public access to information about federally supported human subjects research."

In addition to suggesting specific ways to enhance accountability, the Commission also highlighted other areas where improvement is desirable, including studying methods for compensating people who are injured during research. Since the benefits of research help to improve society, the Commission argued, individual participants who are injured during studies should not be forced to personally bear the costs of treating their injuries. In making this recommendation, the Commission noted that most other developed nations have instituted

policies to require researchers or sponsors to provide treatment, or compensation for treatment, for injuries suffered by research subjects.

While there is no way to eradicate all risk of harm, particularly in some types of medical and translational research, Gutmann noted that "our nation vigorously and rigorously protects people who volunteer for research studies. However, the Guatemala experiments remind us never to take ethics for granted. We must never confuse ethical principles with burdensome obstacles to be overcome or evaded. Good science requires good ethics, and vice versa."

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