US bioethics panel urges stronger protections for human subjects

Present regulations are adequate but not optimal, report says.

Meredith Wadman

15 December 2011

A panel advising US President Barack Obama on bioethical matters says that although human subjects in US government-funded research are generally protected by existing rules and regulations, their safety and well-being could be enhanced with stronger measures, including increased public transparency and a system of compensating subjects who sustain research-related injuries.

Radius Images/Corbis

Greater public access to basic information about government-funded human trials would improve patient protections.

In a 200-page report released on 15 December, the Presidential Commission for the Study of Bioethical Issues further concludes that it "cannot say that all federally funded research provides optimal protections against avoidable harms and unethical treatment".

The reason for this caveat is that several government agencies were unable to readily identify basic information about the human research they fund. For example, the US Department of Defense needed seven months to provide the commission with data such as the titles, locations, funding levels and numbers of subjects associated with the nearly 7,100 human experiments that it funded last year.

"They told us that it was very difficult for them to gather all the information that we requested," said Amy Gutmann, commission chairwoman and president of the University of Pennsylvania in Philadelphia, in a news briefing yesterday. "This creates a barrier to the assurance that the federal government can offer the public about research protection."

Obama requested the report last year in response to revelations that, in the 1940s, the United States funded studies in Guatemala in which more than 1,300 prisoners, soldier, mental patients and sex workers were intentionally infected with sexually transmitted diseases without their knowledge or consent. Obama asked the commission to probe this incident — which was addressed in a report issued in September — and to examine whether the present system of protections for human subjects of US-funded research, at home and abroad, is adequate.

"It is clear that nothing like what happened in Guatemala would be permitted under today's system for human subject protection," Gutmann said. "But there is still a need for more transparency and more public access."

Along with 13 other recommendations, the commission calls for all of the US agencies that fund human research to make the basic data about their studies publicly available. A central web-based portal could link to each agency's data, the commission suggests, or a unified federal database could be created. The report also says that investigators' responsibilities, which are now implicit in the rules governing human studies, should be made explicit.

The report is "thorough and thoughtful," says Paul Root Wolpe, director of the Center for Ethics at Emory University in Atlanta, Georgia. "Their recommendations in general are really important. They cover many neglected areas and pose some bold new challenges." Still, he says, he would have liked to see the report tackle several issues on which it is silent — among them the conflict inherent in enrolling subjects in phase I studies that offer them no health benefits, but that, if successful, may substantially advance the enrolling investigator's career, finances or both.

The report says that individual subjects should be compensated for their medical care if they are harmed during research, and that the government should study whether "a national system of compensation or treatment for research-related injuries" may be required. The idea is not new a new one: in 2002, the Institute of Medicine, part of the US National Academies in Washington DC, also called for

compensation of research-related injuries. For some, the Bioethics Commission report does not do enough to advance the issue.

“No recommendation is made for the sponsor to pay or for the government to pay, just a recommendation to study the issue. This simply shelves the issue of compensation to collect dust,” says Vera Hassner Sharav, the president of the Alliance for Human Research Protections in New York.

Gutmann says that the commission “unequivocally states that there is a strong ethical case” for compensation, a practice that is common to almost all other developed nations. But, she adds, “we also think it’s very important that the federal government study how best to create a system that would ensure such compensation. We want the government to get it right.”

Sidney Wolfe, the director of the Health Research Group at Public Citizen, an advocacy group in Washington DC, says that he is troubled by the report’s “equivalent-protections” recommendation, which urges US agencies funding studies abroad to allow non-US partners and collaborators to work under the rules for patient-protection that pertain in their own countries — so long those rules are equal to or better than the standards adopted by the United States.

But Wolfe points out that in countries where patients and research budgets may be cash-strapped and the ethical reveiw process “not as tight” as it is in the United States, then a reliance on 'equivalent protections' is “very worrisome”.

Terry Collingsworth, a partner at the law firm Conrad & Scherer in Washington DC and the lead lawyer representing five survivors of the Guatemalan experiments, says that he applauds the commission’s recommendations and hopes they will prevent future abuses. But, he adds, “there is still an enormous missing step here: the US government has yet to even discuss with us damages for the admitted crime that they committed upon my clients.”

The plaintiffs sued the United States in March 2011 for compensatory and punitive damages from the experiments, which took place between 1946 and 1948. Collingsworth says that he advised his clients to sue after his attempts to reach high-level state-department officials to discuss remedies went repeatedly unanswered.

Nature | doi:10.1038/nature.2011.9647