Could This Happen Today? Ethical Violations in Research

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At a recent Institutional Review Board meeting I recently attended, members read, reflected upon and discussed two 2011 studies published by the Presidential Commission for the Study of Bioethical Issues. The question proffered for the group was "Could this happen today?" Most participants opined that the reported research would not happen in this century because of international laws, agreements and a compelling ethical consensus. However two board members felt that, sadly, research ethics violations can and still do occur even in these more "enlightened" times. I was among the two nay-sayers.

The first study, "Ethically Impossible: STD Research in Guatemala from 1946 to 1948," was commissioned by President Barack Obama in fall 2010. On Oct. 1, 2010, the President personally called President Ālvaro Colom of Guatemala to apologize to him and to Guatemala's citizens for medical research that was supported by the United States and conducted in Guatemala from 1946 to 1948. The research, focused on sexually transmitted diseases (STDs), involved deliberately infecting persons with STDs without their consent. The purported purpose of the research was to study the progression of these STDs. Human subjects, including prisoners, soldiers, psychiatric patients and prostitutes were exposed to syphilis, gonorrhea and chancroid. President Obama voiced deep regret for the research and declared the U.S. Government's commitment to insuring that medical studies today must meet the highest international and ethical standards in order to protect human subjects.

Any Institutional Review Board in the United States should immediately recognize that research like that conducted in Guatemala violates both the Nuremberg Code of 1947 and the Belmont Report of 1979. The Guatemala experiments were discovered by Dr. Susan Reverby, an historian at Wellesley College, who has spent the greater part of her professional career researching the Tuskegee syphilis experiment. Guatemala's experiments had been funded by a grant from the National Institutes of Health and were directed by Dr. John C. Cutler, a researcher who was later involved in the Tuskegee experiment. While

delving into the Tuskegee papers, Dr. Reverby uncovered alarming information relating to Dr. Cutler's research beyond the United States. She also discovered evidence indicating that the studies involved officials and researchers in both the U.S. and Central America. Although the Guatemala research began before either the Nuremberg Code or the Belmont Report was released, government officials and medical researchers recognized that the experiments violated existing ethical standards. The surgeon general at that time, Dr. Thomas Parran, had noted that the experiment would not be able to be conducted in the United States, but clearly intimated that it was acceptable to conduct in Central America.

The President's Commission report of September 2011 stated that the "events in Guatemala serve as a cautionary tale of how the quest for scientific knowledge without regard to relevant ethical standards can blind researchers to the humanity of the people they enlist into research." Arthur Caplan, head of the Division of Bioethics at New York University Langone Medical Center, remarked even more forthrightly that "the revelation of the Guatemalan research is a stark reminder that racism and indifference to the weak and the vulnerable did permit incredible abuses."

While the first study issued by the President's Commission revealed the egregious Guatemala abuse, its follow-up study, entitled "Moral Science: Protecting Participants in Human Subjects Research," published in Dec. 2011, outlined specific proposals of the President's Commission to insure greater accountability and transparency in such research. Utilizing extensive ethical study and analysis, the members of the commission outlined well-defined recommendations for IRBs, summarizing sound ethical behavior demanded in research as well as citing the particular governmental office to which the IRBs must account for their actions.

Catholic facilities and systems must engage in medical and scientific research if they are to maintain the high quality standards to which they commit themselves. Furthermore, since many Catholic facilities serve as "safety net" hospitals, they are often situated in what researchers call "minority rich" areas, desirable to researchers who must demonstrate a broad population base for their studies. Since one of the primary functions of an IRB is the protection of human subjects, Catholic health's commitment to promote human dignity and to "distinguish itself by service to and advocacy for those people whose social condition puts them at the margins of our society" (*Ethical and Religious Directive* #3) compels both ethics committees and IRBs in Catholic facilities to maintain profound vigilance regarding medical research. A review and study of both President's Commission 2011 documents provide for these committees an excellent review of current ethical literature on medical research as well as a rich case study for scientific and community members of IRBs.