Proposed Rulemaking on Federal Policy for the Protection of Human Subjects

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The U.S. Department of Health and Human Services recently proposed revisions to the regulations for protection of human subjects in research. On October 30, the National Coalition for History (NCH) submitted comments to HHS on the proposed rule. http://historycoalition.org/wp-content/uploads/2015/10/NCH-HHS-Human-Subjects-Proposed-Rule-10-30-15.pdf

NCH's comments focused on the treatment of oral history under the rule and strongly endorsed the recommendation to exclude oral history from the "Common Rule." Fifteen NCH member organizations also endorsed the comments and were listed as individual signatories.

A Notice of Proposed Rulemaking (NPRM) was published in the Federal Register on September 8, 2015, with a 90-day comment period. Below is the link to the HHS webpage that summarizes the issue and the proposed rule itself. http://www.hhs.gov/ohrp/humansubjects/regulations/nprmhome.html

Background

Beginning in the mid-1990s, college and university students, faculty, and staff who conducted oral history interviews increasingly found their interviewing protocols subject to review by their local Institutional Review Board (IRB), a body charged by the federal government with the protection of human subjects in research. Human subject risk regulation had its roots in the explosion of government-funded medical research after World War II as well as with the revelation of glaring medical abuses, including Nazi doctors' experiments on Holocaust victims and the Tuskegee Syphilis Study. History and other humanities disciplines were never originally intended to fall within the purview of the regulation, generally known as the "Common Rule," which addressed biomedical and behavioral research.

The growing inclusion of oral history under IRB review began an often contentious, confusing, and chaotic process. Was oral history – or historical studies more generally – the type of "generalizable" research covered by the Common Rule? What about research that clearly manifested no or minimal human risk? How could oral history be properly evaluated within a framework originally designed to regulate medical and biological science? The ensuing years witnessed numerous examples of IRBs overreaching with regard to oral history, with often damaging results and chilling effects. The list includes class projects which had to be jettisoned; IRBs limiting or rejecting projects citing largely nonexistent risks; and researchers who were asked to submit their questions in advance, guarantee anonymity of the people they interviewed, or even destroy their tapes and transcripts.

Recognizing the disconnect between actual oral history practice and the way in which IRBs frequently treated oral history, federal authorities have periodically attempted to introduce clarifying language. At times the federal Office of Human Research Protections (OHRP) has recommended that most oral history be placed in the "expedited" category before IRBs, at other times that oral history as a rule be "exempt." In 2003, Michael Carome, the associate director for regulatory affairs at OHRP concurred that oral history interviewing activities "in general" fell outside the federal definition of research requiring IRB review. Yet such language did not serve to clarify, or to stop undue regulation. Instead, we continued to have what AHA executive director James Grossman has termed "the hodgepodge of rules and regulations governing oral history research at the various colleges and universities in the United States," and complaints about oral history oversight by IRBs persisted.

In 2011 the Department of Health and Human Services (HHS) called for public comment in response to proposed regulatory changes aimed at "enhancing protection for research subjects and reducing burden, delay, and ambiguity for investigators." The Oral History Association, the AHA, the OAH, and many other individuals and entities commented about oral history in particular. Their remarks centered around a number of points: that oral history interview practice is inherently open-ended and not bound by a set of pre-existing interview questions; that in its focus on particular individuals, oral history fell outside of the "generalizable" research targeted by the Common Rule; that requiring the anonymity of subjects was antithetical to oral history, and to the discipline of history more generally; that oral historians already operated under a code of ethics, including the principle of informed consent; and that efforts to force oral history and historical inquiry into a regulatory framework designed for scientific research caused harm, confusion, and undue burden. Therefore, oral history should be excluded altogether from IRB review.

On September 8, 2015, HHS issued new recommendations for human subject research protection, specifically that "oral history, journalism, biography, and historical scholarship activities that focus directly on the specific individuals about whom the information is collected" be explicitly excluded from "the scope of the Common Rule." Moreover, the recommendations acknowledged the importance and value within oral history, and historical studies more generally, to identify individual actors in history, and recognized that there already existed discipline-specific codes of ethical conduct. This presents a marked shift in both tone and content from previous iterations.