



October 26, 2011

Jerry Menikoff, MD, JD, Director  
Office for Human Research Protections  
US Department of Health and Human Services  
1101 Wootton Parkway, Suite 200  
Rockville, Maryland 20852

Dear Dr. Menikoff:

I write on behalf of the Society of American Archivists (SAA) to provide our comments on the July 26, 2011, advance notice of proposed rulemaking regarding **“Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators” (HHS-OPHS-2011-0005)**. SAA represents more than 6,000 professional archivists and archival repositories in universities, governments, research centers, historical societies, corporations, religious organizations, and other settings. As the professionals most closely identified with identifying, selecting, preserving, and providing access to primary sources—including oral histories—our members have a keen interest in the proposed rulemaking.

Our membership includes archivists who work for hospitals and other types of health care facilities that currently are covered by the provisions of the Health Insurance Portability and Accountability Act (HIPAA), and our profession is ethically bound to ensure the protection of privacy as defined by law. We are well-informed about HIPAA, as well as the Federal Educational Rights and Privacy Act, state privacy laws, and federal security classifications. We have a long record of working to ensure the protection of truly invasive information.

Given that context, our profession believes that only the narrowest set of material should be subject to access restrictions and that even necessary restrictions should not exist into perpetuity. We believe that information once held as intensely private can, after sufficient time, legitimately support intellectual inquiry for the overall advancement of human knowledge. Census records, adoption records (in most states), and other extremely private data have long been accessible after the subject’s death. In the case of medical information, it may be that longer restriction, perhaps even through two generations, is appropriate. However, permanently preventing even name-linked research is ultimately indefensible. Consider, as merely two examples, the importance attached to determining the physical

(and psychological) ailments of Abraham Lincoln and the intense scrutiny of the cause of death (poison or natural causes) of Napoleon Bonaparte. There is justification, in the advancement of various disciplines, for the eventual accessibility to medical data. Furthermore, we believe that current material that does not rise to the level of intensely private should not be restricted. This applies, in our professional canon, to oral histories (with competent adults who have given informed consent), surveys, and questionnaires (for which anonymity was not offered).

As both creators of oral history projects and recipients (via our repositories) for the interviews conducted by others (such as our colleagues in the Oral History Association, the American Historical Association, and the Organization of American Historians), archivists are deeply concerned about the language in the proposed rules. Thus we strongly endorse the significant concerns about the proposed rulemaking expressed by the American Association of University Professors (in an undated letter from B. Robert Kreiser at [www.aaup.org/NR/rdonlyres/DCD4C925-7BCD-4D83-BA8F-601CF0B70312/0/IRBResponse.pdf](http://www.aaup.org/NR/rdonlyres/DCD4C925-7BCD-4D83-BA8F-601CF0B70312/0/IRBResponse.pdf)) and the American Historical Association (in “Oral History and Information Risk: Response to the Federal Proposal,” <http://blog.historians.org/news/1439/oral-history-and-information-risk-a-response-to-the-federal-proposal>). We agree with these organizations that the proposed rulemaking continues an unfortunate tradition of conflating scientific research with social science and humanities research, thereby conflating the need to closely oversee potentially life-threatening or life-altering procedures with an unnecessary and obstructionist requirement to protect competent adults from voluntarily making information about themselves available to researchers through the process of an oral history interview.

As a discipline, oral history has a set of ethics and protocols to ensure that interviewees give informed consent and have a great deal of control over the interview content and process up until the time that they sign off on donating the final product to a repository for access by researchers. This is similar to the ethical protocols of archivists, who ensure competence and consent when a donor gives for research his/her most intimate diaries or letters or the diaries and letters of his/her parents. Indeed, we can find no significant moral or ethical distinction, and no appreciable difference in the threat of harm, between a competent adult consenting to researchers accessing his/her oral history interview and the same adult consenting to donate his/her diaries. Yet under the proposed rulemaking the former requires intense scrutiny by an institutional review board (and the possibility of imposing anonymity) while the latter has no similar oversight.

The donation to repositories of diaries, letters, and other potentially intensely private and/or emotionally sensitive materials for access by researchers has occurred for centuries with no oversight by IRBs and no suggestion that such oversight—or paternalistic protection of the diarist’s identity—was necessary. It is rather a mystery to us that IRB control was ever exerted over the process of creating recordings of interviews conducted by social scientists in the process of historical inquiry, regardless of whether the subject’s

responses are expected to be benign or sensitive. We believe that oral histories should be exempted completely from oversight by IRBs.

Thank you for this opportunity to comment on the proposed rulemaking.

Sincerely,

A handwritten signature in cursive script that reads "Gregor Trinkaus-Randall".

Gregor Trinkaus-Randall  
President, 2011 – 2012