

October 24, 2011

Jerry Menikoff, M.D., J.D., Office of Human Research Protections Department of Health and Human Services 1101 Wootton Parkway, Suite 200 Rockville, MD 20852

In Re: FR Doc No: 2011-18792

Dear Dr. Menikoff,

I write on behalf of the Oral History Association in response to the call for comments on the proposed revisions of the "Common Rule" governing the protection of human subjects in research. The Oral History Association (OHA), which draws scholars from all disciplines, is recognized as the leading professional association in the field of oral history, nationally and internationally. The OHA Executive Council voted earlier this month to vigorously recommend <u>full exclusion</u> of oral history from oversight under the Common Rule, and thus from the purview of Institutional Review Boards. We also believe that the proposed revisions on "information risk" pose significant potential damage to oral history, archival, and historical research.

Responding to the broad question as to whether there are "certain fields of study whose usual methods of inquiry were not intended to or should not be covered" (Question 25), we argue, once again, that the standards and procedures that govern Institutional Review Boards are inappropriate to oral history research; that our work suffers irreparable harm when subjected to oversight by rules largely designed to protect human subjects in medical and health sciences research. Our position is informed both by the nature of oral history research, our own professional principles and best practices, and misapplications by Institutional Review Boards that have cast a pall on research in our field:

a) Oral history research, including archival collection, is designed to elicit an understanding of the past from the idiosyncratic perspective of carefully selected individual narrators. Oral history interviews do not produce "generalizable knowledge" as defined by the Common Rule. Our research is not intended to test a preconceived hypothesis nor can the results be predicted. Moreover, oral history research is not

constructed as "systematic" (as in scientific or social scientific inquiry), even when interviewing large numbers of people on a topic or event. Oral history interview practice is fundamentally dialogic, guided by open-ended conversation with particularly selected interviewees, and it is not scripted by uniformly-applied questions. While we might attempt to guide interviews toward a set of themes or topics, we attempt to create a free and open space for the narrator to establish what is significant and important from her or his own perspective. Oral historians rely on the freedom to ask questions in order to develop accounts that are both truthful and reflective of the interviewee's standpoint. By the same token, interviewees need to be assured the freedom to give honest testimony from their own perspectives.

- b) The Oral History Association maintains its own <u>Principles and Best Practices</u> governing the conduct of oral histories in an ethically responsible way. Oral historians, from students to veteran interviewers, are trained in and guided by these practices, which are also considered by sister associations to be the professional standard. We are not arguing for freedom from ethical practices and standards. To the contrary. We are asking for recognition that our professional principles and standards be acknowledged as addressing the very same ethical concerns and protections that are intended to govern biomedical, scientific, and some social scientific research. We do not require additional oversight by boards and standards that were not designed to rule the practice of oral history, history, and the humanities.
- c) Negative experiences with Institutional Review Boards are now widespread, illustrating the arbitrariness, misunderstanding, and misapplication of the Common Rule. In more than a few cases, IRB rulings have inhibited or prevented oral historians from carrying out legitimate research. Researchers, especially graduate students, have to apply for IRB clearance from their home institutions to listen to oral histories deposited by narrators themselves in public archives, with strict indications for their use. Even some IRBs that "exempt" oral history from research oversight under the "minimal risk" clause, turn around and require application if the research is to be published. The arbitrariness of boards across the country creates confusion and demonstrates poor understanding of what constitutes "generalizable knowledge," frequently leading to misapplication of rules.

While we understand that the currently proposed revisions might seem, from outside our field, to be favorable to oral history research, the proposed "excused" category does not address our concerns. It is our informed, professional view that even requiring oral history projects to register with IRBs continues to subject our field to oversight rules that are inherently alien to our goals and practices as researchers. The proposed revision keeps oral history tied to inappropriate science frameworks, a fundamental problem that has not yet been resolved. The widespread assumption that rules and practices that govern scientific inquiry translate across disciplines is a root problem that we now seek to resolve.

The OHA is further concerned, indeed alarmed, by the implications for oral history, and especially for oral archives, in the proposed extension of rules to prevent "information risk." Established oral history practice mandates that all oral historians fully inform their

narrators of the purposes of the interview, to solicit in advance their permission to conduct the interview, to freely sign a release form that indicates the many possible uses of the material, and to review and correct recordings or transcripts that are freely deposited by the narrator in a public archive. These are standard operating procedures that allow the narrator the freedom to determine how s/he wishes her/his testimony to be used. Under these protocols, oral history research poses minimal information risk, if any, to both living or deceased human subjects. In addition, established interview and archival practices protect confidentiality where privacy concerns may arise. Overregulation of the future use of archival or public-use data has the deleterious effect of obscuring our understanding of the past, including data that would hold scholars accountable for misuse of research subjects.

To limit information risk by requiring anonymity is fundamentally inimical to the practice of history and oral history. Such rules bring to the fore a potential contradiction in the proposed revisions that, on the one hand relax (but do not remove) oversight of oral history research, and on the other subject the information gathered and archived to levels of protection that make its use impossible. Under this logic, there would be no historical record possible. Oral history and history rely on the identification, not the obscuring, of its narrators. This is a clear example of how the application of HIPAA rules to non-medical research reflects a dangerous "one size fits all" approach and threatens to irreparably harm historical knowledge and our field of research.

For these reasons, we argue that oral history should fall <u>outside</u> the realm of IRB oversight, as defined by the Common Rule. Efforts to force oral history and historical inquiry into a regulatory framework that is designed for scientific and biomedical research cause confusion at best, and irreparable harm to building historical knowledge and to our profession. Such a framework of rules distorts the purposes of our research and stifles the process of free and open inquiry on which oral history interpretation is based.

In sum, we trust that the responses you receive from the OHA and the larger historical community will compel you to correct the misapplication of oral history to the Common Rule and IRB authority through full exclusion.

Sincerely yours,

Dr. Rina Benmayor Past President, 2011-2012