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Jerry Menikoff, M.D., J.D.  
Office for Human Research Protections  
1101 Wootton Parkway, Suite 200  
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Dear Dr. Menikoff:

The American Historical Association thanks the Department of Health and Human Services for opening discussion on possible revisions to the Common Rule (“Human Subject Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators,” Federal Register Volume 76, Number 170 [Docket ID number HHS—OPHS—2011—0005]). The AHA is the primary professional association for historians in the United States, incorporated by Congress in 1889 for the promotion of historical studies and the dissemination of historical research, and as such we write on behalf of over 14,000 historian members and nearly 800 history departments and historical organizations. We welcome the opportunity to reiterate our belief that oral history research should be formally excluded from the Common Rule. At the same time, we are deeply concerned about other elements of the notice—centered on proposals to limit “information risk”—that could permanently damage the ability of historians to someday reconstruct the events of the present.

## **Section II, Question 25: Exclude Oral History from the Common Rule**

In response to the proposal’s broad question about 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, yet again, that oral history research should be fully excluded from IRB oversight. Historians who use interview methods focus on eliciting information about particular experiences of the past, and their work suffers irreparable harm when forced into rubrics developed to treat human beings in a general (or “generalizable”) way. The standards and procedures of Institutional Review Boards are alien to oral history research, and over the past decade we have compiled ample documentation of the misapplication of such rules to research projects in the field.

These problems start with the required training courses that many researchers have to take before they can even approach an institutional review board. Our members report

online courses that consist of modules and testing on the proper handling of test samples, and appropriate methods of confidentiality for research data. These bear no relation to oral history methods or research, and simply foster a sense of confusion and alienation from the whole process. This skepticism is exacerbated when those same standards and criteria are applied in the course of review.

At its most basic level, the methodology of oral history research is built on a free and open dialogue with the interviewee with the goal of eliciting information about their particular thoughts and experiences. That cannot be fairly or properly reviewed or assessed in the structured or systematic framework of an IRB, and we have received a substantial number of reports from historians who have been ordered to submit a specific set of questions for review and told specifically which questions they could and could not ask. We view this as a fundamental violation of the principles of oral history research, and a violation of the First Amendment rights of our members.

These problems are aggravated by the hodgepodge of rules and regulations governing oral history research at the various colleges and universities in the United States. An AHA staff survey in 2006 found a patchwork of institutional policies that reflect substantial problems in the way federal policies are translated into practice at the college and university level.<sup>1</sup> A few IRBs explicitly articulate policies to include oral history research, a few others offer procedures that address some of our concerns, but the vast majority of institutions leave oral history in a vague gray area between the two.

As a result, we receive regular complaints from historians and students who have tripped over the rules, and found themselves subject to threats and penalties far out of proportion to their actions. The list of complaints includes a student and his teacher threatened with six-figure fines because he interviewed a family member for a project (apparently in violation of rules about conducting research on someone in a power relationship); a faculty member ordered to cease all research on a project simply for obtaining contact information for potential interviewees without prior approval; and doctoral students whose degrees were withheld for procedural violations. And this does not include the many egregious occasions in which review boards limited or rejected projects citing phantom risks of harm, such as an IRB that turned down a project to interview peace activists in one East European country—more than a decade after the regime they protested against had been turned out of power. The effect of such misguided requirements discourages the use of oral history as a research tool. The proposed “excused” category in the ANPRM does not address our concerns in the least. At a fundamental level, it still subjects oral history research to the inappropriate frameworks and methods of the social and biomedical sciences.

This is not a simple plea to be free of rigorous professional standards. Our *Statement on Standards of Professional Conduct* sets the standard for best practices in the discipline, and these guidelines have been used to hold numerous members of our discipline

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<sup>1</sup> Our previous studies were reported in Robert B. Townsend et al., “Oral History and Review Boards: Little Gain and More Pain,” *Perspectives* (February 2006), <http://www.historians.org/perspectives/issues/2006/0602/0602new1.cfm>.

accountable for malfeasance.<sup>2</sup> And precisely because we believe all history work should be conducted in a rigorous and professional way, the AHA endorses the Oral History Association's *Statement of Principles and Best Practices* and actively promotes its use to members and history department chairs.<sup>3</sup> It is precisely because we value proper standards and their application in appropriate contexts that we reject the use of standards and criteria where they do not apply. While we believe standards are essential, we also believe they need to be overseen and applied in appropriate contexts.

## **Section V: Permanent Data Protections May Harm the Study of the Past**

Other areas of the notice reflect the problems that make us so concerned about the application of the Common Rule to our discipline. As we read the language in Section V, you are preparing to establish a new oversight regime that could set an impossibly high bar for the future use of archival or public data sources. The proposal describes an intention to establish “mandatory data security and information protection standards for all studies that involve identifiable or potentially identifiable data,” and alludes to the Health Insurance Portability and Accountability Act privacy guidelines 51 times. We fear the emphasis on “uniformity” in the application of these rules, and the tendency among IRBs to define their mandates broadly, could impose the same standards of confidentiality on history research that currently apply to medical records. To make matters worse, the responsibilities for administering these policies would also be handed over to a new and as yet undefined entity outside the IRBs. Based on the description in the proposal and practical experience with IRBs, it seems fair to assume that the new privacy boards would be heavily dominated by the interests of biomedical research and impose criteria entirely inappropriate to history research.

Since those standards generally bar the reporting of any identifiable information about the research subject, any history work that seeks information on specific or particular experiences or events would become much more difficult. For years oral historians have complained about absurd mandates from IRBs to destroy their tapes and keep the names of their interviewees secret—requirements that are fundamentally at odds with the canons for most oral history research. The substantial elevation of new privacy concerns would increase those sorts of challenges in ways that could make wide areas of historical work untenable. We believe this would seriously inhibit our understanding of the past, including future projects that could hold scientists accountable for their misuse of research subjects (such as the studies exposing the Tuskegee experiments and U.S. research practices in Guatemala in the 1940s).

In the case of oral history, our protocols already mandate fully informed consent by the interviewee prior to the interview, and a signed “release” at the end of the interview, by means of which the interviewee explicitly states the terms by which the interview can be used in the future. But historians also rely on a wide variety of other sources, buried in

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<sup>2</sup> American Historical Association, *Statement on Standards of Professional Conduct*, 2011 edition, (Washington, D.C: American Historical Association, 2011), <http://www.historians.org/pubs/Free/ProfessionalStandards.cfm>.

<sup>3</sup> Oral History Association, *Principles and Best Practices for Oral History* (adopted October 2009), <http://www.oralhistory.org/do-oral-history/principles-and-practices/>

archives, published in media, and made available in a wide variety of digital databases. We are deeply troubled by language in the ANPRM that hints at future policies that suggest rules encompassing “researchers’ use of pre-existing data (i.e. data that were previously collected for purposes other than the currently proposed research study)” and insisting that a researcher acquire “written consent” if he or she “obtains information that identifies the subjects.”

The proposal is not clear about whether consent agreements obtained by the original interviewer or host archive would be adequate for subsequent research. And these rules present a significant long-term danger for future historians trying to look back on the present, since the restrictions on information covered by the HIPAA rules have no expiration date. This is not an idle concern, as demonstrated last year, when a historian had to go to court in Connecticut to obtain access to treatment records of veterans of the Civil War.<sup>4</sup>

As you prepare the final regulations, please remember that information exists in a time horizon that extends beyond the brief life cycle of a biomedical research study. These materials should be protected in a way that will make them available to serve as a source for future historical research. At the very least, the regulations should allow for some sort of sunset provision—similar to the protections for U.S. census data, perhaps—to assure that someday historians will be able to make use of information collected in the present.

The problems arising from the current and potential application of the Common Rule to historical research is not surprising. Historical research was never envisioned as falling under these rules; it is not mentioned in the enabling legislation and has not been a subject of substantial rulemaking review.<sup>5</sup> We now have ample experience with the unintended consequences of the gradual and often haphazard extension of rules intended for other types of research work to cover our discipline. This review of the rules offers HHS an opportunity to correct the misapplication of those rules and authorities.

We thank you for inviting comments on the proposed revisions, and are available for any further comments or clarifications of these remarks.

Sincerely yours,

James R. Grossman,  
Executive Director

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<sup>4</sup> See Thomas Scheffey, “A Legal Skirmish Over Civil War Records, *Connecticut Law Tribune*, April 26, 2010, available online at <http://www.ctlawtribune.com/getarticle.aspx?ID=36927>

<sup>5</sup> Zachary M. Schrag, *Ethical Imperialism: Institutional Review Boards and the Social Sciences, 1965-2009*. (Baltimore, Md.: The Johns Hopkins University Press, 2010).