

Historians' Comments to OHRP, October-December 2007

Edited by Zachary M. Schrag, George Mason University, February 2008

Introduction

On 26 October 2007, the *Federal Register* announced that “the Office for Human Research Protections (OHRP) is requesting written comments on a proposed amendment to item 5 of the categories of research that may be reviewed by the institutional review board (IRB) through an expedited review procedure, last published in the Federal Register on November 9, 1998 (63 FR 60364).”

Since the 1998 guidance was the first time the federal government had suggested that oral history research might ever be subject to IRB review, I saw this announcement as an opportunity for OHRP to reconsider its policy toward oral history. I stated this on my blog, Institutional Review Blog, <http://institutionalreviewblog.blogspot.com/>, and in a posting on H-OralHist, a message board read by oral historians. In addition, Robert Townsend of the American Historical Association posted a message on the Association's blog, AHA today, encouraging historians to comment.

As a result of these and perhaps other appeals, OHRP received 37 comments on IRB review of oral history, most of them sent by historians, but some by scholars in other fields. It also received one comment on IRB review of research by folklorists, whose concerns are closely aligned to those of oral historians.

The *Federal Register* item noted that “comments received within the comment period, including any personal information provided, will be made available to the public upon request.” Accordingly, I requested copies of all comments sent concerning expedited review, and in January 2008 I received both electronic and paper copies. The comment by Andrew Stuart Bergerson was included in the paper version but not the electronic version, so I requested and received an electronic copy from Professor Bergerson.

Not all comments on expedited review concern review of the humanities and social sciences; some, for example, concern the use of human tissue in medical research. Here I present those comments that focus on oral history and folklore. OHRP numbered all the comments it received, and I have preserved those numbers. For clarity's sake, I have deleted the salutations and closing pleasantries from each comment.

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5. Kelly A. Woestman, Professor and History Education Director, Pittsburg (KS) State University

As someone involved in oral history projects for over 15 years, I implore you not to include it in the listing of human subjects research.

There is no effect on the interviewee and there is no force involved or "hidden agenda/experiment" in getting someone to be involved in an interview. Furthermore, best practices in oral history ensures that oral history interviewees have the right to edit and/or correct the transcripts of their interviews.

Including oral history within these rules and regulations will severely hamper important parts of gathering the historical records.

Even more importantly, it will make it impossible for students in K-12 to participate in oral history interviewing - one of the most vital hands-on activities in which we try to engage them to get them interested in history.

6. Leah DeVun, Assistant Professor of History, Texas A&M University

I am a history professor at a four-year research university and I am writing with respect to the proposed intrusion of internal review into oral histories and other types of research that are commonly used in the humanities. The proposed rules are vague and threaten the collection of oral histories that are unlikely to cause any harm to human subjects, who are typically adults willing to contribute their stories and experiences to historical research. By subjecting these sorts of data to internal review boards (which are intended to protect humans from physical or psychological injury), the proposed rules make such data collection extremely difficult and perhaps prohibitive. IRB requires methods and scripts that are inimical to the kinds of research historians do, and it makes it likely that many oral history collection projects will be rejected by IRB on the basis of inappropriate criteria. It would be best to exempt humanities-based research that consists of conducting surveys or interviews or observing behavior from IRB review.

7. Amber Abbas, University of Texas at Austin

I am writing in regards to proposed changes to proposed changes for IRBs that could bring oral history research under the IRB purview. I do not support the proposed changes.

I support the solution recommended by the American Association of University Professors, that "research on autonomous adults whose methodology consists entirely in collecting data by surveys, conducting interviews, or observing behavior in public places, be exempt from the requirement of IRB review—straightforwardly exempt, with no provisos, and no requirement of IRB approval of the exemption."

11. Dennis N. Mihelich, University Historian, Creighton University

Oral history interviewees are NOT human subjects in need of special protection. Moreover, for the interview to take place they must voluntarily sign a legal-release form donating their memory to the institutional recipient of the interview. Obviously, you cannot force a person to answer a question and the narrator may end the interview at any time. Oral history interviews simply are not in the realm of medical research, which prompted the establishment of IRBs.

12. Carrie Kline, Talking Across the Lines, LLC

Thanks for inviting comments on the value of using IRBs for oral histories. As oral historians and teachers of oral history we implore you not to require IRBs. Any institutionally-based oral history effort is done with clear attention paid to ethnics and is executed in accordance with clearly defined practices addressed in the Oral History Associations revised guidelines. Our field has done a good job at addressing ethical issues in the realm of professional gathering of oral histories. The IRB will have no bearing on amateur projects.

Oral historical work is unlike other areas of social science. It is a collaboration between teller and interviewer, a joint agreement, spoken and written into a release form. Please don't stymie the efforts of those who want to record and those who want to tell by putting up obstacles. Oral history work requires its own set of skills. There is no reason to assume those sitting on an IRB would know enough about the field to make reasonable judgment. Also, we tend to work with the elderly, and waiting for official permission could easily mean we lose an opportunity to record at all. When an old person dies, it is as though a library has burned down.

16. W. Patrick McCray, Professor & Co-PI/Executive Committee Member for the UCSB Center for Nanotechnology in Society, University of California, Santa Barbara

I am writing to express my concern that recent changes to IRB protocols will adversely impact researchers and students who make use of oral history methodologies. It has been my experience that university IRBs do not have the necessary background to appreciate that oral history research is different from other research involving human subjects. I have seen these protocols applied in ambiguous and often arbitrary ways and implemented in a field where the risk of harm is minimal.

The American Historical Association has already made a number of efforts to clarify or reverse this policy of using IRBs to regulate oral history, first by working with the federal Office of Human Research Protections (OHRP) to clarify their policy, and then by encouraging departments to engage the IRBs at their home institutions to clarify these policies.

It is my hope that the OHRP would further clarify its position on oral history as a research methodology and, most importantly, exempt it from the review of IRBs. Failure to do so will have a chilling effect on research in the humanities that, seen from a

common sense perspective, has no adverse effect on its subjects and indeed may do them a disservice by denying them an avenue to record their recollections and experiences for posterity.

17. Eva Marie Garrouette, Associate Professor, Department of Sociology, Boston College

I would like to express my opinion on proposed legislation (<http://www.hhs.gov/ohrp/documents/20071026.htm>) that may subject oral history projects to IRB review. I believe that such a change to existing practice only creates an unnecessary layer of bureaucracy to a research undertaking where the risk of harm to participants is minimal or non-existent. Instead, I urge the policy recommended by the American Association of University Professors: that "research on autonomous adults whose methodology consists entirely in collecting data by surveys, conducting interviews, or observing behavior in public places, be exempt from the requirement of IRB review." Thank you.

18. Robert N. Proctor, Professor of the History of Science, Stanford University

I would like to express my opposition to the proposed extension of IRB procedures to the realm of oral history. I have written extensively on the history of the abuses that led to the founding of IRBs--including two books on the history of Nazi medicine--I have also written on the history of experimental abuse, experimental ethics, and the ethics of science research and publishing more generally. And I have done a great deal of oral history.

The purpose of IRBs is to guarantee that abuses of human rights and bodies do not occur, and whereas there are many fields and inquiries where this is a real and substantial concern, oral history is not one of them. Oral history is rather more like investigative journalism in this sense. The possibility for abuse is very low--and the potential encumbrance of creative research by the proposed limitations is substantial. Regulations of this sort would also be virtually unenforceable, since it will be easy enough simply to "chat" with someone informally rather than doing a formal oral history with all the bells and whistles. Requiring permission from an IRB to do oral history would be a procrustean bureaucratic perversion of the original logic behind such boards. Even if such requirements are passed, I do not believe they will be followed. Nor should they be. Oral history is as much an art as a science, and I think it would be about as fair to ask artists to have the subjects of their canvases approved by an IRB, as to require such an encumbrance for historians.

19. Bernice Hausman, Professor, Department of English, Virginia Tech

I understand that revisions to IRB requirements concerning category 5 of the federal regulations overseeing IRB exemptions and approvals are being considered by the OHRP. I have looked at the proposed changes and am concerned that the language, while in some instances clearly indicating medical contexts for the new restrictiveness concerning IRB exemption, does not always do so, thereby unnecessarily subjecting

historians, social scientists, and humanists working with human subjects in contexts of little or no risk to unnecessary and cumbersome IRB oversight. Specifically, language that discusses "data and documents" should specify what kind of data and documents should come under the IRB's supervisory purview, and which (such as archival documents, like letters, etc.) can be exempt from oversight. The vagueness of the language suggests increasing local IRB authority for types of research that involve human subjects, like oral history, but which do not involve risk to those subjects.

This is a particularly difficult issue because IRB boards typically do not include humanists or social scientists; thus, the applications for exemption from historians and other scholars are examined by faculty unfamiliar with the protocols of research in these fields. I encourage the OHRP to further specify the language in category 5 to make it clear that the language pertains to medical research (as is clear in the references to "clinical" and "research" data and documents later in the Federal Register notice of October 26, 2007). It seems that there also may be problems with the expansion of category 7 as well.

I agree with the American Association of University Professors that "research on autonomous adults, whose methodology consists entirely in collecting data by surveys, conducting interviews, or observing behavior in public places, be exempt from the requirement of IRB review—straightforwardly exempt, with no provisos, and no requirement of IRB approval of the exemption."

20. Philip C. Brown, Associate Professor, Japanese History, The Ohio State University

I strongly urge the adoption of the AAUP language as it pertains to oral history projects, vis., "research on autonomous adults whose methodology consists entirely in collecting data by surveys, conducting interviews, or observing behavior in public places, be exempt from the requirement of IRB review—straightforwardly exempt, with no provisos, and no requirement of IRB approval of the exemption."

In my own experience, opportunities to conduct oral history have been almost entirely opportunistic, unscheduled and informal. My work in this area involves no experimentation, but seeks only to elicit recollections of public events/practices in which interviewees have participated. There is no way that I can plan for such interviews or secure advance permissions and clearance, actions that the language of proposed regulations seems to require. Given the circumstances in which I work, no one can have the necessary foresight to comply.

Currently proposed language will seriously hamper my historical research. Please adopt the language as proposed by the AAUP.

21. Susan M. Hartmann, Professor of History, Ohio State University

As a history professor and scholar with forty years of experience, I urge you to put an end to the strongly object to obstacles created to students and scholars who do oral history interviews. Oral history interviews simply ask subjects about their experiences in and

knowledge of the past. They have the potential to pose only very minimal if any harm. They are not unlike a journalist interviewing someone for a news story.

Please make totally exempt from IRB review research on autonomous adults in the form of collecting data by surveys, conducting interviews, or observing behavior in public places.

22. Leon Bradlow, Senior Scientist HUMC, Adjunct Professor of Endocrinology UMDNJ, Adjunct Professor of OBGYN UMDNJ, Professor of Research Tuoro University

As a long term life scientist, who has both served on IRB panels and had to process projects through IRBs from the time that IRB panels were created I do not understand the rationale for putting oral history and archival history projects under the aegis of an IRB panel working under Belmont or Helsinki rules. In these research studies in animals or people the issues deal with the safety of subjects and assurance that they understand the project and have signed an informed consent for their participation in the study.

In an oral history study the subject is free to tell or not to tell his life story in whole or part and to exclude anything he does not want to tell. Since the person carrying out the history does not know in advance what he will hear, he cannot provide a protocol listing the questions to be asked. Nor can he get signed written consent in English from illiterate tribesmen (as one IRB panel requested according to a recent account in the Hastings Review).

The goals of oral historians and social scientists are so far removed from the topics listed in an IRB protocol that I just filled as grounds for exclusion, they could not be fit into that mold. It is also not clear what the risks would be to subjects who participate. The simplest thing to do is to put them in an exempt category not requiring IRB approval, with the possible exception for psychological studies in which the subjects are purposely misled as part of the study.

I would urge that the new proposal be drastically modified to decrease its restrictive nature and modified to include an exempt category as I outlined above

23. J. E. R. Staddon, James B. Duke Professor of Psychology, Professor of Biology and Neurobiology, Emeritus, Duke University

Given the first amendment to the constitution, I cannot see that any case can be made for requiring IRB approval for *any* non-invasive procedure, requiring a verbal response only, for which the subject has given his or her consent. Any regulation infringes equally on the researcher's right to ask questions and the respondent's right to answer them

The existing regulations are already highly intrusive and no extension can be justified.

25. John Parascandola, President, American Association for the History of Medicine

As President of the American Association for the History of Medicine, I am writing on behalf of the Association to voice our concerns about proposed changes in IRB regulations involving oral history. Under the present interpretation, most oral histories are exempt from IRB review. It is my understanding, however, that the proposed new rules would change this situation and subject most or all oral history efforts to IRB review. This would create an excessive burden on historians and social scientists, as well as on IRBs, and we believe it is an unnecessary burden. Interviewers doing oral histories do so, of course, with the consent of those being interviewed. In addition, there are standard procedures and protocols that guide oral history interviewers. An oral history would not be of any use, for example, if the interviewer does not obtain a signed release from the interviewee giving permission for the interview to be used. Copyright laws would protect the oral history document from being reproduced or quoted without the permission of the interviewee unless he or she had signed a release. Oral history interviews are not really "experimental" research and, in our view, should not be subjected to IRB review. I know that various other organizations have expressed similar concerns, and we hope that these concerns will be taken into account in formulating any new legislation or regulations concerning IRBs.

26. Gregory Wilson, Associate Professor, Department of History, University of Akron

I wish to add my voice to that of the American Historical Association's and others regarding the proposed regulations regarding oral history and human subjects research. The still critical goal of protecting subjects from harmful research experiments ought not to be expanded to include oral history interviews. I agree with the 2004 ruling, quoted here from the website of the American Historical Association:

We are pleased to report that after a conference call on January 7, 2004, the Office for Human Research Protection confirmed its concurrence with the existing policy statement. In an e-mail dated January 8, 2004, Michael Carome, the associate director for regulatory affairs at the OHRP, stated to us:

To summarize from OHRP's perspective, OHRP yesterday reaffirmed its concurrence with your policy statement that oral history interviewing activities, in general, are not designed to contribute to generalizable knowledge and therefore do not involve research as defined by Department of Health and Human Services (HHS) regulations at 45 CFR 46.102(d) and do not need to be reviewed by an institutional review board (IRB). OHRP has tried consistently to confirm this concurrence whenever it received inquiries about this matter from representatives of IRBs or other institutional officials.

(<http://www.historians.org/Perspectives/Issues/2004/0403/0403new1.cfm>)

Please keep IRB and oral history separate. Government oversight should not expand to conversations, recorded or otherwise; this would be an unnecessary and dangerous step. Sincerely,

27. Edward E. Curtis IV, Millennium Scholar of the Liberal Arts, Associate Professor of Religious Studies and American Studies, Indiana University-Purdue University Indianapolis

I write to express my concern about the new draft guidelines for IRBs. These new guidelines will make worse an already-bad problem for social scientists and humanities scholars. Please change them to adopt the American Association of University Professor suggestion: "Research on autonomous adults whose methodology consists entirely of collecting data by surveys, conducting interviews, or observing behavior in public places, be exempt from the requirement of IRB review—straightforwardly exempt, with no provisos, and no requirement of IRB approval of the exemption."

28. Joseph C. Fitzharris, Professor of History, University of St. Thomas

I am an historian. I do, and have my students do oral histories. Under these proposals, I would have enormous and unnecessary issues with my campus IRB.

As things stand, oral history is, they agree, outside their necessary purview. That is as it should be.

I understand the need to protect human subjects of research. However, oral interviews of the kind historians do are not these kinds of researches. I commend the AAUP's recommendation on IRBs to you (cited in Robert Townsend, "Historians Get Rare Opportunity to Comment on Federal Policy on Oral History Projects," *Perspectives* 45:9 (Dec 2007):18). A simple, to the point statement. Save the complexities for the areas where complexity is necessary.

29. Hillary Jenks, Doctoral Candidate, American Studies and Ethnicity, University of Southern California

I am a doctoral candidate at the University of Southern California (I will be completing my dissertation this May) and my work focuses on American history. I use oral history fairly extensively in my research, and having to comply with IRB regulations, which I feel have been inappropriately applied to oral history, has caused serious delays in the timely completion of my dissertation. It is my hope that the new policy on IRBs currently being drafted will recognize that oral history is in no way similar to medical or psychological research on human subjects, and will specifically exempt it from IRB oversight.

30. Margaret Lynch-Brennan, Associate, NY State Education Department, Office of Planning and Professional Development

As an historian who engages in oral history, I am writing to request the specific exclusion from IRB review of oral history projects conducted by members of the historical profession. Oral historians deal with autonomous adults and use methods such as conducting interviews with them. Unlike other social scientists, in no way do we pose potential harm to the subjects of our interviews.

31. Jennifer Ross-Nazzal, Historian, NASA Johnson Space Center

As a historian, I am concerned with the new IRB proposed regulations.

I am concerned that this will tie the hands of historians in the federal government who regularly conduct oral history interviews with current and former staff. How long will approval take? Will approval have to be sought before each person is interviewed, or could approval be granted to each office for a year, two years, indefinitely? I have concerns because it is possible that an agency could lose the opportunity to talk with a former staff member due to age and health reasons if approval has to be sought first. If this is the case, interviews could not be conducted on the spot, if a former staff member is leaving or travels into town on a whim. I am concerned that this will negatively impact the ability to preserve the history of the various federal agencies.

32. Jay L. Spaulding, Professor of History, Kean University

Please add my name to the list of individuals who support the position of the American Association of University Professors:

"research on autonomous adults whose methodology consists entirely in collecting data by surveys, conducting interviews, or observing behavior in public places, be exempt from the requirement of I[institutional] R[eview] B[oard] review--straightforwardly exempt, with no provisos, and no requirement of IRB approval of the exemption."

The notion that a team of hacks who know nothing about the communities I study, let alone their histories, are somehow qualified to tell me what I may and may not discuss with people is insane. Given the nature of the IRB comments I have received, it is also clear that such hacks often have political and cultural agendas that are not consistent with sound historical scholarship.

The IRB system is totally unsuited to history.

33. Daniel C. Snell, L. J. Semrod Presidential Professor of History, The University of Oklahoma

Sirs: I do hope you will be able to eliminate the unnecessary harassment by IRBs of historians doing oral history. People consent to be interviewed and they are told how their memories will be used. They do not talk to us if they do not want to remember. And though memory can be painful, it can also be therapeutic, as experience has shown. I do not understand why this medical model was ever extended to history.

Proposed changes seem to be ambiguous and arbitrary. Section 5(c) in particular appears to open up even more study projects to IRB review. People don't talk to us who do not want to! Please exempt historians, as you exempt journalists.

35. Claytee D. White, Director, Oral History Research Center at UNLV

When we started our Oral History Research Center in 2004, we did not adhere to the IRB human subjects rules. Our IRB office became more and more concerned and wanted us to comply with institutional policies followed by every one else even though my contact was on a different level. I stopped protesting after I conducted by first Katrina interviews. I wasn't sure what would happen when I left those homes and because I was so uneasy, I began to comply to IRB regulations willingly. Now the process requires about 15 minutes of my time as I design each new project. Our IRB office here is staffed by professionals who walked me through the process once. Now I complete the online forms without a hitch and my projects are approved in less than 48 hours.

36. Alice Dreger, Associate Professor of Clinical Medical Humanities and Bioethics, Feinberg School of Medicine, Northwestern University

I am writing to object to the plan to include oral history work in the type of research requiring IRB oversight. I have sometimes sought IRB approval for oral histories that I have conducted (in order to protect myself from charges by my university that I was operating outside regulations, before the OHRP clarification with the Oral History Association), and my experience is that IRBs--which were designed (and still are, by in large) to handle scientific work--do not have an understanding of how to protect subjects of oral histories.

They do not, for example, understand why subjects are often encouraged to keep their names attached to their personal life histories rather than being made anonymous in the historical record; they do not understand why we do not destroy data; they do not understand (or have the first clue how to handle) the fact that we often do highly interactive interviews with many open-ended questions that we cannot run by a committee in advance of the interviews; they want us to say what kind of generalizable knowledge we are seeking, when typically we are not.

It is true that IRBs might be adapted to deal with these things, but I sincerely doubt this will happen at most institutions since most institutions do not have the number of oral historians to staff IRBs appropriately. (They are therefore likely to continue in the model of scientific inquiry, which doesn't translate well.) Certainly subjects of oral histories deserve ethical treatment. This is not the best way to achieve that. My own approach is to have a clear, written agreement with subjects of oral histories, complete with a description of their and my rights and responsibilities.

37. Elena Razlogova, Assistant Professor, Department of History, Concordia University

I would like to support the solution recommended by the American Association of University Professors, that “research on autonomous adults whose methodology consists entirely in collecting data by surveys, conducting interviews, or observing behavior in public places, be exempt from the requirement of IRB review— straightforwardly exempt, with no provisos, and no requirement of IRB approval of the exemption.”

Although I'm not affiliated with a US institution, I specialize in United States history, conduct oral histories in the United States, and am a member of the American Historical Association.

38. Lise Steinhauer, History Speaks

I wish to go on record to say, quite simply, that IRBs should not be applicable to oral history, where the risks of any negative effects on interviewees are, at the most, minimal. I do not consider these people "subjects," but participants in a collaboration.

39. Thomas L. Hendrix, U.S. Army Military History Institute

I am writing to express my concerns about the inappropriate and often arbitrary way federal policy has lead to the intrusion of institutional review boards (IRBs) into oral history research.

I specifically want to comment on two items that have been most troubling to oral historians-category 5 (which seems to open the door to oversight of archival research) and category 7 (which specifies oral history).The proposed coverage is arbitrarily broad.You should specifically and positive exclude interviews done for historical purposes from this proposal.I respect the need for protecting human susbjects who are the focus of research BUT oral history interviews are a completely separate enterprise.Please don't let the word interview supplant your commons sense in this regard.

I support the solution recommended by the American Association of University Professors, that "research on autonomous adults whose methodology consists entirely in collecting data by surveys, conducting interviews, or observing behavior in public places, be exempt from the requirement of IRB review-straightforwardly exempt, with no provisos, and no requirement of IRB approval of the exemption."

I have been responsible for the U.S. Army War College oral history programs since 1995.What I see in these proposals does not pass the common sense test.Please specifically exclude interviews conducted to record historical experiences from IRB review.

40. Mark A. Greene, Director, American Heritage Center; President, University of Wyoming; Society of American Archivists

Dear friends at HHS, please accept this brief message as a formal comment from the Society of American Archivists to the call for comments on the Expedited IRB Review Process, particularly the research material in Category 7, and specifically oral histories.While we appreciate the direction taken by this effort, to expedite IRB review of oral history projects, we wish to go on record as believing that oral history projects should be exempted entirely from IRB review.We will be submitted a more detailed statement early next year, explaining our stance, but in short we accept the rationale put forward by the Oral History Association and the American Historical Association that oral histories should be one of the categories of exempt research.

41. David K. Robinson, Professor of History, Truman State University

I am a professor of history who has helped colleagues prepare materials for our university's Institutional Review Board, although I have never submitted such papers on my own research or on that of students that I supervise. These projects of my colleagues and their students all involved perfectly straightforward oral history methods, employing release forms recommended by the Oral History Association. Following advice of OHA and the American Historical Association, and using their documentation, I tried (in vain) to get our university's IRB to declare that such projects were exempt from consideration by our IRB. It was the opinion of the untrained staff member that coordinated the faculty group that "personal issues are involved in oral histories," and that the university "might be sued," and so full treatment by IRB was required, even though I pointed out that the categories of "research using human subjects" had nothing to do with the oral history methods pursued by my colleagues and their students.

Now that your office is at the point of clarifying the status of oral history projects with IRBs, I hope that you will clarify it in the only way possible. Please follow the recommendation by the American Association of University Professors (of which I am an active member), that "research on autonomous adults whose methodology consists entirely in collecting data by surveys, conducting interviews, or observing behavior in public places, be exempt from the requirement of IRB review—straightforwardly exempt, with no provisos, and no requirement of IRB approval of the exemption." For more, please see

<http://www.aaup.org/AAUP/pubsres/academe/2004/JF/NB/OralHist.htm>

By making such a clear break with the muddled past, your office will avoid future legal challenges that AAUP and ACLU will surely pursue, if IRB screws are further tightened on research involving oral history. Academic freedom and freedom of speech (for the sources and for the historians) are at stake.

44. Nathaniel Comfort, Associate Professor, Department of the History of Medicine, The Johns Hopkins University

I wish to comment on the proposed revisions to the policy on expedited IRB review.

While the revised language is reasonable and appears to protect all legitimate forms of behavioral research, the context in which it will be applied raises a significant risk of unnecessarily complicating or even inhibiting harmless and valuable historical research. I know this from personal experience as a historian of recent science and medicine at a major research university.

My primary appointment is in a medical school, but I have a joint appointment in a department in the college of Arts and Sciences. I therefore have access to two Institutional Review Boards and the luxury of choosing which one to which I submit my research protocols. Those protocols involve oral history interviews with scientists, physicians, and other personnel associated with biomedical research. I have submitted several research protocols to my IRB and have always had them exempted from review.

One of my projects involves the creation of an oral history archive. My colleagues and I are collecting life-history interviews with scientists and physicians and placing them online in a searchable format for us and other scholars to use. My understanding is that this would be considered a “non-research” purpose and would therefore potentially be subject to category 5. The revisions to category 7 specifically name oral history as a category of research potentially subject to review. The danger posed by the proposed revisions, to this and similar projects, lies in the squeezing of oral history research into a Procrustean bed designed for biomedical research using wholly different methods—and in asking IRBs accustomed to biomedical research models to evaluate historical research.

Let me illustrate with an example. I also teach a graduate seminar in oral history theory and method. For a session on IRBs and the legal aspects of consent, I bring in representatives from both the medical school and the arts school IRBs for dialogue and discussion. They are both highly intelligent, open-minded people with the best interests of researchers at heart. The resulting class session is always eye-opening and often quite disturbing for the students. First, the heads of the two IRBs hardly know each other. They seem to see one another rarely outside my class. Thus, there is little communication or sharing of information between them. Second, although both individuals are dedicated and serious about their responsibilities on the IRB, they have not been able to follow the tribulations of oral history as its role in the IRB process is debated. I educate them on the progress of the matter since our last meeting (indeed, this is one reason for holding the session!). As they must do, they tend to interpret the rules conservatively, in order to protect the institution from possible lawsuits. One aspect of the class session that troubles my students is how little the medical school IRB knows about oral history. It tends to treat oral testimony as if it were a bodily fluid, which needs to be collected as painlessly as possible, anonymized, and destroyed after use. About halfway through the class session, my students all wilt as oral history begins to appear impossible to do in a university. One “creative” solution is to cast our work as not being “research”! This would solve the problem by making it extremely difficult for oral historians to win research grants in the first place.

To her credit, the head of our medical school IRB recognizes the discordance and has encouraged me to send my protocols to the arts school IRB, where they see more oral history protocols. But the graduate students in my department may not have that luxury. It required much discussion and hand-wringing last summer to conclude that one of our history of medicine students, who is also working in the public health school, could submit her protocol to the arts school IRB; she succeeded because I agreed to be the PI on this aspect of her research. This tricky situation was resolved only through some creative and sane navigation of a morass of regulations that were not clearly understood. The student was able to do most of her research—although she was not permitted to conduct some of the interviews she wanted, with rural Africans on their experiences of child health practices. But she did so only because of some special circumstances and enlightened interpretations of obscure regulations. It is certain that other students at my institution and elsewhere will not be so fortunate.

My concern is that by listing oral history as qualifying for expedited review, IRBs unfamiliar with oral history methodology will assume it is not exempt. This will create

needless headaches for researchers and may obstruct that is at worst harmless to the participants and in many cases beneficial. Subjecting research that involves conversation to the same strictures as that which involves drawing blood or administering experimental drugs effectively prohibits oral history research. And as long as IRB members are active, overworked faculty volunteering their time, they will be unable to track the nuances of a style of research they see very rarely. They quite reasonably play it safe and demand the same protections for our research participants as they do for those in clinical trials.

Oral history research has its own set of protections in place, which do not map well onto this biomedical model. The protections of biomedical research— anonymity, rigidly structured and consistent questionnaires, prohibitions on subsequent use, and so forth— castrate oral history. Oral history is a method designed to illuminate the particular (hence the discussion about not being research designed to produce “generalizable” knowledge). Instead, we guarantee our interviewees the right to review their interview transcripts, to annotate them, and to redact portions for an agreed-upon period of time (including “forever,” should they wish). These protections are not stipulated by IRB regulations and make no sense in a biomedical research model.

There are, then, two avenues open. One is to create a special category for oral history research that specifies the conditions under which the research will be exempt from review. This would require major review and consultation with oral historians to craft a set of guidelines appropriate to our work, but it would provide overworked university IRB members with a clear set of guidelines for evaluating oral history research protocols. The other is to simply exempt all oral history from IRB review. This is the position of the American Historical Association, and I support it. This option has the advantage of being inexpensive, and it raises no risk for the research participants.

I urge you to drop the phrase “oral history” from category 7 and to specifically exempt oral history from IRB review.

47. Zachary M. Schrag, Assistant Professor of History, George Mason University

The Federal Register of 26 October 2007 states that "OHRP is requesting comments on the entire expedited review list that was last published in the Federal Register on November 9, 1998 (63 FR 60364) to determine if other changes are needed." I would like to recommend that "oral history" be removed from this list, and that OHRP make an unambiguous statement that oral history does not constitute human subjects research as defined in 45 CFR 46.

I believe that other historians and the American Historical Association will submit comments describing the harm done to historical scholarship by well-meaning but inexperienced IRBs. Since I have spent much of 2007 researching the history of IRB review of the social sciences, I think I can be most helpful by explaining the historical significance of the inclusion of oral history in the 1998 guidance. Put simply, the 1998 guidance unintentionally overturned half a century of oral history practice and a quarter century or more of federal policy toward oral history.

While I hope to learn more about the origins of the 1998 guidance, I have found nothing to suggest that its authors anticipated the results it has had. I hope that as it reconsiders this guidance, OHRP will do so with more information and deliberation. To this end, I offer the following brief account of the current regulations, and I would be happy to elaborate on any of these points if asked.

1. CONGRESS DID NOT INTEND TO REQUIRE IRB REVIEW OF ORAL HISTORY

Today's regulations for human subjects research draw their authority from two sets of congressional hearings. The first, the 1965 Special Inquiry on Invasion of Privacy, conducted by the House Committee on Government Operations, concerned itself with "a number of invasion-of-privacy matters" including "psychological testing of Federal employees and job applicants, electronic eavesdropping, mail covers, trash snooping, peepholes in Government buildings, the farm census questionnaire, and whether confidentiality is properly guarded in income-tax returns and Federal investigative and employment files." [1] The second, the Senate Subcommittee on Health's 1973 hearings on human experimentation, focused almost exclusively on medical research. [2]The only non-medical research the Senate investigated were behavioral experiments, such as B. F. Skinner's "research in to the modification of behavior by the use of positive and negative rewards and conditioning." [3] It was out of concern about this sort of behavior modification that that Congress included "behavioral research" in the National Research Act (93-348). [4]

At no point in either set of hearings, in subsequent reports, or in legislation did Congress concern itself with anything resembling oral history. Congress has never required IRB review of oral history research by its own staff or by the Library of Congress.

2. THE NATIONAL COMMISSION DID NOT INTEND TO REQUIRE IRB REVIEW OF ORAL HISTORY

As OHRP's website notes, the current regulations were intended to effect the recommendations of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. But the National Commission never intended to require IRB review of oral history research. Oral history is not mentioned in any of its publications. In the course of my research I have spoken with the two leading authors of the commission's IRB report (Bradford Gray and Barbara Mishkin) and two of the leading authors of the Belmont Report (Tom Beauchamp and Albert Jonsen). All assured me that they had no intention of imposing IRB oversight on oral history.

3. THE AUTHORS OF 45 CFR 46 DID NOT INTEND TO REQUIRE IRB REVIEW OF ORAL HISTORY

In 1978 and 1979, officials at the Department of Health, Education, and Welfare (later the Department of Health and Human Services) worked to translate the commission's recommendations into a revised version of 45 CFR 46. Within the department, there was considerable debate between the Office of General Counsel, which did not believe that federal law provided for IRB oversight of any social science research, and officials of the

health agencies, which sought broader coverage. But even the health agencies agreed to exempt "product and marketing research, historical research, journalistic research, studies on organizations, public opinion polls and management evaluations where the potential for invasion of privacy is absent or minimal." [5] In a careful review of NIH records of the period, I have found no document by any of the authors of the 1974 or 1981 regulations even hinting that oral history should be subject to review. Nor have I found any mention of oral history in the debates leading up to the 1991 revisions that produced the current regulations.

4. THE 1998 GUIDANCE WAS AN EFFORT TO RESTRAIN OVERZEALOUS IRBs

While all of this was going on, oral history had proceeded in federally supported institutions since at least 1948 and the founding of Columbia University's Oral History Research Office. Thus, over the course of thirty years, from the Public Health Service's first policies on extramural research in 1965, through the passage of the National Research Act in 1974, and through three versions of 45 CFR 46, oral historians had continued their work undisturbed by IRBs or OPRR, and without provoking any ethical scandals worthy of federal attention.

In the 1990s, however, some university IRBs began insisting on their jurisdiction over oral history. In 1995, for example, the University of Delaware threatened to reject a doctoral dissertation because its author had not sought IRB approval for oral history interviews. [6] Historians at the university had long conducted such interviews without IRB supervision.

In response to the interference by university IRBs, historians sought common ground with regulators and IRBs, based on their shared concern with ethical research. [7] As part of this effort, in 1998 the Oral History Association (with the endorsement of the American Studies Association and the American Historical Association) asked OPRR to make oral history projects eligible for expedited review procedures. [8] In the 1998 guidance now being reconsidered, OPRR agreed to this request, noting that "research on oral history has been included in response to approximately six comments," presumably including the Oral History Association comment. [9]

5. THE 1998 GUIDANCE HAD THE PERVERSE EFFECT OF RATIFYING THE BEHAVIOR IT SOUGHT TO RESTRAIN

Yet instead of improving relations between IRBs and historians, the inclusion of oral history in the 1998 guidance has disrupted oral history research throughout the United States, since IRBs have taken the list as evidence that OPRR wants oral history to be reviewed. For example, the CITI Program, a widely used training system for IRBs and researchers, claims erroneously that "the regulations specifically refer to interviews, oral history, focus groups, and other qualitative methods." [10] And Northwestern University's IRB claims that "Federal guidance defines social and behavioral science methodologies as those that include research on individual or group characteristics or behavior . . . or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies," using the

language of the 1998 guidance. [11] My impression is that many IRBs have taken a similar position, interpreting the 1998 guidance as a list of activities that should be reviewed.

In response to such misinterpretation of the guidance, the Oral History Association and the American Historical Association have asked OHRP to return to the regulatory situation of the 1970s and 1980s, in which no one considered oral history to be subject to federal regulation. In 2003, in response to such requests, OHRP stated that "oral history interviewing activities, in general, are not designed to contribute to generalizable knowledge and, therefore, do not involve research as defined by Department of Health and Human Services (HHS) regulations at 45 CFR 46.102(d) and do not need to be reviewed by an institutional review board (IRB)." [12]

As it stands, then, OHRP takes contradictory positions on the applicability of 45 CFR 46 to oral history interviewing. The 1998 guidance suggests that oral history can be subject to mandatory review, while the 2003 letter suggests that "in general" it is not. This contradictory guidance has contributed to the unhappiness of historians and IRB members across the country.

CONCLUSION: OHRP SHOULD REPLACE THE 1998 GUIDANCE WITH GUIDANCE CONSISTENT WITH FEDERAL LAW AND REGULATION

The 1998 guidance constituted a radical break with previous policy and a decision of lasting importance. Yet unlike the bulk of human subjects regulations and guidance, the current guidance concerning oral history is not based on the will of Congress or the findings of any federal commission. It was based on the request of historians' professional organizations, but since 2003 those same organizations have sought a very different policy.

The inclusion of oral history in the 1998 guidance was a well-intentioned effort, but it has proven harmful to ethical scholarship. With the reconsideration of the guidance, OHRP has a splendid opportunity to return to the original intent of Congress and the National Commission by unambiguously excluding oral history from review.

NOTES

[1] U.S. House of Representatives, Committee on Government Operations, Special Inquiry on Invasion of Privacy (89th Cong., 1st sess., 1965), 5.

[2] U.S. Senate, Quality of Health Care-Human Experimentation, 1973: Hearings before the Subcommittee on Health of the Committee on Labor and Public Welfare, Part 3 (93d Cong., 1st sess., 1973).

[3] U.S. Senate, National Research Service Award Act (S. Report. 93-381, 93d Cong., 1st sess., 1973), 15.

[4] Sharland Trotter, "Strict Regulations Proposed for Human Experimentation," APA Monitor 5 (February 1974), 8.

[5] Gerald L. Klerman, Administrator, to Assistant Secretary for Health and Surgeon General, 30 March 1979, FRC box 78, Res 3-1-B Proposed Policy Protections Human Subjects 1978-79, RG 443, National Archives.

[6] Donald A. Ritchie, *Doing Oral History: A Practical Guide* (New York: Oxford University Press, 2003), 196.

[7] Linda Shopes, "Remarks before President's National Bioethics Advisory Commission," 6 April 2000, <http://www.oah.org/pubs/nl/2000may/bioethics.html> (20 December 2007).

[8] Linda Shopes, President, and Rebecca Sharpless, Executive Secretary, Oral History Association, to Office for Protection from Research Risks, 2 March 1998, copy in author's possession.

[9] Federal Register, November 9, 1998 (Volume 63, Number 216), pp. 60364-60367, <http://www.hhs.gov/ohrp/humansubjects/guidance/63fr60364.htm> (18 December 2007).

[10] Lorna Hicks, "Defining Research with Human Subjects," CITI Program, <https://www.citiprogram.org> (30 October 2006).

[11] Northwestern University, "Schools, Departments and Programs Served by Panel E of the Institutional Review Board,"

<http://www.northwestern.edu/research/OPRS/irb/training/docs/panelEReviews.doc> (18 December 2007).

[12] Michael Carome to Linda Shopes and Donald Ritchie, 22 September 2003, http://grants.nih.gov/grants/policy/hs/Oral_History.doc (20 December 2007).

50. Andrew Stuart Bergerson, Associate Professor, History Department, UMKC

I write to you today greatly concerned about the prospect of Institutional Review Boards (IRBs) conducting (regular or expedited/delegated) reviews of research projects in oral history. I am an historian who employs narrative interviews as one technique in my historical research. I have recently been engaged in a constructive dialogue with the responsible research officers on my campus about oral history and "human subject research." It is my belief that extending the authority of IRBs over oral history is unwarranted, unconstitutional, and dangerous for the health of our democracy.

There is no question that historians have ethical and legal responsibilities to their interview partners that result from our interactions with them. Our extensive professional guidelines clarify not only questions of informed consent but also anonymity, copyright, and so on. Based in traditional practices of academic self-governance, they have functioned reliably well in protecting the rights and responsibilities of interviewers and interviewees. For the vast majority of research projects in oral history, there are simply no compelling reasons to subject historians to the kind of IRB review that is typical of

“human-subject research.” As I explain in my enclosed comment (“Oral History and IRB Review,” #1):

- IRB review will *not significantly enhance the protection of human subjects* beyond what is already available through professional guidelines for “best practices” in oral history.
- The vast majority of research projects in oral history will be *exempt by the very nature of their research methodology*.
- Indeed, it is more likely that IRBs will *mistakenly constrain perfectly ethical research protocols* because the existing regulative guidelines for “human subject research” do not make sense for most research in oral history.

Even an expedited/delegated review process *would thus represent an unnecessary regulative hindrance to research*. There are far more compelling reasons *not* to subject historians to the kind of IRB review that is typical of “human-subject research,” even if expedited/delegated. As I explain in more detail below (#2):

- Fighting these regulative battles will have a *chilling effect on scientifically and ethically valid research* in oral history.
- Once legally mandated, even expedited/delegated review would *unconstitutionally restrict the freedom of speech* of both interview partners.
- Moreover, it would *unfairly* restrict the freedom of speech *for insular minorities*.
- And finally, it would *undermine the crucial public role of historians* in fostering a public debate about the events of contemporary history.

I conclude this comment with some concrete policy recommendations (see # 3 below):

- The OHRP should *clarify the existing guidelines concerning oral history*.
- The OHRP should allow historians to give themselves a *straightforward exemption* from IRB review for a *long-term research agenda* through the submission of a precise and concise on-line form.
- Historians should continue to base their research practices on the *existing disciplinary standards for ethical conduct* as outlined in our professional guidelines and monitored through peer review.
- Historians who wish to vet their research with peers may do so *voluntarily* through locally based Oral History Ethics Committees comprised of experienced oral historians. For the very small number of ambiguous cases that might merit review, these Committees could advise the local IRB as *experts within this disciplinary specialization*.

Oral History and IRB Review

By Andrew Stuart Bergerson, Associate Professor of History, University of Missouri-Kansas City, December 2007

1. Oral history is not “human subject research.” IRB review will not serve any useful purpose not already served by our professional guidelines.

The American Historical Association and the Oral History Association have already informed the Office of Human Research Protections (OHRP) about the many reasons why oral history does not typically fit into the category of “human subject research” as defined by relevant statutes. Historians certainly believe that their histories provide insights into the human condition; but oral history *does not reach for generalizable principles of historical or social development which could have predictive value and could be applied to other circumstances for the purpose of controlling or engineering outcomes*. Historians often study human subjects as members of larger groups, but no historian could get away with ignoring their unique setting and context. Preoccupied with human *experience*, we are professionally obliged to interpret and narrate those life stories as embedded in particular times and places. Because we are interested in telling the story of this person in terms of its specific details, historians personalize their interviews to suit the particularities of each interview partner. As a discipline, then, historians tend to focus on the experiences of *particular individuals contextualized in particular times and places*. This tendency is especially characteristic of oral histories given their methodological focus on unique persons in unique contexts.

To be sure, our discussions do have very important public functions (see #2 below), and we do employ theories of human behavior from the social sciences to help explain those human experiences. Yet the insights that history provides into our collective identities and responsibilities must not be confused with the kinds of conclusions that social scientists draw when they generalize to universal human principles. Most academic historians are woefully bound to particular national, group, or even local histories. Indeed, most would insist that the only so-called “law of history” is that there are no such laws. Even comparative history expends considerable energy highlighting irreconcilable differences between case studies. The point here is simply that *the vast majority of research projects in oral history fall beyond the scope of the legal definitions of “human subject research.”* It therefore makes little sense in subjecting historians to IRB review.

Two of the main considerations that IRBs look for during review – proper research protocols and preserving the anonymity of interview partners – will almost always be mooted by our methodology. Oral history typically does not involve standard questionnaires whose research protocols could usefully be reviewed by an IRB, but rather *open-ended, narrative interviews where the interviewer must respond dynamically to the specific life history of that interviewee*. Moreover, historians *can never ensure the anonymity of their interviewees* because of the requirement that historians make their primary sources publicly available. The presence of an archived and typically taped record of their memories makes interviewees readily identifiable with current technologies. In our published histories, we are beholden to our ethical responsibility to

do the best we can to make identification as hard as possible; but a resolute third party will almost always be able to discover the identity of our informants because we always contextualize those people in particular times and places. Telling the story of a Vietnam War veteran, for instance, can be made only so anonymous by changing names; a careful investigator would be able to reconstruct that information by comparing the particular events described in those narratives to other records. OHRP guidelines recognize that research conducted on information in the public sphere is beyond the scope of IRB review; the point about oral history is that our discipline requires that we bring it into the public sphere (as an archival record, as a narrative of unique people, times, and places) in such a way that undermines the possibility of truly preserving the interviewee's anonymity. Since there is *no useful benefit* for IRB oversight of oral history questionnaires or anonymity procedures beyond the professional guidelines already in place for "best practices" in oral history, that review process would represent *an unnecessary regulative burden on research*.

The same could be said for the "minimum harm/maximum benefit" clause. In keeping with the Hippocratic principles behind medical research, IRB review is primarily designed to ensure that a research protocol does the least harm to, and the most good for, its human subjects. The principle underlying the methodology of history, *source criticism*, is measured on a completely different scale. Professional historians are trained to investigate the biases, context, motives, deceptions, and so on, of our sources. We spend our graduate and doctoral seminars learning these techniques ranging from hermeneutic readings of textual sources and empathic understanding to semiotic readings of images and triangulation between multiple sources not to mention the proper application of various theories of human behavior. Source criticism teaches us that historians are *professionally obliged* to ask our interview partners probing questions *independent of the benefit or harm for the interviewee*.

Historians certainly do not set out to either hurt or harm our interviewees; our professional guidelines clearly require us to take these questions of benefit or harm into consideration when we conduct our interviews. But it is nonetheless *our job to ask tough, critical questions*. Consider, for instance, the many kinds of challenging questions that one would have to ask those veterans of Vietnam if one were to fully understand the soldiers' experience such as disobedience to officers, black markets, illicit sexual relations, war crimes, and so on. Yet the same is true of the historian's responsibility when the topic of the interviews seems rather innocuous such as the everyday life of African-Americans in pre-Katrina New Orleans. The open-ended nature of narrative interviews and the obligation to criticize our sources would still require the historian to push our interlocutors beyond their comfort level to sensitive, political, private, and at times even traumatic memories. Add to this our inability to provide true anonymity as described above, and there is also no way for us to protect these informants from the kind of harm that might come once their stories have become part of a public record in archival collections and historical publications.

That is, historians assume a posture vis-à-vis our sources *fundamentally different* from the relationship between a biomedical or clinical researcher and their human subjects. More akin to a prosecuting attorney, *we use an almost adversarial posture of source*

criticism to get at the truth about the past. Because IRB guidelines largely miss the point of oral history, the benefits of IRB oversight for historians pale in comparison to the far more useful professional guidelines already in place for “best practices.” The danger here is that IRBs could inappropriately prevent perfectly acceptable oral history from being implemented and students from graduating by applying principles to oral history that do not meet its disciplinary logic. In keeping with the OHRP efforts to reduce regulatory burdens that do not contribute significantly to the protection of human subjects, it makes sense to *exclude oral history from IRB review in a simple and straightforward manner.*

2. IRB review would unconstitutionally curtail the freedom of speech and undermine the crucial public role of history in a democratic society

The purpose of historical research is to uncover the truth about a past that both interlocutors to some degree believe impacts their lives. Historical interviews must be understood not just as “research” but also as *a voluntary “conversation” held between consenting adults, in their public capacity as citizens, about matters of public concern:* that is, the causes, consequences, and character of past human behavior. This is true, I would argue, even when the oral history focuses on quite personal experiences, for the interviewer and interviewee are *implicitly or explicitly framing those experiences in terms of a shared history.* The testimony of the victims of genocide, for instance, are certainly recounting very personal experiences of trauma, and yet they are not discussing them with a psychologist or medical doctor where they are seeking care for their distress. They are discussing them with an historian. The context for those discussions – as per our “best practices”: a recorded, open-ended, narrative interview with informed consent between the interview partners – clearly implies that both wish that dialogue *to become part of a public record for the communities to which they belong.*

I am not a constitutional lawyer, but it seems to me that this kind of speech is protected under the First Amendment. Any restriction of it in part or in whole by an Institutional Review Board would constitute *an illegal violation,* by the Federal Government as well as the IRBs, *of our constitutional right to freedom of speech.* There is no question that IRB oversight of historical research, even if managed through expedited/delegated review, would have *a chilling effect on the willingness of researchers to engage in oral history.* The problem is not peer review or ethical consideration per se, since both are already part of the “best practices” of oral history; rather the problem lies in the regulatory framework of IRB review that will certainly stifle enthusiasm for oral history. In response to the national debate on IRB’s and oral history, I included in my Fall 2007 course on Historical Research Methodologies at the University of Missouri-Kansas City a unit on historical ethics that included an oral history project, peer review of those projects, and an extensive presentation on “human subject research” by the local responsible officer at UMKC. After this presentation, I asked my students if they plan on using oral history for their masters or doctoral research. Most insisted that they would rather not engage in oral history at all if they would be compelled to seek even expedited/delegated review from an IRB with legal authority over their research. I have heard similar arguments made by working historians. Directly or indirectly, IRB review of oral history research protocols would thus *impinge on the freedom of speech of future historians to discuss the past with their fellow citizens.*

IRB review of oral history would also serve to unlawfully – and *unfairly* – restrict the freedom of speech of our interviewees as members of so-called “insular minorities.” Given the fact that most archives house the records of governmental institutions, and most printed and even most manuscript sources speak with the voice of dominant groups, oral history is often one of the only vehicles for documenting the lives of typically marginalized populations. Oral history boomed as a research methodology in the 20th century in large part in an effort to recover the stories of the victims of modern history: the working classes, women, former slaves, persecuted religious groups, victims of genocide, forced laborers, survivors of natural catastrophes, undocumented immigrants, speakers of dying tongues, and so on. Particularly when judicial processes fail to bring the perpetrators of these crimes to justice, or when the injustice persists to this day and is supported by historical myths, oral history steps in as the crucial social mechanism for raising critical awareness about these tragedies in the public sphere. Historians give voice to those whose voices have been silenced or grown mute. IRB review will certainly have a chilling effect on the willingness of these typically marginalized populations to participate in such research. One can reasonably expect that even the scent of governmental presence would greatly reduce the pool of, say, undocumented workers or illiterate persons who are willing to participate in oral histories. Combined with the fact that fewer oral histories will be produced because of the very presence of regulation, the extension of human subject research procedures to oral history will *indirectly, yet significantly, impinge on the First Amendment rights of insular minorities* to share their experiences and perspectives with a wider public sphere.

Above all, it also seems to me that there exists a compelling public interest in a healthy democracy in reserving a maximum possible free range for public debate about our shared history. Along with source criticism, professional historians are obliged to engage in *historical criticism*. That is, historians are trained to use individual stories to challenge existing interpretations of the causes, consequences and characteristics of the past, proving old accounts wrong and suggesting new ones in their place. In this capacity, just as journalists are the historians of the present, historians are the journalists of the past. Our job is to challenge the myths, misperceptions, and misrepresentations that persist in the public sphere about the past. Like journalists, we treat all of our “informants” (from “great men” to “ordinary people”) not as private persons but as public individuals whose stories in some way, shape, or form influenced our collective history. Professional historians may typically be employed by universities, but we are in fact *public servants whose primary professional responsibility is to provide that public with ever more accurate accounts of their inherited history*.

Here again, our posture vis-à-vis our interview partners is completely different from the clinical relationships usually scrutinized by IRBs. We certainly are not equal interlocutors: historians are sensitive to the unequal power relations between interviewer and interviewee, and have ethical guidelines for professional behavior to accommodate these differences. Yet when we discuss the past with them, we do so *as two public citizens voluntarily inquiring into the making of our shared history*. It seems to me that one reason why information in the public domain is not subject to IRB review must lie in the fact that our society has recognized the significant social benefits that come from the wide dissemination of information by the public relating to the public. In oral history, the

interviewer and the interviewee are discussing the interviewee's life *as if he or she was a public figure*: in terms of his or her contribution to the collective history, and ultimately with a sense of *responsibility to the public* for "getting it right." (I suspect specialists in other disciplines would argue that their research also falls into this definition of oral history. For instance, most humanists interview artists, architects, authors, directors, planners, and so on as members of the public discussing the works of a public figure.) I would argue that this kind of research is, by definition, beyond the mandate of the IRB: it falls under the umbrella of the kind of public debate and mutual scrutiny that is a cornerstone of our democracy.

Even an expedited/ delegated review of this kind of critical investigation by an IRB *legally empowered by the government to restrict research* would, at least, reduce the willingness of citizens to engage in it and, at worst, provide a possible mechanism for far greater abuses. One reason why professions like journalism, law, doctors, and historians have the authority to review themselves through professional mechanisms, rather than legal oversight by governmental institutions, is to protect these crucial civil liberties from potential abuse. Give the existence of viable and functioning professional codes of conduct with regards to the ethics of research, IRB review is superfluous at best and will *far more likely serve to curtail the public's right to know about and debate their shared past*.

3. Policy Recommendations

A vibrant critical discourse about the public consequences of past behavior is a sufficiently compelling public interest that we allow journalists to conduct their "human subject research" without formal institutional review processes. They monitor themselves through informal mechanisms of professional codes of conduct. That is, our society in effect provides journalists with a *straightforward exemption from all governmental oversight* except in the extraordinary cases of abuse. The same processes of professional self-monitoring have been the standard by which historians have worked in the United States and still work in many other parts of the world. The benefits of IRB review would be marginal at best given the degree to which their premises and concerns do not coincide with those of historians and their function in our society; the likely dangers to our free and democratic society far outweigh those possible benefits. Indeed, *if this public policy protocol were itself to be subjected to IRB scrutiny*, then the simple formula of "maximum benefits and minimum harm" would cause it to be *sent back for a complete revision*.

There is a far simpler solution. As recommended by the American Association of University Professors, American Historical Association, and Oral History Association, the Federal Government should clarify its currently ambiguous policy such that *oral history is given a "straightforward exemption"* from IRB review. Insofar as academic institutions might be justly concerned about their liability in our litigious society, the Federal Government might wish to encourage local institutions to create simple web-based forms that describe the characteristics of oral history as a research methodology so that researchers can clearly identify the kinds of research that are "straightforwardly exempt." Individual researcher could then use that form to declare that her or his *long-*

term research agenda (rather than a *specific research protocol*) meets the definition of oral history described therein. This simple procedure would allow historians to exempt themselves from IRB oversight until such a time as their methodology changes to include “human subject research” as defined by the statute. This summary exemption would not only reduce a regulatory burden that does not contribute significantly to the protection of human subjects but also free local IRBs to focus their efforts on the kinds of “human subject research” that pose far more risk to its human subjects.

Historians should continue to base their research practices on the existing disciplinary standards for ethical conduct as outlined in our professional guidelines and monitored through peer review, though we might consider making one change in our customary practice. In the tradition of academic self-governance historians might consider forming *Oral History Ethics Committees* staffed by locally based historians experienced in oral history. The simple on-line form described above could provide then researchers with the means to contact this Committee for advanced peer review of their research protocol should they desire it. This Committee could also be available to the local IRB for advice in ambiguous cases that do merit review in keeping with the OHRP principle of review by local specialists in the relevant methodology. Yet rather than state mandated and legally binding, its advice would be based on “best practices” of ethical conduct as determined by the specialists in the field. Relying on the traditional academic Committee system would have all the benefits of additional peer review in advance of research without any of the drawbacks of drawing oral history into the regulatory orbit of “human subject research.”

51. Jennifer Phillips, IRB Chair. University of Rhode Island

As an IRB Chair with 25 years of various IRB experiences from biomedical to socio-behavioral-educational research, I find the proposed wording for category 5 expedited reviews as confusing in its own way as the current wording. The 3rd subcategory in particular, would leave me wondering about a PI who collects data to use in one study and then wants to use the same data pool for a second study, or does a phase 1 study and a separate phase 2 study using the same or overlapping data, which in fact they had in mind when they did the first study. If the bottom line is that OHRP wants to loosen the restrictions so that, as the Human Research Report puts it, "all minimum risk research involving human biological materials --- regardless of how they were collected -- should be eligible for expedited IRB review", then why not have the regulation say that? This would put the emphasis entirely on the assessment of risk rather than who collected the data with what intention at what moment in time. Then if an IRB expedited reviewer is not comfortable with some aspect of the study, they can always use their prerogative to bump it up to a full committee review and get more input.

Like many places, we are beginning to see genetic research studies with human subjects, banked DNA, etc. and determining whether these are minimal risk and should be expedited poses its particular set of problems, since what risks may emerge from these data banks longterm is still largely unknown.

Category 7 as proposed would open the whole complex issue of oral history, some of which seems to fit the expedited category intentions (done to in some manner generalize and disseminate data which may be entirely identifiable in some cases, versus exemptable story collection, archiving, and retelling with consent). I think departments of history and sociology and publishers might be better qualified to assess whether most oral history research papers fit ethical and professional standards of their fields than IRBs.

Some studies we've seen that, for example, have a student from overseas returning to their own homeland or traveling abroad to collect stories and observations (often in foreign languages to the IRB) in order to do ethnographic research are things it is virtually impossible for the IRB to assess, or monitor in any useful way, but the supervising professor who knows both the student and often the community they are researching and the languages used there may be in an ideal situation to assess risk, suitable consent/assent, and data monitoring, community feedback, etc. It is often not feasible for the IRB to try to find an outside expert about a remote and nontechnological community, who speaks the language(s) and has cultural expertise to make a genuine review of the ethics and proper conduct of such research. With the new wording it becomes even less clear what might be exemptable and what should be expedited in oral history and ethnographic research.

It might be useful to have a category number for research submissions to the IRB that we deem after review to be Not Human Subjects Research (deceased subjects, or secondary deidentified data, e.g.) but that have been reviewed by the expedited reviewer because the PI was unsure and submitted a protocol... instead of just marking such files "exempt NHSR" -- once there is a submission and an assigned protocol number, there needs to be a paper trail of their disposition and a niche in the filing system.

52. Thomas Zoumaras, Professor, Department of History, Truman State University

I implore adoption of the AAUP position that IRB guidelines and policies exempt oral interviews of adults from IRB review. I base this recommendation on my experience conducting almost 1000 hours of interviews for a biography of C. Douglas Dillon. Most of my subjects are sophisticated individuals who have served as high level policy makers in the government, quasi private institutions such as the Metropolitan Museum of Art, or private organizations and firms. In every case I have written and called to seek and arrange formal taped interviews, produced transcripts, and obtained permission to publish material based, in part, on the interviews, and often to house tapes and transcripts at repositories of my choosing. IRB guidelines make no sense under these real world conditions. Instead, they add a layer of bureaucratic oversight which complicates the interaction of the scholar and the interviewee without useful purpose.

52. Patrick H. Patterson, Assistant Professor, Department to History, UC San Diego

I am writing with reference to the OHRP's request of 26 October 2007 for written comments on a proposed amendment to item 5 of the categories of research that may be reviewed by the institutional review board (IRB) through an expedited review procedure. Specifically, I would like to express my serious concern about what is apparently a

continuing provision under the proposed rules that IRBs may, in their discretion, treat oral history research as subject to their review.

The production of important historical scholarship is being slowed, hindered, and made more expensive -- and high-quality work is deterred -- as the result of the continuing treatment of oral history work as subject to IRB oversight. For the reasons set forth below, I ask that OHRP resolve the uncertainty over IRB supervision once and for all with a clear direction that oral history research be treated as excluded from review and removed completely from IRB oversight.

THE PROBLEM:

The current expedited review list, as published in the Federal Register on November 9, 1998, provides in pertinent part that oral history may be subject to expedited review:

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

Of note here is that the current rule provides that "some research," possibly including oral history, "***may** be exempt from the HHS regulations for the protection of human subjects." (Emphasis added.) The status of oral history work is thus left unclear -- and has been unclear for years, notwithstanding long efforts by the American Historical Association and other professional historians to fix the problem. It therefore has fallen to university IRBs to determine whether or not they will treat oral history work as exempt (excluded from review) or not. There is abundant evidence, documented by the American Historical Association, the American Association of University Professors, and others, that many institutional IRBs, in an abundance of caution and a likely desire to avoid litigation, still continue to insist that oral history work not be treated as excluded from review, as the federal regulations clearly permit (but, critically, do not require). I want to stress that as a professional researcher with a great concern for research ethics, and as a lawyer with a real appreciation of the need to preserve and protect individual rights, I am very supportive of the mission of the OHRP to protect research subjects, and I am deeply sympathetic to the aims of the federal regulations governing research. But with regard to the particular practices and methods of oral history, I can find no persuasive rationale for the continuation of IRB oversight, and many strong reasons for an extension of a status as excluded from review.

THE SOLUTION: ORAL HISTORY RESEARCH SHOULD BE TREATED AS EXCLUDED FROM REVIEW, EVEN FROM EXPEDITED REVIEW

Under the current rules, *any* conversation between a historian and another person about that person's recollections of the past might be treated by an IRB as non-excluded

"research" subject to the IRB's requirements of advance approval. Any such conversation could, moreover, result in IRB sanctions, including even the prohibition of publication or the denial of a student's degree, if advance approval were not obtained. Historians (and, critically, not just those who believe they are practicing oral history!) thus have reason to wonder whether, legally, they are *ever* permitted to talk about past events with a person involved in those events without ensuring in advance that their IRB will approve such conversations. That is the unfortunate implication of the present rules. A fair and comprehensive assessment of the nature and practice of oral history research, however, leads to the conclusion that it is simply not the kind of research that the regulations promulgated by HHS were intended to cover. In oral history research, interviewees are simply asked in a straightforward way for their recollections about historically significant events. Those recollections are then preserved and reported. No experimentation is undertaken, the techniques used are minimally invasive, and interviewees may refuse to answer questions or terminate the interview at any time. Indeed, some of OHRP's past rulings and communications with the professional representatives of oral history practitioners have acknowledged that oral history logically should not be subject to IRB regulation, but as yet there has been no clear ruling requiring exclusion from review.

Along these lines, I refer you, for example, to one of the OHRP's determinations about the nature of oral history research, as published on the web site of the American Historical Association:

"In response to a query about whether one of OHRP's own oral history projects had been subject to IRB review, he [Prof. Zachary Schrag of George Mason University] was told that 'OHRP determined that obtaining oral histories of members and staff of the National Commission did not represent research as defined at 45 CFR 46.102(d) because the activity was not a systematic investigation, nor was it intended to contribute to generalizable knowledge. This oral history activity was designed merely to preserve a set of individuals' recollections; therefore, this activity was not subject to IRB review.' "(Robert Townsend for the AHA, at <http://blog.historians.org/advocacy/111/blogging-the-irb>)

By no means do I intend to imply any criticism of OHRP practice here: the OHRP's determination here is, without a doubt, the right one. The problem for other oral history researchers across the country is that, because of an apparent excess of caution on the part of their institutions, university counsel, and IRBs, they often do not have the same freedom to pursue oral history projects that has been enjoyed by the OHRP's own researchers, whose work is treated as excluded from review (i.e., not "research as defined" by the Code of Federal Regulations).

To remedy this continuing problem, we need an unequivocal ruling by the OHRP that IRBs are to treat oral history research as excluded from review. A proper solution to the problem requires a recognition that a number of the essential features of oral history research (which is very much akin to the journalistic method in many respects) may be weakened or thwarted entirely by requirements that various IRBs have imposed or have attempted to impose. In order to have real and lasting value as a contribution to scholarly knowledge, oral history research may require -- absolutely require -- that researchers be

able to pursue their historical research as dictated by the professional canons and indeed the very logic of the field of oral history, i.e., using methods that might well be inappropriate for other, potentially harmful and more invasive forms of research:

* For oral history work to be as valuable as possible (and in many instances, for oral history interviews to have any real value at all), researchers must have the freedom to conduct interviews in which the persons interviewed are clearly identified by name, so as to establish the veracity, relevance, and historical significance of the informant who is interviewed and whose recollections are being treated as historical evidence.

The conclusions of historical research must be testable and verifiable; without the ability to clearly identify interviewees, a vital tool in the writing of good, reliable history may well be lost. In appropriate circumstances, anonymity and confidentiality certainly might be granted, but it is important to recognize that anonymity and confidentiality may be antithetical to the purpose of historical research. The matter should be left to researchers and interviewees, and not to IRBs that may be largely unfamiliar with oral history methods and aims.

* Researchers must have the freedom to conduct interviews in an open-ended fashion, with the ability to ask questions that naturally arise from the findings revealed in the interview itself, and unconstrained by pre-approved questionnaire texts or scripts. Like journalists, oral history practitioners simply cannot do their jobs if they are required to submit questions for approval in advance. Flexibility, open-endedness, and the ability to pursue new leads and lines of inquiry that may arise only during the course of the interview itself are all absolute necessities. Indeed, it seems safe to conclude that many if not most oral history projects, if confined to lists of pre-approved questions, would have so little academic value that they would not be worth engaging in. Concerns about interviewee privacy and sensitivities are well placed, but the solution clearly rests not with IRB oversight, but with the unquestioned ability of adult interviewees to simply decline to answer specific questions or to terminate the interview if they desire. Finally, it is important that OHRP be aware that the prospect of burdensome IRB compliance is a real and significant deterrent to oral history work, and thus to the advancement of knowledge. Concerns about the potential burdens of IRB oversight may cause researchers to forgo or abandon planned oral history projects with great potential value. I know that worries about the legality of oral history research and concerns about non-excluded status have caused me to reconsider the wisdom and practicality of pursuing a major oral history project, on the history of communism in Eastern Europe, that I had hoped to undertake in the future. Important historical evidence comes to us through oral history, and often oral history is the **only** way to find and preserve such evidence. (This is certainly the case, for example, when it comes to the historical experience of everyday life under communism, where ordinary citizens were often denied real opportunities to have their views heard and documented. Oral history is our best path to this part of the past.) Precious historical material may well be lost because of the continued insistence on IRB review.

Whereas the burdens and harms to which oral historians are exposed by the continuing treatment of their work as not excluded from review are very real indeed, the potential

harms that IRB oversight may help avoid are, in the case of oral history work, minimal. Moreover, they are easily avoided by the interviewees themselves. The balance of the equities thus falls decidedly in favor of treating oral history work as wholly excluded from review. Accordingly, I must concur with the recommendation of the American Association of University Professors that "research on autonomous adults whose methodology consists entirely in collecting data by . . . conducting interviews . . . be exempt from the requirement of IRB review -- straightforwardly exempt, with no provisos, and no requirement of IRB approval of the exemption." (As historical research typically does not involve administering surveys or observing behavior in public places, I am not commenting on the AAUP's recommendation that these activities also be excluded from review.) I further concur with the AAUP's finding that such changes to the rules "would eliminate a considerable amount of the hardship that they have imposed on researchers" and "would eliminate a considerable amount of totally unnecessary work currently done by IRBs, freeing them to devote attention to seriously risk-imposing research projects."

55. Mark D. Higbee, Professor of History, Eastern Michigan University

I write to comment on the proposed revisions of the IRB regulations, as they pertain to oral history research. I write as an historian who has studied the history of the ethical misconduct of some medical researchers that created the need for federal regulations of biomedical research. I have not practiced oral history myself, in any formal sense, but I have read and used countless works of scholarship that were based on oral history. What is clear to me is that the kind of research activities engaged in by oral historians, or by other scholars who merely observe normal human behavior, are inappropriate subjects for IRB oversight. Merely talking to a person about that person's experience is extraordinarily unlikely to produce any harm. You might as well regulate the speech of all college students who get federal financial aid as regulate the work of oral historians, since both engage in speech that is equally unlikely to produce the types of harm to human subjects that these regulations are designed to protect.

Therefore, I urge the Office of Human Research Protections to adopt the recommendation of the American Association of University Professors. The AAUP holds that "research on autonomous adults" using "methodology" that "consists entirely in collecting data by surveys, conducting interviews, or observing behavior in public places, be exempt from the requirement of IRB review—straightforwardly exempt, with no provisos, and no requirement of IRB approval of the exemption." There is no risk in this recommendation, as oral history activities entail nothing beyond ordinary human conversations and reflections on the past.

Unlike the relationship between, say, a medical school based researcher and patient-subject, the oral historian and her subject have a relationship entirely voluntary and with no threat of compulsion or harm: The interview subject is always at liberty to decline to participate in oral history interviews – yet they are usually eager to share their experiences. People grant oral history interviews because they want to share their experiences with interested people, and in order to create a record of their experiences. Frequently, when I meet individuals while traveling or at social events, I am urged, as a

historian, to do an oral history interview with the person I have meet or someone they know, on the grounds that they have had important experiences that should be “recorded for history.”I mention this because it underscores how different oral history interviewees are from human subjects in the biomedical sciences: Oral history interviewees are typically proud of their past, and eager to share it and have it recorded, and they grant their interviews are partners, not dependents, of the researcher. The regulations are troublesome, because since there is no none instance of oral history work having “harmed” a subject, the IRBs are often arbitrary in trying to imagine what activities might be harmful; for instance, is is psycholo gically traumatizing, one IRB member suggested, to ask a retired person to recollect her professional accomplishments? Why should an IRB worry about this hypothetical risk and require the scholar to address it in advance of doing the research?

There is neither surgery nor drugs nor behavior modification nor experiments of any kind involved in oral history interviews. Oral history uses the most ordinary of human activities, conversation, to collect accounts of individual people’s experiences and observations. There is no more justification for requiring IRB review of this methodology than there is for requiring it of journalists who ask questions of their sources and note the responses, or of teachers who ask questions of their students and make records of the students’ responses. Indeed, there is much risk in attempting to regulate oral history work, as it is a needless intrusion, unwarranted by relevant federal statutes, into the realm of scholarship and it poses a potential threat to academic freedom, without achieving any benefit for the public.

Further, oral history, while used by scholars who work at universities, is also practiced by countless non-scholars who are unaffiliated with universities --- people interested in the history of their families, communities, ethnic groups, and professions frequently engaged in forms of oral history research, to document the memories of people from these groups. That kind of research is, appropriately, not regulated by IRBs. Neither should comparable research by university affiliated oral historians.

Likewise, the idea that the collection of historical sources in an archive, whether those sources are oral history recordings or transcripts or other materials, should be regulated is equally offensive: It is an unwarranted extension of the Government’s power into the realm of scholarship. It could easily constitute a form of prior restraint on scholarship, and it would risk restricting scholarly activities to those agenda approved by governmental authorities.

Oral history has more in common with a conversation between a waitress and customer in a restaurant than with a biomedical researcher examining the efficacy of a medicine, or of a psychologist asking questions of people in therapy. Oral history is not therapy. And saving historical records and making them available to interested researchers, which is at root what archival collections do, has more in common with a grandmother’s effort to save family letters, diaries, and photographs, and to make them available to interested people, than it does with a medical school’s need to properly maintain the privacy of medical records.

Not all academic research on living people is meaningfully categorized as being potentially harmful. Yet protecting human subjects from harm is the basis for these important regulations. The validity of the regulations, and the efficiency of IRBs, will be enhanced if the Office of Human Research Protections adopts the recommendation of the AAUP to make exempt from the requirement of IRB review all “research on autonomous adults” whose methodology “consists entirely in collecting data by surveys, conducting interviews, or observing behavior in public places, be exempt from the requirement of IRB review.”

60. Timothy Lloyd, American Folklore Society

American Folklore Society Policy Statement Research with Human Subjects

December 2007

I. The American Folklore Society II. The American Folklore Society, founded in 1888, is an association of people who create and communicate knowledge about folklore. The more than 1,200 members of the Society today are scholars and teachers at colleges and universities, professionals in arts and cultural organizations, and community members involved in folklore work. The purposes of the Society are to stimulate and encourage interest and research in folklore in all its aspects; to aid in the dissemination of the results of such research; to promote responsible application of such research in the broad variety of settings in which folklorists work; to publish and distribute publications, reports and journals; and to serve as a bond among those interested in the study of folklore.

2. Folklore and folklorists

Folklore is the body of traditional art, literature, knowledge, and practice that is disseminated largely through oral communication and behavioral example. Every group with a sense of its own identity possesses and shares such a body of traditions which may be called folklore. Folklorists are trained scholars who undertake to record, describe, catalog, analyze, and explain such traditional knowledge and expression and to disseminate the products of this research in books, articles, films, recordings, museum exhibitions, and display events.

3. Folklore research

Most folklore research should be exempt from IRB review.

Folklore research is conducted to record and describe traditional art, literature, belief, material objects, and custom. Folklore research is ethnographic and participatory. Folklorists are instructed in traditional culture by the members of ethnic, occupational, religious, and other groups. The folklore being studied may be relatively public (festival, community dance, musical performance) or relatively private (family story, quilt making, home recipe or remedy).

In either case, the folklorist needs to build rapport with community members in order to describe the traditions and to learn how and why they are created and maintained and how and under what conditions they are performed and transmitted. Such fieldwork takes time and depends upon the development of a trusting relationship between folklorists and community members.

Folklore research is not conducted in laboratories or offices. Folklore research is not carried out with testing instruments, standardized questionnaires, or 'control groups.' Folklorists are not experimentalists or clinicians. The people with whom folklorists work are not selected from a pool, are not randomly chosen, and they are not subordinate to some experimental design. Folklore fieldwork is conducted in the public and private spaces of a community.

Folklorists are guests in such communities. They can only work successfully at the invitation of and with the collaboration of the members of that community.

Bio-medical clinical and experimental models are inappropriate models for folklore research. Folklorists build relationships with people in order to learn about their ways of life and art. Not infrequently, these relationships last a lifetime. The people with whom folklorists work are not "human subjects"; they are artists, performers, hosts, teachers, and often, over time, they come to be friends. They help the folklorist understand their culture and its expressive forms.

The knowledge that results from folklore research is not quantitative but overwhelmingly qualitative. On occasion, a folklorist may employ a questionnaire or other survey instrument at the initial stages of research, but these are rapidly abandoned in favor of close conversation, careful observation, and prolonged participation. Folklorists seek to be educated by the people with whom they work. Consequently, folklorists seek instructions, demonstrations, explanations, commentaries, reflections, and reminiscences.

There is almost no folklore research that can be conducted using a preformulated set of questions. As folklorists learn more about the traditions that are the focus of their research, the kinds of questions they ask will necessarily change. Each response provokes new and unanticipated questions, each question leads to new areas of inquiry. In folklore and other ethnographic research, the questions to be asked cannot be known or formulated in advance. In many respects, folklore research is a type of investigative journalism; but it is deeper, longer lasting, and more responsible: the bonds established between the researchers and community members are more personal and enduring.

4. Folklore research and the protection of human subjects

Documentation of informed consent

Folklorists inform their consultants about the aims and methods of research. The nature of the relationships that folklorists build with their consultants, however, is such that a written, signed, legally effective document would be inimical to the relationship upon which folklore research is based. Folklorists cannot go as guests into people's home

communities, build trust and friendships, and then present a legal document for signature. Nor can they ask for signatures to be witnessed.

Informed consent is given orally, and possibly can be recorded on audio- or videotape, but introducing a written legal document into the folklorist-consultant relationship would generally prove an insult to the consultant and bring folklore research to a halt. Institutional review boards should alter or waive the requirements for written informed consent in the case of folklore and other forms of ethnographically based research.

There is clear justification for this position as well in the Federal regulations: "An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent ... or waive the requirement to obtain informed consent provided that ... the research could not practicably be carried out without the waiver or alteration" (45 CFR § 46.116). "An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds ... that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context" (45 CFR § 46.117).

Confidentiality

Folklorists document folk traditions. They do not destroy such documentation but preserve it in their own files, in archives, and make it known through publications and exhibitions. Folklorists inform consultants of identifiable materials prior to publication and exhibition and obtain written consent for the placement of materials in public archives. Folklorists guard the confidentiality of their consultants when such confidentiality is requested. In most, instances, however, consultants want their contributions to research to be made known. They want to be acknowledged for their contributions and be recognized as community artists and experts in local traditions.

In such cases, the folklorist acknowledges their contributions in books, articles, exhibition catalogs, and displays. However, the folklorist would keep confidential such information as might place the consultant "at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation" and would forewarn the consultant that such information might not be kept confidential were records subpoenaed as part of some legal action.

Student class projects

Folklore courses in universities often require students to establish relationships, collect folklore, and interview consultants as part of the instruction in the theories and methods of folklore research. Such classroom assignments are educational and are not intended to result in a "systematic investigation, including research development, testing and evaluation, designed to contribute to generalizable knowledge." They do not constitute "research" in any sense intended by the section of 45 CFR § 46.102 just cited, and should be exempted from institutional review. It should be left to class instructors to inform the

students of their ethical responsibilities and oversee the assignments that are a part of course curricula.

5. Code of Ethics of the American Folklore Society

The American Folklore Society has its own code of ethics that spells out the responsibilities of folklorists to those studied, to the public, to the discipline, to students, and to sponsoring organizations and governments. What follows is the American Folklore Society's statement on folklorists' responsibilities to those whom they study:

In research, folklorists' primary responsibility is to those they study. When there is a conflict of interest, these individuals must come first. Folklorists must do everything in their power to protect the physical, social, and psychological welfare of their consultants and to honor the dignity and privacy of those studied.

Where research involves the acquisition of materials and information transferred on the assumption of trust between persons, the rights, interests, and sensitivities of those studied must be safeguarded. The aims of the investigation should be communicated as much as is possible to the informant.

Consultants have the right to have their identities remain confidential. The right should be respected both where it has been promised explicitly and, as much as possible, where no clear understanding to the contrary has been reached. These strictures apply to the collection of data by means of cameras, tape recorders, and other data-collecting devices, as well as to data collected in interviews.

There shall be no exploitation of individual informants for personal gain. Fair return should be given them for all services.

There is an obligation to reflect on the foreseeable repercussions of research and publication on the general population being studied.

The anticipated consequences of the research should be communicated as fully as possible to the individuals and groups likely to be affected.

62. Arnita A. Jones, Executive Director, American Historical Association

On behalf of the American Historical Association(AHA), I thank the Office for Human Research Protections for inviting comments on "Categories of Research That May Be Reviewed by the Institutional Review Board Through an Expedited Review Procedure" [Federal Register: October 26, 2007 (Volume 72, Number 207)]. 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. In that capacity, we write on behalf of the 15,000 members and 3,000 institutions we represent to express our concern about the changes proposed in expedited review category 5, and ask that "oral history" be removed from the language in expedited review category 7.

We approach the proposed changes with deep concern. Not because we doubt the good intentions of the staff at OHRP or the members of Secretary's Advisory Committee on Human Research Protections who have offered this proposal, but based on our long and unhappy experience with the way these policies have been implemented. In that light, we find the proposed changes to category 5 deeply troubling for the discipline of history and fear that, if implemented, the changes would severely limit our ability to collect information about the present and recent past for historians in the future.

As we read the proposal, the change to category 5 could potentially bring the collection of oral histories as well as web-based archival collection projects such as George Mason University's September 11 Digital Archive (online at <http://911.digitalarchive.org>) more firmly under IRB purview. The current language, as we read it (and judging from discussions with scholars in our field, as some IRB's understand it), leaves an opening to view such projects as exempt. The new language appears to remove that exemption by failing to include category (c)-"Research involving materials (data, documents, records, or specimens) that... will be collected solely for nonresearch purposes - among the items that may be exempt from the regulations for the protection of human subjects. At the same time, this also seems to invite further scrutiny and oversight over the use of materials gathered by other scholars and projects, and placed on deposit in an oral history archives. Within our discipline, the research/nonresearch distinction that OHRP makes in this category is not appropriate to oral history. The proposed change also seems to contradict current regulations, insofar as they state that "research involving the collection or study of existing data" is exempt from review (paragraph 46.101 (b) (4).

In 1998, the AHA joined a number of other historical organizations in proposing the inclusion of oral history among the expedited categories. After seeing how the addition of oral history has been implemented in practice, we now deeply regret that recommendation and ask that it be reversed. In practice, many oral historians have discovered that IRBs are typically comprised of faculty with no expertise in oral history methods, and who insist on scrutinizing oral history projects using standard scientific protocols. As a result, oral historians report that IRBs are applying rigid research criteria that are fundamentally at odds with oral history practices - insisting on specific sets of questions, for instance (and thereby suppressing the opportunity for dialogue, which is a vital part of the interview process), and occasionally insisting on the confidentiality of the sources (even though the interviewee's particular knowledge is often the purpose of the interview and precisely why it would be of value to current and future historians). This is made even more troubling by the application of vague and inconsistent notions about the potential harm that can be done by oral history interviews. In some cases the IRBs suggest it is the trauma of reliving a bad experience, in others, the potential personal or legal jeopardy to interviewees or their surviving relatives. Over the past seven years, the AHA has made a number of efforts to clarify or reverse the policy of using IRBs to regulate oral history, first by working with OHRP to clarify their policy, and then by encouraging history departments to engage the IRBs at their home institutions and clarify these policies at the local level. Despite all these efforts, 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.¹

As implemented by many institutional review boards, expedited review of oral history and elements of the Common Rule conflict with the essential canons of our practice. At times information in an interview, if made public, could indeed, in the language of 45 CFR 46, "reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation." Yet historians' deepest responsibility is to follow the evidence where it leads, to discern and make sense of the past in all its complexity; not to protect individuals from the possible repercussions of past mistakes or misdeeds. In this we are akin to journalists and unlike medical professionals, who are indeed enjoined to do no harm. We believe that "oral history" should therefore be removed from category 7 and explicitly exempted from IRB review. Given our research into the way these policies are infringing on historical research that poses minimal risk of harm, we side with the recent recommendation from the American Association of University Professors, that "research on autonomous adults whose methodology consists entirely in collecting data by surveys, conducting interviews, or observing behavior in public places, be exempt from the requirement of IRB review - straightforwardly exempt, with no provisos, and no requirement of IRB approval of the exemption."² However well meaning and well intentioned the original decision to include oral history in Category 7, in practice, the application of these rules to oral history are not appropriate and fundamentally impede and abridge scholarly work in our discipline. The proposed changes to category 5 seem to increase the likelihood that the harm being done to current members of our profession will be extended to future generations, as the simple gathering and use of such materials will become more circumscribed and difficult.

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

Sincerely,

Arnita A. Jones, Executive Director

1 Our previous studies were reported in Robert B. Townsend et al., "Oral History and Review Boards: Little Gain and More Pain," *Perspectives* (February 2006) available online at <http://www.historians.org/perspectives/issues/2006/0602/0602new1.cfm>. and Robert B. Townsend and Meriam Belli, "Oral History and IRBs: Caution Urged as Rule Interpretations Vary Widely." *Perspectives* (December 2004) available online at <http://www.historians.org/Perspectives/2004/0412/0412new4.cfm>.

2 The report from the AAUP, "Research on Human Subjects: Academic Freedom and the Institutional Review Board (2006)" is available online at <http://www.aaup.org/AAUP/comm/rep/A/humansubs.htm>.