

**COLUMBIA UNIVERSITY INSTITUTIONAL REVIEW BOARD
POLICY**

IRB REVIEW OF ORAL HISTORY PROJECTS

I. SCOPE:

This policy clarifies which oral history research activities conducted by Columbia University (CU) faculty, staff, and students require Institutional Review Board (“IRB”) review.

II. EFFECTIVE DATE: December 27, 2007

III. DEFINITIONS:

“Human Subject”: A living individual about whom an investigator conducting research obtains (a) data through intervention or interaction with the individual, or (b) identifiable private information.

“Research”: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

“Human Subjects Research”: “Research” involving “human subjects”.

“Oral History”: The National Oral History Association (“OHA”) defines oral history as “a method of gathering and preserving historical information through recorded interviews with participants in past events and ways of life”. Oral history is a recorded conversation about the past with named individuals in which knowledge about specific events and individual lives is narrated in story form and made available to the public through deposit in archives. Biographical in nature and historical in scope, the scholarly oral history interview is rooted in particular recollections about history based on the individual perspective of the narrator.

IV. BACKGROUND:

This policy is consistent with the federal regulations for the protection of “human subjects” in “research” (45 CFR 46, Subpart A; i.e., the “Common Rule”), the policies of Columbia University Oral History Research Office (“OHRO”), and the position of the Office for Human Research Protections (“OHRP”) of the U.S. Department of Health and

Human Services (“HHS”) on IRB review of oral history research as articulated in a letter, dated September 22, 2003 (attached hereto as Appendix A).

A. Columbia University Oral History Research Office (OHRO)

The CU OHRO administers the world’s oldest formal university oral history archive and program open to the public. Founded in 1948 by the Pulitzer Prize winning historian Allan Nevins, the archive was created to document national and international political and social history. The methodology of the OHRO is defined by a biographical approach to historical, cultural and social research, in which change over time is documented through the individual life story.

The OHRO has played a leadership role in the national and international oral history associations, and is considered a center for education about oral history in the academic world and the public at large. The procedures of the OHRO require that those who are interviewed receive copies of recordings, and where possible transcripts, and are given proper time to review and edit these materials before the interviews are deposited in archives. Legal releases include a variety of options for interviewees regarding restrictions and permission to use donated interviews. For students conducting oral histories for submission into the archives these procedures are recommended.

The OHRO website can be found at: <http://www.columbia.edu/cu/lweb/indiv/oral/>

B. Oral History Association (OHA) Guidelines

It is the policy of the OHRO that all oral history projects undertaken by CU should be conducted in accordance with the guidelines established by the OHA for the ethical and professional practice of oral history. Such guidelines can be found in full at http://www.dickinson.edu/oha/pub_eg.html

C. OHRP Position

In the September 22, 2003 letter, OHRP stated that it concurred with the policy, dated August 26, 2003, proposed by the OHA and the American Historical Association that oral history interviewing activities, in general, are not designed to contribute to generalizable knowledge and, therefore, do not involve “research” as defined by 45 CFR 46.102 (d). Thus, such activities that do not constitute “human subjects research” do not need to be reviewed by an IRB. OHRP clarified in the 2003 letter that some investigators may use oral history interviewing procedures in a manner which would be considered “human subjects research” as defined by 45 CFR 46.

D. University Policy

Oral history activities conducted by CU faculty and students are not required to be submitted for CU IRB review unless such activities constitute “human subjects research” as defined by 45 CFR 46.

Oral history activities conducted by CU faculty and students that meet the definition of “human subjects research” must be submitted to the CU IRB for review.

Determining what constitutes “human subjects research” rests on whether the activities are part of a systematic investigation designed to contribute to generalizable knowledge. As the regulations have not defined “generalizable knowledge”, one has to examine particular oral history activities on a spectrum.

Oral history interviews, that only document specific historical events or the experiences of individuals or communities over different time periods would not constitute “human subjects research” as they would not support or lead to the development of a hypothesis in a manner that would have predictive value. The collection of such information, like journalism, is generally considered to be a biography, documentary, or a historical record of the individual’s life or experience; or of historical events. Oral history interviews of individuals are not usually intended to be scientific or to produce generalizable information and hence are not usually considered “research” in accordance with the federal regulations or CU policy. Therefore, such oral history activities should not be submitted to the CU IRB for review.

On the other hand, oral history activities that are conducted in the context of systematic investigations involving interviews that are designed to elicit generalizable information regarding living individuals are likely to constitute “human subjects research”. Hence, the latter activities must be submitted to the IRB for review and prospective approval.

V. Examples of Oral History Activities that Do or Do Not Require IRB Review

A. Oral History Activities Not Considered “Human Subjects Research”

Oral history activities, such as interviews that serve only to document an individual’s life history or general reflections on past events are not considered “human subjects research”.

Example: Veterans Oral History Project

A student is planning a dissertation on the long term social impact of the Vietnam War on American culture. The student wants to conduct life histories of a group of veterans for the sake of documenting the broad meaning of the war in the rest of their lives. The interviews will be contributed to the Veterans Oral History Project at the Smithsonian Institution which offers professional training to oral historians, the costs of which were underwritten by Congress. To ensure that oral histories are conducted in a professional manner the student will follow the protocols and guidance developed for this project by the Smithsonian, as well as the guidelines of the national Oral History Association

Rationale:

The above project does not require IRB approval because based on the information provided in the example the information collected from the interviews is not a systematic investigation (it is not intended to address a hypothesis). Furthermore, it is neither intended nor likely to contribute to generalizable knowledge.

Other details, such as the external financial support for the oral history activity and following the OHA or sponsor's guidelines are irrelevant in determining whether IRB approval is required by the Columbia IRB. Of course, the conduct of oral histories by Columbia faculty, staff, or students should follow the OHA guidelines.

B. Oral History Activities Considered "Human Subjects Research"

Systematic investigations involving open-ended interviews that are designed to develop or contribute to generalizable knowledge (e.g., designed to draw conclusions in an effort to address a hypothesis or serve to collect pilot data for a future "research" study) WOULD constitute "research" as defined by HHS regulations at 45 CFR Part 46, and therefore does need to be submitted for IRB review.

Example: Long-term Post-Traumatic Stress Disorder in Vietnam War Veterans

A faculty member is planning to conduct oral histories to gain an understanding of the impacts of the Vietnam War on post-traumatic stress disorder. The faculty member wants to work with a veterans Post-Traumatic-Stress-Disorder [PTSD] support group to take life histories to see how the war influenced the rest of the veterans' lives. The group agrees in writing to allow the faculty member to meet with the members as a part of the group, and individually. One goal of the research, in addition to understanding general ways in which the war affected the subsequent lives of soldiers, is to make assessments that will allow the faculty member to predict what kinds of exposure in war situations leads to the development of PTSD. In order to prepare for this analysis, the faculty member will consult published research done on PTSD with reference to Vietnam veterans, and will use PTSD related materials specific to the individuals in the group. While the veterans want to contribute their memories to the national Veterans oral history project run by the Smithsonian, they want to keep specific information which would link PTSD material to their life histories private. The faculty member and/or the psychiatrist who runs the group plans to use the data collected through these life histories to prepare a scientific presentation.

Rationale:

The above project does require prospective IRB approval because based on the information provided the information that will be collected from the interviewees will be designed to contribute to generalizable knowledge.

The veterans' interest to keep specific information which would link PTSD material to their life histories private is irrelevant to the determination that this project needs IRB approval. Such consideration would be taken by the OHRO office even for projects that do not require IRB approval.

VI. Consultation

Questions as to whether any particular oral history projects involve "human subjects research" may be addressed to the Columbia University IRB or the OHRO by e-mail or phone.

George Gasparis	Asst. V.P. and Sr. Asst. Dean for Research Ethics	<i>George Gasparis</i>	December 27, 2007
Approved by:	Title:	Signature:	Date:

Appendix A: OHRP Letter to the leaders of the Oral History Association

Office for Human Research Protections
Rockville, Maryland 20852

September 22, 2003

Ms. Linda Shopes
Division of History
Pennsylvania Historical and Museum Commission
Commonwealth Keystone Building - PL
400 North Street
Harrisburg, Pennsylvania 17120-0053

Mr. Donald A. Ritchie
Senate Historical Office
United States Senate
Washington, D.C. 20510

Dear Ms. Shopes and Mr. Ritchie:

The Office for Human Research Protections (OHRP) has reviewed your August 26, 2003, memorandum and proposed policy regarding application of the Federal Policy for the Protection of Human Subjects (i.e., the Common Rule) to oral history interviewing.


OHRP concurs with the proposed policy stating 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). Please be aware that OHRP's concurrence is made only on behalf of HHS and does not represent concurrence by any other Federal department or agency that has adopted the Common Rule.

At this time, OHRP would like to suggest a few additional minor revisions to the proposed policy (see enclosed document with suggested revisions bolded and underlined).

OHRP notes that on occasion, investigators conducting human subjects research as defined by the HHS regulations may use oral history interviewing procedures. Unless such research is exempt under HHS regulations at 45 CFR 46.101(b), IRB review would be required if the research is conducted or supported by HHS or conducted under an applicable OHRP-approved assurance.

OPIRP appreciates the opportunity to work with you on this important issue. Please feel free to contact me at any time if you have questions or concerns.

Sincerely,



Michael A. Carome, M.D.
Associate Director for Regulatory Affairs
Office for Human Research Protections

Proposed Policy Statement Re: Application of ~~the Federal Policy for the Protection of Human Subjects (i.e. the Common Rule, codified by the Department of Health and Human Services [HHS] Regulations for the Protection of Human Subjects at 45 CFR Part 46, Subpart A)~~ to Oral History Interviewing

August 26, 2003

Most oral history interviewing projects are not subject to the requirements of the ~~Federal Policy for the Protection of Human Subjects (i.e. the Common Rule, codified by the Department of Health and Human Services [(HHS)] regulations for the protection of human subjects at 45 CFR part 46, subpart A,~~) and can be excluded from institutional review board (IRB) oversight because they do not involve research as defined by the HHS regulations. HHS regulations at 45 CFR 46.102(d) define research as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” The Oral History Association defines oral history as “a method of gathering and preserving historical information through recorded interviews with participants in past events and ways of life.”

It is primarily on the grounds that oral history interviews, in general, do not designed to contribute to “generalizable knowledge” that they are not subject to the requirements of the HHS regulations at 45 CFR part 46 and, therefore, can be excluded from IRB review. Although the HHS regulations do not define “generalizable knowledge,” it is reasonable to assume that the term does not simply mean knowledge that lends itself to generalizations, which characterizes every form of scholarly inquiry and human communication. While historians reach for meaning that goes beyond the specific subject of their inquiry, unlike researchers in the biomedical and behavioral sciences they do not reach for generalizable principles of historical or social development; nor do they seek underlying principles or laws of nature that have predictive value and can be applied to other circumstances for the purpose of controlling outcomes. Historians explain a particular past; they do not create general explanations about all that has happened in the past, nor do they predict the future.

Moreover, oral history narrators are not anonymous individuals, selected as part of a random sample for the purposes of a survey. Nor are they asked to respond to a standard questionnaire administered to a broad swath of the population. Those interviewed are specific individuals selected because of their often unique relationship to the topic at hand. Open-ended questions are tailored to the experiences of the individual narrator. Although interviews are guided by professional protocols, the way any individual interview unfolds simply cannot be predicted. An interview gives a unique perspective on the topic at hand; a series of interviews offer up, not similar “generalizable” information, but a variety of particular perspectives on the topic.

For these reasons, then, oral history interviewing, in general, does not meet the regulatory definition of research as articulated in 45 CFR part 46. ~~If~~The Office of for Human Research Protections concurs with this policy statement, and it is essential that such an interpretation be made available to the many ~~Institutional Review Boards~~ IRBs currently grappling with issues of human subject research.

**Application of the Department of Health and Human Services Regulations
for the Protection of Human Subjects at 45 CFR Part 46, Subpart A
to Oral History Interviewing**

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