

SEP 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.

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, which is 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, doare 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.

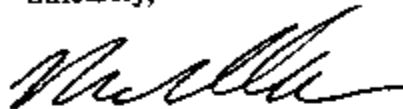
Moreover, oral history narrators are not anonymous individuals, selected as part of a random sample for the purposes of a survey. Nor are they asked to respond to a standard questionnaire administered to a broad swath of the population. Those interviewed are specific individuals selected because of their 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.

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OHRP 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,

A handwritten signature in black ink, appearing to read "M. Carome".

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

Enclosure