ORAL HISTORY EXCLUDED FROM IRB REVIEW

The U.S. Office for Human Research Protection (OHRP), part of the Department of Health and Human Services (HHS), working in conjunction with the American Historical Association and the Oral History Association, has determined that oral history interviewing projects in general **do not involve the type of research defined by HHS regulations and are therefore excluded from Institutional Review Board oversight**.

At the October 2003 meeting of the Oral History Association in Bethesda, Maryland, George Pospisil of the OHRP's Division of Education and Development, explained the OHRP decision regarding the application of the "Common Rule" (45 CFR part 46), which sets regulations governing research involving human subjects. These federal regulations define research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." The type of research encompassed by the regulations involves standard questionnaires with a large sample of individuals who often remain anonymous, not the open-ended interviews with identifiable individuals who give their interviews with "informed consent"that characterizes oral history. Only those oral history projects that conform to the regulatory definition of research will now need to submit their research protocols for IRB review.

Following is the text of a policy statement that was developed by the Oral History Association and the American Historical Association in consultation with the Office of Human Research Protection. This policy applies to oral history that takes place within an institution that has filed a multiple project assurance with OHRP. As one of the seventeen federal agencies that have signed on to the Common Rule, the Department of Health and Human Services deals most directly with the type of clinical research that the federal regulations were originally intended to cover, and its concurrence with the policy statement should set the way for a uniform interpretation by other federal agencies. Oral historians should make this statement available to department chairs, directors of graduate study, deans, and other officers concerned with institutional compliance with federal regulations.

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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

Most oral history interviewing projects are not subject to the requirements of 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, are 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 they 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. The Office for Human Research Protections concurs with this policy statement, and it is essential that such an interpretation be made available to the many IRBs currently grappling with issues of human subject research.

QUESTIONS AND ANSWERS

RESOURCE BIBLIOGRAPHY

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