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| From the **News** column of the December 2003 **Perspectives**

## 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 with the advice of the American Historical Association (AHA) and the Oral History Association (OHA), has determined "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)."

As one of the 17 federal agencies that have signed on to the Common Rule (45 CFR part 46), HHS deals most with the type of "clinical" research involving human subjects that the federal regulations were originally intended to cover. The policy, however, applies only to research that is funded by HHS or that takes place within institutions that have filed a multiple project compliance with OHRP. It does not apply to research funded by any of the other 16 signers of the common rule. However, according to Donald A. Ritchie of the Oral History Association, "the HHS determination along with the agency's concurrence with a policy statement drawn up by the OHA and AHA should pave the way for a uniform interpretation by other federal agencies."

Oral historians have long argued that federal regulations were developed mostly to protect human subjects in biomedical and behavioral research. Consequently, for several years, representatives of major professional historical associations have been working to persuade the federal research-protections office to "clarify" its definition of research as it applies to oral history scholarship and to make it clearer to IRBs what kinds of scholarship need be monitored.

During the October 2003 meeting of the OHA in Bethesda, Maryland, OHRP officials announced the agency's decision regarding the application of the common rule. Officials stated that these federal regulations define research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." It was explained that the type of research encompassed by the regulations involves standard questionnaires with a large sample of individuals who often remain anonymous, and not the open-ended interviews with identifiable individuals who give their interviews with "informed consent" that more typically characterize oral history research. Officials state that only those oral history projects that conform to the fairly narrow regulatory definition of "research" will now need to submit their research protocols for IRB review. Historians applauded the decision. According to Linda Shopes, a Pennsylvania Historical and Museum Commission historian who represented the AHA in talks with government officials, the federal office "heard our concern and has responded appropriately."

—Bruce Craig

*Editor's Note: See also correspondence on the subject in the [Letters to the Editor](#) column.*

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400 A Street, S.E., Washington, DC 20003-3889 | tel: (202) 544-2422 | fax: (202) 544-8307 | [contact us](#)

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