

The NIU research community has recently become aware of reports that the Department of Health and Human Services-Office for Human Research Protections (DHHS-OHRP) may have changed their guidance regarding Oral History types of research. The NIU Office of Research Compliance (ORC) contacted Dr. Michael Carome, DHHS-OHRP Associate Director for Regulatory Affairs, to discuss the reports and seek his guidance for education of the NIU research community and our IRBs regarding the reports and their impact on qualitative research utilizing open-ended interviews, especially activities performed by oral historians and other social scientists.

The discussion confirmed that communication between OHRP and the Oral History community does ***not*** change the DHHS interpretation of the Federal regulations for the protection of human subjects nor does it change NIU policy on such research.

The following information, confirmed by Dr. Carome, clarifies the reports and his [September 22, 2003 letter](#) to Ms. Linda Shopes, Pennsylvania Historical and Museum Commission and Mr. Donald Ritchie, Senate Historical Office. Included are helpful examples and general principles for evaluation of such research.

More formal guidance from OHRP is expected in 2004.

>>>E-mail message from Michael Carome <MCarome@OSOPHS.DHHS.GOV>
12/01/03 9:23 AM

Dear Ms. Bross,

Thank you for your thoughtful comments regarding oral history activities. Dr. Schwetz has asked me to respond to you on behalf the Office for Human Research Protections (OHRP).

As you are aware, representatives of oral history organizations earlier this year asked OHRP to review a policy statement that they had drafted regarding the relationship between research (as defined by the Department of Health and Human Services (HHS) regulations at 45 CFR 46.102(d)) and oral history activities. They also asked whether OHRP agreed with the content of their draft policy.

OHRP responded to the oral historians with a letter stating OHRP's concurrence with the draft policy statement that oral history activities in general do not involve research as defined by the HHS regulations and providing some suggested edits. I have attached a pdf file containing a copy of OHRP's letter below. Please note that the inclusion of the words "in general" in OHRP's response means that certain human subjects research activities may include oral history activities, and such research activities should be reviewed by an institutional review board (IRB) unless the research is exempt under HHS regulations at 45 CFR 46.101(b). Indeed, in its September 22 letter, OHRP noted 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.

Based upon comments that we have received since OHRP's letter regarding oral history activities was issued, it appears that many institutions and IRBs took the position that oral histories always involve research. Based upon the nature of oral histories, OHRP does not agree with such a position. As articulated in OHRP's letter, OHRP has taken the position that the activity of performing an oral history in and of itself does not make the activity research as defined by 45 CFR 46.102(d). OHRP could have issued a similar statement about many activities. For example, OHRP could have stated that activities that involve taking a medical history, a blood draw for serum chemistries, a chest x-ray, or a CT scan of the head in general do not involve human subjects research; however, when investigators conducting non-exempt human subjects research use such procedures, the research must be reviewed by an IRB if the research is conducted or supported by HHS or conducted under an applicable OHRP-approved assurance.

Some commenters have suggested that because oral history appears on the list of research activities that may be reviewed by the IRB under an expedited procedure, oral history activities must be research. In response, OHRP has noted that the fact that an activity, such as oral history, appears on the list of activities that may be reviewed by an IRB through an expedited review procedure does not mean that such an activity always involves research. For example, collection of blood samples; weighing or testing sensory acuity; magnetic resonance imaging; electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; moderate exercise, muscular strength testing, body composition assessment, and flexibility testing are also on the expedited review category list; however, the use of these procedures most commonly occurs outside the research context.

Some commenters have suggested that OHRP's comments regarding oral history activities can be extrapolated to all activities that involve open-ended, qualitative interviews. In response, OHRP has noted that its position regarding oral history was not based upon the fact that oral history activities involve open-ended, qualitative interviews of a nonrandom sample of individuals. Other activities involving open-ended interview that have characteristics similar to oral histories can involve research as defined by HHS regulations when the activities are part of a systematic investigation designed to develop or contribute to generalizable knowledge.

Finally, below is the content of an email that summarizes OHRP's discussion with officials at another institution about oral history activities that may provide you with

some additional helpful information:

History:

Issues regarding oral history and human subjects research date back to the National Commission and most recently emerged with NBAC, NHRPAC, and a letter from oral historians to OHRP.

The regulatory definition of research:

A decision whether oral history or other activities solely consisting of open ended qualitative type interviews are subject to the policies and regulations outlined in an institution's FWA and HHS regulations for the protection of human research subjects (45 CFR 46) is based on the prospective intent of the investigator and the definition of "research" under HHS regulations at 45 CFR 46.102(d): "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

Specifically, for the purposes of our discussion, the evaluation of such activities hinges upon whether the person is engaged in the creation of "generalizable knowledge" that is, whether the activity represents a systematic investigation in which the person engaged in such activities intends to develop or contribute to generalizable knowledge. However, 45 CFR 46 does not provide a definition of "generalizable knowledge". Oral history activities, as described to OHRP by the oral history representatives, in general are designed to create a record of specific historical events and, as such, are not intended to contribute to generalizable knowledge.

General principles for evaluating Oral History type activities:

1. Oral history activities, such as open ended interviews, that ONLY document a specific historical event or the experiences of individuals without an intent to draw conclusions or generalize findings would NOT constitute "research" as defined by HHS regulations 45 CFR part 46.

Example: An oral history video recording of interviews with holocaust survivors is created for viewing in the Holocaust Museum. The creation of the video tape does NOT intend to draw conclusions, inform policy, or generalize findings. The sole purpose is to create a historical record of specific personal events and experiences related to the Holocaust and provide a venue for Holocaust survivors to tell their stories.

2. Systematic investigations involving open-ended interviews that are designed to develop or contribute to generalizable knowledge (e.g., designed to draw conclusions, inform policy, or generalize findings) WOULD constitute "research" as defined by HHS

regulations at 45 CFR part 46.

Example: An open ended interview of surviving Gulf War veterans to document their experiences and to draw conclusions about their experiences, inform policy, or generalize findings.

3. Oral historians and qualitative investigators may want to create archives for the purpose of providing a resource for others to do research. Since the intent of the archive is to create a repository of information for other investigators to conduct research as defined by 45 CFR part 46, the creation of such an archive WOULD constitute research under 45 CFR part 46.

Example: Open ended interviews are conducted with surviving Negro League Baseball players in order to create an archive for future research. The creation of such an archive would constitute research under 45 CFR part 46 since the intent is to collect data for future research.

An institution should perform an initial two step evaluation prior to deciding whether an activity constitutes human subject research:

- a. determine whether the activity constitutes "research" as defined by 45 CFR 46.102(d), and
- b. determine whether the "research" includes human subjects as defined by 45 CFR 46.102(f).

In summary, the August 26, 2003 Policy Statement attached to OHRP's September 22, 2003 letter was not drafted by OHRP, does not constitute OHRP guidance, and the characterizations of oral history activities in the third paragraph of the Policy Statement alone do not provide sufficient basis for OHRP's determination that oral history activities in general do not involve research as defined by HHS regulations at 45 CFR part 46. Other activities involving open-ended interview that have similar characteristics can involve research as defined by the HHS regulations when the activities are part of a systematic investigation designed to develop or contribute to generalizable knowledge.

I hope this information is helpful. Please feel free to contact me if you would like to discuss this matter further.

Mike

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