

## Clarification of OHRP's Position on Oral History Information

Note: The following is from an email sent by Michael Carome, M.D., Associate Director for Regulatory Affairs, Office for Human Research Protections that clarifies the OHRP position on oral history research.

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Thanks for sharing this information. Regarding oral history activities, the OHA policy statement, and the UCLA posting on this topic, the following is OHRP's position on these matters:

As you are aware, in 2003 representatives of oral history organizations asked the Office for Human Research Protections (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 (see attached pdf file with copy of OHRP's September 22, 2003 letter).

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.

Regarding the outline of a discussion about oral history activities between OHRP and UCLA staff, OHRP concurs with the content of this outline and believes that this discussion does not contradict OHRP's position that oral history activities in general do not involve research as defined by HHS regulations.  
Feel free to share my message with others as needed.