



# MEMORANDUM

OFFICE FOR PROTECTION OF RESEARCH SUBJECTS  
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## **Outline of October 30, 2003 Discussion with Dr. Michael Carome, Associate Director, HHS-OHRP, Regarding Oral History, Qualitative Interviews, and Human Subjects Research**

### **History:**

Issues regarding oral history and human subjects research date back to the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research and most recently emerged with the National Bioethics Advisory Commission (NBAC), the National Human Research Protections Advisory Committee (NHRPAC), and a letter from oral historians to the Department of Health and Human Services - Office for Human Research Protections (HHS-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 Federalwide Assurance (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" in 45 CFR 46: "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."<sup>1</sup>

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 in 45 CFR 46.

ex: An oral history video recording of interviews with holocaust survivors is created for viewing in the Holocaust Museum. The creation of the videotape 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

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<sup>1</sup> 45 CFR 46.102(d)

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 46.

ex: 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 46, the creation of such an archive WOULD constitute research under 45 CFR 46.

ex: 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 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, and
- b. determine whether the "research" includes human subjects as defined by 45 CFR 46.<sup>2</sup>

In summary, the August 26, 2003 Policy Statement attached to [Dr. Carome'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 HHS regulations when the activities are part of a systematic investigation designed to develop or contribute to generalizable knowledge.

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<sup>2</sup> 45 CFR 46.102(f)