

Considerations for IRB Review of Oral History

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 this guidance, 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 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.

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.

Information on this topic from the Oral History Association is available at <http://www.oralhistory.org/about/do-oral-history/oral-history-and-irb-review/>.