

UB SBSIRB Policy on Oral History Projects

The social and Behavioral Sciences Institutional Review Board (SBSIRB) has been aware of reports that the Department of Health and Human Services-Office for Human Research Protections (HHS-OHRP) may have changed their guidance regarding Oral History types of research. After reviewing the clarifications provided by OHRP representatives along with policies posted on websites of a number of other Universities regarding projects that use the methodology of obtaining an oral history to obtain information, the University at Buffalo SBSIRB in conjunction with the Office of the Vice-President for Research (OVPR) has determined that the communication between OHRP and the Oral History community does not change the HHS interpretation of the Federal regulations for the protection of human subjects nor does it change UB policy on such research.

The following materials, extracted from the Northern Illinois University IRB website, documenting an e-mail from Dr. Michael Carome, HHS-OHRP Associate Director for Regulatory Affairs, provides clarification on the issue of when Oral History activities are considered 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."

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 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 46.2 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.

Based on this information, it is the institution's responsibility to determine if a project of any type involves research including human subjects and if so, for an IRB to review the research. The UB OVPR has designated the IRB to make this determination.

In making this determination for oral history projects the following rationale will be applied:

An oral history procedure by definition involves human participants so the operative question is, “Does the project meet the federal definition of research, a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge?” After data is collected, in order to contribute to generalizable knowledge, a project must involve two components, an analysis of the data to draw conclusions or generalizations and a method of recording and/or disseminating the information. If the answer to either of the following questions is no, then an oral history project would not constitute research and therefore not subject to the federal regulations requiring IRB review.

1. Is the project being conducted solely to document a specific historical event or the experiences of individuals without an intent to draw conclusions or generalize findings (note that any present or potential future analysis would make the answer to this question yes)?
2. Is there a record being produced that will potentially be publicly available (dissertation, thesis, paper, documentary film, website, audio library, etc.)?

In many cases the application of these two questions will result in a project qualifying as research. However, the SBSIRB has encountered cases when oral history projects do not qualify as research and provided confirmation of this to the project directors. In order to request a determination from the SBSIRB for a project that an investigator deems not to be research, a memo or e-mail should be submitted to the SBSIRB requesting this determination. In the memo the following must be described in detail:

1. The recruitment procedure.
2. The data collection procedure.
3. The procedures describing what will be done with the data after it is collected.
4. The anticipated final product(s) of the project and where the product(s) will reside.
5. The measure taken, if any, to protect confidentiality.
6. The risks presented to people, e.g., embarrassment, stigma, distress, invasion of privacy due to breaches of confidentiality.
7. The extent to which the standards of the field are consistent with the Belmont Report on the protection of people that volunteer for research.

The SBSIRB administrator in consultation with the SBSIRB chair or other members of the board will then respond in kind with a determination as to whether 1) a project does not require review, 2) a protocol must be submitted for review, or 3) if more information is needed before making a determination. This determination will be based upon the applicability of the definition of research and risks presented to people who participate in the project.