MU Position on IRB Review of Oral Histories and Related Projects

Background:

The following was patterned after a posting by the University of California—Los Angeles General Campus Institutional Review Board (GCIRB). The GCIRB contacted Dr. Michael Carome, Associate Director for Regulatory Affairs at the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP), to request guidance regarding recent reports from the Oral History Association. That 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 research subjects, nor does it change MU policy on such research.

Issues regarding oral history and human subjects research date back at least as far as the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research, the National Bioethics Advisory Commission, the National Human Research Protections Advisory Committee, and most recently a “proposed policy statement” from oral historians to the OHRP dated August 26, 2003, and attached to a letter from Dr. Carome dated September 22, 2003.

Regulatory Definition of Research:

Whether oral history or similar activities consisting of open-ended, qualitative interviews are subject to Institutional Review Board (IRB) oversight is based on the prospective intent of the investigator and the definition of “research” in 45 CFR 46.102(d) as a “systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”

The evaluation of whether such projects implicate IRB review thus hinges on whether the investigator is engaged in the creation of “generalizable” knowledge; that is, whether the activity represents a systematic investigation intended to develop or contribute to generalizable knowledge. The latter term is not defined in 45 CFR 46, but the sorts of activities described to OHRP by the Oral History Association representatives are intended to create a record of specific historical events and as such are not intended to contribute to generalizable knowledge. This is the same analysis that MU has applied to many journalistic activities.

General Principles for Evaluating:

1. Oral history and similar open ended interview activities that only document a specific historical event or the experiences of individuals, without an intent to draw conclusions or to generalize findings do not constitute “research” as defined in 45 CFR 46 and thus are not subject to IRB review.

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

**Example:** A journalist interviews various people and asks them about their opinions on the war in Iraq.

2. Systematic investigations involving open-ended interviews that are designed to develop or contribute to generalizable knowledge (that is, designed to draw conclusions, create policy or generalize findings) would constitute “research” that implicates IRB review.

**Example:** An open-ended interview of surviving Gulf War veterans intended to document their experiences and to draw conclusions about their experiences would constitute “generalizable” knowledge and thus meet the federal definition of “research.”

**Example:** An advertising journalist designs three video ads and then shows them to randomly selected individuals, who are then interviewed to determine which ad is most likely to influence a decision to purchase.

3. Oral historians and other qualitative investigators may want to create archives for the purpose of providing a resource for others to do research. Because 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 the archive is “research” that must be reviewed by the IRB.

**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 46 because the intent is to collect data for future research.

**Institutional Procedure:**

A two-step analysis is performed in determining whether an activity constitutes human-subjects research:

1. Determine whether the activity constitutes “research” as defined by 45 CFR 46.

2. Determine whether the activity involved living human subjects (45 CFR 46.102(f)).

If the activity does not involve living human subjects, it is not reviewable by the IRB (note that some decedents’ information may be protected under HIPAA). If the activity does not involve research, it is not reviewable by the IRB.

**Summary:**

The August 26, 2003, “policy statement” attached to Dr. Carome’s September 22nd letter 1) was not drafted by OHRP, 2) does not constitute OHRP guidance, and 3) the characterizations of oral history activities in the third paragraph of the “policy statement” alone do not provide a
sufficient basis for the claim that oral history activities in general are not “research” as defined in 45 CFR 46. Oral history, as well as other open-ended interviews, can implicate research as defined in federal regulations when such activities are part of a systematic investigation designed to develop or contribute to generalizable knowledge.