1.0 Purpose
The purpose of this policy is to clarify which oral history research activities conducted by the University of Nebraska-Lincoln (UNL) faculty, staff, and students require Institutional Review Board (IRB) review.

2.0 Definitions

2.1 “Human Subject”: A living individual about whom an investigator conducting research obtains (a) data through intervention or interaction with the individual, or (b) identifiable private information.

2.2 “Research”: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge

2.3 “Human Subjects Research”: “Research” involving “human subjects”.

2.4 “Oral History”: The National Oral History Association (OHA) defines oral history as “a method of gathering and preserving historical information through recorded interviews with participants in past events and ways of life”. Oral history is a recorded conversation about the past with named individuals in which knowledge about specific events and individual lives is narrated in story form and made available to the public though deposit in archives. Biographical in nature and historical in scope, the scholarly oral history interview is rooted in particular recollections about history based on the individual perspective of the narrator.

3.0 Background
This policy is consistent with the federal regulations for the protection of “human subjects” in “research” (45 CFR 46, Subpart A; i.e., the “Common Rule”), the policies of UNL Human Research Protections Program (HRPP), and the position of the Office of Human Research Protections (OHRP) of the U.S. Department of Health and Human services (HHS) on IRB review of oral history research as articulated in a letter, dated September 22, 2003 (letter can be found on-line at http://research.unl.edu/orr/forms.shtml).

3.1 Oral History Association (OHA) Guidelines
It is the policy of the HRPP that all oral history projects undertaken by UNL should be conducted in accordance with the guidelines established by the OHA for the ethical and professional practice of oral history. Such guidelines can be found in full at http://alpha.dickinson.edu/oha/pub_eg.html.

3.2 OHRP Position
In the September 22, 2003 letter, OHRP stated that it concurred with the policy, dated August 26, 2003, proposed by the OHA and the American Historical Association that oral history interviewing activities, in general, are not designed to contribute to generalizable knowledge and, therefore, do not involve “research” as defined by 45 CFR 46.102 (d). Thus, such activities that do not constitute “human subjects research” do not need to be reviewed by an IRB. OHRP clarified in the 2003 letter that some investigators may use oral history interviewing procedures in a manner which would be considered “human subjects research” as defined by 45 CFR 46.

3.3 University Policy

Oral history activities conducted by UNL faculty and students are not required to be submitted for UNL IRB review unless such activities constitute “human subjects research” as defined by 45 CFR 46.

Oral history activities conducted by UNL faculty and students that meet the definition of “human subjects research” must be submitted to the UNL IRB for review.

Determining what constitutes “human subjects research” rests on whether the activities are part of a systematic investigation designed to contribute to generalizable knowledge. As the regulations have not defined “generalizable knowledge”, one has to examine particular oral history activities on a spectrum.

Oral history interviews, that only document specific historical events or the experiences of individuals or communities over different time periods would not constitute “human subjects research” as they would not support or lead to the development of a hypothesis in a manner that would have predictive value. The collection of such information, like journalism, is generally considered to be a biography, documentary, or a historical record of the individual’s life or experience; or of historical events. Oral history interviews of individuals are not usually intended to be scientific or to produce generalizable information and hence are not usually considered “research” in accordance with the federal regulations or UNL policy. Therefore, such oral history activities should not be submitted to the UNL IRB for review.

On the other hand, oral history activities that are conducted in the context of systematic investigations involving interviews that are designed to elicit generalizable information regarding living individuals are likely to constitute “human subjects research”. Hence, the latter activities must be submitted to the IRB for review and prospective approval.

4.0 Examples of Oral History Activities that Do or Do Not Require IRB Review

4.1 Oral History Activities Not Considered “Human Subjects Research”

Oral history activities, such as interviews that serve only to document an individual’s life history or general reflections on past events are not considered “human subjects research.”

Example: Veterans Oral History Project
A student is planning a dissertation on the long term social impact of the Vietnam War on American culture. The student wants to conduct life histories of a group of veterans for the sake of documenting the broad meaning of the war on the rest of their lives. The interviews will be contributed to the Veterans Oral History Project at the Smithsonian Institution which offers professional training to oral historians, the costs of which were underwritten by Congress. To ensure that oral histories are conducted in a professional manner the student will follow the protocols and guidance developed for this project by the Smithsonian, as well as the guidelines of the national Oral History Association.

Rationale:

The above project does not require IRB approval because based on the information provided in the example the information collected from the interviews is not a systematic investigation (it is not intended to address a hypothesis). Furthermore, it is neither intended nor likely to contribute to generalizable knowledge.

Other details, such as the external financial support for the oral history activity and following the OHA or sponsor’s guidelines are irrelevant in determining whether IRB approval is required by the UNL IRB. Of course, the conduct of oral histories by UNL faculty, staff, or students should follow the OHA guidelines.

4.2 Oral History Activities Considered “Human Subjects Research”

Systematic investigations involving open-ended interviews that are designed to develop or contribute to generalizable knowledge (e.g., designed to draw conclusions in an effort to address a hypothesis or serve to collect pilot data for a future “research” study) WOULD constitute “research” as defined by HHS regulations at 45 CFR Part 46, and therefore does need to be submitted for IRB review.

Example: Long-term Post-Traumatic Stress Disorder in Vietnam War Veterans

A faculty member is planning to conduct oral histories to gain an understanding of the impacts of the Vietnam War on post-traumatic stress disorder. The faculty member wants to work with a veterans Post-Traumatic-Stress-Disorder [PTSD] support group to take life histories to see how the war influenced the rest of the veterans’ lives. The group agrees in writing to allow the faculty member to meet with the members as a part of the group, and individually. One goal of the research, in addition to understanding general ways in which the war affected the subsequent lives of soldiers, is to make assessments that will allow the faculty member to predict what kinds of exposure in war situations leads to the development of PTSD. In order to prepare for this analysis, the faculty member will consult published research done on PTSD with reference to Vietnam veterans, and will use PTSD related materials specific to the individuals in the group. While the veterans want to contribute their memories to the national Veterans oral history project run by the Smithsonian, they want to keep specific information which would link PTSD material to their life histories private. The faculty member and/or the psychiatrist who runs the group plans to use the data collected through these life histories to prepare a scientific presentation.
Rationale:

The above project does require prospective IRB approval because based on the information provided the information that will be collected from the interviewees will be designed to contribute to generalizable knowledge.

The veterans’ interest to keep specific information which would link PTSD material to their life histories private is irrelevant to the determination that this project needs IRB approval. Such consideration would be taken even for projects that do not require IRB approval.

5.0 Consultation

5.1 Questions as to whether any particular oral history projects involve “human subjects research” may be addressed to the UNL IRB by email or phone.

<table>
<thead>
<tr>
<th>Administrative Approval:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mario Scalora, Ph.D.</td>
</tr>
<tr>
<td>IRB Chair</td>
</tr>
</tbody>
</table>