Oral History Guidance Document

Goal- To elucidate the IRB's decision-making process for determining when IRB review of oral history projects is required.

Guidance from the Office of Human Research Protections (OHRP) – OHRP issued a letter in September 2003 indicating that they agree that "...oral history interviewing activities, in general, are not designed to contribute to generalizable knowledge and, therefore, do not involve research as defined by the Department of Health and Human Services (HHS) regulations at 45 CFR 46.102(d) and do not need to be reviewed by an institutional review board (IRB)". The letter goes on to note that "...investigators conducting human subjects research as defined by the HHS regulations may use oral history interviewing procedures" and such research would require review by an IRB unless it is determined by an IRB to be exempt.

UWM IRB Guidance:

The UWM IRB understands that there are two types of oral history projects:

Type 1: Oral history projects where the goal is to document a historical event or an individual's experience and the results are not intended to create generalizable knowledge or conclusions.

This type of study would not meet the OHRP definition of research ("a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable* knowledge" -45 CFR 46.102 (d)) and IRB review would not be required. Investigators conducting oral history projects that fall outside the purview of the IRB should ensure that they are following the guidelines and best practices of the Oral History Association (http://www.oralhistory.org/about/principles-and-practices/). If a formal determination that the study does not need IRB approval is needed, please complete and submit a "Determination of UWM IRB submission" form (http://uwm.edu/irb/submission/do-you-need-to-submit-to-the-irb/)

Type 2: This would be either: **a**) an oral history study where the results were going to be analyzed and used to create generalized understanding* of an event or experience with the hope of using that knowledge to understand current or future events; **b**) collection of oral history interviews with the intent of depositing them into an archive which others could access for research purposes.

This type of study would meet the OHRP definition of research (45 CFR 46.102 (d)) and would need to be submitted to the IRB for review and approval. Please see the UWM IRB website for submission instructions (http://uwm.edu/irb/submission/submission-instructions/)

- *"Generalizable/generalized understanding" are commonly defined as being applicable to a wider population than those individuals from whom the data were collected.
- **If you are unsure if your project will need IRB review and approval, please complete and submit the UWM determination of Human Subjects Research form or contact the IRB Office with questions.

Helpful link:

Oral History Association: http://www.oralhistory.org/