

Overview

According to the Office of Human Research Protections (OHRP) of the U.S. Department of Health and Human Subjects (HHS), human subjects research is “an activity that is a systematic investigation designed to develop or contribute to generalizable knowledge” [45 CFR 46.102 (d)]. Oral history can be conducted for a variety of purposes and can fall under this definition.

Basic Terms and Definitions

Defining “vulnerable: populations: The UNG IRB defines the following groups as “vulnerable” populations:

- C1: prisoners
- C2: minors /under age 18
- C3: poor/uninsured
- C4: immigrants
- C5: limited or non-readers
- C6: wards of the state (e.g., foster children)
- C7: pregnant women
- C8: elderly/nursing home residents recruited in a nursing home
- C9: students of principle investigator (PI) or staff/research team
- C10: students in an education setting, (i.e., in class or at school)
- C11: employees supervised by PI or research team member
- C12: employees of research site or sponsor
- C13: military personnel to be recruited by military personnel
- C14: cognitively impaired
- C15: adult subjects who cannot consent for themselves
- C16: others, please specify _____

(From: IRB Form 1.1: Application for Approval of Research)

Specific Guidelines

Scholarly Research Projects:

- 1) Is the researcher conducting oral history interview(s) to gather first-hand information to answer a scholarly research question or to test a hypothesis?
- 2) Does the researcher plan to publish his/her work in a scholarly thesis (undergraduate, Masters, or Ph.D. dissertation), journal, book, or other peer-reviewed, publically-available publication?

IRB Review? If YES to 1 and 2, the project is a systematic investigation designed to develop and contribute to generalizable knowledge and requires **EXPEDITED OR FULL** IRB review.

Archival Collection and Preservation:

- 1) Is the researcher conducting oral history interview(s) to create or contribute to an archival collection of first-hand narratives about the past?
- 2) Will the researcher analyze or interpret oral history to construct a generalizable narrative about the past?

IRB Review? If YES to #1 and NO to #2, the project is not a systematic investigation designed to develop and contribute to generalizable knowledge and thus does not constitute research as defined by OHRP guidelines. No IRB review is needed. . Although the project will not undergo formal IRB review, project directors must be familiar with Principles and Best Practices for Oral History and ensure that project protocols adhere to these standards: <http://www.oralhistory.org/about/principles-and-practices/>

If YES to #1 and YES to #2, the project is a systematic investigation designed to develop and contribute to generalizable knowledge and requires **EXPEDITED OR FULL** IRB review.

EXCEPTION TO this policy: Will the project involve participants that are defined as “vulnerable populations” and/or will the project place participants at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation?

IRB Review? If yes, the project requires **FULL** IRB review regardless of the purpose of the project.

IRB Review Process:

For oral history projects that require IRB review, UNG researchers must complete and submit the following to the UNG IRB Chair:

- IRB Form 1.1: Application for Approval of Research with Human Research Participants
- IRB Form 3.1: Informed Consent Forms
- CITI/NIH Training certificates for all researchers

All forms can be accessed at: <http://ung.edu/institutional-review-board/forms.php>

For non-UNG researchers and/or UNG researchers that have obtained IRB approval from another university/institutions, please submit the following documents to the IRB:

- IRB Form 3.1: Simplified IRB Application
- a copy of the existing IRB approval
- a copy of the complete original IRB application (with informed consent documents etc.)

CITI/NIH Training certificates for all researchers?

The IRB will determine if the project receives expedited review or full review.

- **For EXPEDITED review:** The project must meet ALL of the following criteria:
 - Involves procedures listed in one or more of OHRP Categories of Research that may be reviewed through expedited review (specifically: Category 6 – Collection of data from voice, video, digital, or image recordings for research purposes, and Category 7 – Research on individuals or group characteristics or behavior ... or research employing ... oral history. For more information: <http://www.hhs.gov/ohrp/policy/expedited98.html>)
 - Does not involve participants from defined “vulnerable” populations.
 - Does not place the participants at risk of criminal or civil liability or would be damaging to the subjects’ financial standing, employability, or reputation.
 - Includes protections so that risks related to invasion of privacy or breach of confidentiality are no greater than minimal.

- Ensures voluntary participation without penalty for withdrawing participation before the project is completed.
- **For FULL review:** The project must meet AT LEAST ONE of these criteria:
 - Involves participants from defined “vulnerable” populations
 - Places the participants at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation
 - Does not include protections so that risks related to invasion of privacy or breach of confidentiality are no greater than minimal.

The IRB will review the project application and decide to:

- Approve the application without modifications or clarification
- Request more detailed information or clarification of methodology and/or planned use of oral history testimony.
- Deny approval for the project with clear explanation of reasons for rejection.

If you need this document in another format, please email irbchair@ung.edu or call 706-867-2969.