



## Human Research Participant Protection Program

### Guidance on IRB Review of Projects Collecting Oral (or Life) Histories, Journalism or Case Studies

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#### I. Subject

Some research involving the collection and use of oral histories or life histories may not meet the federal definition of 'human subjects research' and therefore may not require involvement of the IRB office; other research using the same methods may meet this definition of human subjects research and can be exempted from IRB review; and some may require IRB review. Likewise, determining whether journalism projects or the development of case studies is subject to oversight by the IRB office is not always clear. This document is intended to provide guidance on the policies that govern whether projects in the areas of oral history, journalism or case study development constitute human subject research as defined under the Federal Regulations. Investigators should contact the [IRB office \(irbhp@cornell.edu\)](mailto:irbhp@cornell.edu) if they have further questions about this guidance or how it applies to their particular research project.

#### II. Scope

This document provides guidance on applying IRB policy 'Determining whether a research activity needs IRB review and approval: [SOP#1](#)' to the use of oral history or life history techniques, journalism and case studies.

If funders of sponsored research (e.g. the National Institutes of Health) require IRB approval or certification of exemption from IRB review as a condition of the award, that requirement takes precedence over this guidance.

#### III. Terms and Definitions (please see the Cornell IRB [glossary for more definitions](#))

- Research is a 'systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.'<sup>1</sup>
- Generalizable knowledge has not been explicitly defined in federal regulations, but can be: a) applied to individuals outside the research sample; b) predictive of future events; or c) widely applied as theories or principles that enhance scientific or academic understanding<sup>2</sup>; or d) create general explanations about *all* that has happened in the past.
- Human Subjects or Human Participants are 'living individuals about whom an investigator (whether professional or student) conducting research obtains:

1. data through intervention or interaction with the individual or
  2. identifiable private information.<sup>1</sup>
- Interaction: ‘includes communication or interpersonal contact between investigator and subject.’<sup>1</sup>
  - Human Subjects Research is ‘research’ involving ‘human subjects’ (as defined above).
  - 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 through 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.<sup>3</sup>
  - Life histories (or life stories): include ‘any retrospective account by the individual of his [or her] life in whole or part, in written or oral form, that has been elicited or prompted by another person.’<sup>4</sup> Life stories intend ‘to show something about the kind of person a speaker is.’<sup>5</sup>
  - Case studies are in-depth explorations of a particular project, policy, institution, program or system in a ‘real life’ context.<sup>6</sup> Case studies are sometimes developed for classroom instruction using the ‘case method’.
  - Journalism includes activities focused on the collection, verification, and reporting of information or facts on current events, trends, newsworthy issues or stories about people or events, with no intent to develop or test a hypothesis.<sup>7</sup>

#### IV. Guidance

Determining whether research in oral history, journalism or case study development constitutes federally-regulated ‘human subjects research’ rests on whether the activities are part of a systematic investigation designed to contribute to generalizable knowledge.<sup>8</sup>

##### 1. Projects that *only* document or report

Projects that only document or report on events, situations, policies, institutions or systems without the intent to form hypotheses, draw conclusions, or generalize findings outside the sample are generally not considered research with human participants as defined in the federal regulations. These include:

- Case studies developed for pedagogical use, such as those commonly used in business and law schools
- Reporting of current events, trends, newsworthy issues or stories about people or events, such as those presented in the news, magazines and non-scholarly periodicals
- Oral history interviews that document specific historical events or the experiences of

individuals or communities over periods of time

Example: Veterans Oral History Project<sup>8</sup>

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 what the war meant in the rest of their lives. The interviews will be contributed to the Veterans Oral History Project at the Smithsonian Institution.

Rationale:

The project, as described above, is not considered research with human subjects because the information collected from the interviews is not intended to develop or contribute to generalizable knowledge.

Investigators undertaking such projects **do not need to take any action with the IRB office**. Investigators should continue to exercise professional ethics appropriate to the field.

## **2. Projects that intend to develop generalized knowledge**

Systematic investigations involving interviews that are designed to develop or contribute to generalizable knowledge are 'research' under federal definitions, and need to be assessed for potential risk to participants. Much research using oral history or life history methods involves **minimal risk to participants**. A risk is minimal when the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of any proposed activities if they occurred outside the research context.<sup>1</sup> Talking with participants about past events and life experiences, even unpleasant ones, is generally not considered more than minimal risk.

Such studies include:

- Ethnographic studies designed to describe human beliefs or behaviors in a specific cultural setting<sup>9</sup>
- Studies that use multiple case studies to draw conclusions that are applicable in a generalizable context, or to address a hypothesis
- Reporting intended to draw conclusions in an effort to influence public policy or opinion

Example: Returning Veterans Employment Study

A post-doc is planning a study on the transition from active military service to civilian life, and the long term economic impact of war on the lives of American veterans. The post-doc wants to conduct life histories of a group of veterans, including their experiences job hunting immediately following active service, and their employment history before and after active service. The interviews will be contributed to the Veterans Oral History Project at the Smithsonian Institution. Findings would be used to better target future employment-related services provided by the Veterans

Administration.

Rationale:

Based on the information provided, this project would collect information that is designed to contribute to generalizable knowledge. Information gained through the interviews would be used to predict the behavior and circumstance of future veterans, and to tailor service for those future veterans. However, it is unlikely that the disclosure of the interview data would reasonably place the participants at risk. The above project does require submission of an application to the IRB office, but is likely to be considered exempt from further IRB review.

Researchers conducting projects that involve oral and life history interviews that meet the regulatory definition of human subject research but pose minimal risk to participants should submit a [Request for Exemption](#) from IRB review to the IRB office. Research can begin once a certification of exemption is issued by the IRB office.

It is possible that participating in research that uses oral history or life history methods could place participants at greater risk, or face a different type of risk, than they would in their daily lives. The most likely **risk from research** in studies that use oral or life history techniques, case studies or journalism is that the “disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.”<sup>1</sup>

Such risks might include:

- Being seen speaking to the investigator of a study of historical changes in HIV-related drug availability might inadvertently disclose an individual’s health condition.
- Investigators may ask about sensitive topics such as participants’ criminal activity or unethical behavior, or may obtain other information that is perilous or stigmatizing in the cultural context in which the research takes place.

For projects with such risk, the IRB will want details about the data security provisions of the planned archive, in addition to other information and materials described in the application for IRB review.

Example: Post-Traumatic Stress Disorder in Veterans<sup>8</sup>

A faculty member is planning to conduct oral histories to gain an understanding of the impacts of 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 war has 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 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. 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 plans to use the data collected through these life histories to prepare a scientific presentation.

Rationale:

The above project does require IRB approval because, based on the information provided, the information that will be collected from the interviewees is designed to contribute to generalizable knowledge. Further, the accidental disclosure of individually identifiable private health information, such as about PTSD, could damage the participant's financial standing, employability, or reputation. This study requires IRB oversight of research procedures including the data security measures put in place by the investigator to minimize any risk of disclosure.

Researchers should make a preliminary assessment of risk to participants, and submit an [Initial Approval Request](#) to the IRB office for review. Research can begin once an approval is issued by the IRB office.

## V. References

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<sup>1</sup> 45 CFR 46.102 <http://www.hhs.gov/ohrp/policy/ohrpreulations.pdf>

<sup>2</sup> Adapted from: University of California-San Diego, Human Research Protections Program, Oral History/Journalism Fact Sheet (2013). Available at: [http://irb.ucsd.edu/History\\_Journalism.pdf](http://irb.ucsd.edu/History_Journalism.pdf). Accessed 3/5/2014.

<sup>3</sup> Shopes, Linda. Oral History, Human Subjects, and Institutional Review Boards (date unknown). Available at: <http://www.oralhistory.org/about/do-oral-history/oral-history-and-irb-review/>. Accessed 1/13/2014.

<sup>4</sup> Watson, LC and Watson-Franke, MB (1985). *Interpreting Life Histories: An Anthropological Enquiry*. New Jersey: Rutgers University Press.

<sup>5</sup> Linde, Charlotte (1993). *Life Stories: The Creation of Coherence*. New York, NY: Oxford University Press. p. 22.

<sup>6</sup> Simons, H. (2009). *Case study research in practice*. London: SAGE.

<sup>7</sup> Adapted from University of California Los Angeles, Office of Human Research Protection Program (2013). *Guidance: Determining Which Activities Require UCLA OHRPP/IRB Review*. Available at: [http://ora.research.ucla.edu/OHRPP/Documents/Policy/3/Activities\\_Requiring\\_Review.pdf](http://ora.research.ucla.edu/OHRPP/Documents/Policy/3/Activities_Requiring_Review.pdf). Accessed: 3/17/14.

<sup>8</sup> Adapted from: Columbia University Institutional Review Board Policy: IRB Review of Oral History Projects. Available at:

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<http://www.columbia.edu/cu/irb/policies/documents/OralHistoryPolicy.FINAL.012308.pdf>  
Accessed 1/13/2014.

<sup>9</sup> American Anthropological Association Statement on Ethnography and Institutional Review Boards (2004). Available at: <http://www.aaanet.org/stmts/irb.htm> Accessed 2/17/2014.