

SOP 1.2.1 **Histories and Journalism**

General Description:

Many projects involving histories or journalism methods are not likely to meet the definition of “research” stated in the Department of Health and Human Services (HHS) Regulations for the Protection of Human Subjects at [45 CFR Part 46, Subpart A](#): “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” The regulations state that “scholarly and journalistic activities (*e.g.*, oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected” are deemed not to be research, and therefore these projects do not need to be submitted to the IRB for review.

Historians and journalists typically use collected information to explain past or current events but not to create theories, principles, or statements of relationships that are predictive of future events or that can be widely applied. Such activities would not be considered “generalizable knowledge.”

However, when projects at Mason are, in fact, designed to develop or contribute to generalizable knowledge, such projects must be submitted to the IRB office. Upon submission, such projects may be granted exemption from IRB review, handled through the expedited review process, or reviewed by the full IRB, as appropriate.

Oral history projects conducted by, or under the supervision of, Mason faculty, staff or students should be conducted in accordance with the guidelines established by the [Oral History Association Principles and Best Practices](#). Journalism projects conducted by, or under the supervision of, Mason faculty, staff or students should be conducted in accordance with the [Society of Professional Journalists Code of Ethics](#). A flow chart and examples, intended to be helpful in this evaluation, are provided at the end of this SOP.

Procedures:

1. **Determination of whether the project is Human Subjects Research.** When formulating the project, the investigators should consider whether the project meets the federal definition of research with human subjects. The IRB offers a Human Subjects Determination form (available in IRBNet) to help researchers make this determination.
 - a. If yes, a qualified PI must submit a full IRB application for IRB review and approval through IRBNet.
 - b. If no, then an IRB application is not required.

2. **Optional: Formal documentation**
 - a. If funders, publications or other entities require formal documentation, the PI may submit a Human Subjects Research Determination form to the IRB office through IRBNet to request a formal letter of acknowledgement as verification that the project does not require prospective IRB review and approval.
 - b. The PI must provide the IRB office with the Human Subjects Determination form that includes a detailed summary of the project.
 - c. Provided that the IRB staff agrees with the determination that the project does not meet the definition of human subjects research and does not require IRB review, staff will issue the formal documentation to the PI through IRBNet within 10 business days of receipt of request and summary.

Acknowledgement:

The UCSD Human Research Protection Program is gratefully acknowledged for the use of language from their Oral History/Journalism Projects Fact Sheet available at: http://irb.ucsd.edu/History_Journalism.pdf. The Columbia University IRB is gratefully acknowledged for the use of their examples from their IRB Review of Oral History Projects Policy.

References:

- 45 CFR 46.102

Related Forms, Guidance, and SOPs:

- 2.1.2 Determination of activities that require IRB review
- OHRP Guidance on Engagement of Institutions in Human Subjects Research
- OHRP Human Subject Regulations Decision Charts
- Waiver of Consent; 45 CFR 46.116(d)

Responsibility:

Execution of SOP:
Principal Investigator
Study Team Members
IRB office/Research Development, Integrity and Assurance
Institutional Review Board

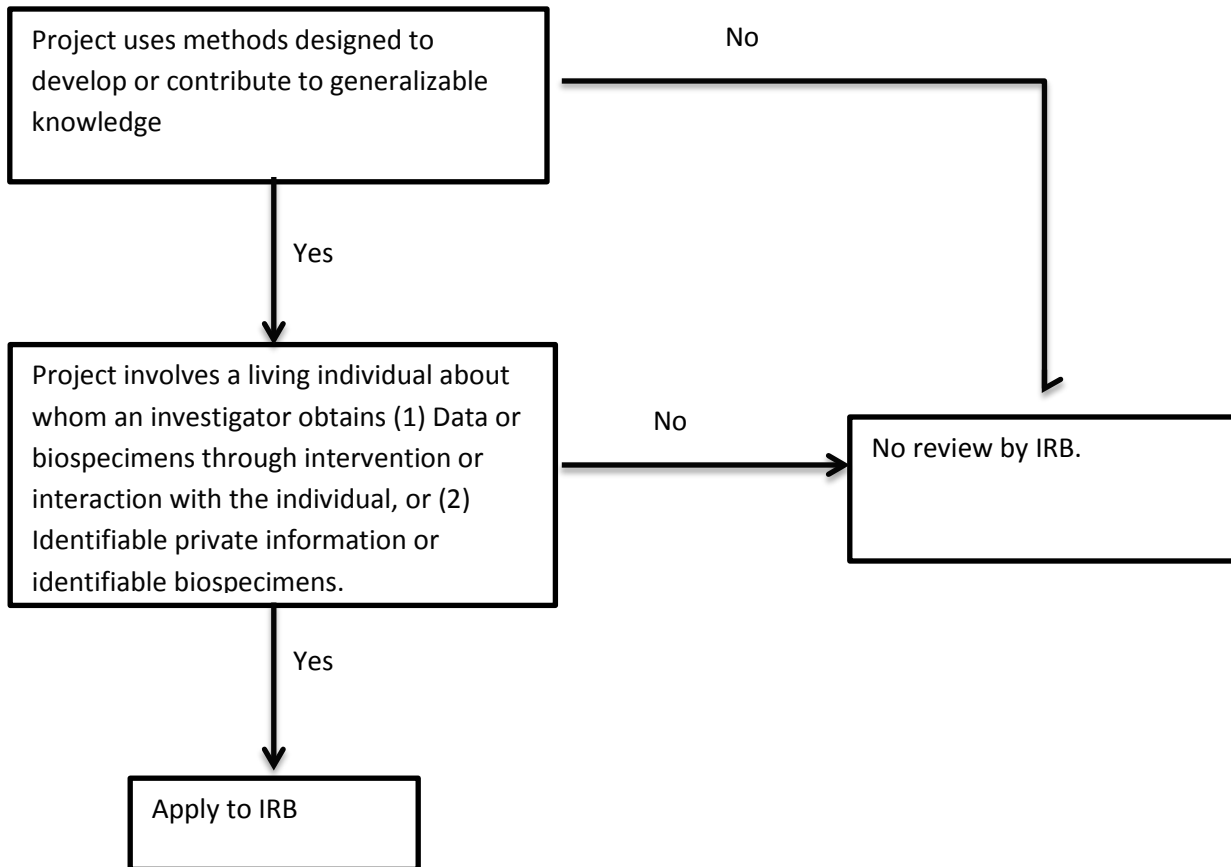
Approval and Version History:

Please contact irb@gmu.edu if you have any questions about this policy or the version and approval history.

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Approved By	Title and Division	Date Approved
Aurali Dade	Associate Vice President, Research Development, Integrity and Assurance	January 21, 2019
Laurie Meamber	IRB Chairperson	January 21, 2019

Decision Flowchart



Examples:

A. 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 in the rest of their lives. The interviews will be contributed to the Veterans Oral History Project at the Library of Congress 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 Library of Congress, as well as the guidelines of the national Oral History Association (OHA).

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 sponsor's guidelines are irrelevant in determining whether IRB approval is required by the Mason IRB. Of course, the conduct of oral histories by Mason faculty, staff, or students should follow the OHA guidelines.

B. 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 Library of Congress, 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 IRB review and approval because the project involves a systematic investigation and interaction with living individuals with the goal of contributing to generalizable knowledge.