

# IRB Guidance for Oral History, Journalism, Biography, and Historical Scholarship Projects

## Purpose:

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Federal regulations set forth by the Office for Human Research Protections (OHRP) within the U.S. Department of Health and Human Services (HHS), known as the “Common Rule,” as well as Iowa State University Policy require prior review and approval by the Institutional Review Board (IRB) for all projects that involve *Research with Human* participants.

The information in this guidance is intended to aid investigators in the sometimes complex determination of whether oral history, journalism, biography, historical scholarship, and other similar projects may be subject to IRB oversight.

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## Definitions

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**Biography** – documentation (typically written) of an individuals’ life or experiences

**Generalizable Knowledge** – activities that attempt to make comparisons or draw conclusions based on the data; seek underlying principles that have predictive value and can be applied to other circumstances; develop or test scientific theories or hypotheses; identify general explanations or themes that can be extrapolated to another situation.

**Human Subject** – a living individual about whom and investigator conducting research obtains

- i) information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens; or
- ii) obtains, uses, studies, analyzes, or generates identifiable private information or biospecimens

**Identifiable information** – the identity of the subject is, or may be readily ascertained (directly or indirectly) by the investigator (or others) or associated with the information.

**Interaction** –communication or interpersonal contact between investigator and subject.

**Intervention** -- includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

**Journalism** -- the activity of gathering, assessing, creating, and presenting news and information. It is also the product of these activities.<sup>1</sup>

**Oral History** -- field of study and a method of gathering, preserving, and interpreting the voices and memories of people, communities, and participants in past events.<sup>2</sup>

**Private information** -- information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, as well as information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.

**Research** -- a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

**Scholarship** -- creative, systematic, rational inquiry into a topic and the honest, forthright application or exposition of conclusions drawn from that inquiry. It builds on existing knowledge and employs critical analysis and judgment to enhance understanding.<sup>3</sup>

## What does the IRB Oversee?

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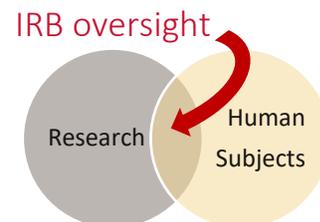
Projects subject to IRB oversight are those that meet the federal definitions for both “research” and “human subjects.” The federal definition for “research” may differ from how disciplines define work or projects within their field.

Current federal regulations governing human subjects research, known as the 2018 Revised Common Rule, provide the following definitions:

**Research** – a *systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge*.<sup>4</sup>

**Human subject** – A living individual about whom an investigator (whether professional or student) conducting research obtains:

- (1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- (2) Obtains, uses, studies, analyzes, or generates identifiable private information or biospecimens.<sup>5</sup>



Order is important when making this assessment, as reversal can yield different results. The first consideration is whether the proposed project is “**research**.”

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<sup>1</sup> American Press Institute | What is journalism <https://www.americanpressinstitute.org/journalism-essentials/what-is-journalism/>

<sup>2</sup> Oral History Association (OHA) | Oral History: Defined <https://www.oralhistory.org/about/do-oral-history/>

<sup>3</sup> Iowa State University | Faculty Handbook | January 2020

<sup>4</sup> 45 CFR 46.102(l)

<sup>5</sup> 45 CFR 46.102(e)

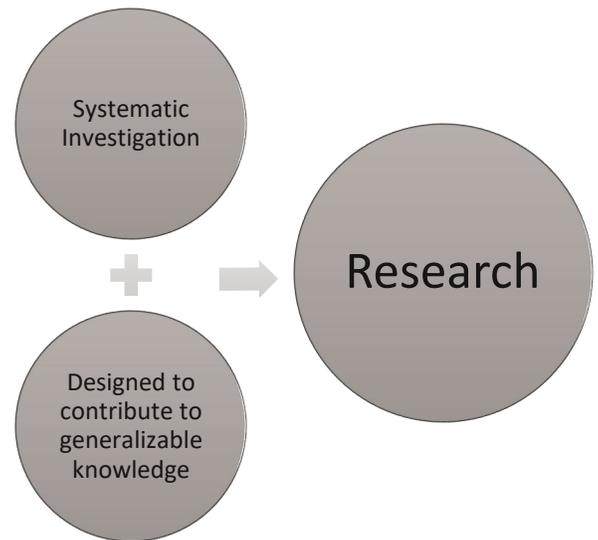
## Is it “research”?

Oral history, journalism, biography, historical scholarship, and other similar projects frequently involve interactions with, and the collection of information from, people in ways that are not considered to be *research* with human subjects. A project must involve both a *systematic investigation* and be *designed to contribute to generalizable knowledge* to meet the definition of “research.”

*Systematic investigation* means that a plan is followed to gather information. The methods and organization of these plans for qualitative and quantitative research can look very different, but in both types of research the investigator has a plan that includes ideas about what they would like to learn and how they intend to do it.

In general, activities that contribute to *generalizable knowledge* are those that:

- attempt to make comparisons or draw conclusions based on the data;
- seek underlying principles that have predictive value and can be applied to other circumstances;
- develop or test scientific theories or hypotheses;
- identify general explanations or themes that can extrapolated to another situation.



### 2018 Revised Common Rule: Activities deemed “not research”

The 2018 Revised Common Rule (effective January 21, 2019) includes a clause in the definition of research outlining examples of activities that are deemed not to be *research*, and as such not subject to IRB oversight.

*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. 45 CFR 46.102(l)(1)*

While official guidance related to interpretation of this clause has not been released, draft federal guidance<sup>6</sup> and the preamble to the updated 2018 Common Rule<sup>7</sup> provide some direction regarding intended interpretation. The preamble indicates that the scholarly and journalistic activities are excluded from the definition of IRB-overseen research when the collection and use of the information is limited to recounting or documenting information about specific individuals themselves and is not for generalizing to other individuals, groups, or situations.

Additional preamble discussion clarifies that when “investigators gather information from individuals...and the findings apply to the study community or group, and not just the individuals from whom the information was obtained, [the activities] fall within the scope of the definition of research”<sup>8</sup> such that IRB oversight would be required.

<sup>6</sup> HHS | OHRP Draft Guidance *Scholarly and Journalistic Activities deemed not to be research*

<sup>7</sup> Federal Register/Vol. 82, No. 12, January 19, 2017 pgs 7174-7175

<sup>8</sup> Federal Register/Vol. 82, No. 12, January 19, 2017 pg 7175

The 2018 Revised Common Rule regulations do not provide blanket exclusion of IRB oversight for the entire disciplines of Oral History, Journalism, Biography, etc.; rather the aim is to acknowledge and highlight *examples* of fields that commonly conduct activities that fall outside of the IRB's regulatory responsibilities. Those disciplines explicitly cited in the regulations serve as *examples* of fields that frequently collect and use information about specific individuals themselves with an objective of providing an accurate and evidence-based portrayal of the individual rather than generalizing to other individuals or groups. These examples are not intended to imply that all activities within a given discipline or using a certain methodology always fall outside of IRB oversight.

*It is not the particular field that removes the activity from the definition, but rather that the purpose and design of the particular activity is to focus on specific individuals and not to extend the activity's findings to other individuals or groups.*

*-OHRP Draft Guidance (July 19, 2018)*

Quite often, historians, biographers, and journalists conduct interviews that serve to document an individual's life history or individuals' reflections on past events with aim of documenting an individual's experiences. These activities are typically not considered to be federally-defined research because of their narrow specificity - they are not designed to contribute to generalizable knowledge. *In these cases, IRB approval is not required.* Conversely, the same activities would require IRB approval when those activities also constitute federally-defined research (i.e., the oral history interviews are obtained to answer research questions, draw broadly-applicable conclusions, test or contribute to scientific theories/hypotheses, are for a student's thesis or dissertation research, etc.).

## Examples:

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1. Oral history activities that document a specific historical event or the experiences of individuals but are not designed to draw conclusions or generalize findings.

*A faculty member creates a collection of videos of open-ended interviews of nursing home residents experiencing shelter-in-place and lockdowns during the COVID-19 pandemic. The sole purpose of the videos is to create a historical record of personal events and experiences during this time. The information will not be analyzed to inform policy, draw conclusions, or generalize the experiences to a larger population.*

- The above example would not meet the federal definition of *research* (not designed to contribute to generalizable knowledge). IRB oversight would not be required.

2. An oral history project involving open-ended interviews designed to draw conclusions about experiences or generalize to other contexts, individuals, or populations.

*A faculty member is planning to conduct oral histories to gain an understanding of the impacts of 9/11 on post-traumatic stress disorder. The faculty member wants to work with support groups to take life histories to see how events of 9/11 impacted the rest of their lives. One goal of the project, in addition to*

*understanding general ways in which 9/11 affected the subsequent lives of individuals, is to make assessments that will allow the faculty member to make predictions about the kind of situations that may contribute to development of PTSD.*

- 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.
3. A biographer collects information and conducts interviews to create an account of an individual's life events.

*A biographer gathers documents/artifacts, analyzes speeches, reviews news articles, collects photographs, conducts interviews with the governor, aides, supporters and detractors, state representatives, and family members, to publish an account of her term in office.*

- As summarized above, the interviews and data collection would not be considered *research* as the purpose is to document an individual's experience as governor and not to draw conclusions generalizable to others. As described, this project would not require IRB oversight.

*However, the same biographer, using the same methodology (gathering artifacts, analyzing speeches, conducting interviews, etc.) but now with the aim of conducting an intersectional examination of race and gender dynamics of women of color holding leadership positions historically held by white cisgender men.*

- As described here, the interviews and data collection (which may well include much of the same content) would be considered *research* as the project is designed to apply a theoretical framework, to analyze the information to draw conclusions, and develop insights and knowledge that can be generalized to others. IRB oversight would be required.
4. A journalist observes interactions and conducts interviews with the aim of informing the public

*A journalist conducts interviews with #BlackLivesMatter protestors and with a spokesperson from the city police department. The aim is to present a representative and informative picture of current events to the public.*

This project, would not require IRB oversight as, from the information given, the purpose is to provide the public information and not to contribute to generalizable knowledge.

## Is IRB Approval Required?

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*Research* projects that involve human subjects require prospective IRB approval. Projects not meeting the federal definition of *research* do not require IRB oversight; submission of an application for IRB review/approval is not necessary.

IRB staff assume that if an IRB application has been submitted for review, the project has been assessed by the investigator and determined to meet the definition of *research* such that IRB oversight is required. Investigators may complete the [online self-test](#) in IRBManager or contact IRB staff ([irb@iastate.edu](mailto:irb@iastate.edu)) if documentation that a project is “Not Human Subjects Research” (thus not requiring IRB oversight) is needed.

Individuals conducting history, biography, and journalistic projects who are *uncertain* about whether IRB approval is required may:

- Complete the [online self-test](#) in IRBManager. The online self-test generates an outcome based on the responses provided within the form.
- Consult the IRB webpage [Is IRB Approval Required?](#) for information and decision trees
- Contact IRB staff for guidance on whether a specific project meets the definition of *research*. Contact IRB staff via email [irb@iastate.edu](mailto:irb@iastate.edu).

## Additional Information:

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### [Is IRB Approval Required?](#)

Iowa State University | IRB | Policies and Guidance

### [2018 Common Rule Changes to Research Definition Summary](#)

Iowa State University | IRB | Policies and Guidance

OHRP [Draft Guidance: Scholarly and Journalistic Activities deemed not to be research](#) (July 19, 2018)

HHS.gov | OHRP | Regulations and Policies

### [Oral History Principles and Best Practices](#)

Oral History Association (OHA) | About

### Document History

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*Created/Approved: 7/21/2020*

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