Scholarly and Journalistic Activities vs. Human Subjects Research

A Guide to Understanding When IRB Review is Required

Scope

Determining when a research activity requires Institutional Review Board (IRB) review and approval hinges upon a few critical variables. This document outlines the parameters for when activities, such as oral histories, journalistic interviews, or ethnographies, will require IRB review and approval, and when they will not.

Key Definitions

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

Human Subject - A living individual about whom an investigator (whether professional or student) is conducting research:

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Generalizable Knowledge - Information that is intended to expand the knowledge base of a scientific discipline or other scholarly field, and whose results are expected to be applicable to a larger population beyond the specific site or subjects studied.

Scholarly and Journalistic Activities - Activities such as autobiography, biography, historical scholarship, journalism, legal research, literary criticism, and oral history, including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

Oral History - The recording in interview form of personal narratives from people with first-hand knowledge of historical events or current events.

The Critical Distinction

The focus of IRB review is limited to research activities that meet ***both*** the definition of research ***and*** human subject, including an intent to contribute to generalizable knowledge.

Conversely, when the purpose and design of a particular activity is to focus on specific individuals, a specific event, or a literary work, and ***not*** to extend the activity's findings to other individuals or groups—the activity does not constitute human subjects research and does not require IRB review and approval.

Key Questions to Ask

When evaluating whether your activity requires IRB review, ask yourself:

1. **What is my intent?** Am I trying to tell the story of specific individuals or events, or am I trying to develop findings that apply beyond these specific cases?
2. **Who is my audience?** Is this for public interest, historical documentation, or journalism—or is it for a scientific/scholarly field expecting generalizable findings?
3. **How will I use the data?** Will I analyze patterns across multiple subjects to draw broader conclusions, or will I preserve individual narratives as unique stories?
4. **What are my outcomes?** Will my work result in academic publications claiming generalizable findings, or will it result in documentaries, articles, or historical records focused on specific people and events?

Visual Framework: When Does It Become Research?

NOT Human Subjects Research	IS Human Subjects Research
• **Focus: Specific individuals or events** • **Intent: Document, preserve, inform** • **Outcome: Individual stories, historical records** • **Audience: General public, specific communities**	• **Focus: Patterns applicable beyond study subjects** • **Intent: Contribute to generalizable knowledge** • **Outcome: Scholarly findings, theoretical frameworks** • **Audience: Scientific/academic community**

Illustrative Examples

Example 1: Journalist Interviewing a Musician

Scenario:

A journalist video records firsthand accounts of a renowned musician's experience within their profession for publication in an online magazine.

Analysis:

- **Focus:** This specific musician and their unique career journey
- **Intent:** To tell this individual's story to the public
- **Outcome:** A profile article or documentary about this musician
- **Generalizable knowledge?** No - findings are not meant to apply to other musicians or contexts

Decision: NOT human subjects research. IRB review not required.

Example 2: Oral Historian Documenting WWII Pilots

Scenario:

An oral historian conducts open-ended interviews with World War II pilots to solely document their experiences on specific events throughout World War II. The interviews will contribute to a documentary.

Analysis:

- **Focus:** Specific historical events and the individual pilots who experienced them
- **Intent:** To preserve firsthand accounts of these specific events
- **Outcome:** A documentary presenting individual narratives
- **Generalizable knowledge?** No - the goal is historical documentation, not broader conclusions about pilots or war experiences

Decision: NOT human subjects research. IRB review not required.

Example 3: Researcher Studying Pilot Trauma Patterns

Scenario:

A psychology researcher interviews 50 World War II pilots using a standardized protocol to identify common patterns of post-traumatic stress. The researcher plans to publish findings in an academic journal about trauma responses in combat veterans.

Analysis:

- **Focus:** Patterns of trauma responses across multiple individuals
- **Intent:** To develop generalizable knowledge about combat-related trauma
- **Outcome:** Academic publication with findings applicable to broader veteran populations
- **Generalizable knowledge?** Yes - findings are meant to inform understanding of trauma in similar populations

Decision: IS human subjects research. IRB review REQUIRED.

Example 4: Biography vs. Psychological Study

Scenario A (Biography):

A writer interviews a CEO and their colleagues to write an authorized biography about the CEO's life and career.

Decision: NOT human subjects research. The focus is on this specific individual's story.

Scenario B (Psychological Study):

A researcher interviews 30 CEOs using standardized questions to study common personality traits and leadership styles, planning to publish findings about what makes effective leaders.

Decision: IS human subjects research. The intent is to develop generalizable knowledge about CEO traits.

When the Line Gets Blurry

Some activities may start as journalistic or oral history projects but cross into research territory. Watch for these warning signs:

- You begin analyzing data across multiple subjects to find patterns or draw broader conclusions
- You develop a systematic protocol or standardized questions designed to enable comparison
- Your intended audience shifts from the general public to an academic or scientific community
- You plan to submit findings to peer-reviewed journals claiming generalizable insights
- Your work begins to focus less on individual narratives and more on aggregated findings

Important: If any of these shifts occur during your project, you should immediately consult with the IRB to determine if your activity has become human subjects research.

IRB Recommendation

When in doubt or to obtain confirmation of the IRB requirements for your research activity, submit a request for a

Not Human Subjects Research (NHSR) determination. The NHSR determination will formally document whether your research activity can transpire without IRB approval.

This proactive step protects both you and your institution by ensuring compliance with federal regulations and ethical research standards.

References

- Oral History Association
- Office for Human Research Protections (OHRP)
- 45 CFR 46.102