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# Yale University Institutional Review Boards

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## 100 GD.1 Humanities Projects and IRB Review

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### Overview

This document provides guidance for determining when humanities projects are subject to IRB review.

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### Do Humanities Projects Require IRB Review?

The majority of humanities projects do not require review by the IRB. There are, however, cases where the project would fall under the purview of the IRB. Studies which qualify as “research” and which involve “human subjects,” as defined in the federal regulations and further explained below, would require IRB review under Yale policy. The most common reason for humanities projects to not require IRB review is that they do not fit the federal definition of research.

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### Do Oral History Projects Require IRB Review?

In 2003, the American Historical Association and the Oral History Association developed a statement on the applicability of the regulations on the protection of human participants (45 CFR 46, Subpart A) with which the Office of Human Research Protections within the Department of Health and Human Services concurred. The relevant statement is that: “Most oral history interviewing projects are not subject to the requirements of the Department of Health and Human Services (HHS) regulations for the protection of human participants at 45 CFR part 46, subpart A, and can be excluded from institutional review board (IRB) oversight because they do not involve research as defined by the HHS regulations.” As above, the determination as to whether or not a project requires IRB review is determined based on whether or not the project meets the federal definition of research. Those projects which do not meet this definition do not need to be submitted to the IRB for review.

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### What Constitutes “Research”?

Research is defined as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge” (45 CFR 46.102(d)).

Under this definition, the project must intend at the outset to generate conclusions which can be applied in or be predictive of similar circumstances. Thus a case study of a single individual would not be considered research. In contrast, a study of a single event involving interviews of the relevant parties, whether or not they all respond to the same set of questions, but which intends to analyze the responses to reach conclusions on how people in general react to such event would be research.

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### What Constitutes a “Human Subject”?

A human subject is defined as a “living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) obtains identifiable private information” (45 CFR 46.102(f)).

Key to this definition is that the information collected is about an identified person. Information collected without any identifiers or other details which could lead to identification of an individual would not be considered to involve human participants. Information which involves interaction with an individual but which does not collect information about a person, such as interviews on government or corporate policies or historical events are also not considered to involve human participants. Such interviews would include human participants if the questions were to turn to issues of an individuals’ involvement in such matters or of their opinions and compliance with these issues.

**Note that the determination of whether or not a project involves human participants is separate from whether or not the project constitutes research and only when both definitions are met does the study require IRB review.**

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## **When Are Humanities or Oral History Projects Considered to be Human Participants Research Requiring IRB Review?**

If the proposed project will involve collecting identifiable information about a living individual AND will be used to reach conclusions, inform policy or generalize findings, then the project must be submitted to the IRB for review.

For example, the following may be indicators that IRB review is required:

- The study is funded by an agency which seeks to support projects designed to create generalizable knowledge such as U.S. Department of Health and Human Services, National Science Foundation, U.S. Department of Education (including the Fulbright program) etc.
- The study will involve multiple individuals' perspectives on the issue of interest AND these perspectives will be analyzed to reach generalized conclusions.

The following examples are projects which would not require IRB review:

- The goals of the project are to document a specific issue or event or the experiences of individuals and will not be used for further analysis for commonalities predictive of future instances.
- The project will compare and contrast policies, procedures or events to identify general commonalities or inform policy decisions without collection of information about identified individuals.

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## **What if it is unclear if the project falls within the scope of the IRB?**

The IRB can provide assistance in determining if a given project must be reviewed under Yale policy. This is most commonly done through a phone call (436-3650) or e-mail ([human.subjects@yale.edu](mailto:human.subjects@yale.edu)) to the Human Subjects Committee providing a brief description of the nature of the project.

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## **What must be submitted for IRB review?**

Detailed information is available on the Human Research Protection Program web site ([www.yale.edu/hrpp](http://www.yale.edu/hrpp)) including an application form and checklist. In general, applications include the application cover page and a description of the study including the goals of the study, the type of information to be collected, who will be the subject of the research, and what information will be provided to the participants to obtain their agreement to be interviewed. Please note that the checklist included with the application instructions is intended to cover various human research projects and the items listed may not all be applicable to a given project.

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## **What if the interview questions will differ for each participant?**

Although each participant will have their own unique area of expertise to lend the project, the goals of the project define what general areas will be the focus of the interviews and this can usually be defined broadly if not by specific questions. In some case the populations to be interviewed can be categorized and the information to be gained from each group can be described. For example, a project on the effectiveness of a public policy can be parsed into interviews with government officials on the reasoning for the policy and how it is enforced and interviews with the public stakeholders regarding their reaction to the policy and their adherence to it.

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## **Consent vs. Publication Release Forms**

Unlike consent which can be obtained without a signed form under appropriate circumstances, release forms are required if transcripts will be published verbatim or if video testimonies will be shown publicly. Consent refers to obtaining the interviewee's agreement to be interviewed and usually involves explaining

the nature of the interview and what will be done with the information. Depending on the depth of the interview and the sensitivity of the questions, the consent information may or may not be written up as a form which also may or may not involve signature by the interviewee. Publication release forms require signature and serve to notify the interviewee that they will not retain rights or control in the final dissemination of the interview.

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### **Will the IRB Require that the Data be Made Anonymous?**

Many humanities projects do not intend to keep the identity of the interviewees confidential let alone anonymous. In fact it is not uncommon for the interviewees to want to have their name associated with their responses. There is no IRB requirement that the information be anonymous, only that the participants be made aware of whether or not their names will be associated with their responses and any inherent risks associated with such disclosure. It must be noted, however, that projects that pose significant risk to the participants from disclosing their responses without a counterbalancing benefit anticipated from the project would be considered unethical.