

Humanities Projects and IRB Review

What projects require IRB Review?

The IRB is charged with reviewing projects which are “research” and which involve “human subjects” as defined in the federal regulations at 45CFR46. **Note that the determination of whether or not a project involves human subjects is separate from whether or not the project constitutes research and only when both regulatory definitions are met does the study require Committee review.**

What constitutes “research” in the regulations?

Research is defined as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge” (45CFR46.102(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 if the case study’s analysis relates to the individual rather than classes of similar like individuals. 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 an event would be research.

What constitutes a “human subject” in the regulations?

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” (45CFR46.102(f)).

Under this definition, the data must be collected about a living person and the data is either collected directly from that person or the data would be considered to be private information about that person. Information collected without interacting with the individual or without any identifiers or other details which could lead to identification of an individual would not be considered to involve human subjects. 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 subjects. Such interviews would include human subjects if the questions were to turn to issues of an individuals’ involvement in such matters or of their opinions and compliance with these issues.

Do Humanities Projects Require IRB Review?

Sometimes. The majority of humanities projects do not require review by the IRB. While these projects are clearly scholarly work, they do not always meet the regulatory definitions of research. 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, would require IRB review under Yale policy.

Do Oral History Projects Require IRB Review?

Sometimes. 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 as described above. Those projects which do not meet this definition do not need to be submitted to the IRB for 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 subjects (45CFR 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 subjects 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.” A careful review of the project in relation to the federal definition provided above is needed to determine whether or not a given project should be submitted to the IRB.

When are humanities or oral history projects considered to be human subjects research requiring IRB review?

If the proposed project will involve analyzing data to reach conclusions, inform policy or generalize finding AND that data is either identifiable private information about a living individual OR collected directly from the individual about him or herself, then the project should be submitted to the IRB.

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.

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) to the Human Subjects Committee providing a brief description of the nature of the project.

What must be submitted for IRB review?

Detailed information is available on the Human Subjects Committee web site (www.yale.edu/hsc) 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 subjects research projects and the items listed may not all be applicable to a given project.

What if the interview questions will differ for each participant?

Although each participant will have his or her own unique area of expertise to lend the project, the goals of the project define the general areas to be covered in the interviews and this can usually be defined broadly if not by specific questions. In some cases 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 may be parsed into interviews with government officials on the reasons 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.

Consent vs. Publication Release Forms

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.

Release forms are used to obtain the interviewee's permission to quote the interviewee in publications and serve to notify the interviewee that they will not retain rights or control in the final dissemination of the interview. Unlike consent which can be obtained without a signed form under appropriate circumstances, release forms are required to be signed if transcripts will be published verbatim or if video testimonies will be shown publicly.

Will the IRB require that the data be made anonymous?

There is no IRB requirement that the information be anonymous. The IRB does require 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. 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. Maintaining identified data is allowable by the IRB. Projects that pose significant risk to the participants from disclosing their responses without a counterbalancing benefit anticipated from the project, however, would be considered unethical.