

IRB Determination Worksheet -Does My Project Need IRB Review?

Instructions: Use this worksheet to determine if an IRB application is required for your research project. This worksheet is designed help researchers determine if their project constitutes human subjects research, per the definitions provided by [the federal regulations](#) for the protection of human subjects.

Completed By:

Date:

Signature of Faculty Supervisor (if applicable):

Date:

Project Title:

Does It Meet the Federal Definition of "Research"?

1. Is your project a *systematic investigation*, including research development, testing, and evaluation?

A ***systematic investigation*** refers to a strategy of study involving a methodical procedure or plan that is theoretically grounded, specifies a focused and well-defined research problem or question, is informed by the empirical findings of others, is analytically robust, and provides a detailed and complete description of data collection methods. A study that is systematic allows conclusions to be drawn from the results. Although some qualitative research projects are exploratory in nature and may not have specific aims or hypotheses at the outset, these may still be systematic investigations if their purpose is to compare results to other assessments or to draw conclusions.

- Yes, or Not Sure? Continue to question #2.
- No → **STOP**. A protocol submission is NOT required even if you answer yes to questions on the remainder of the worksheet. Projects that are not systematic investigations do not meet the federal regulatory criteria for oversight. **NOTE: Please review the section below "Not Human Subjects Research: Additional Information and Restrictions" prior to beginning your project.**

2. Is the project designed to develop or contribute to *generalizable knowledge*?

Generalizable knowledge refers to a set of conclusions, facts, or principles that enhances scientific or academic understanding by applying broadly to a whole category, such as a population or field of knowledge. Generalizable knowledge is produced when investigators make the components of their research design (procedures, methods, and instruments) as well as the analyzed findings/results available for other professionals or academics to peer review, replicate, and utilize. Traditionally this occurs when publishing or presenting at a professionally refereed venue, conference, or competition, but it may also occur through new media methods of discourse. In qualitative research, generalizable knowledge may emerge when the research generates detailed descriptions of phenomena which may be transferable to like situations or when new theories, principles, or statements of relationships are developed as a result of the data collection. Master's theses are published and made available outside USA and are usually considered research that contributes to generalizable knowledge. However, projects which are disseminated exclusively at USA and are not intended for dissemination beyond the instructional setting are *typically* not designed to contribute to generalizable knowledge. Likewise, research projects which are designed as common biographical research, oral histories, and journalism are *typically* not designed as a systematic investigation to contribute to generalizable knowledge. The purpose of these activities is often to create a record of specific historical events or persons, and findings are usually not generalized to a broader population or group.

- Yes, or Not Sure? Continue to question #3.
- No → **STOP**. A protocol submission is not required even if you answer yes to questions on the remainder of the worksheet. Projects that are not designed to develop or contribute to generalizable knowledge do not meet the federal regulatory criteria for oversight.
NOTE: Please review the section below "Not Human Subjects Research: Additional Information and Restrictions" prior to beginning your project.

Does It Involve "Human Subjects"?

3. Will the research involve *interaction or intervention* with living individuals or the collection of *individually identifiable private information*?

Interaction includes communication or interpersonal contact between the investigator and the subject that solicits personal information. Examples of interaction may include collecting personal data through questionnaires, interviews, tests, and performance evaluations. Persons involved in a research activity are not considered to be human subjects when the person interviewed/surveyed is asked to provide information specific to his/her expertise or institutional information as opposed to personal information (examples of personal information include opinions, thoughts, perceptions, performance metrics, and private data about the individual). For example, welders asked to describe the composite of shielding gas,

shielding gas flow rate, and formation of the weld bead are not disclosing information about themselves and, as such, are not research subjects in this context. Likewise, when investigators wish to collect information about institutions or social processes from individuals, such activities do not constitute research involving human subjects when the focus of the research is not on the characteristics or personal views of the informant. There is often a fine line between what is defined to be “human subjects research” and research that collects information from people in order to understand institutions or social processes. For example, asking the same welders in the above example how industry consolidation has affected the safety practices in their work environment would constitute research involving human subjects. Research on institutions or social processes, the purpose of which is to create generalizable knowledge about the attitudes, beliefs, or behaviors of individuals or groups (e.g., voters, prisoners, employees) as being representative of these institutions or social processes, is human subjects research.

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. The researcher need not collect personal information in order for the work to qualify as an intervention that involves human subjects. For example, an experiment that tracks participants' eye movements across a screen would still involve human subjects, even if no personal information is recorded.

Individually identifiable private information means that the identity of the human subject is or may be readily ascertained by the investigator or associated with the information collected. This includes information about behavior that occurs in a context in which the subject 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 (e.g., medical/clinical records, academic records, social services records, new media forms of disclosure which are not made public but which you may have access to by accident or privilege).

- No → Continue to question #4.
- Yes, or Not Sure? The research requires review. NOTE: Please review the section below “Human Subjects Research: Expectations for IRB Protocols” prior to submitting your research protocol to the IRB.

4. Will the research utilize *existing or secondary data* which contain *individually identifiable private information*?

Existing or secondary data include records as well as tissue, organs, fluids, and other biospecimens that were not originally collected for the research or will not be collected specifically for the research in the future.

Individually identifiable private information is defined in #3 above.

- Yes, or Not Sure? The research requires review. Please review the section below “Human Subjects Research: Expectations for IRB Protocols” prior to submitting your research protocol to the IRB.
- No → Continue to question #5.

5. Is there any possibility that the researcher or collaborators (e.g., student assistants, professional partners) could ascertain the identity of a living individual from the existing or secondary data utilized at any point during the course of the research?

- Yes, or Not Sure? The research requires review. Please review the section below “Human Subjects Research: Expectations for IRB Protocols” prior to submitting your research protocol to the IRB.
- No → **STOP**. A protocol submission is not required. Using non-identifiable information does not meet the federal regulatory criteria for oversight. If your research utilizes data which are irrevocably de-identified or have already been coded by a third party in such a way that the researcher and collaborators cannot ascertain the identity of a living individual, the project does not need to be reviewed by the IRB.

Not Human Subjects Research: Additional Information and Restrictions

Some activities, though they may be deemed "not human subjects research," **may still pose risks** if they:

- Involve protected or vulnerable populations
- May cause participants harm (e.g., psychological, physical, legal, educational, social and/or economic)
- Pose risk to *you* as the researcher.

Student Research: Faculty members should engage their students in a discussion about whether their goals include conducting research that contributes to new scholarly knowledge. Students should only be routed to the IRB if they have indicated, using this worksheet, that their project is a systematic investigation designed to contribute to generalizable knowledge involving human subjects. There is no requirement or verification with the IRB Office needed if the work is determined to not meet the criteria for oversight.

Human Subjects Research: Expectations for IRB Protocols

If upon completion of this worksheet you determine that your research requires submission of a protocol to the IRB Office, see the [IRB Getting Started](#) web page for steps to submit a protocol. The basic expectations for all IRB protocols are as follows:

- The purpose of the study is clearly identified.
- A rationale is provided for the study that builds on previous research and includes appropriate citations, if applicable.
- The research team has made every effort to optimize meaningful informed consent/assent and voluntary participation. Consent/assent language is simple; straightforward; appropriate for the level of literacy, education, developmental and cognitive capacity of the participants; and culturally appropriate.
- The protocol is well-written and includes sufficient detail outlining the proposed research study.

Source: Office of Research, San Jose State University