



Institutional Review Board for the  
Protection of Human Subjects in Research  
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## **What projects require IRB review?**

According to federal regulations (specifically, 45 CFR 46), Institutional Review Boards have the responsibility of overseeing the ethical standards in **research involving human subjects**. This responsibility is broken down in more detail below to clarify what projects should and what projects should not be reviewed by the IRB.

### What is research?

Research, in the federal regulatory sense, is “a systematic investigation that is designed to develop or contribute to generalizable knowledge.” This includes research development, testing, and evaluation that contributes to generalizable knowledge. In order to determine if a proposed project qualifies as research, the IRB must know the intent of the researcher. Will findings be published or presented to external audiences? Will any outcome of the study, whether in the form of data analysis or methodological advances or anything else, be reported as a means to disseminate knowledge and advance the field? These possibilities should be considered when deciding if your project needs to be reviewed by the IRB. Projects done in fulfillment of a course or “class project” and that will be presented to the class are not considered to contribute to generalizable knowledge. Program evaluation projects in which the findings are reported to an oversight agency or other interested party or used to develop a quality improvement plan also are not considered to contribute to generalizable knowledge. If a researcher is unsure about whether or not a project qualifies as research under the authority of the IRB, the researcher should contact the IRB office.

### What are human subjects?

The federal regulations define human subjects as “living individual about whom an investigator conducting research obtains: 1) data through intervention or interaction with the individual, OR 2) identifiable private information.” Research involving records from deceased individuals, such as in historical studies, does not need to be reviewed by the IRB. Projects in which information about a thing, such as a process, is collected from individuals, but personal identifiers nor any information ABOUT the informant is not collected also do not need to be reviewed by the IRB. Research collecting private information must be reviewed by the IRB. Private information is information that can cause the identity of the participant to be associated with the information provided or allow the participant’s identity to be readily ascertained by the researcher. Researchers unsure about whether or not a project involves living human subjects should contact the IRB office.

Projects must meet the criteria described under both of the questions above to require review by the IRB. That is, the project must both be research (as defined above) AND involve living human subjects to necessitate IRB review.