Is my project “regulated research”?

Research projects meeting the regulatory definition of research with human subjects require review and approval by an IRB, or a determination that the research is exempt. Not all activities that involve people, their data, or specimens are covered by the regulations governing human subjects research and may not require review by an IRB.

The question that must be considered when determining whether IRB review and approval is required is whether a project fits the regulatory definition of research (“regulated research”), and if so, whether it also involves human subjects.

**Step #1:** Let’s start with the definition of research.

While an activity may be considered research, it is important to highlight that not all research meets the threshold of “regulated research” requiring IRB review. The federal regulations have a very specific definition of what is considered regulated research that requires IRB review.

The federal regulations define research as “a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.”

What does a "systematic investigation" mean? A systematic investigation involves a methodical procedure and plan, 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.

What does "generalizable" mean? Generalizable knowledge is information that is expected to expand the knowledge base of a scientific discipline or other scholarly field of study and yield one or both of the following:

- Results that are applicable to a larger population beyond the site of data collection or the specific subjects studied.
- Results that are intended to be used to develop, test, or support theories, principles, and statements of relationships, or to inform policy beyond the study.
- Note that publication or other dissemination of findings does not in and of itself make the activity “research”. It has been a long-standing myth that if you publish, IRB review is required.

What isn’t generalizable?

- A quality assurance/quality improvement/organizational effectiveness study where the intent is to assess, improve, or develop programs or services for an organization. Outcomes will remain specific to the organization, programs or services, although other organizations may use the results for their own programs.
- An oral history or journalistic piece. These are published materials that are limited to only documenting or reporting on events, situations, policies, institutions, or systems without the intent to form hypotheses, draw conclusions, or generalize findings. It will **not** involve stories that will or may draw broad conclusions about the population, cultures, norms, and practices.
- A note about class/educational “research” activities – Class projects and research methods classes may involve data collection activities for training purposes that do not require IRB review and oversight because the intent is to teach methods, not to contribute to generalizable knowledge. The intent of other class projects may be to provide the student with real world experiences, information gathering techniques, and report writing. However, when the primary focus and initial intent of the class activities are to collect data to be used by students or other researchers beyond the classroom thereby contributing to “generalizable knowledge,” IRB review may be needed.
• **A note about student internships** – Students within many departments or schools of the University are involved in internships or practica. Some student practica/internships may include research activities that are designed to contribute to generalizable knowledge and, thus, involve research that requires IRB review.

• Please also know that even though your research activity may now not qualify as "regulated research" now this does not mean that you may not use these data for future "regulated research" activities. The use of data that was initially collected for non-research purposes is known as “secondary use of data not initially collected for research”.

**Does my project involve human subjects?**

**Step #2:** If your activity meets the federal regulatory definition of regulated research, the next step is to determine whether your research involves human subjects. Let’s looks into what a “human subject” is according to the federal regulations.

The federal regulations define a **human subject** as a **living individual about whom** an investigator conducting research obtains (1) **data through intervention or interaction** with the individual or (2) **identifiable private information** (45 CFR 46.102(f)(1)(2)).

• **“Living individual”** refers to data (information or specimens) collected from living subjects. For example, research using data from the 1880 Census would not be human subjects research.

• **“About whom”** refers to the fact that the information collected must be personal information about an individual. For example, a survey that collects data about the activities of an organization is not human subjects research.

• **“Intervention”** includes physical procedures and manipulations of the subject or the subject’s environment for research purposes. For example, taking a saliva or blood sample from a subject or having a subject view a video would be considered a research intervention.

• **“Interaction”** refers to communication between the researcher and the subject. This includes face-to-face, mail, internet and phone interactions, as well as other modes of communication.

• **“Individually identifiable”** means the identity of the subject is or may be readily ascertained by the researcher or others. Research with a de-identified data set is not research with human subjects because the data are not individually identifiable.

• **“Private information”** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Examples of private information include medical or academic records or personal journals.