

Is IRB Review Required ?

Before submitting an IRB application, first determine if IRB review is actually required for your project.

The Regulations

Federal regulations require that research projects involving human subjects be reviewed by an Institutional Review Board (IRB). The IRB must approve or determine the project to be exempt prior to the start of any research activities. The IRB cannot provide approval or determinations for research that has already been concluded.

IRB review and approval is required for projects that:

- Meet the definition of research
- Involve human subjects and
- Include any interaction or intervention with human subjects
- Involve access to identifiable private information

What is Research?

Research is defined as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

A Systematic Investigation follows a predetermined plan for looking at a particular issue, testing a hypothesis or research question, or developing a new theory that may include:

- Collection of quantitative or qualitative data
- Collection of data using surveys, evaluation procedures, interviews, or focus groups
- Collection of data using experimental designs such as clinical trials
- Observation of individual or group behavior

Contribute to Generalizable Knowledge means that the purpose or intent of the project is to test or to develop scientific theories or hypotheses, or to draw conclusions that are intended to be applicable and/or shared beyond the populations or situations being studied. This may include one or more of the following:

- Presentation of the data at meetings, conferences, seminars, poster presentations, etc.
- The knowledge contributes to an already established body of knowledge
- Other investigators, scholars, and practitioners may benefit from this knowledge
- Publications including journals, papers, dissertations, and master's theses

If the project does not meet the definition of research (i.e. is not a systematic investigation or does not contribute to generalizable knowledge), as described above, then the project does not require IRB review and an IRB application is not required.

My Project is Considered Research, Now What?

If the project meets the definitions of research (i.e. is a systematic investigation or does contribute to generalizable knowledge), as described above, the next set of questions apply.

Are Human Subjects Involved?

A Human Subject is a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information.

If the project does not meet the definition of research or the project does not include human subjects, as described above, then the project does not require IRB review.

My Project Includes Human Subjects, Now What?

If the project does include a human subjects aspect, you need to determine if there is any interaction or intervention with subjects or if there is any access to identifiable information.

- **Interaction**—Any communication or interpersonal contact between the investigator(s) and the subjects. This includes in-person, mail, telephone, etc. Online surveys (even if anonymous) involve interaction.
- **Intervention**—Physical procedures or manipulations of the subject or his/her environment (e.g. taking blood samples, exercise studies, use of devices, cognitive tasks, etc.)

Access to Identifiable Private Information

- **Private Information**—Information about behavior that occurs in a context in which the individual can reasonably expect that no observation or recording is taking place (e.g. person's home, exam room, public restroom, etc.) OR has been provided for specific purposes with a reasonable expectation that it will not be made public (e.g. medical records, student records, employee file, etc.)
- **Identifiable Information**—The identity of the individual is or may be readily ascertained by the investigator or others either directly or indirectly through the use of codes or a combination of data points.

If the project does not include any interaction or intervention with human subjects or include any access to identifiable private information, then the project does not require IRB review. If even one of the above categories are met (interaction, intervention, access to identifiable private information), an IRB application is required.