

Does My Research Need IRB Review?

Per the U.S. Department of Health and Human Services regulations, 45 CFR 46

1. Is it Research?

As defined by the Code of Federal Regulations, 45 CFR 46

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

NO

YES

2. Does it Contribute to Generalizable Knowledge?

Contribute to Generalizable Knowledge means that the purpose or the intent of the project's conclusions are intended to be applicable and/or shared beyond the populations or situations being studied. This may include:

- Presentation of the data at professional conferences or meetings
- The knowledge contributes to an already established body of knowledge
- Other investigators, scholars, or practitioners may benefit from this knowledge
- Publications including journals, papers, dissertations, and master's thesis

NO

YES

3. Are Human Subjects Involved?

As defined by the Code of Federal Regulations, 45 CFR 46

A Human Subject is a living individual about whom an investigator conducting research obtains:

1. Data through interventions or interaction with the individual, or
2. Identifiable private information.

NO

YES

4. Does the Research Involve Interaction, or Intervention, or will it Access Identifiable Information?

Interaction – Any communication or interpersonal contact between the investigator(s) and the subjects. This is in-person, mail, telephone, email, etc. Online surveys (even if anonymous) involve interaction.

Intervention – Physical procedures or manipulations of the subject or his/her environment (e.g. exercise studies, use of devices, cognitive tasks, exposure to stimulus, 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.

NO

YES

STOP
Does NOT
Require IRB
Review

YES Requires IRB Review! Fill out IRB Research Application