

# 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**