



Defining Human Subjects Research

Research: A **systematic investigation**, including research development, testing, and evaluation, designed to develop or contribute to **generalizable knowledge**

Human Subject: A living individual **about whom** an investigator conducting research

1. Obtains information through **intervention** or **interaction** with the individual, and uses, studies, or analyzes the information or biospecimens
—or—
2. Obtains, uses, studies, analyzes, or generates **Identifiable private information** or biospecimens

Systematic Investigation: Methodically testing (quantitatively or qualitatively) a hypothesis or research question by gathering and analyzing data with the intention of drawing conclusions

Generalizable Knowledge: Data designed to apply to a population beyond the research subjects themselves and contribute to current academic understanding

About Whom: Refers to information the subject discloses about him/herself (including his/her opinions), as opposed to information/facts the subject shares regarding an external topic (such as a program, product, or procedures) about which the subject can be considered an expert.

Intervention: Both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment are performed for research purposes

Interaction: Communication or interpersonal contact between investigator and subject

Identifiable: The identity of the subject is or may readily be ascertained by the investigator or associated with the information

Private Information: Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record)