

## Guidance for Defining Human Subjects Research

It can be difficult to determine when someone is conducting research involving human subjects. This guidance provides definitions and examples of human subjects research requiring IRB review.

### 1. When Is An Activity Considered Human Subjects Research?

There are a variety of factors which help determine when someone is conducting research involving human subjects. This is an important determination because a researcher may not conduct research involving human subjects without IRB approval.

The IRB first asks if something involves “research,” and then if that research involves “human subjects.” If so, it requires IRB review. The following the definitions provided in 45 CFR 46 guide the Lindenwood University IRB when determining if an activity constitutes human subjects research.

<b><i>What is Research?</i></b>	<ul style="list-style-type: none"> <li>• “Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.”</li> </ul>
<b><i>What is Human Subjects Research?</i></b>	<p>Research involving a “living individual about whom an investigator (whether professional or student) conducting research:</p> <ul style="list-style-type: none"> <li>• (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or</li> <li>• (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.</li> </ul>
<b><i>What Is Not Considered Research?</i></b>	<p>The regulations provide a specific activities which are not considered “research,” though additional examples are provided below:</p> <ul style="list-style-type: none"> <li>• Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.</li> <li>• Public Health Surveillance Activities.</li> <li>• Collection and analysis of data or biospecimens by criminal justice agencies.</li> </ul>

## 2. What are some important features of this definition?

- Research is:
  - *Systematic*: When a researcher wants to answer a specific question, the researcher will design a systematic, intentional plan or protocol for answering the research question. Research does not necessarily include casual, unplanned observations or similar activities which may be more broadly defined as “research” in society.
  - *Generalizable*: Researchers often design projects or protocols because they want to influence the way other people perform or behave. A clinical researcher may want to change the way other doctors treat their patients or prescribe medication. A behavioral researcher may want to change the way therapists interact with their clients. An education researcher may want to change the way school districts develop curriculum for their students. In such cases, the researcher has collected research data locally and in a specific context but would like to share their findings generally as they may be useful in other contexts.
  
- Human Subjects Research involves:
  - *Interventions*: A researcher may intend to change or later an aspect of a research subject’s experiences. In clinical research, an intervention is easy to identify as it would involve having subjects take experimental drugs or treatments. Interventions also include things like having subjects watch videos, listen to sounds, or experiencing some manipulation of their environment. Randomizing counseling clients to different methods or students to different educational strategies would be considered an intervention.
  - *Interactions*: Researchers often use interactions such as surveys, focus groups, or interviews to collect data from participants. Collecting data from existing sources, such as medical records, publicly available databases, or other sources is also considered an interaction with a human subject.

### 3. What are some activities which are considered Human Subjects Research?

Discipline	Examples	Consideration
Biomedical Research	<ul style="list-style-type: none"> <li>• A researcher is studying the effect of a drug or device on participants with a specific disease.</li> <li>• A researcher is conducting a survey to better understand the dietary and exercise habits of a specific population.</li> </ul>	Biomedical Research typically involves an <i>intervention</i> , but also often requires <i>interaction</i> with identifiable or deidentified data about subjects available in medical records.
Social and Behavioral Research	<ul style="list-style-type: none"> <li>• A researcher is studying the effect of different environmental factors on the ability of participants to perform complex tasks.</li> <li>• A researcher is conducting a survey to better describe the connection between sexual identity and disparities in health care or counseling services.</li> <li>•</li> </ul>	While some Social and Behavioral Research involves a physical or environmental <i>intervention</i> , it more often entails surveys, focus groups, or similar types of <i>interactions</i> .
Educational Research	<ul style="list-style-type: none"> <li>• A researcher is studying the effect of a change in curriculum on a specific grade level.</li> <li>• A researcher is collecting data from existing student records to study the effect of a program.</li> </ul>	While some Educational Research involves a classroom or school-based <i>intervention</i> , it also often entails <i>interaction</i> with identifiable or deidentified student records.
Oral History and Ethnographic Research	<ul style="list-style-type: none"> <li>• A researcher is studying the effect of a specific traumatic event on the long term relationships of individuals present for the event.</li> <li>• A researcher is interviewing people to describe a correlation between their demographics and their experience of a historical or cultural event.</li> </ul>	Some instances Historical Research focus <i>directly on the specific individuals about whom the information is collected</i> and their recollections of events in the past.

## 4. What are some activities which are not considered Human Subjects Research?

Discipline	Examples	Consideration
Biomedical Research	<ul style="list-style-type: none"> <li>A hospital employee is studying the effect changing a specific administrative process will have on overall efficiency in a specific department.</li> </ul>	Activities focused on quality improvement in a specific location may not be generalizable, and are therefore not considered research.
Social and Behavioral Research	<ul style="list-style-type: none"> <li>A researcher is using an anonymous, publicly available data set to study demographic features of a specific type of psychological condition.</li> <li>A researcher is using a publicly available data set to study cross-cultural features of a group or location.</li> <li></li> </ul>	Activities requiring access to publicly available, anonymized sets of data do not constitute interaction with an <i>identifiable</i> human subject.
Educational Research	<ul style="list-style-type: none"> <li>A researcher receives anonymized data from a state agency or department monitoring elementary and secondary education data.</li> </ul>	Activities requiring access to publicly available, anonymized sets of data do not constitute interaction with an <i>identifiable</i> human subject.
Oral History and Ethnographic Research	<ul style="list-style-type: none"> <li>A researcher is talking to specific people to gather recollected, first-hand details about a specific historical event.</li> <li>A researcher is accessing records of deceased individuals.</li> </ul>	Activities focused on historical events and their data, or data from deceased individuals, do not require IRB review.