

What is Human Subjects Research?

Human subjects research is any research that involves human subjects. Investigators conducting human subjects research must satisfy DHHS regulations [45 CFR Part 46] and FDA regulations [21 CFR Part 50 and 56] regarding the protection of human subjects research, as applicable. When considering whether an activity meets the definition of human subjects research per DHHS regulations one must consider two federal definitions: **research** and **human subject**.

What is Research?

Research means a *systematic investigation*, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

A *systematic investigation* is an activity that involves a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a question.

Examples of systematic investigations include:

- surveys and questionnaires
- interviews and focus groups
- analyses of existing data or biological specimens
- epidemiological studies
- evaluations of social or educational programs
- cognitive and perceptual experiments
- medical chart review studies

Investigations designed to develop or contribute to *generalizable knowledge* are those designed to draw general conclusions, inform policy, or generalize findings beyond a single individual or an internal program (e.g., publications or presentations). However, research results do not have to be published or presented to qualify the experiment or data gathering as research. The intent to contribute to "generalizable (scholarly) knowledge" makes an experiment or data collection research, regardless of publication. Research that never is published is still research. Participants in research studies deserve protection whether or not the research is published.

Examples of activities that typically are not generalizable include:

- biographies
- oral histories that are designed solely to create a record of specific historical events
- service or course evaluations, unless they can be generalized to other individuals
- services, courses, or concepts where it is not the intention to share the results beyond the MSU-Northern community
- classroom exercises solely to fulfill course requirements or to train students in the use of particular methods or devices
- quality assurance activities designed to continuously improve the quality or performance of a department or program where it is not the intention to share the results beyond the MSU-Northern community

What is a Human Subject?

A **human subject** is as a living individual about whom an investigator conducting research obtains (1) data through *intervention* or *interaction* with the individual; or (2) identifiable private information.

Intervention includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject. *Private information* includes 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). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Note: Action research, thesis, or dissertation projects involving human subjects conducted to meet the requirement of an undergraduate or graduate degree are usually considered generalizable, and require IRB review and approval.

Educational Activities that are not Human Subjects Research

To be research, an activity must be designed with the intent to develop or contribute to "generalizeable knowledge." Clearly, some classroom activities are designed to teach research techniques and have no such intent.

Simulations of human experimentation and course-assigned data collection do not constitute human subjects research if the activities are designed for educational purposes only; and the data will not be generalized outside the classroom (reporting of data within the class is acceptable because the activities were performed solely for teaching purposes); and the data will not result in a master's thesis, doctoral dissertation, poster session, abstract, or other publication or presentation; and the student volunteers or other participants are clearly informed that the activities are an instructional exercise, and not actual research.

Exceptions: any activity that is a clinical investigation or involves medical intervention or procedures, even when they are a part of a course curriculum, always constitutes human subjects research and requires prior IRB review and approval.

Quick Sheet

What is Human Subjects Research?

Research:

- Systematic investigation (question, prospective plan, quantitative or qualitative data collection, and data analysis)
 - o Examples:
 - surveys/questionnaires
 - interviews/focus groups
 - analyses of existing data or biological specimens
 - epidemiological studies
 - evaluations of social or educational programs
 - experiments
 - medical chart review studies
- Designed to develop or contribute to generalizable knowledge (draw general conclusions, inform policy, or generalize findings beyond sample), regardless of whether research is published or presented in any forum
 - o Examples of activities typically NOT generalizable:
 - biographies
 - oral histories to create a record of specific historical events
 - service or course evaluations, unless they can be generalized to other individuals
 - services, courses, or concepts where it is not the intention to share the results beyond the MSU-Northern community
 - classroom exercises solely to fulfill course requirements or to train students in the use of particular methods or devices
 - quality assurance activities designed to continuously improve the quality or performance of a department or program where it is not the intention to share the results beyond the MSU-Northern community

Human Subject:

- Living individual
- Data obtained through intervention or interaction OR identifiable private information obtained
 - o *Intervention*: physical procedures or manipulation of subject or their environment
 - o *Interaction*: communication or contact between investigator and subject
 - o *Private information*: information about behavior that occurred in a context with a reasonable expectation of privacy or provided for specific purposes with the expectation that it would not be made public; individually identifiable (either directly or can be ascertained by the collective information)