What is Considered Human Subject Research?

Research is considered to involve human subjects when an investigator conducting research obtains (1) data through intervention or interaction with a living individual, or (2) identifiable private information about a living individual. (45 CFR 46)

- Research: a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

  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.

- 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.

- Intervention: physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.

- Interaction: communication or interpersonal contact between investigator and subject.

- Individually Identifiable: the identity of the subject is or may be readily ascertained by the investigator or readily 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). 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.

What is Not Typically Considered Human Subject Research?

- 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 Walsh University 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 Walsh University community.
• Publically available information on the Internet such as comments on TripAdvisor, content of public tweets and blogs, information on public Facebook pages, census information, or freely-available datasets (whether or not anonymous).
• Archives that contain identifiable information about individuals in a public archive.
• Datasets that are anonymous datasets, whether privately held or publicly available.