

## **What is Considered Human Subject Research?**

Research is considered to involve human subjects when an investigator conducting research (1) obtains information or biospecimens through intervention or interaction with a living individual and uses, studies, or analyzes the information or biospecimens, or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. (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 information or biospecimens are gathered (for example, venipuncture) or manipulations of the subject or the subject's environment are performed for research purposes.
- Interaction: communication or interpersonal contact between investigator and subject.
- Identifiable Biospecimen: specimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
- Identifiable: "for which the identity of the subject is or may readily be ascertained by the investigator or associated with the [information or biospecimen]."
- Identifiable Private Information: private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

## **What is Not Typically Considered Human Subject Research?**

- Scholarly and journalistic activities: includes the collection and use of information, that focus directly on the specific individuals about whom the information is collected (not generalizable). Examples include: oral history, journalism, biography, literary criticism, legal research and historical scholarship.
- Public health surveillance activities: limited to those activities conducted, supported, requested, ordered, required or authorized by a public health authority.
- Collect and analysis of information, biospecimens or records by or for a criminal justice agency for criminal justice or investigative purposes: for activities authorized by law or

court order solely for criminal justice or criminal investigative purposes. This does not include social and behavioral studies of the causes of criminal behavior.

- Authorized operational activities for national security purposes: authorized operation activities in support of intelligence, homeland security, defense, or other national security missions.
- Secondary research use of nonidentifiable private information or nonidentifiable biospecimens.