A human subject is any individual, living or deceased, about whom the investigator collects data through direct intervention or interaction, or from sources such as medical records, clinical databases, billing records and pathologic or diagnostic tissue specimens. Data from these sources is called identifiable private information. *NOTE: Washington State law considers a deceased person a human subject if the research uses private identifiable health information (PHI) about the deceased person.*

**Regulatory Definitions of Human Subject:**

**Human subject** [DHHS 45 CFR 102(f)]: A living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, OR identifiable private information.

**Human Subject** [FDA 21 CFR 50.3(g) & 56.20(e)]: An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient.

**Additional Definitions and Considerations:**

**Intervention** [DHHS 45 CFR 46.102]: includes both 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 (includes interviews or surveys).

**Interaction** [DHHS 45 CFR 46.102]: includes communication or interpersonal contact between investigator and subject (includes online contact via surveys).

**Private Information** [DHHS 45 CFR 46.102]: 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. (Examples of studies using private information include medical chart reviews, obtaining lab results on identifiable tissues and specimens, using identifiable information from data or tissue repositories, obtaining school grades, private interviews, or surveys of opinions and attitudes.)

**Projects with a business or event focus:** Projects with a business or event focus are typically *non-human subject research*. For example interviewing a grocery store management about a particular brand of milk and how well it sells would be non-human subject research. *Note: If you ask the grocery store manager about how they feel about their pay wage or working conditions, then the project would qualify as human subject research because opinions or private data are being collected.*
**Data or Specimens Research:** may be considered human subject research when the specimens or data are individually identifiable and are obtained for the purpose of conducting research.

**Coded Data or Specimens:** means that data or specimens having identifying information that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain (e.g., name, social security number, etc.) has been replaced with a code (e.g., a number, letter, symbol, or combination of letters and numbers), and a key code to the data exists, enabling linkage of the identifying information to the private specimen or information. (OHRP Guidance on Research Involving Coded Private Information or Biological Specimens, Oct. 16, 2008)