Regulatory Definitions

HUMAN SUBJECT [DHHS 45 CFR 46.102(f)]: A living individual about whom an investigator (whether professional or student) conducting research obtains:

(1) Data through intervention or interaction with the individual, or

(2) Identifiable private information.

HUMAN SUBJECT [FDA 21 CFR 50.3(g) & 56.201(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.

See GUI 42 for regulatory definitions pertaining to Department of Defense

Additional Considerations:

'About' living individuals: Although data may be obtained ***from*** living individuals, it may not be ***about*** them (i.e. the research is about a "what", rather than a "whom."). Also, research dealing with tissues or specimens obtained from deceased individuals or cadavers is not considered to be about ***living individuals***. (Note: Identifiable medical information or specimens from deceased individuals may nonetheless be subject to HIPAA regulations.)

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 (including interviews or surveys).

Interaction: Includes communication or interpersonal contact between investigator and subject (including online surveys).

Obtaining: Receiving or accessing identifiable private information or identifiable specimens for research purposes. OHRP interprets ***obtaining*** to include an investigator's use, study, or analysis for research purposes of identifiable private information or identifiable specimens already in the possession of the investigator. Note: If private individually identifiable information is ***received*** by the researcher and subsequently de-identified, the study is still considered to involve human subjects.

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, school grades, or height and weight measurements). Private information must be ***individually identifiable*** (i.e., the identity of the subject is or may 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 chart reviews, obtaining lab studies on identifiable tissues and specimens, or using identifiable information from data or tissue repositories, obtaining school grades, private interviews, or surveys of opinions and attitudes.

Coded: Data or specimens are considered coded when 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 thereof), and a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

The following activities are <u>not</u> considered to involve human subject(s):

- Cadaveric or autopsy specimens or data.
- Private data or specimens were not collected specifically for the currently proposed research through an intervention or interaction with living individuals ***AND*** the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because the investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators ***under any circumstances***, until the individuals are deceased (note that the HHS regulations do not require the IRB to review and approve this agreement).