

Who is a subject in professional
cluster studies?

- (f) *Human subject* means 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.
- ***Intervention*** 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. 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.

3 ways to be a subject

- A living individual about whom an investigator conducting research obtains data through intervention;
- A living individual about whom an investigator conducting research obtains data through interaction with the individual; or
- A living individual about whom an investigator conducting research obtains identifiable private information.

First criterion

- A living individual about whom an investigator conducting research obtains data through intervention;
- “*Intervention* 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.”
- Key Question: when do professional randomized cluster studies constitute “manipulations of the subject or the subject's environment .”

Second Criterion

- A living individual about whom an investigator conducting research obtains data through interaction with the individual.
- “Interaction includes communication or interpersonal contact between investigator and subject.”
- This one is pretty straight forward.

Third Criterion

- A living individual about whom an investigator conducting research obtains identifiable private information.
- “*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.”

- Any of the three criterion independently cause an individual to be a subject under 45 CFR 46.