

8.2 Does it involve human subjects?

A human subject is defined by Federal Regulations as “a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.” (45 CFR 46.102(f)). The FDA defines a human subject as “an individual on whom or on whose specimen a device is used” (21 CFR 812.3) or “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 either be a healthy human or patient.” (21 CFR 50.3 (g))

“Identifiable private information” includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation is taking place,” (such as a public restroom) “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 health care record).” (45 CFR 46.102(f)). Although there is no definition of “identifiable” information in the Common Rule, HIPAA provides a list of 18 identifiers, the removal of which renders a data set de-identified for the purpose of determining if a human subject is involved. (See Appendix N)

Intervention includes physical procedures, manipulations of the subject or manipulations of the subject's environment for research purposes. Interaction includes communication between the investigator and the subject. This includes face-to-face, mail and phone interaction as well as any other mode of communication. Private information includes observation of behavior when an individual can reasonably expect that no observation is taking place, or information for specific purposes (such as a health care record) that individuals can reasonably expect will not be made public. Thus, approaches involving only existing records or human specimens or observations may still constitute human subjects research requiring IRB approval. The IRB will make this determination. Simple observational studies of public behavior (including television and internet chat rooms) do not involve human subjects as defined, because there is no intervention or interaction and the behavior is not private. Also, studies based on data collected for non-research purposes may not constitute human subjects research if individual identity is not identifiable. Examples include programmatic data such as service statistics, school attendance data, crime statistics, or election returns. Studies based on data that are individually identifiable data but also are publicly available may not constitute human subjects research [45 CFR 46.101(b)(4)]; however, the term “publicly available” is intended to refer to record sets that are readily available to the broad public, such as death certificates.