

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)) 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, “identifiable” means that the information contains one or more data elements that can be combined with other reasonably available information to identify an individual. See Appendix N for further information on individual identifiability of data.

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 truly readily available to the broad public, such as death certificates.

8.3 Is it conducted under the aegis of UNC Chapel Hill?

In the interests of protecting human subjects participating in research that is either under university aegis or would appear to be under university control, human subjects research that meets any of the following criteria will be subject to UNC-Chapel Hill IRB review and monitoring:

- The research is sponsored by UNC-Chapel Hill.

- The research is conducted or directed by any employee or trainee of the university in connection with his or her UNC-Chapel Hill responsibilities.
- The research involves access to any property or facility of UNC-Chapel Hill other than access to open spaces on the University campus that are readily available to the public at large.
- The research involves the use of non-public information in the custody of UNC-Chapel Hill to identify or contact human research subjects or prospective subjects.

References:

21 CFR 50.3(g)

21 CFR 56.102(e)

21 CFR 56.103

45 CFR 46.101(b)(4)

45 CFR 46.102(d)

45 CFR 46.102(f)