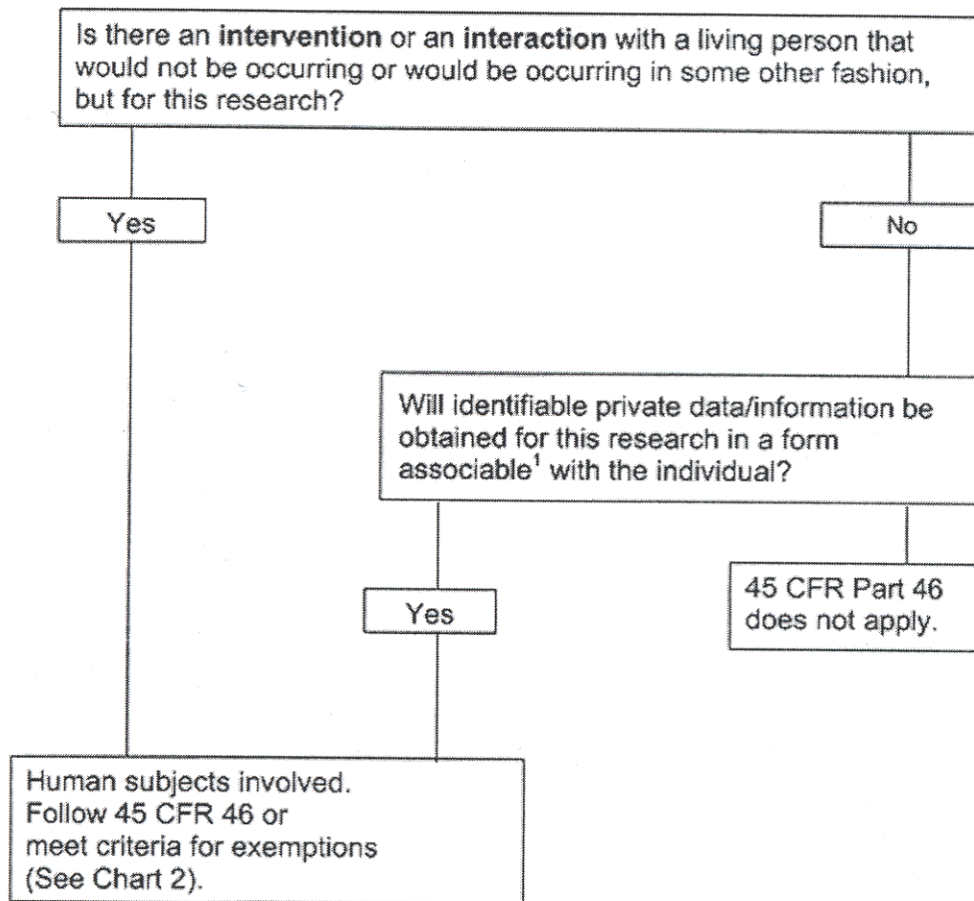


Human Subject Regulations Decision Charts

Is the definition of "human subject"⁵ at Section 46.102(f) met in this research activity?

Decision Chart 1



¹That is, the identity of the subject is or may readily be ascertained or associated with information.

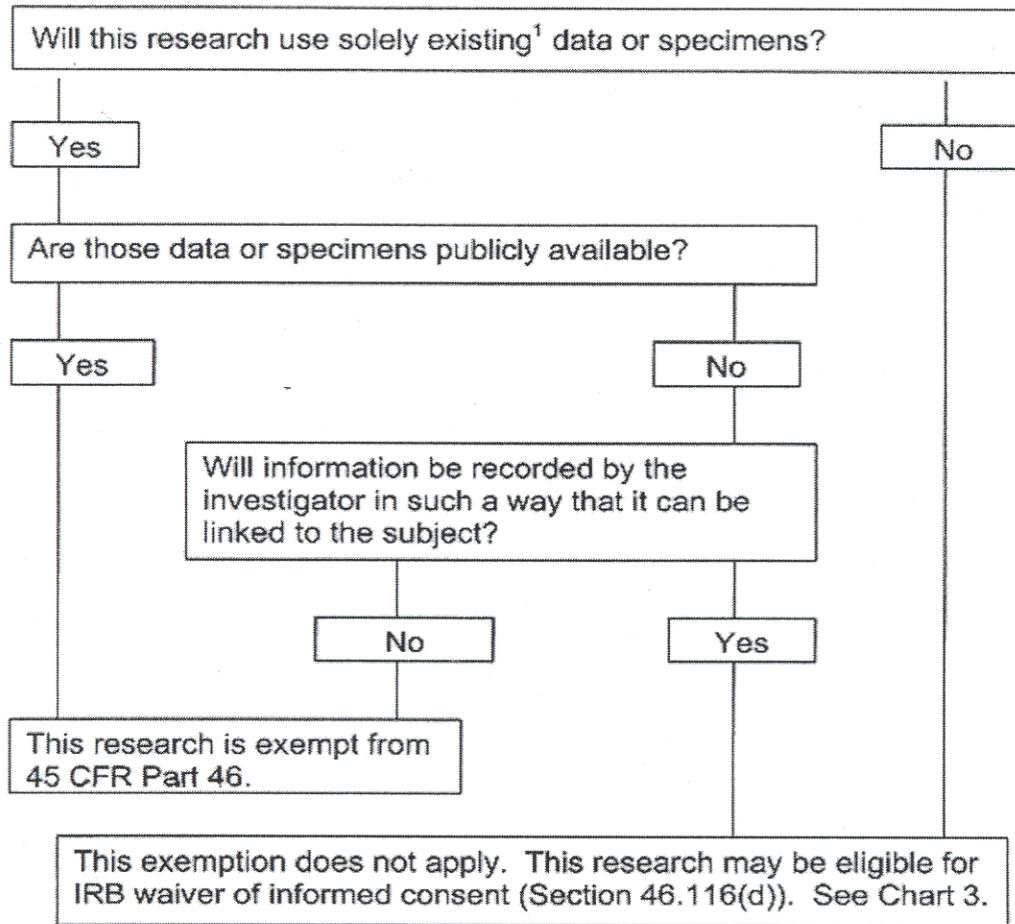
⁵ **Human subjects** - living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

Private information - 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, client or medical records or information obtained in an interview).

Is the research⁶ exempt in accordance with Section 46.101(b)(4)?

The regulations at 45 CFR Part 46 do not apply if the criteria for exemption under Section 46.101(b)(4) are met.

Decision Chart 2



¹"Existing" means collected (i.e., on the shelf) prior to the research for a purpose other than the proposed research. It includes data or specimens collected in research and nonresearch activities.

Can the Institutional Review Board employ Section 46.116(d) to waive informed consent or alter informed consent elements?

⁶ **Research** - a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. This includes collection of scholarly materials for theses and dissertations done by students, and investigations carried out by faculty and staff for publication and/or presentation.

