

Single IRB: Institutional Engagement Definitions

Institution [45CFR§46.102(f)]: any public or private entity, or department or agency (including federal, state, and other agencies).

Employees or agents: individuals who (1) act on behalf of the institution; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities. “Employees and agents” can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation.

Human subject [45CFR§46.102(e)]: a living individual about whom an investigator (whether professional or student) conducting research (1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Research [45CFR§46.102(l)]: a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. See [OHRP Decision Chart 1](#) for more information.

Exempt research [45CFR§46.104]: research activities that are included in one or more of the categories in [45CFR§46.104\(d\)](#) and are therefore not required to follow requirements of the Common Rule 45CFR§46. See [45CFR§46.104](#) and [OHRP Decision Chart 2](#) for more information.

Interact for research purposes or Interaction [45CFR§46.102(e)(3)]: communication or interpersonal contact between investigator (or designee) and the subject. Examples of interacting include engaging in protocol dictated communication or interpersonal contact; asking someone to provide a specimen by voiding or spitting into a specimen container; and

Intervene for research purposes or Intervention [45CFR§46.102(e)(2)]: 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.

Manipulating the environment: examples include controlling environmental light, sound, or temperature; presenting sensory stimuli; and orchestrating environmental events or social interactions.

Procedures (invasive or noninvasive): examples include drawing blood; collecting buccal mucosa cells using a cotton swab; administering individual or group counseling or psychotherapy; administering drugs or other treatments; surgically implanting medical devices; utilizing physical sensors; and utilizing other measurement procedures.

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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record). See OHRP [Coded Private Information or Specimens Use in Research, Guidance \(2008\)](#) for additional information.

Identifiable private information: private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Identifiable biological specimen: a biological specimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

The definitions above are from the [Common Rule \(45 CFR§46\)](#) and/or the [Office for Human Research Protections \(OHRP\) guidance on Engagement of Institutions in Human Subjects Research](#). For U.S. Food and Drug Administration research, refer to [21CFR§50](#).

To learn more about CTTI’s sIRB work, please visit <https://ctti-clinicaltrials.org/our-work/ethics-and-human-research-protection/single-irb/>