

IRB Glossary of Terms

Generalizable Knowledge is generally used to refer to the intent to disseminate the research results and conclusions beyond an individual or internal group. Generalizable knowledge is usually created to share with other people through publication of an article in a journal, presentation at a local or national conference, or preparation of a thesis or dissertation

Human Subject is defined as 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) obtains identifiable private information" (45 CFR 46.102(f)). Key to this definition is that the information collected is about an identified person. Information collected without any identifiers or other details which could lead to identification of an individual would not be considered to involve human participants (such as public use databases like U.S. Census Bureau statistics). Information which involves interaction with an individual but which does not collect information about a person, such as interviews on government or corporate policies or oral history accounts of historical events are also not considered to involve human subjects. Oral history accounts and journalism/documentary activities that do not intend to test a hypothesis do not need IRB approval.

Identifiable is where the identity of the subject is, or may be ascertained by, the researcher or will be associated with the information.

Identifiers include names, Social Security numbers, medical record codes, and internal code numbers that permit data to be linked to individuals. Audiotapes contain identifiers even if they are not labeled with clear identifiers (e.g. name, initials), the recording does not contain individually identifiable information like someone saying a name, or the tape will not be used for any purpose outside of the research, because the voice itself is considered to be identifiable. Video tapes would include identifiers, even if they are not labeled with codes/identifiers, unless the person's image is blacked out or blurred such that they cannot be identified and the voice has been disguised.

Interaction includes communication or interpersonal contact between investigator and subject.

Intervention includes both physical procedures by which data are gathered and manipulations of the participant or the participant's environment that are performed for research purposes.

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, medical record information). Private information is information that is individually identifiable.

Public Information refers to public sources of data, such as telephone books, data bases, libraries, and the internet. Data obtained from data banks, archives, or organizations that make data sets broadly accessible at a reasonable cost to the research community are also considered publicly available.

Systematic Approach involves a predetermined system, method or a plan for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing a theory. A systematic approach includes the collection of information and/or biospecimens, and analysis either quantitative or qualitative.

