

Research and Human Subject Definitions

Standard

This standard defines those activities that constitute human subject research and fall under the jurisdiction of the Institutional Review Board.

Definitions

From the Department of Health and Human Services Common Rule, [45 CFR 46.102](#)

Research: A **systematic investigation**, including research development, testing, and evaluation, designed to develop or contribute to **generalizable** knowledge.

- **Systematic investigation:** A study following a methodological plan to investigate a specific hypothesis, theory, or research question.
- **Generalizable:** Knowledge that may be justifiably transferred or extrapolated to a broader population or situation than that in which it has been derived.

The following activities are deemed not to be research overseen by the IRB:

(1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Human Subject: A living individual about whom an investigator (whether professional or student) is conducting research, which (1) obtained 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**.

- **Intervention:** Includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
- **Interaction:** includes communication or interpersonal contact between investigator and subject.
- **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 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).

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

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

Minimal Risk: the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Document Attributes

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