Defining Research with Human Subjects - SBE

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Introduction

The federal regulations define both "research" and "human subject." Studies must be reviewed by an Institutional Review Board (IRB) only if both definitions apply.

A study that meets the federal regulation's definition of research, but does not involve human subjects, does not need IRB review. Similarly, a study may involve human subjects, but not meet the definition of research and would, therefore, not require an IRB review.

This module interprets words and phrases used in the definitions of research and human subject from the perspective of research in the social and behavioral sciences, education, and the humanities.

Learning Objectives

By the end of this module, you should be able to:

- Explain the definition of research.
- Explain the definition of human subject.
- Describe the differences between private and public information and behavior.

Defining Research

Research is defined by federal regulations at 45 CFR 46.102 (Protection of Human

Subjects 2018), as "a systematic investigation including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."

This definition was revised in the 2018 Requirements version of the Common Rule to specifically exclude the following activities:

- Scholarly and journalistic activities (for example, oral history, journalism, biography, literary criticism, legal research, and historical scholarship)
- Public health surveillance activities
- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order or criminal investigative purposes
- Authorized intelligence, homeland security, defense, or national security mission operational activities

Note: For research subject to the pre-2018 Requirements version of the Common Rule, the definition of research does not specifically exclude those activities. It is important to know which set of requirements applies to each individual research study.

Systematic Investigation

The definition of research starts by stating that the activity must be a systematic investigation. A **systematic investigation** is the opposite of a disorganized, random venture. In other words, researchers need to have constructed a research plan with ideas about what they want to learn and how best to do that.

Both qualitative and quantitative researchers use systematic investigation in the course of their research. Both types of research are organized, albeit around differing notions about the role of the researcher, the purpose of the research, the nature of the data collected, and so on.

Quantitative researchers may test hypotheses and theories with the data they collect, while qualitative researchers may generate hypotheses or theories based on the data they gather.

Quantitative researchers may focus on statistical analyses based on precise measurements; however, it is not necessary for precise, replicable measurements to be collected in order for research to be considered systematic.

Including Research Development, Testing, and Evaluation

It is important to understand what activities qualify as “research development, testing, and evaluation” under the definition of research.

Pilot studies and other preliminary studies fall under the definition of research. Both of the following preliminary components of a study constitute research with human subjects:

- Convening a focus group to help researchers develop a questionnaire
- Pilot testing a questionnaire

Designed to Develop or Contribute to Generalizable Knowledge

The definition of research requires that the activity

is “designed to develop or contribute to generalizable knowledge” (Protection of Human Subjects 2018).

To generalize is to derive general conclusions from particulars. Although some qualitative research may be less generalizable than some quantitative research, it is not the case that only hypothesis-driven, replicable research may be considered generalizable. Even research about the most narrowly defined topic (such as, an individual case study or an isolated community study) may be intended to contribute to a body of knowledge (such as, the function of culture, expression of gender, or political views of marginalized community members).

There is no regulatory guidance on the meaning of generalizability. The essential consideration is whether it was the researcher's intent to contribute to a body of knowledge or whether the results were replicable. It really depends on the intent.

The definition of research excludes certain scholarly and journalistic activities that collect and use information with a “focus directly on the specific individual about whom the information is collected”, not the generalizability of that information (Protection of Human Subjects 2018).

Some activities that involve interactions with humans and data gathering may not meet the definition of research because they are designed to accomplish something else, such as program improvement (also called quality improvement activities).

For example, university library staff may conduct a survey of members of an academic unit to find out if the library is meeting the department's need. The project may be a systematic investigation, but is not considered research because the intent of the project is to improve the library's service to its patrons, rather than contribute to a body of knowledge (such as, improving all libraries’ service methods).

Publication of results is sometimes used, incorrectly, as an indicator that a project meets the definition of research. It is the intent of the project that matters. In the example above, the library staff could share the results of their program improvement activity at a conference without changing the intent. The project would not become research by virtue of sharing its results.

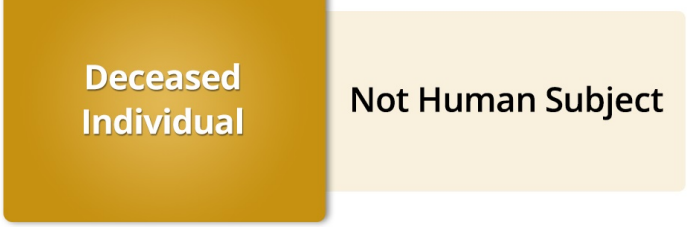
Defining Human Subject

According to the federal regulations at 45 CFR 46.102 (Protection of Human Subjects 2018), a human subject is a "living individual about whom an investigator (whether professional or student) conducting research: (i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

The following sections review key words and phrases in the definition.

A Living Individual

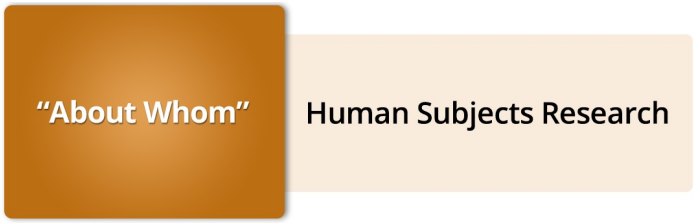
Research about deceased people does not meet the federal definition of research with human subjects.



About Whom

Another key part of the human subjects definition is the “about whom” wording.

Some research that involves interactions with living individuals does not meet the regulatory definition of research with human subjects because the focus of the investigation is not on the opinions, characteristics, or behavior of the individual. Instead, the individual is asked to provide information about something. How many micro-loans were made last year? What is the average amount of those loans? These are not "about whom" questions, but can be thought of as "about what" questions.



If a researcher calls the director of a shelter for battered women and asks her for the average length of stay of the women who use the shelter, that inquiry would not meet the definition of research with human subjects, even though there is an interaction between the researcher and a living individual, because the information requested is not "about" the director. If the researcher interviewed the director about her training, experience, how she defines the problem of battering, or how she manages stress, then the inquiry becomes about her - and thus "about whom" - and therefore, meets the definition of research with human subjects.

Interactions and Interventions

The researcher must obtain the information or biospecimens about the subjects either by intervention or interaction.

Interventions include:

- Physical procedures through which data are gathered, such as measuring brain function to supplement paper and pencil inquiries into the development of language

- Behavioral interventions such as experimental education programs or unproven

psychosocial therapies.

Interventions also include manipulation of the subject or the subject's environment performed for research purposes, for example, studies investigating the effect of music on memory.

Interactions include communication or interpersonal contact between the subject and the researcher. Communication does not have to be face-to-face, and may even exist entirely on paper or in electronic realms. Online surveys that do not ask for any identifying information about the subjects are considered interactions. Participant observation is a variant of interaction, often including both formal and informal interviews in addition to observation.

Private Information, Identifiable Private Information, and Identifiable Biospecimen

The Common Rule provides definitions for the terms private information, identifiable private information, and identifiable biospecimen to help clarify how they are used in the human subject definition.

As defined in the regulations at 45 CFR 46.102 (Protection of Human Subjects 2018), **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" (for example, a school record).

The regulations further state that **identifiable private information** is private information that the researcher can readily identify whom it is from or associated with.

The regulations provide no explanation of the words "readily ascertained," but one can assume that this means the information is available to the researcher (for example, the researcher has access to the linking code of subject ID and subject name).

An **identifiable biospecimen** is just that – a biospecimen that the researcher can identify whom it is from or associated with. The regulation uses the wording that the subject's identify "may readily be ascertained" but does not say what this means.

The regulation further requires that federal agencies implementing the Common Rule must reexamine the meaning of "identifiable private information" and "identifiable biospecimen" regularly, especially in light of emerging technologies and techniques that can be used for identification/re-identification purposes (Protection of Human Subjects 2018).

Observing and Recording Private Behavior

It is important to keep in mind that whether a setting is public, by federal definition, is determined in large part by the potential subjects' reasonable expectations of privacy, rather than any absolute distinctions between public and private spaces.

For example, one might expect that certain

behavior, even if conducted in public spaces, is in fact private, such as a conversation in a public park. It is reasonable to assume that one might expect not to be taped while dining with a date at a restaurant.

Researchers who wish to obtain information in a context in which subjects would have a reasonable expectation of privacy, may choose to use covert observation (concealed audio or video recording devices, or using a one-way mirror) or assume a role in the setting or group being studied. Such studies raise significant concerns about violation of privacy and require additional protections and safeguards for subjects. Observational studies in quasi-public places, for example, hospital emergency rooms, also may raise such concerns.

Private Information Provided by Individuals for Specific Purposes

Individuals, in a variety of settings, provide personal information with the expectation that it not be made public, such as at work, at school, when receiving health care, or as a member of an organization.

Some of this personal information is protected by law. Additional laws to protect individuals' privacy include:

Family Education Rights and Privacy Act (FERPA) protects the privacy of school records

Health Insurance Portability and Accountability Act (HIPAA) protects private health information

The Family Education Rights and Privacy Act (FERPA) protects the privacy of school records. Similarly, the privacy provisions of the Health Insurance Portability and Accountability Act (HIPAA) protect private health information. Generally, although there are some exceptions, school and medical records can only be released with express written permission.

Data files including identifiable private information are compiled and maintained by both public and private institutions. Owners of identifiable data impose restrictions on the use of the data they provide researchers. Institutions may release de-identified data publicly, but only release identifiable data to researchers with IRB-approved data protection plans.

Revised Common Rule and On-going Research

Revisions were made to update regulations at 45 CFR 46, Subpart A - "Federal Policy for the Protection of Human Subjects" (the Common Rule) by the U.S. Department of Health and Human Services (HHS) and other Common Rule agencies and departments, with a general compliance date of 21 January 2019. The revised Common Rule is referred to as the "2018 Requirements" and the previous Common Rule is referred to as the "pre-2018 Requirements."

On-going research that was initiated, determined to be exempt, or waived prior to the

general compliance date of the revised Common Rule (21 January 2019) is allowed to continue being governed by the pre-2018 requirements for the duration of the research (Protection of Human Subjects 2018).

Note: This module reflects the 2018 Requirements version of the Common Rule, not the pre-2018 Requirements version. It is important to know which rule governs which research and ensure compliance with the appropriate version of the rule, as there are differences that affect research conduct and review.

Summary

The definitions of research and human subject are essential for determining which research activities are subject to regulation and review. Important concepts include generalizability, identifiability, and public versus private information.

Reference

- Protection of Human Subjects, 45 CFR § 46 (2018).

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