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i This module was updated to reflect the 19 June 2018 Final Rule. In addition, there are pending regulatory changes that have a general compliance date of 21 January 2019. This module will be further updated in January 2019 to reflect those changes. We invite you to review the [CITI Program's Final Rule Resources](#) for more information on all the changes to the Common Rule. We also recommend contacting your organization and/or appropriate IRB for more information.

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 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 definition of research and of 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 2009), as "a systematic investigation including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."

Note: This is the definition from the pre-2018 requirements, not the definition from the revised Common Rule (2018 requirements). (See section below on “Understanding the Revised Common Rule Delay and Burden-Reducing Provisions.”)

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

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



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.

Although there is no regulatory guidance on the meaning of generalizability, the regulations refer to interviews, oral history, focus groups, and other qualitative methods. Therefore, the essential consideration is whether it was the researcher's intent to contribute to a body of knowledge or whether the results were replicable.

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. 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 systematic, 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.

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 45 CFR 46.102 (Protection of Human Subjects 2009), a human subject is 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) Identifiable private information."

The following sections will consider key words and phrases in the definition.

A LIVING INDIVIDUAL

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

ABOUT WHOM

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 research 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

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.

INTERVENTIONS

Interventions include physical procedures through which data are gathered, such as (1) measuring brain function to supplement paper and pencil inquiries into the development of language, and (2) behavioral interventions such as experimental education programs or unproven psychosocial therapies. They 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.

IDENTIFIABLE PRIVATE INFORMATION



As defined in the regulations at 45 CFR 46.102 (Protection of Human Subjects 2009), 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"
- "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, a school record)"

The regulations further state that private information must be individually identifiable, that is, the identity of the subject is or may be readily ascertained by the researcher or associated with the information in order for obtaining the information to constitute research involving human subjects. 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).

The following two sections expand on the definition of identifiable private information.

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' 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. For example, 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. They may release de-identified data publicly, but only release identifiable data to researchers with IRB-approved data protection plans.

UNDERSTANDING THE REVISED COMMON RULE DELAY AND BURDEN-REDUCING PROVISIONS

The Final Rule to update the current regulations at 45 CFR 46, Subpart A - "Federal

Policy for the Protection of Human Subjects" (the Common Rule) was published by the U.S. Department of Health and Human Services (HHS) and other Common Rule agencies and departments on 19 January 2017 in the *Federal Register*. This rule was not immediately effective.

On 19 June 2018, HHS and 16 other agencies published a Final Rule (“2018 Final Rule”) to delay the general compliance date until 21 January 2019, but allow for three provisions from the revised Common Rule (2018 requirements) to be available in the delay period (HHS 2018).

[Read more about the delay and the effect on ongoing research.](#)

Which definition of “research” applies to the activity?

During this delay period (19 July 2018 – 20 January 2019), some studies may be subject to the pre-2018 requirements and others subject to the three burden-reducing provisions from the 2018 requirements depending on if they were transitioned or not.

This may affect SBE research because one of the provisions is the revised definition of “research.” The revised definition of “research” from the 2018 requirements excludes certain activities as not research. It is important to know which regulation (pre-2018 requirements or revised Common Rule) is in effect for each research study to determine which definition of “research” to use.

The following activities are **not** considered research by the Common Rule’s 2018 requirements if the activity only involves (HHS 2017):

- Scholarly or journalistic activities
- Public health surveillance activities
- Criminal justice activities (collection and analysis of information,

biospecimens, or records) conducted for criminal justice purposes

- Authorized operational activities in support of intelligence, homeland security, defense, or other national security missions

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.

REFERENCES

- Protection of Human Subjects, 45 CFR § 46 (2009).
- U.S. Department of Health and Human Services (HHS). 2017. “[Federal Policy for the Protection of Human Subjects](#).” *Federal Register* 82(12):7149-274.
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