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Fact Sheet: Human Subjects Research Triage

EPA's Program in Human Research Ethics and Oversight (PHREO) has created this Fact Sheet to assist the research community in conducting ethical human subject research (HSR) that complies with the EPA regulations for HSR.

Use the following definitions and guiding questions to help understand whether your project may constitute human subjects research (HSR) according to the EPA HSR regulations, codified at 40 CFR Part 26 Subpart A (Protection of Human Subjects).

Key Definitions:

- *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. [40 CFR 26.102(l)].
- *Human subject* means 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. [40 CFR 26.102(e)].
- *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). [40 CFR 26.102(e)].
- *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.
- *An 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.

Whether or not your project may constitute HSR according to the federal regulations is not always easy to determine. Your project must satisfy the definitions of BOTH “research” AND “human subject” to be considered human subjects research per 40 CFR 26.102:

- It is required that institutions consider the definition of HSR sequentially when assessing their project. First, does the project constitute “research,” and second, does the research involve “human subjects.” If the project does NOT constitute “research,” then it should NOT be deemed HSR. Similarly, if the project DOES constitute “research,” but does NOT involve “human subjects,” then it should NOT be deemed HSR.

Step 1: Assessing if your project is “research” per the federal regulations.

Notice: Any solicitation issued by an EPA program or regional office for research involving human subjects shall require compliance with 40 CFR 26 and follow the provisions of [EPA Policy Order 1000.17A \(pdf\)](#). The EPA program or regional office that conducts or supports research is responsible for its compliance.

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Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. [40 CFR 26.102(l)].

Please consider if the project is **systematic**. In assessing this, consider the following questions:

- Does the activity/project use information collection and analysis activities to answer a question?
- Is the project carried out according to a plan? For example, does the project include:
 - A Hypothesis?
 - Randomization?
 - A Comparison of two or more products/processes?
 - Are there methods for data collection or subject recruitment?
 - Is there an analysis plan?
 - Are the results compared to historical controls/literature?

Please consider if the intent of the project is **to develop or contribute to generalizable knowledge**. To assess this, consider the following questions:

- Will the Activity/Project expand scientific understanding or the knowledge base of a scholarly field of study?
- Will the project form the basis for or add to the understanding of a particular discipline?
- Are you planning to disseminate this information to others to inform future research or policy?
- Will you share your findings so that they can be applied to populations outside of the specific study population?

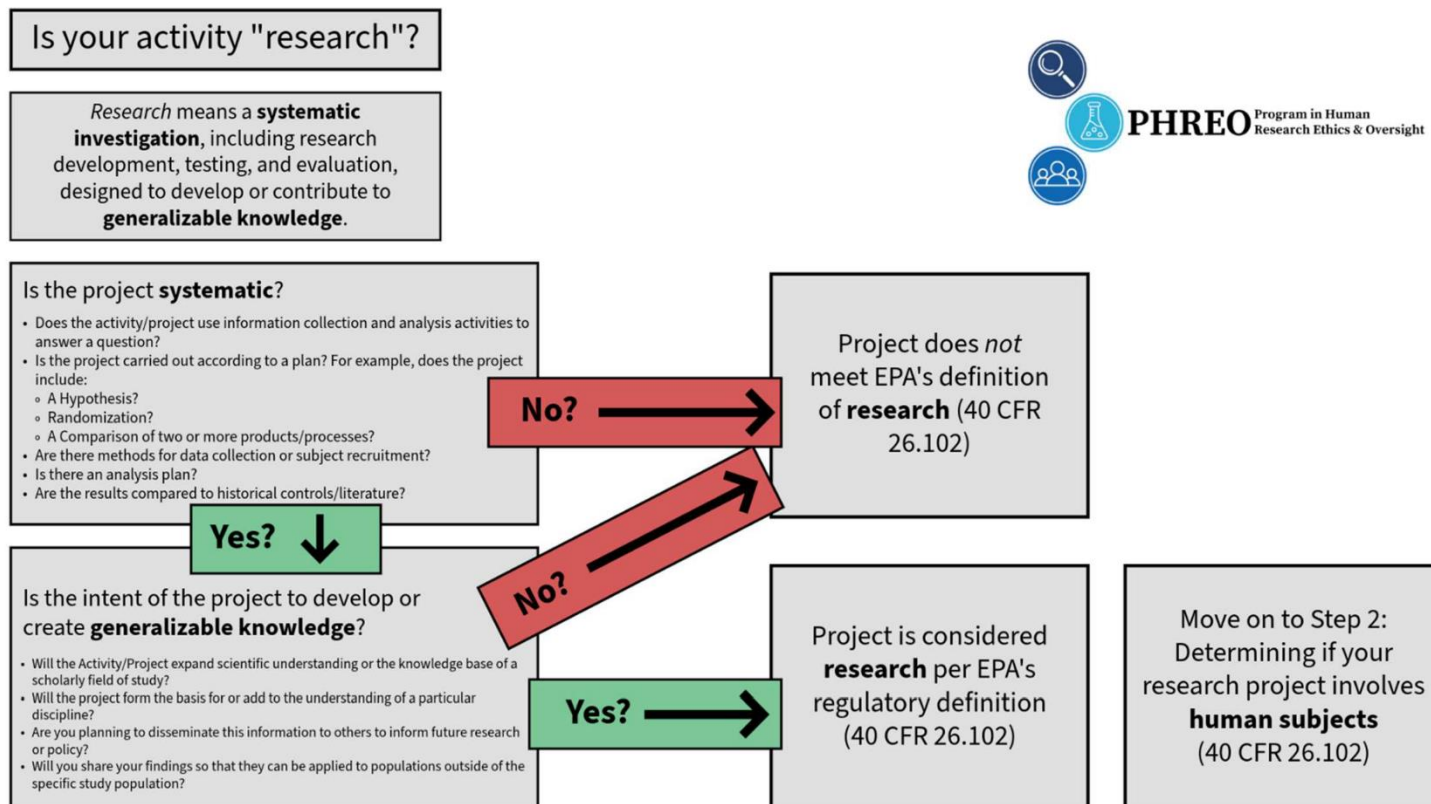
Please see the following page to view a flowchart describing the triage process for Step 1 (is it research?):

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HSR Fact Sheet – Step 1 Flowchart: Assessing if your activity constitutes “research”



“My project constitutes research. What now?”

If a given project fits the definition of “research” [40 CFR 26.102(l)], then that project may constitute HSR, depending on whether that research project fits the definition of “human subjects.”

Step 2: Assessing if your research project involves “human subjects” per the federal regulations.

Human subject means 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. [40 CFR 26.102(e)].

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Please consider if the research project involves a **living individual**.

- To be considered HSR, the research at hand must be about people who are currently living.
 - Research on the deceased (including the newly deceased) or on health data of deceased individuals follows a different set of regulations and policies and is not included in HSR.

Consider if the research project seeks to answer an “**about whom**” question. To assess this, consider the following questions:

- Does the research seek an opinion from the individual you’re studying?
- Does the research seek to determine a characteristic of the individual you’re studying?
- Does the research focus on the behavior of the individual you’re studying?

At this point, if the research involves living individuals and seeks to answer a question about the individuals, there are two possible pathways for research to qualify as HSR

Only one of the below pathways must be provoked to qualify your project as HSR:

Pathway 1) The researchers involved will obtain data through intervention or interaction.

Pathway 2) The researchers will seek to obtain identifiable private information about the subject(s).

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Step 2 (Continued): Assessing if your research project involves “human subjects” with consideration of the two possible pathways.

Pathway 1) The researchers involved will obtain data through **intervention or interaction**. To assess this, consider the following questions:

- Will data be gathered through physical procedures involving the subjects being studied?
 - If your answer is “Yes” then **intervention** is involved.
- Will research involve manipulation of the subject or the subject’s environment?
 - If your answer is “Yes” then **intervention** is involved.
- Does the research involve communication or interpersonal contact between the subject and the researcher? Communication includes both face to face and electronic correspondence.
 - If your answer is “Yes” then **interaction** is involved.
- Does the research involve communication or interpersonal contact between the subject and the researcher? Communication includes both face to face and electronic correspondence.
 - If your answer is “Yes” then **interaction** is involved.

Pathway 2) The researchers will seek to obtain **identifiable private information** about the subject(s). To answer this, consider the following examples:

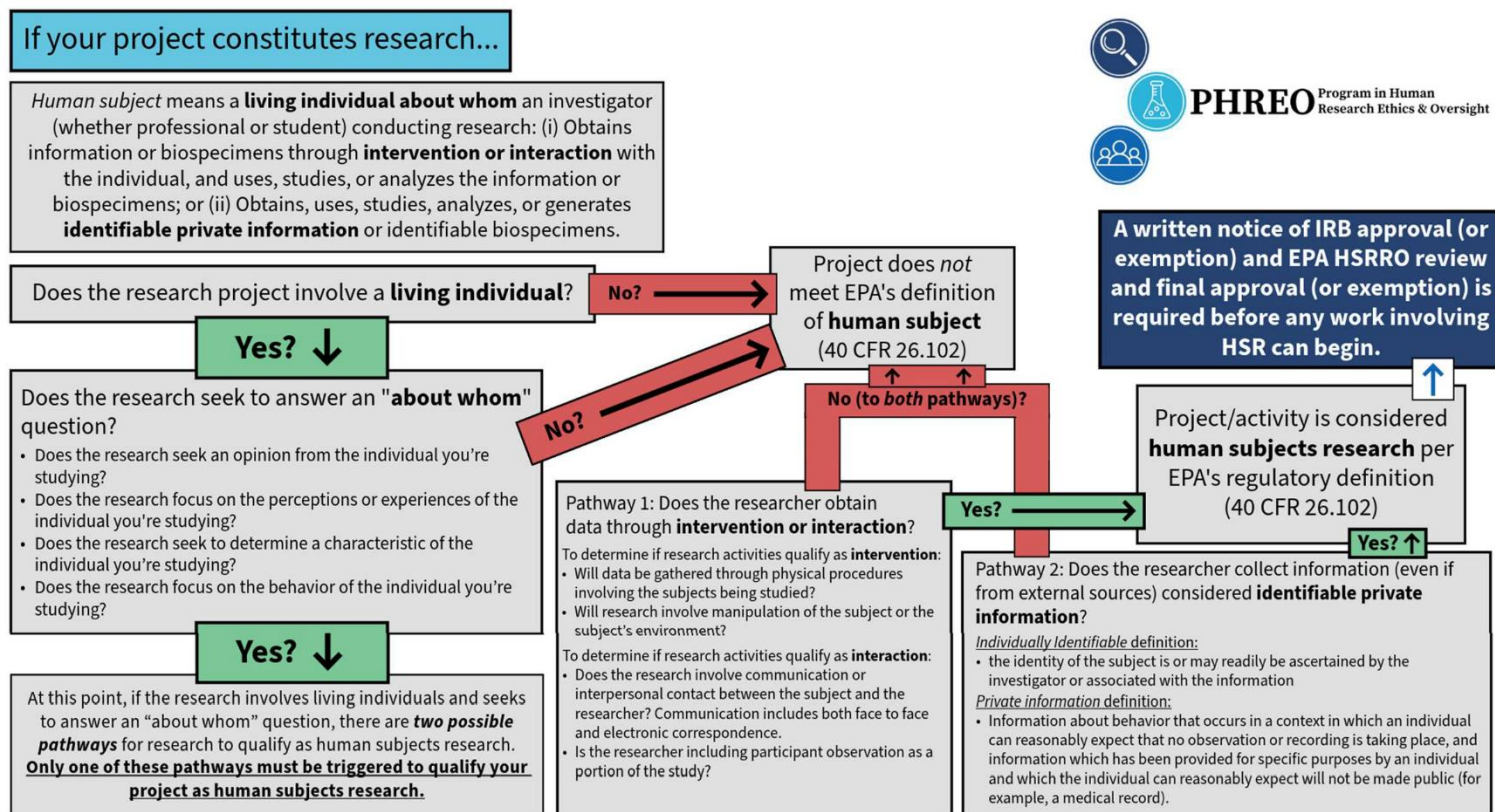
Suppose that researchers want to compare responses to a survey before and after a particular intervention. They do not need to know the identity of the person completing the survey, but simply want to track that individual’s responses from time T1 to time T2. Researchers can code those responses so that they keep individual responses paired, but do not reflect personal identifiable information (provided they do not ask for any identifiable information in the survey). On the other hand, researchers could also develop a code that represents something significant: birth month, date, and first two letters of the subject’s first and last name. In that case, the code would make the subject identifiable to investigators, which would then constitute HSR. To qualify as HSR under this definition, information must be BOTH individually identifiable AND private if there is no intervention or interaction in any other way. If information is not individually identifiable and not private (e.g. comes from public observations, etc.), then the project will not constitute HSR.

Please see the following page to view a flowchart describing the triage process for Step 2 (Does this research project involve human subjects?):

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HSR Resource Tool – Step 2 Flowchart: Assessing if your research project involves “human subjects”



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