



## Does My Project Need IRB Review?

The IRB is responsible for reviewing **human subjects research** and ensuring that it is conducted in accordance with applicable regulations and institutional policies.

Determining whether or not a project meets the federal definition of human subjects research is a two-step process. The investigator must first determine if the project meets the federal definition of research and, if so, *then* determine if the project includes human subjects.

### Step 1: Is your Project Considered Research?

The [Federal Policy for the Protection of Human Subjects \(Common Rule\)](#) defines "research" as a systematic investigation, including research development, testing, and evaluation, that is designed to develop or contribute to generalizable knowledge.

#### Systematic Investigation

A "systematic investigation" is a detailed or careful examination that has or involves a prospectively identified approach to studying a specific topic, answering a specific question(s), testing a specific hypothesis(es), or developing theory based on a system, method, or plan. Systematic investigations include observational studies, interview or survey studies, group comparison studies, test development, and interventional research. Program evaluation is seen as a gray area and requires further assessment of design and intent.

#### Generalizable knowledge

Developing or contributing to "generalizable knowledge" means that the intent or purpose of the systematic investigation is to produce knowledge from which conclusions will be drawn that can be applied to populations outside of the specific study population. This usually includes one or more of the following concepts:

- knowledge that contributes to a theoretical framework of an established body of knowledge;
- the primary beneficiaries of the research are other researchers, scholars, and practitioners in the field of study;
- dissemination of the results is intended to inform the field of study (this alone does not make an activity constitute research "designed to contribute to generalizable knowledge");
- the results are expected to be generalized to a larger population beyond the site of data collection;

- the results are intended to be replicated in other settings.

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**The following activities are deemed by the federal regulations** not to be research: 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. 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.

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**If your project *does* meet the definition of research, proceed to Step 2.**

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## **Step 2: Does it involve human subjects?**

The [Federal Policy for the Protection of Human Subjects \(Common Rule\)](#) defines a human subject 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) identifiable private information.”

Examples that do not meet the definition of Human Subjects:

- Analysis of data about people who are deceased
- Secondary analysis of anonymous data
- Interviews with “key informants” about topics other than themselves

Note that the definition of human subject focuses on what information is obtained about people or material that is acquired from people. If **either** of the following is true, your research activity involves human subjects.

Human subjects research typically includes:

### **Data collected about living individuals through intervention or interaction**

An **intervention** may be physical procedures (*e.g.* venipuncture) or manipulations of living individuals or the living individuals’ environments.

An **interaction** may be communication or interpersonal contact between the investigator (or research team) and the living individual. Examples include interviews, questionnaires, surveys, observations, manipulations of subject behavior, diet, or environment, physical measurements, specimen collection (*e.g.* blood tissue), and administration of experimental drugs or devices.

### **Why “about whom” is key**

Consider if the project focuses on the person or if the focus is on policies, practices or procedures about which the person is knowledgeable. Projects which collect information about policies, practices or procedures – even if the person who provided that information is identified – do not constitute human subject research.

### **Identifiable private information about living individuals**

**Identifiable** means 1) the identity of the individual from whom the information was obtained is ascertained or may be readily ascertained by the investigator; or 2) the identity of the individual from whom the information was obtained is associated or may be readily associated with the information.

**Private Information** is information about behavior that occurs in a context in which the individual can reasonably expect that no observation or recording is taking place or information that has been provided for specific purposes that the individual can reasonably expect will not be made public (e.g. medical record, employee or student records).

**Examples of identifiable, private information** include the subject's name, address, phone number, social security number, medical record number, student or employee identification number, or in some cases, the combination of data such that they can identify a single individual through deductive reasoning. For example, data about employer, job title, age and gender may not individually identify a subject, but when combined, could in certain cases, identify a specific individual.

**What is NOT considered identifiable, private information:** If the information cannot be linked to a living individual, or is considered public or is given with the expectation that it will be made public and that it will be linked to the individual (e.g. biography or news story), then it would not be considered private identifiable information. For example, use of a publicly available data set that does not contain identifiers or codes linked to individuals does not involve human subjects research. However, use of a publicly available data set that does contain identifiers or codes linked to individuals does involve human subject research.

If you obtain/purchase/are given specimens/cells/material/data that has already been collected by someone else for some other purpose, and the specimens/cells/material/data are not linked to any identifiers that would make it reasonably possible to identify an individual, the activity is not considered research with human subjects.

***Important Note: Per the GSU IRB Policy, investigators are discouraged to make a determination that their project is not research involving human subjects or a clinical investigation. Only the IRB makes this determination.***

#### **Questions?**

If you have questions, please contact us [irb@govst.edu](mailto:irb@govst.edu)