Human Subjects Research Determinations

Do I need IRB Review? Is This Human Subjects Research?*

Research projects meeting the regulatory definition of **human subjects research** require review and approval by an Institutional Review Board. Federal regulations define **Research (45CFR46.102(l))** as "a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed 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. 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.

The federal regulatory definition of a **Human Subject (45CFR46.102(e)(1))** as:

A living individual about whom an investigator (whether professional or student) conducting research:

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

The regulations further define:

- **Intervention (45 CFR 46.102(e)(2))** 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 (45 CFR46.102(e)(3))** includes communication or interpersonal contact between investigator and subject.
- **Private information (45 CFR46.102(e)(4))** 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.* medical record)
- **Identifiable private information (45 CFR 46.102(e)(5))** 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 (45 CFR46.102(e)(6))** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

There are three categories to be considered:

- studies that are human subjects research
- studies that may be considered human subjects research (gray area)
- studies that do not qualify as human subjects research

Resources:

"Do I need IRB Review? Is This Human Subjects Research? A Guide for Investigators"

This guide provides a basic explanation of the regulations and provides examples of what may or may not constitute human subjects research. As noted in this booklet, there are certain studies which may have the characteristics of human subjects research, but may not meet the regulatory definition. Studies which meet the definition require IRB review.

HawkIRB Human Subjects Research Determination Form (HSRD)

Any investigator who is unsure of whether his/her proposal constitutes “human subjects research” may submit a HSRD form through HawkIRB. The IRB Chair and/or their designee will determine if their Human Subjects Research Determination request meets the definition of human subjects research.

If a HSRD request form does not qualify as human subjects research, HawkIRB will issue a memo stating that the project does not require IRB review or approval.

If the project is determined to meet the regulatory definition of research, the HawkIRB application will initiate a DRAFT new project application on your behalf based on the responses provided in the Human Subjects Research Determination (HSRD) request form. It is the Investigator's responsibility to complete this DRAFT new project application and submit it to the IRB for review. Research can not begin until formal IRB approval is granted!

Frequently Asked Questions

For any questions or concerns regarding the information found on this page, please contact the Human Subjects Office at irb@uiowa.edu or (319) 335-6564.