

Does my research activity require review by the Institutional Review Board (IRB)?

Tell Me

Any activity that meets either the Department of Health and Human Services' (DHHS) definitions of "research" and "human subjects" OR the Food and Drug Administration's (FDA) definitions of "clinical investigation" and "human subjects" requires review and approval by the IRB.

1. The DHHS regulatory definitions (45 CFR 46) of research and human subjects must be met in order to require IRB review. If a project meets the regulatory definition of 'research' but not 'human subjects', then IRB review is not needed. And, vice versa, if a project meets the definition of 'human subjects' but not 'research' then IRB review is not needed.

Note

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

2. The following offers further information on what constitutes systematic investigation and generalizable knowledge (note: these are not regulatory definitions but rather guidance):
 - a. A systematic investigation is a cohesive, predetermined method for studying a specific topic or answering a specific question(s), involving data collection (quantitative or qualitative) from one or more individuals and analysis to address a question or test a hypothesis or developing theory.
 - b. Generalizable knowledge includes results or outcomes (conclusions) gained from a systematic investigation, which are intended to be extended beyond a single individual (relevant beyond the specific participant population) or internal program that may be published, archived, presented, or viewed. Also included are activities where there is an intent to publish the results in a peer-reviewed journal or to present at regional or national meetings, as well as theses or dissertation projects.

A human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains:

- i. Data through intervention or interaction with the individual, or
 1. Intervention includes both physical procedures by which data are gathered (for example, 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 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 medical record).
- ii. Identifiable private information
 1. Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

3. The FDA regulatory definition (21 CFR 56) is as follows:
 - a. A **clinical investigation** involves use of a test article (i.e., drug, device, food substance or biologic), one or more human subjects, meets requirements for prior submission to FDA, or results are intended to be part of an application for research or marketing permit.
 - b. A **human subject** is an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient.
4. A **human subject (FDA for medical devices)** is a human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control. A subject may be in normal health or may have a medical condition or disease. [21 CFR 812.3(p)] (Medical Devices)

Info

For additional guidance regarding activities that MAY or MAY NOT require IRB review and approval, [see the Guidance: Examples of Activities that Do and Do Not Require UNC Charlotte IRB Review and Approval](#) document.

Students conducting projects specifically to fulfill class/course requirements should review the [Guidance: Examples of Activities that Do and Do Not Require UNC Charlotte IRB Review and Approval](#) document and consult with their class/course instructor BEFORE beginning the IRB review process.

Related Articles

- [How do I submit my IRB protocol application & supporting materials?](#)
- [How do I make changes to my IRB approved study?](#)
- [Does my honor's thesis, master's thesis, or/doctoral dissertation require review by the Institutional Review Board \(IRB\)?](#)
- [Does my research activity require review by the Institutional Review Board \(IRB\)?](#)
- [How do I close my IRB Protocol?](#)