

What needs IRB Review and Approval?

Any research activity involving human subjects conducted by USC faculty, staff, and students must be reviewed and approved for compliance with regulatory and ethical requirements before it may be undertaken. These activities include a wide variety of procedures such as, but not limited to, research on medical records, collection of data through surveys or observation, research using existing pathological specimens, discarded tissue or secretions, use of investigational drugs or devices and randomized trials.

Certain studies involving human subjects may be exempt from IRB review. Exempt projects fall into defined categories (see [Categories for Exempt Research](#)). Exemptions must be approved by the IRB.

The project must be approved by the IRB if it meets the following criteria as defined under “Research” **and** “Human Subject”:

Research is defined as:

A systematic investigation, including research development, testing and evaluation, designed to develop or to contribute to generalizable knowledge, **or**

Activities portrayed (explicitly or implicitly) by faculty, students, or staff as “research”, **or**

Work that is intended to fulfill requirements for a master’s thesis, doctoral dissertation, or other research requirements of the University.

Human subject is defined as:

A living individual about whom an investigator conducting research obtains

- 1) data through intervention or interaction with the individual, **or**
- 2) identifiable private information.

Intervention includes both physical procedures by which data are gathered or manipulations of the subject or the subject’s environment that are performed for research purposes. Interaction includes communications or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which the 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.

NOTE: The FDA additionally defines a human subject as 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. Because the above definition excludes non-living humans, research that uses autopsy materials or cadavers is not 'human subjects research' and therefore is exempt from review.

Non-Research Activities (IRB review not required)

Certain activities have the characteristics of research but do not meet the definition of research for IRB review. These activities do not require review by the IRB. Examples of data collection or observation activities that do not require review include:

- Data collection for internal departmental or other University administrative purposes (e.g. teaching evaluations, student evaluations, and “customer service” surveys), and
- Program evaluation carried out under independent contract for an external agency that is for their internal purposes only. Examples include personnel studies, human cost benefit analysis, treatment effectiveness studies, and customer satisfaction studies.

Course related activities (e.g. research methods instruction) that involve the use of human participants but have no connection with research beyond the instructional function preclude the need for IRB review. However, efforts that lead to presentation outside of the classroom and/or the publicizing of the student-prepared documents in any manner are considered research. Instructors of research courses are encouraged to consult with their IRB Liaison or IRB staff to determine the appropriate procedures for assuring that student projects conform to ethical guidelines.

Categories for Exempt Research

Please note: Under no circumstances may research begin without written approval by the IRB.

Exempt Research (45 CFR 46.101b(#))

Certain categories of research have been designated as exempt from federal regulations related to the use of human subjects. Institutions may choose to recognize these categories of exemption and waive the requirement for review by an Institutional Review Board (IRB). The University of South Carolina requires review of all research involving human subjects but imposes different requirements for research meeting the criteria for exemption.

A project is exempt from IRB review if all of the research activities fall into one or more of the categories designated by federal regulation. Exemptions pertain to legal adults in non-compromised situations. Projects involving interaction with prisoners, persons incompetent to provide valid consent, pregnant women where pregnancy is the focus of the research, and fetuses in *utero* cannot be exempt. Experiments, interviews, and surveys with children are not exempt.

Note to Investigators: All exempt research involving human subjects must maintain an adequate standard of informed consent and confidentiality of data. In some exempt research projects, standard written informed consent should be obtained. An example would be obtaining the consent of parents for research involving educational strategies for their children.

The following categories are established by regulation as exempt research:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

5. Research and demonstration projects, which are conducted by or subject to the approval of the federal government, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the federal government.