

Categories for Exempt Research

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

Exempt Research (45 CFR 46.101(b))

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.