

15.3 Categories for exemption from continuing review

Research activities involving other human subjects may be exempted from IRB review if the only involvement of human subjects fits within one or more of the following categories (45 CFR 46.101(b)):

- Category 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.
 - Category 2 Research not involving children that is limited to the use of educational tests, survey procedures, interview procedures or observations 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 human 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. Note: This exemption does not apply to research involving children except for research involving observations of public behavior when the investigator does not participate in the activities being observed, or interact directly with the children. All other exemptions apply to research involving children. [45 CFR 46.101(b)(2) as modified by Subpart D 45 CFR 46.401(b)]
 - Category 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 Category 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.
 - Category 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.
 - Category 5 Research and demonstration projects conducted by or subject to approval of a federal agency and designed to study, evaluate or otherwise examine some aspect of (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. Additionally the following should be considered (1) the program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older
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Americans Act.); or (2) the research is conducted pursuant to specific federal statutory authority; or (3) there is no statutory requirement that an IRB review the research; or (4) the research does not involve significant physical invasions or intrusions upon the privacy of participants.

Category 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 or an agricultural chemical or environmental contaminant, the food ingredient or agricultural chemical or environmental contaminant is at or below the level and for a use found to be safe, by the Food and Drug Administration, the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.