

Exempt Categories

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.

This category should be limited to the study of normal educational practices, and should not include radically new instructional strategy or instructional methods, or research involving deception.

Category 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 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.

This category should not be used when tests, surveys or interviews could potentially cause the subject discomfort or distress. For example if the testing is psychologically invasive in nature.

Research involving survey or interview procedures in children are not exempt. Research involving observations of public behavior in children are not exempt unless the investigator(s) do not participate in the activities being observed.

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 paragraph (b)(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.

This category is an extension of Category 2, but without the same level of privacy protections for public officials. However, the IRB will consider the risks associated with the information to be collected in making a determination about exempt status.

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.

Existing data means that the data or specimens exist at the time the research study is submitted to the IRB. Research that involves the ongoing (i.e., prospective) collection of specimens and/or data is not exempt under this category.

Publicly available means information that is available to the general public, such as census data.

Non-public data or specimens must be de-identified according to the HIPAA standards, and may not be linked to identifiers by a code available to the investigator(s). If the investigator(s) intend to retain or can access any identifiers, the research project is not exempt under this category.

Category 5: Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, 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.

This category allows research on public benefit or service programs, such as welfare, Medicaid, unemployment and Social Security. However, research in these categories may involve vulnerable populations who require additional protections.

Category 6: Taste and food quality evaluation and consumer acceptance studies if:

- (i) wholesome foods without additives are consumed; or
- (ii) 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 Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Research in this category should be limited to taste and food quality studies that do not involve a type or volume of food that could pose any risk to subjects. Studies that involve consumption of alcohol, vitamins, or supplements do not qualify for exempt status.

<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm#46.101>