

Certification of Exemption

List of Exemption Categories

Important Notes:

- None of these exemption categories apply to research involving prisoners.
- Categories 1-5 do not apply to FDA regulated research.
- The following types of research do not qualify for exemption from UCLA IRB review:
 - Research involving deception
 - Research involving access to UCLA medical records
 - Research involving the use of human embryonic stem cells and human embryonic germ cells

Exempt status applies to research activities in which the *only* involvement of human subjects will be in one or more of the following categories:

Exemption 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.

Exemption 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.

The above exemption category applies to research with children as follows:

- Research involving the use of educational tests is exempt;
- Research involving survey or interview procedures is **not** exempt;
- Research involving observations of public behavior is exempt only when the investigator does not participate in the observed activities.

Exemption 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), 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.

Exemption 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.

Exemption Category #5:

Research and demonstration projects that are conducted by or subject to the approval of [federal] department or agency heads, and that 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.

Exemption 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 at or below the level and for a use found to be safe, or agricultural chemical or environmental containment at or below the level found to be safe, by the FDA or approved by the EPA or the Food Safety and Inspection Service of the USDA.