

Exempt Status

Categories of Research

To qualify for exempt status, the research must fall into one of the following 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.

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.

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.

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 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.

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 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.

Core Questions

To qualify for exempt status, the research also must answer no to the following questions:

1. Will the research expose participants to discomfort or distress beyond that normally encountered in daily life?
2. Will research be conducted in a location currently or recently experiencing significant unrest, warfare or repression (e.g. riots, rebellions, political or religious repression)? This includes research in a context (e.g., organization or nation) that restricts individual liberties or freedom of speech.
3. Will the research design might contradict the ethical norms of the local culture (e.g., males speaking with single women in Muslim countries).
4. Could disclosure of participants' responses outside the research reasonably place participants at risk of criminal or civil liability or be damaging to participants' financial standing, employability, or reputation?
5. Does any part of the research require the use of deception or incomplete disclosure of information to participants?
6. Will prisoners (or their data and/or specimens) be participants in the research?
7. For research proposed under category 1, will the research be conducted outside of commonly accepted educational settings or deviate from normal educational practices?
8. For research proposed under category 1, will the researcher be adding an activity or exercise for research purposes?
9. For research proposed under category 1, will the researcher be modifying the curriculum for research purposes?
10. For research proposed under category 1, will the researcher be participating in classroom activities with his/her students?
11. For research proposed under category 2, will the research involve surveys or interview procedures with children?
12. For research proposed under category 2, will the research involve observations of the public behavior of children, during which an investigator participates in the activities being observed?
13. For research proposed under category 4, will any of the data, documents, records, or biological specimens be collected or created after the date of this application for exemption?

14. For research proposed under category 4, will any of the information obtained from private sources of data, documents, records, or biological specimens be recorded by the investigator in such a manner that participants could be identified directly or through identifiers linked to the participants?

15. For research proposed under categories 1-5, is the research subject to FDA regulations?