

EXEMPT CATEGORIES OF RESEARCH (6)

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

- a. Research on regular and special education instructional strategies or
- b. Research on the effectiveness of or the comparison among instructional techniques, curricula or classroom management methods.

AND

- c. Research is not subject to FDA regulations.
- d. Research does not involve prisoners as participants.
- e. Research does meet the University's ethical standards governing the conduct of the research.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

- a. Information obtained is recorded in such a manner that subjects can be identified, directly or through identifiers linked to the subjects and
- b. 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.
- c. Research involves children, with the exception of research involving observations of public behavior when the investigator(s) do not participate in the activities being observed. (45 CFR 46.101(b))
- d. Research is subject to FDA regulations.
- e. Research involves prisoners as participants.
- f. Research fails to meet the University's ethical standards governing the conduct of the research.

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 if:

- a. The human subjects are elected or appointed public officials or candidates for public office, or
- b. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- c. Research is not subject to FDA regulations.
- d. Research does not involve prisoners as participants.
- e. Research meets the University's ethical standards governing the conduct of the research.

Institutional Review Board

University of Utah

- 4. Research involving the collection or study of existing data, documents, record, pathological specimens or diagnostic specimens,** if these sources are publicly available or the information is recorded by the investigator in such a manner that the subjects cannot be identified directly or through identifiers linked to the subjects.

AND:

- a. Research is not subject to FDA regulations.
- b. Research does not involve prisoners as participants.
- c. Research meets the University's ethical standards governing the conduct of the research.

- 5. Research and demonstration projects which are conducted by or subject to the approval of (Federal) department or agency heads and which are designed to study, evaluate or otherwise examined:**

- a. Public benefit or service programs,
- b. Procedures for obtaining benefits or services under those programs,
- c. Possible changes in or alternatives to those programs or procedures or
- d. Possible changes in methods or levels of payment for benefits or services under those programs.
- e. Research or demonstration project must be conducted pursuant to specific federal statutory authority.

AND

- f. There must be no statutory requirement that the research or demonstration project be reviewed by an Institutional Review Board.
- g. The research or demonstration project must not involve significant physical invasions or intrusions upon the privacy of participants.
- h. The research or demonstration project must have authorization or concurrence from the funding agency before invoking this exemption.

- 6. Taste and food quality evaluation and consumer acceptance studies, if:**

- a. Wholesome foods without additives are consumed, or
- b. 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.

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.