

## Exempt Review Categories

(See 45 CFR 46.101, 21 CFR 56.104, 38 CFR 16.101 for full text)

(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

- (1) Research conducted in established 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.
- (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), surveys, interviews, or observation of public behavior  
**UNLESS**
  - i. information is recorded in such a manner that subject can be identified (either directly or indirectly) **AND**
  - ii. subjects' responses could place subjects at risk (e.g., criminal or civil liability, financial standing, employability or reputation). \*

\*or risk of loss of insurability 38 CFR 16.101 (VA)
- (3) Research involving educational tests, surveys, interviews, or observation of public behavior if:
  - i. the subjects are elected or appointed public officials or candidates for public office; or
  - ii. federal statute requires confidentiality of identifiable information to be maintained permanently.
- (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens. Sources must either be **publicly available** or information must be **recorded in such a manner that subject cannot be identified** (either directly or indirectly).
- (5) Research or demonstration projects conducted by or subject to the approval of Federal Department or Agency head, and meeting the following criteria:
  - (i) 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 Americans Act).

(ii) The research or demonstration project must be conducted pursuant to specific federal statutory authority.

(iii) There must be no statutory requirement that the project be reviewed by an Institutional Review Board (IRB).

(iv) The project must not involve significant physical invasions or intrusions upon the privacy of participants.

(v) The project has authorization or concurrence from the funding agency

- (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.

### ***Exempt status shall not be granted when:***

- Research involves prisoners as participants, pursuant to subpart C (45 CFR 46.305 (a))
- Research involves Human Embryonic Stem Cells, pursuant to California Health and Safety Code Section 125119
- Categories (1) through (5) apply and research is subject to FDA regulations
- Category (b)(2) applies and research involves children as participants, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed, pursuant to subpart D (45 CFR 46.401 (b)).
- The project involves significant physical invasions or intrusions upon the privacy of participants.

***All protocols must meet*** STANFORD HRPP ethical standards governing the conduct of research (e.g., acceptable risk-benefit relationship, equitable selection, informed consent, protections of privacy, maintenance of confidentiality, and protections for vulnerable populations).