

45 CFR 46.101(b) Categories of Exempt Human Subjects Research*

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.
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.
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 (above) 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.
4. Research involving the **collection or study of existing data**, documents, records, 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**.
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 examine:
 - (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.
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.

* Important Notes:

- UCI IRB registration is required for all exempt research.
- **"Existing"** means at the time the research is proposed.
- These exemptions **do not apply** to research involving prisoners (45 CFR Part 46 Subpart C).
- Exempt, Category 2 **does not apply** to research with children (45 CFR Part 46 Subpart D) **except** for research involving **educational tests** (cognitive, diagnostic, aptitude, achievement) or **observations of public behavior** when the researcher(s) do not participate in the activities being observed.