

Fresno Pacific University
Institutional Review Board Policies

Categories of Research that do not require full IRB review

Exempt Categories: Research activities in which the only involvement of human subjects is in one or more of the following categories are exempt from regulations requiring review. The exempt categories apply to both children and adults, except as noted under paragraph #2 below.

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: research on regular and special education instructional strategies; or 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: information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and 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.

Note: For children, educational tests are exempt from review. Observation of public behavior is exempt if the investigator does not materially participate in the activity being observed. Surveys and interviews are not exempt.

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 of this section, if: the subjects are elected or appointed public officials or candidates for public office; or federal statutes require 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, 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.
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: public benefit or service programs; procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those program or procedures; or possible changes in methods or levels of payments for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies, if:
wholesome foods without additives are consumed; or a food is consumed that contains a food ingredient or agricultural chemical or environmental contaminant at or below the level and for a use found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Service and Inspection Service of the U. S. Dept. of Agriculture.

Expedited Categories: Research in the following categories, if it presents no more than minimal risk to human subjects, may be reviewed using an expedited procedure. The categories apply to both children and adults. **Note:** The descriptions below are abbreviated from the original. The IRB will be guided by the official wording as printed in the Federal Register (63 FR 60364), available from the Research Office, the IRB web site (www.gsu.edu/irb), or the NIH web site (www.nih.gov/grants/oprr/library/human.htm).

- Clinical studies of approved drugs and medical devices used in accordance with standard approved medical practice.
- Collection of blood by finger stick, heel stick, ear stick, or venipuncture, in amounts and under schedules specified by federal regulation 63 FR60364-60367. Note: The regulation places differing restrictions on studies of adults and children.
- Collection of biological specimens by noninvasive means. Examples are: (a) hair and nail clippings, (b) teeth routinely shed or extracted, (c) excreta and external secretions, (d) uncannulated saliva, (e) placenta re-moved at delivery, (f) amniotic fluid collected at the time of rupture of the membrane, (g) dental plaque and calculus collected in accordance with accepted prophylactic techniques, (h) mucosal or skin cells collected by scraping, skin swab, or mouth washing, and (i) sputum collected after saline mist nebulization.
- Collection of data through noninvasive procedures routinely used in clinical practice, excluding x rays and microwaves. Examples are (a) physical sensors that involve no significant input of energy into the subject or invasion of the subject's privacy; (b) weighing or testing sensual acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the subject's age, weight, and health.
- Research involving existing data, documents, records, or specimens collected solely for nonresearch purposes. Note, some research of this kind may fall into one of the exempt categories.
- Voice, video, digital, or image recordings made for research purposes.
- Research on individual or group characteristics or behavior (including but not limited to perception, cognition, motivation, identity, language, communication, cultural beliefs or

practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Note: Some research of this kind may fall into one of the exempt categories.

- Continuing review of research previously approved at an IRB meeting, where no new human subjects have been enrolled, data collection is relatively inactive, and no new risks have been identified.
- Continuing review of research previously determined at an IRB meeting to involve only minimal risk, where no new risks have been identified.

<http://www.gsu.edu/%7Ewwwosp/Compliance2002/web-irb/IRB/ReviewCategories.htm>