

## Exempt Review Categories

### Introduction

There are six federal categories of research activities involving human subjects that may be exempt from the requirements of the Policy for the Protection of Human Subjects ([45 CFR 46](#)). Additionally, a *separate* seventh category of exempt (#7) research activities has been adapted by the UC system. This category does not exist in the federal regulations and is used by the University of California's system of campuses.

The exempt review process involves less oversight than an expedited or full-committee review. Research eligible for exempt review are studies that do not present more than minimal risk to the participants and meets the criteria for one of the seven categories. Also, if a study meets the requirements for an exemption, an abbreviated process for obtaining consent may be used. Consent can be verbal, but participants must be provided with the study information through an information sheet or a written script.

### 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.

Examples:

- Evaluating the use of accepted or revised standardized tests
- Testing or comparing a curriculum or lesson

Additional [guidance](#) on Exempt #1

### 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.

Note: The section of this category pertaining to standardized educational tests may be applied to research involving children. This category may also apply to research with children when the investigator observes public behavior but does not participate in that behavior or activity. This section is not applicable to survey or interview research involving children.

Examples:

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- Surveying teachers, nurses, or doctors about a technique or an outcome
- Interviewing managers about a management style or best practice
- Conducting a focus group about an experience or an opinion of a community program

### 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 (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.

Example:

- Interviewing public officials about a local or global issue

### 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.

\*Note: "Existing" means existing before the research is proposed to the institutional review board to determine whether the research is exempt.

Example:

- Analyzing existing tissue samples or data set which are recorded by the investigator without identifiers

### 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.

Exemption Category 5 only applies to research on public benefit programs (such as Social Security) conducted by the federal government. Research and demonstration projects in general (e.g., state or city funded public service programs) do not fit under this exempt category.

See [OHRP's guidance regarding this category](#)

### Category 6

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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.

### FDA Exempt Categories 21 CFR 56.104

- a. Any investigation which commenced before July 27, 1981 and was subject to requirements for IRB review under FDA regulations before that date, provided that the investigation remains subject to review of an IRB which meets the FDA requirements in effect before July 27, 1981.
- b. Any investigation commenced before July 27, 1981 and was not otherwise subject to requirements for IRB review under Food and Drug Administration regulations before that date.
- c. Emergency use of a test article, provided that such emergency use is reported to the IRB within 5 working days. Any subsequent use of the test article at the institution is subject to IRB review.
- d. Taste and food quality evaluations and consumer acceptance studies, if wholesome foods without additives are consumed or 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

### UCR Exempt Category 7

Research that involves no greater than minimal risk to subjects, but does not conform to a specific exempt category under 45 CFR 46.101(b), and does not fall within the exclusions listed below.

Such research is NOT exempt if it involves any of the following:

1. **Federally funded research, or funding from non-Public Health Service (PHS) agencies that adhere to federal regulations in their award contracts** (for a current list of these agencies see [http://sites.nationalacademies.org/PGA/fdp/PGA\\_070596](http://sites.nationalacademies.org/PGA/fdp/PGA_070596)).
2. Prisoners as subjects.
3. Children/minors as subjects.
4. Vulnerable populations as subjects.
5. Federal personnel or the Department of Veterans Affairs.
6. Procedures, devices, or drugs subject to FDA oversight.
7. Biomedical procedures.
8. Clinical interventions.
9. Sponsor or other contractual restrictions.
10. An NIH-issued Certificate of Confidentiality to protect identifiable research data.
11. Deception or incomplete disclosure to subjects.
12. Identifiable, private existing data.

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13. The information obtained is recorded in such a manner that subjects can be identified, directly or through identifiers linked to the subjects, **and** any disclosure of the subject's responses outside of the research could reasonably place the subject at risk of criminal or civil liability, be damaging to the subject's financial standing, employability, insurability, or reputation, or be stigmatizing in any other way.

Category 7 minimal risk exempt research activities that will not induce distress beyond that of daily life may include (but are not limited to) non-physically invasive interventions or performance of tasks such as:

- Reading/writing/drawing tasks
- Physical activities such as walking, sitting, or manipulating an object
- Computer tasks and/or Internet searches
- Talking and/or listening to words, then making selections, or "think-aloud" exercises
- Viewing media
- Role-playing
- Completing a specific physical or mental action ("imagining")
- Passive monitoring of space (environment) with sensors
- Playing a game
- Height/weight measurements

If the research is determined to qualify for Category 7 Exempt status and later becomes federally funded, supported, regulated, or changes so that it includes any of the exclusion factors listed above, the researcher must immediately cease research activities until IRB approval is obtained. **This will require submission of a new application.**