

Exempt Categories

Category 1

Research conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Examples of studies under this Category:

1. A study evaluating the effectiveness of a commonly accepted science curriculum. For the study, researchers will observe classroom instruction and collect quizzes and class evaluations that are part of the curriculum and classroom practices.
2. A study comparing two curricula that are currently being implemented in a school. Researchers will observe classrooms as well as interview instructors about their experiences implementing the instructional materials (but not about specific students).
3. A study comparing driver's education curricula offered by area driving schools. The researcher will observe classes and compare group driving test scores at the end of the courses

Category 2

Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

- (ii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- (iii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
- (iv) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 46.111(a)(7).

Examples of studies under this Category:

1. A study involving an anonymous survey regarding workplace satisfaction at area firms.
2. An observational study of pedestrians crossing a street; the researcher takes notes of what occurs, recording the sex, race, and type of clothing of pedestrians, but does not interact with participants.

3. A study involving interviews with college seniors (age 18 and older) about their plans after graduation. The answers to questions asked would present no risks to subjects if divulged outside the research.
4. A study involving focus groups with expectant mothers regarding their perceptions of parenting education.

Category 3

- (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
 - (A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects;
 - (B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
 - (C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).
- (v) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.
- (vi) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Examples of studies under this Category:

1. A study that involves asking subjects to play an online game that takes about 90 minutes to complete.
2. A study that involves asking subjects to solve puzzles under various noise conditions. Study procedures take about 30 minutes.
3. Healthy adult subjects are asked to take part in two 2 hour-long assessments of memory, attention, and information processing speed before and after 1 hour of cognitive enhancement exercise using specially designed computer software.

Category 4

Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

- (i) The identifiable private information or identifiable biospecimens are publicly available;
- (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
- (iii) Not applicable at Chapman since it is not a HIPPA-covered entity. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or
- (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995.

Examples of studies under this Category:

1. A research study of treatment outcomes for a drug that involves only the review of patient charts.
2. A graduate student has access to identifiable data from a study previously conducted by her faculty advisor, but she only records de-identified data into her own research records.

Category 5

This category is rare, and unlikely to apply to Chapman. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees and studies under contracts or consulting arrangements, cooperative

agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

- (i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

Category 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.

Examples of studies under this Category:

1. A taste study evaluating the differences in taste of various types of apples grown nationally
2. A taste study analyzing the effects of an additive to beef if the additive has been determined to be safe by the FDA
3. The taste effects of a low-level environmental contaminant on a food product that has been deemed safe by the FDA and EPA