

Exempt Review Categories (8)

45 CFR 46 identifies 8 different categories of minimal risk research as exempt from the requirements of these regulations.

NOTE: The term “Exempt” does NOT mean that the study is exempt from any sort of IRB review, just that some of the federal requirements that apply to non-exempt studies are not applicable to studies that are deemed exempt.

Exempt 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.

Exempt 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:

- (i)** 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;
- (ii)** 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
- (iii)** 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).

Exempt 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).

(ii) 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.

(iii) **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.

Exempt 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) **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.

Exempt Category (5)

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

Exempt 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.

Exempt Category (7)

Storage or maintenance for **secondary research** for which **broad consent is required**: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by § 46.111(a)(8).

Exempt Category (8)

Secondary research for which **broad consent is required**: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

- (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with § 46.116(a)(1) through (4), (a)(6), and (d);
- (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with § 46.117;
- (iii) An IRB conducts a limited IRB review and makes the determination required by § 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and
- (iv) The investigator does not include returning individual research results to subjects as part of the study plan.