# PURPOSE

* 1. All exemption categories, of which there are now EIGHT, appear in 45 CFR 46.104 of the Final Rule.
  2. "Exempt" does not always mean exempt from all the Common Rule's requirements – the activity must fit the description of the exempt category and not include nonexempt research activities.
  3. Exemption categories 7 and 8 in the Final Rule identify specific regulatory requirements that must be met (e.g., limited IRB review, use of broad consent) as a condition of being exempt from other regulatory requirements.

# REVISIONS FROM PREVIOUS VERSION

* 1. The revised Common Rule contains a number of changes. The previous list of exempt categories was listed under 45 CFR 46 101(b). Please make sure that you use the list of review categories from the revised rule here, which is 45 CFR 46 104(d).

# POLICY

* 1. None

# RESPONSIBILITIES

* 1. Researchers are responsible for understanding these categories and correctly selecting the appropriate categories as they apply to their own research.
  2. IRB members are responsible for understanding these categories to ensure ethical oversight during an IRB Review.

# 45 CFR 46.104(d)

1. Research involving 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 such as: (1) Most research on regular and special education instructional strategies; or (2) Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management.
2. Research that only includes interaction involving the use of 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 is met: (1) Information obtained is recorded by the investigator in such a manner that the identity of human subjects cannot be readily ascertained, directly or through identifiers linked to the subjects; or (2) Any disclosure of the human subjects’ responses outside of 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; (3) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can be readily ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7). Children may only be included in research under this exemption when involving educational tests or observation of public behavior if the investigator(s) do not participate in the activities being observed and the information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained directly, or through identifiers linked to the subjects.

The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects= financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

1. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collected and at least one of the following is met; (1) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained, directly or through identifiers linked to the subjects; (2) 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 (3) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can be readily ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7). 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 (e.g., playing an online game, solving puzzles, etc.)If the research involves deception, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research and the subject is informed that they will be unaware of or they will be misled regarding the nature or purposes of the research. Children may not be included in research under this exemption.
2. 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 are met: (1) The identifiable private information or identifiable biospecimens are publicly available; or (2) 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; or (3) 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 160 and 164, Subparts A and E (HIPAA), for the purposes of “health care operations” or “research” as those terms are defined under HIPAA or for “public health activities and purposes” under HIPAA; or (4) The research is conducted by, or on behalf of a Federal department or agency using government-generated or government-collected information obtained for non-research activities. Categories one (1) through seven (7) pertain to both initial and continuing IRB review.
3. 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: (1) Public benefit or service programs; this exemption is for Federally supported projects and is most appropriately invoked with authorization or concurrence by the funding agency. The following criteria must be satisfied to invoke the exemption for research and demonstration projects examining “public benefit or service programs:”

* The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services under the Older Americans Act);
* The research or demonstration project must be conducted pursuant to specific Federal statutory authority;
* There must be no statutory requirements that the project be reviewed by an IRB; and
* The project must not involve significant physical invasions or intrusions upon the privacy of participants.  (2) Procedures for obtaining benefits or services under those programs; (3) Possible changes in or alternatives to those programs or procedures; or (4) Possible changes in methods or levels of payment for benefits or services under those programs. (5) This exemption is for projects conducted by or subject to approval of Federal agencies and requires authorization or concurrence by the funding agency.

1. Taste and food quality evaluation and consumer acceptance studies; (1) If wholesome foods without additives are consumed; or (2) 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.
2. 45 CFR 46.104(d)(7): Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for post secondary research use if an IRB conducts a limited IRB review and makes the determinations required by 45 CFR 46.111(a)(8).
3. Secondary research for which broad consent is required: Research involving the use of identifiable private health information or identifiable biospecimens for secondary research use, if the following criteria are met: (1) Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens was obtained in accordance with 45 CFR 46.116 (a)(1)-(4), (a)(6), and (d); (2) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with 45 CFR 46.117; (3) An IRB conducts a limited review and makes the determination required by 45 CFR 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in (d)(8)(i); and (4) The investigator does not include returning individual research results to subjects as part of the study plan. (This provision does not prevent an investigator from abiding by any legal requirements to return individual research results).

# LIMITED IRB REVIEW

* 1. 45 CFR 46.111(a)(7) review will be conducted by the IRB sub-committee or designee: (1) For exempt categories 104(d)(2), 104(d)(3), 104(d)(7), and 104(d)(8) to verify adequate provisions to protect the privacy of subjects and to maintain confidentiality of the data are assessed. (2) For exempt category 104(d)(7) and 104(d)(8) to verify broad consent or a waiver of documentation for broad consent is appropriate. Any change in the way identifiable private information or identifiable biospecimens are stored or maintained will also require review.

# REFERENCES

* 1. [The Revised Common Rule 45 CFR 46](https://www.gpo.gov/fdsys/pkg/FR-2018-06-19/pdf/2018-13187.pdf)