Exemption Categories

The Revised Common Rule went into effect in January 2019. Under the Revised Common Rule some of the categories of exempt research have changed, while a few new ones have been added. In some cases, a study that was expedited under the old Common Rule may now be eligible for determination of exempt status. For more information about the Revised Common Rule and its potential implications for study design, informed consent and IRB review see OHRP's website **Revised Common Rule Q&As** https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/revised-common-rule-q-and-a/index.html

How to apply the Subparts:

Subpart B: Studies involving pregnant women, fetuses & neonates are eligible for exemption under all 8 categories
Subpart C: Exemptions DO NOT APPLY to research involving prisoners **EXCEPT** "research aimed at involving a broader subject population that only incidentally includes prisoners"
Subpart D: Children are allowed in categories 1, 4, 5, 6, 7 & 8. Limitations & exclusion of children apply to categories 2 & 3.

Exemption Category	Description	Information	Requires Limited IRB Review
1 **46.104(d)(1)** ***(Revised)***	Research in established or commonly accepted educational settings	The condition that the research must not have a negative impact on the students required learning, or on the assessments of the educator/instructor.	N/A
2 **46.104(d)(2)** ***(Revised)***	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:	• The 2018 Common Rule allows for this exemption as long as one of the three criteria (i, ii, **or** iii) is met. • This category now allows visual and auditory recordings as research methods. • Surveys cannot include collection of biospecimens or interventions	
	(i) The information obtained is recorded in such a manner that the identity of the subject cannot readily be ascertained, directly or through identifiers linked to the subjects; ***or***	For (i) and (ii) - Subpart D may only apply to research involving educational tests or the observation of public behavior when the investigator does not participate in the activities being observed	N/A
	(ii) Any disclosure of the 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***		N/A
	(iii) The information obtained is recorded with identifiers, and an IRB conducts a limited IRB review.	Subpart D may not be applied. Category 2(iii) **is not applicable to research with children**.	**Yes**

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3 ***New Category*** **46.104(d)(3)(i)**	Research involving benign behavioral interventions in conjunction with the collection of information from an <u>adult subject</u> 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:	• Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact, and there is no reason to think the subjects will find the interventions offensive or embarrassing. • May not include Medical Interventions • This exemption is only for benign behavioral research with adults, and **is not applicable to research with children** • Subjects must prospectively agree • When using deception, subjects must prospectively authorize the deception through a prospective agreement	
	*(A) The information obtained is recorded in such a manner that the identity of the subjects cannot readily be ascertained, directly or through identifiers linked to the subjects**; or***		N/A
	*(B) Any disclosure of the 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***		N/A
	(C) The information obtained is recorded with identifiers, and an IRB conducts a <u>limited IRB review.</u>		**Yes**
4 **46.104(d)(4)** ***(Revised)***	Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if <u>at least one</u> of the following criteria is met:	Note: Data do not need to be existing at the time the research study is proposed. Allows **both retrospective and prospective** secondary research use.	
	(i) The identifiable private information or identifiable biospecimens are publicly available; **or**		N/A
	(ii) Information, which may include information about biospecimens, is recorded in such a manner that the identity of the subjects cannot readily be ascertained directly or through identifiers linked to the subjects. Investigator does not contact subjects, and will not re-identify subjects; **or**		N/A
	(iii) Collection and analysis involving the Investigator's use of identifiable health information when that use is regulated by HIPAA for the purposes of "health care operations" or "research" or for "public health activities and purposes"; **or**	HIPAA protections apply (e.g., Authorization or Waiver of Authorization)	N/A
	(iv) 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, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with certain federal laws.		N/A

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5 **46.104(d)(5)** ***(Revised)***	Research and Demonstration Projects that Are Conducted or Supported by a Federal Department or Agency	The research or demonstration project must be published on publicly accessible Federal Web Site	N/A
6 **46.104(d)(6)** **(Unchanged)**	Taste and food quality evaluation and consumer acceptance studies		N/A
7 ***New Category*** **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 potential secondary research use if an IRB conducts a limited IRB review.	Refusals must be tracked – IRBs may not waive consent for use identifiable materials for anyone who refuses	**Yes**
8 ***New Category*** **46.104(d)(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:	Refusals must be tracked - IRBs may not waive consent for use identifiable materials for anyone who refuses	**Yes**
	(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained;		
	(ii) Documentation of informed consent or waiver of documentation of consent was obtained;		
	(iii) An IRB conducts a limited IRB review and makes the determination that the research to be conducted is within the scope of the broad consent; **and**		
	(iv) The investigator does not plan to return research results to subjects.		