

New and Revised Exemption Categories and Examples

Category	Description	Examples
1	<p>Research, conducted in established or commonly accepted educational settings, which 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.</p>	<ul style="list-style-type: none"> • Assessment of attitudes about learning • Evaluation of classroom or school activities • Innovative instructional methods • Use of educational tools such as an online course, computer software, or smart phones
2	<p>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:</p> <p>(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;</p> <p>(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</p> <p>(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</p>	<ul style="list-style-type: none"> • 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 • An online survey about sexual behavior that does not collect email or IP address or any other identifying information about respondents. If data are truly anonymous, then almost any survey or interview project could qualify for Exemption #2 no matter how sensitive the questions. • A focus group discussion for which participants are audio recorded and identified by name in transcripts, but for which breach of confidentiality would pose no risk. Audio and/or video recording of interactions or observations is permitted under Exemption #2. • Observation of behavior in a public park or on the street.

	determination required by §46.111(a)(7).	
3	<p>(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:</p> <p>(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;</p> <p>(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</p> <p>(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).</p> <p>(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</p>	<ul style="list-style-type: none"> • Performing cognitive tasks • Providing educational materials to participants with the intention of changing their behavior (e.g. smoking cessation, eating habits) • Playing an online game • Playing economic games • Being exposed to stimuli such as color, light or sound at safe levels • Solving puzzles under various noise conditions

	<p>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.</p> <p>(iv) 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.</p>	
4	<p>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:</p> <p>(i) The identifiable private information or identifiable biospecimens are publicly available;</p> <p>(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;</p> <p>(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"</p>	<p>(i) Data or biospecimens in publicly available databases such (SEER database for data)</p> <p>(ii) Research with information for which identifiers have been removed when the original collection of information or biospecimens was obtained</p> <p>(iii) Prospective or retrospective data reviews - Permits secondary use of identifiable PHI</p>

	<p>as described under 45 CFR 164.512(b); or</p> <p>(iv) (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, 44 U.S.C. 3501 et seq.</p>	
<p>5</p>	<p>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.</p>	<ul style="list-style-type: none"> • CMS research

	<p>(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.</p> <p>(ii) [Reserved]</p>	
6	<p>Taste and food quality evaluation and consumer acceptance studies:</p> <p>(i) If wholesome foods without additives are consumed, or</p> <p>(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.</p>	<ul style="list-style-type: none"> • A taste-test on different varieties of a fruit to determine consumer preference, when the fruits do not have any additives and subjects are asked to indicate which fruit they prefer. • A study that involves taste-testing of various beef products from cattle that have been given feed with a chemical additive. If the researcher can document that the amount of the additive was at or below the levels approved by the USDA, the research may qualify for an exemption.
7	Not being applied at MD Anderson	
8	Not being applied at MD Anderson	