



Title: Comparing Expedited Research Category 7 and Exempt Research Categories 1, 2, 3

Date of Last Revision: 05/16/19

Audience: Researchers

Author: Laverne Estanol, M.S., CIP, CIM, CHRC, MROA

Citation: <https://escholarship.org/uc/item/2rw6k01p> (supplemental material)

	EXPEDITED RESEARCH CATEGORY 7	EXEMPT RESEARCH CATEGORY 1	EXEMPT RESEARCH CATEGORY 2	EXEMPT RESEARCH CATEGORY 3
MINIMAL RISK CRITERIA	<input type="checkbox"/> Human Subjects Research <input type="checkbox"/> Minimal Risk <ul style="list-style-type: none"> ▪ Background (pages 6-7) ▪ Case Examples 			
SHARED ELEMENTS	<input type="checkbox"/> Does not involve prisoners, <u>except</u> for research aimed at involving broader population that only incidentally includes prisoners <input type="checkbox"/> Research is not classified research conducted or supported by DOE <input type="checkbox"/> Research is consistent with the ethical principles of the Belmont Report <input type="checkbox"/> DOJ / FDA has not adopted the revised Common Rule <input type="checkbox"/> Additional protections required for American Indian or Alaska Native Tribe			
SPECIFIC ELEMENTS	<input type="checkbox"/> Research on individual or group characteristics <input type="checkbox"/> Research methods include survey, interview, focus group, etc	45 CFR 46 Preamble <input type="checkbox"/> Research about normal educational practices <input type="checkbox"/> Participation in research will not adversely impact student's opportunity to learn	45 CFR 46 Preamble <input type="checkbox"/> Subpart D (children population) <u>applicable only</u> when involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed <input type="checkbox"/> If identifiers are maintained and disclosure would reasonably place subjects at risk, a limited IRB review is required (continuing review is not required for research approved under limited IRB review) <input type="checkbox"/> Subpart D (children population) is not applicable if information is recorded in a manner that the identity of the subject can readily be ascertained , directly or through identifiers linked to the subjects <input type="checkbox"/> Specific to research that only includes interactions involving education tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, observation of public behavior (including visual or auditory recording) uninfluenced by the investigator if one of the three criteria is met <input type="checkbox"/> Specifically, procedures should not include an intervention <input type="checkbox"/> Expanded to include research involving identifiable private information that might be sensitive or potentially harmful if disclosed , which will require a limited IRB review ; this specifically excludes Subpart D (children population) <input type="checkbox"/> Must consider the potential harms (criminal/civil liability, damage to financial status, employability, reputation), including a new element of harm (potential damage to subjects' educational advancement) <input type="checkbox"/> Definition of survey: information collected about individuals through questionnaires or similar procedures; does not include the collection of biospecimens <input type="checkbox"/> Definition of human subjects: do not include organizations or businesses	45 CFR 46 Preamble <input type="checkbox"/> Subpart D (children population) is not applicable <input type="checkbox"/> Subjects must only be adults ; although provision does not specify that adult subjects must be competent, tests of competency are not necessary, however subject subjects should not be exploited <input type="checkbox"/> If identifiers are maintained and disclosure would reasonably place subjects at risk, IRB conducts a limited IRB review (continuing review is not required for research approved under limited IRB review) <input type="checkbox"/> Definition of benign interventions: limited to behavior interventions (excludes medical tests, procedures, and devices); brief, harmless, painless, not physically invasive, not likely to have a significant lasting impact, will not be offensive or embarrassing to/for subjects <input type="checkbox"/> Category is specifically for benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses or audiovisual recording if the subject prospectively agrees to the intervention and the information collection and at least one of three criterias are met <input type="checkbox"/> Use of deception must be authorized prospectively <input type="checkbox"/> Allows recording of identifiable information directly or through identifiers linked to the subject, which requires a limited IRB review <input type="checkbox"/> Allows collection of data through audiovisual and video recording

	EXPEDITED RESEARCH <u>CATEGORY 7</u>	EXEMPT RESEARCH <u>CATEGORY 1</u>	EXEMPT RESEARCH <u>CATEGORY 2</u>	EXEMPT RESEARCH <u>CATEGORY 3</u>
CORE DEFINITION	Research on <i>individual or group characteristics or behavior</i> (including, but not limited to, <i>research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior</i>) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.	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.	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 § __.111(a)(7).	(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 § __.111(a)(7). (3)(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. (3)(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.