

## Exemption Categories

45 CFR 46.104

<u>CATEGORY D1:</u>	<p>Research conducted in established or commonly accepted educational settings, 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:</p> <ol style="list-style-type: none"> <li>i. research on regular and special education instructional strategies, or</li> <li>ii. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.</li> </ol>
<u>CATEGORY D2:</u>	<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> <ol style="list-style-type: none"> <li>i. the information obtained is recorded in such a manner that human participants cannot be readily ascertained, directly or through identifiers linked to the participants; <u>OR</u></li> <li>ii. any disclosure of the human participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, educational advancement, or reputation; <u>OR</u></li> <li>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 participants, and an IRB conducts a limited IRB review to make the determination required by §__.111(a)(7).</li> </ol> <p>NOTE: Survey and interview techniques which include minors are not exempt. Observation of the public behavior of minors, if the researcher is not a participant, is exempt.</p>
<u>CATEGORY D3:</u>	<p>Research involving benign behavioral interventions* in conjunction with the collection of information from an <u>adult</u> participant through verbal or written responses (including data entry) or audiovisual recording if the participant prospectively agrees to the intervention and information collection and at least one of the following criteria is met:</p> <ol style="list-style-type: none"> <li>i. the information obtained is recorded in such a manner that human participants cannot be readily ascertained, directly or through identifiers linked to the participants; <u>OR</u></li> <li>ii. any disclosure of the human participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, educational advancement, or reputation; <u>OR</u></li> <li>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 participants, and an IRB conducts a limited IRB review to make the determination required by §__.111(a)(7).</li> </ol> <p>*Benign behavioral interventions are brief, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the participant and the investigator has no reason to believe the participant will find the intervention offensive or embarrassing.</p>
<u>CATEGORY D4:</u>	<p>Secondary research uses of identifiable private information or identifiable biospecimens (consent is not required) if at least one of the following criteria is met:</p> <ol style="list-style-type: none"> <li>i. The identifiable private information or identifiable biospecimens are publicly available; <u>OR</u></li> <li>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 be readily ascertained directly (e.g., name) or through identifiers linked to the participants (i.e., through ANY code used with the intent of being traced back to the participant) and the investigator will not re-identify the participants.</li> </ol>

<u>CATEGORY D5:</u>	Research and demonstration projects which are conducted by or subject to the approval of appropriate Federal Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: <ul style="list-style-type: none"><li>a. public benefit or service programs; or</li><li>b. procedures for obtaining benefits or services under those programs; or</li><li>c. possible changes in or alternatives to those programs or procedures; or</li><li>d. possible changes in methods or levels of payment for benefits or services under those programs.</li></ul>
<u>CATEGORY D6:</u>	Taste and food quality evaluation and consumer acceptance studies, <ul style="list-style-type: none"><li>a. if wholesome foods <u>without</u> additives are consumed, or</li><li>b. 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.</li></ul>