

Exemption Categories

45 CFR 46.101

<u>CATEGORY B1:</u>	<p>Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:</p> <ol style="list-style-type: none"> a. research on regular and special education instructional strategies, or b. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
<u>CATEGORY B2:</u>	<p>Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, <i>unless</i>:</p> <ol style="list-style-type: none"> i. the information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; <u>AND</u> ii. any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation. <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 B3:</u>	<p>Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under Category 2, <u>IF</u>:</p> <ol style="list-style-type: none"> a. the human participants are elected or appointed public officials or candidates for public office; <u>OR</u> b. federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
<u>CATEGORY B4:</u>	<p>Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified directly or through identifiers linked to the participants.</p>
<u>CATEGORY B5:</u>	<p>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:</p> <ol style="list-style-type: none"> a. public benefit or service programs; or b. procedures for obtaining benefits or services under those programs; or c. possible changes in or alternatives to those programs or procedures; or d. possible changes in methods or levels of payment for benefits or services under those programs.
<u>CATEGORY B6:</u>	<p>Taste and food quality evaluation and consumer acceptance studies,</p> <ol style="list-style-type: none"> a. if wholesome foods <u>without</u> additives are consumed, or 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.