

Summary of Exemption Categories

Vulnerable populations in exempt research		
Subpart B	Research Involving Pregnant Women, Fetuses & Neonates	– eligible for exempt under all categories
Subpart C	Research Involving Prisoners	– Exemptions do not apply to research involving prisoners <u>except</u> “for research aimed at involving a broader subject population that <u>only incidentally</u> includes prisoners”
Subpart D	Research Involving Children	– Children allowed in exemption categories 1, 4, 5, & 6 Limitations/exclusion of children in category 2 & 3

Exemption Category	Exemption Description	Conditions/Allowances/Limitations
1	<p>45 CFR 46.104(d)(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices*, such as:</p> <ul style="list-style-type: none"> o research on regular and special education instructional strategies, or o research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. 	<p>*Practices cannot adversely impact students’ opportunity to learn required education content or the assessment of educators who provide instruction.</p>
2	<p>45 CFR 46.104(d)(2) 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) Recorded information cannot readily identify the subject (directly or indirectly/linked)</p> <p>(ii) Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, or reputation)</p> <p>(iii) Information obtained is recorded by the P.I. in such a manner that the identity of the subjects <i>can</i> be readily ascertained, directly or indirectly through identifiers linked to the subjects & the IRB conducts a Limited Review §46.111(a)(7)</p>	<p>Exemption 2 applies to studies that collect data using one or more of the following research methods ONLY:</p> <ul style="list-style-type: none"> • Surveys • Interviews (including cognitive interviews) • Focus groups • Educational tests (e.g. cognitive, diagnostic, aptitude, achievement) • Observation of public behavior (occurs in a public place with no expectation of privacy, such as a public street or park.) <p>YES: visual or auditory recording</p> <p>NO: interventions or manipulations that are distinct from the information collection methods</p> <p>Subpart D – Research involving children</p> <p>YES: educational tests or observation ONLY when investigators do <u>not</u> participate in activities being observed</p> <p>NO: intervention procedures, or surveys & interviews</p>

3	<p>45 CFR 46.104(d)(3)</p> <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 and ONE of following met:</p> <p>A. Recorded information cannot readily identify the subject (directly or indirectly/linked)</p> <p>B. Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation)</p> <p>C. Information is recorded with identifiers & IRB conducts Limited Review §46.111(a)(7)</p>	<p>No children; May not include medical interventions;</p> <p>Benign Behavioral Intervention must be:</p> <ul style="list-style-type: none"> • Brief in duration • Painless/Harmless • Not physically invasive • Not likely to have a significant adverse lasting impact on subjects • Unlikely that subjects will find interventions offensive or embarrassing <p>No deception unless participant prospectively agrees</p>
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4	<p>45 CFR 46.104(d)(4)</p> <p>Secondary research for which consent is not required: use of identifiable Information or identifiable biospecimen that have been or will be collected for some other 'primary' or 'initial' activity, if ONE of following criteria met:</p> <p>(i) Biospecimens or information are publicly available</p> <p>(ii) Information recorded so subject cannot readily be identified (directly or indirectly/linked); Investigator does not contact subjects and will not re-identify the subjects</p> <p>(ii) Collection and analysis involving Investigators Use of Identifiable Health Information when use is regulated by HIPAA "health care operations" or "research" or "public health activities and purposes"</p> <p>(iv) Research information collected by or on behalf of federal government using government generated or collected information obtained for non-research activities</p>	<p>No primary collection from subjects for the research; Allows both retrospective and prospective secondary use</p> <p>HIPAA still applies;</p> <p>HIPAA protections include authorization or waiver of authorization;</p> <p>If research generates identifiable private information it is subject to specified federal privacy laws</p>
5	<p>Research and demonstration projects supported by a Federal Agency/Dept. AND designed to study, public benefit or service programs.</p>	<p>Must be posted on a federal web site</p>
6	<p>Taste and Food Quality</p>	