

Exemption 2 [45 CFR 46.104(d)(2)]
Tests, Surveys, Interviews, or Passive Observations of Public Behavior
Modified

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Exemption 3 [45 CFR 46.104(d)(3)]

Benign Behavioral Intervention

New

“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

Research procedures in this exempt category should generally be limited to:

- communication or interpersonal contact with the subject,
- the performance of a cognitive, intellectual, educational or behavioral task, or
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Criterion 4 – Research conducted on behalf of Federal Agencies:

Option 4 pertains to research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected data obtained for non-research activities. The study team must demonstrate compliance with the policies detailed in the regulation, specified above.

The 2018 changes significantly broaden the type of secondary research that can be do

Exemption 5 [45 CFR 46.104(d)(5)]

Research and Demonstration Projects Conducted or Supported by a Federal Department or Agency Modified

“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.”

The scope of this category has been broadened. Prior rules required that the Federal demonstration projects be conducted by the Federal agency. This category has been updated to allow projects that are simply funded by a Federal agency. The scope has been expanded to include purposes not only to study and evaluate but also to improve these programs. Note that projects eligible for this exemption will be posted on a Federal website.

Exemption 6 [45 CFR 46.104(d)(6)]
Taste and Food Quality Evaluation and Consumer Acceptance Studies
Unchanged

“Taste and food quality evaluation and consumer acceptance studies: if wholesome foods without additives are consumed, or 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.”

This exemption category was not changed in the revised Common Rule. Note that it is the only exemption that is allowable for FDA-regulated research.

Applicability to vulnerable populations:

Pregnant women may be included in this type of research.

Research that targets a prisoner population is not eligible for this exemption. The exemption is allowable if the research is aimed at a broader population and only incidentally includes prisoners.

Research involving children is eligible for this exemption.

Research involving decisionally-impaired persons could be allowed if their inclusion was justified.