



Understanding the common rule

Exempt Category 5

See Introduction to Exempt and Exempt and Vulnerable Populations for Additional Details

Exempt Category 5 (to be effective January 21, 2019)

The New Rule makes a lot of changes to the exempt categories. This document discusses the change to exempt category 5.

What is the current Exempt Category 5?

Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

- i. Public benefit or service programs;
- ii. procedures for obtaining benefits or services under those programs;
- iii. possible changes in or alternatives to those programs or procedures; or
- iv. possible changes in methods or levels of payment for benefits or services under those programs.

What are the key changes?

- The wording of the exemption has added “improve” to the purposes of these activities, to make more explicit the idea that the Federal Government conducts these activities in order to enable them to make the public benefit and service programs better, and not just to gauge their current quality.
- It also adds requirement about posting the projects on a public website.

Why was it changed?

This revision is designed to clarify the scope of the exemption so that more research studies would be eligible, and to make the exemption easier to apply. It is also designed to allow the Federal Government to carry out important evaluations of its public benefit and service programs to ensure that those programs are cost effective and provide the intended benefits or services, consistent with the principle of beneficence.

What is the New Rule Exempt Category 5?

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

	<p>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. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.</p> <ul style="list-style-type: none"> i. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects. <p>Some caveats:</p> <ul style="list-style-type: none"> - Exemption only permitted if the research is listed on a federal website (or other similar mechanism). The research or demonstration project must be published on this list before beginning the research involving human subjects.
<p>Implications for Researchers:</p>	<p>None – not likely to use this category!</p>
<p>Examples:</p>	<p>1. None- not likely to use this one!</p>