



Understanding the common rule

Exempt Category 3

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

**Exempt Category 3
(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 3.

What is the current Exempt Category 3?

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 paragraph (b)(2) of this section, if (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

What are the key changes?

- The old one was dropped; all new!

Why was it changed?

Almost all of the research activities in this category would already be exempted under the final rule under category 2, without needing to single out elected or appointed officials as being treated differently in this way.

What is the New Rule Exempt Category 3?

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 to the intervention and information collection and at least one of the following criteria is met:

- (A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- (B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
- (C) 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 subjects,

	<p>and an IRB conducts a limited IRB review to make the determination required by § II.111(a)(7).</p> <p>Some caveats:</p> <ul style="list-style-type: none"> - For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else. - If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research - No kids in this one!
<p>Implications for Researchers:</p>	<ul style="list-style-type: none"> • No guidance has been issued about what “brief” means. The IRB will provide more information when that guidance is received. • Some studies in this category will be required to undergo the new type of review called “limited” IRB review. The limited IRB review will be designed to ensure that good privacy safeguards are in place to lower the risks.
<p>Examples:</p>	<ol style="list-style-type: none"> 1. A research study involves a medical EKG. Would it be exempt under this category? Answer: No, because only behavioral interventions are allowed under this category. 2. A research study will withhold information about the true purpose of the research. Would it be eligible for exemption under this category? Answer: Possibly, but only if the participant will be told that they will not know or will be misled about the purpose of the study, and they agree to that and to the study.