



# Understanding the common rule

## Exempt Category 2

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

### Exempt Category 2 (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 2.

#### What is the current Exempt Category 2?

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

- i. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
- ii. any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

#### What are the key changes?

- One key change is that the New Rule specifically states that visual or auditory recording is now allowed.
- As noted above, the current (pre-2018) rule identifies two specifics (i and ii). The New Rule adds a third possibility: a study that involves identifiable information and the IRB conducts a "limited review".

#### Why was it changed?

- The regulators noted that the potential risks of research in this category are mostly risks related to a potential loss of confidentiality. The IRB's most important role in minimizing this risk is to make sure that the study has appropriate privacy safeguards. This is accomplished through 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.

#### What is the New Rule Exempt Category 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:**

	<ul style="list-style-type: none"> <li>i. 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;</li> <li>ii. 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</li> <li>iii. 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, and an IRB conducts a limited IRB review to make the determination required by .111(a)(7).</li> </ul>
<p><b>Implications for Researchers</b></p>	<ul style="list-style-type: none"> <li>• Please be aware that a study that involves interventions, in addition to the educational tests, survey or interview procedures, or observation of public behavior, cannot be exempt under this category.</li> <li>• This category is restricted with regard to children. Only research that involves educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed is allowed.</li> <li>• No federal guidance has been issued about the privacy standards. When that guidance is available, the IRB will provide more information about the privacy standards that will need to be met.</li> </ul>
<p><b>Examples</b></p>	<ol style="list-style-type: none"> <li>1. A research study will randomly assign adult students to take an educational test in a quiet room or in a room with a moderate level of noise. Would this research be exempt under this exemption? Answer: No, because the study involves an intervention (quiet vs noisy room); and interventions are not allowed under this category.</li> <li>2. A research study will survey elementary school kids about how much television they watch each week. Would this research be exempt under this exemption? Answer: No, because this category is restricted with regard to children (only research that involves educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed is allowed).</li> </ol>