

Understanding the common rule

Introduction to Exempt

See Exempt Overview and Exempt and Vulnerable Populations for Additional Details

Exempt Revisions (to be effective January 21, 2019)

The New Rule makes a lot of changes to the exempt categories. This document discusses the changes to exempt category 1.

What is the current Exempt Category 1?

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods

What is the key change?

The key change is the addition of a qualifier - not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction.

Why was it changed?

There were some concerns about whether the conduct of some research projects of this type might draw enough time and attention away from the delivery of the regular educational curriculum that they could have a detrimental effect on student achievement.

What is the New Rule Exempt Category 1?

Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Implications for Researchers:

Just like the current practice, when you submit a New Protocol Submission, you will be asked to indicate which level of review you think your study requires. ETSU will also continue the current practice of the IRB Chair or Vice Chair making the actual exempt determinations.

In your New Protocol Submission, if you are anticipating that your study may be exempt under category 1, be sure to explain:

- whether your study would be likely to adversely impact students' opportunity to learn required educational content (and if not, why not)
- whether your study would be likely to adversely impact the assessment of educators who provide instruction (and if not, why not)

Example:

A research study about job performance will be conducted by department or program chairs who also hold responsibility for evaluation of faculty. This study would not be eligible for exempt under category 1 because the study could adversely impact the assessment of the faculty members. The study would require expedited or full review.