

Definition and Criteria

Exemption #1 covers research conducted in educational settings that involves normal educational practices. The 2018 Common Rule criteria for Exemption #1 is more protective of student and teacher as research subjects.

For the U-M 2018 Flexibility Initiative:

Exemption #1 is eligible for **all research** that meets the criteria.

An “established educational setting” is any place where educational activities regularly occur. In addition to schools and colleges, an educational setting could be an after-school program, work place, library, museum, training center, etc.

“Normal educational practices” are activities that typically occur in a classroom or other educational setting. Generally, these are best practices that benefit students and support the required curriculum. Examples include:

- Assessment of attitudes about learning
- Evaluation of classroom or school activities
- Innovative instructional methods
- Test development
- Use of educational tools such as an online course, computer software, or smart phones

In order to qualify for Exemption #1, the research must *not*:

- take time or attention away from normal instruction in a way that might negatively affect student achievement (e.g., negative impact on standardized test scores)
- impact individual teachers in a way that could adversely affect assessments of their practice/performance.

Self-exemption is permitted for Exemption category #1, *except where research involves access to student education records under the Family Educational Rights and Privacy Act (FERPA).*

- Education records include any records held by an educational institution that contain personally identifiable information about students, including records related to an individual student’s performance such as written or electronic records typically found in transcripts (grades/courses/GPA/test scores); student work products such as tests and homework assignments; and interactions with online student learning systems.
- Education records of students in most K-12 schools and colleges/universities are subject to FERPA regulations.



Examples of research studies that are exempt under category #1:

- Development and testing of a science curriculum that meets state standards, but is presented in an innovative manner. Data are collected via tests, student attitude surveys, and classroom observations.
- Research on the use of electronic “clickers” in the classroom to elicit immediate feedback from students on their understanding of course concepts.

Examples of research studies that are *not* exempt under category #1:

- Research that collects information about personal characteristics beyond basic demographics of students, families, or teachers (such as mental health, personal beliefs or opinions beyond those associated with learning or curricula).
- Implementation of an untested curriculum that is not consistent with current required curriculum.

Although an exemption determination eliminates the need for continuing IRB review and approval, investigators still have an obligation to understand and abide by generally accepted principles of responsible and ethical conduct of research. Examples of these principles can be found in the Belmont Report (such as the obligation to obtain informed consent) as well as in guidance from professional societies and scientific organizations.

Regulatory Citations:

Current – 45 CFR 46.101(b)(1)

2018 Revised Common Rule – Section 104(d)(1)



Examples

Exemption category	Study example	Exempt? Y/N	Explanation
#1	Assessment of student attitudes about learning in high school.	Yes for all	The study involves a normal educational practice in an established educational setting.
#1	Evaluation of instructional methods for college course offered online.	Yes for all	The study involves a normal educational practice in an established educational setting.
#1	Educational test development in a prison setting.	No	Research that targets prisoners is not eligible for exemption.
#1	A previously untested educational intervention that does not support the current curriculum is implemented.	No	The study does not involve a normal educational practice .
#1	A lengthy research intervention is implemented; teachers do not have time to cover required content; students have less time to prepare for exams.	No	The research activity detracts from normal instruction and could negatively affect student achievement.
#1	An educational intervention is implemented in an elementary school. The project involves a pre- and post-intervention survey is administered that includes numerous questions about the child's mental health and information about the home environment.	No	The focus of the research must be limited to the educational practice (evaluation of educational intervention, curriculum, etc.), not focused on the child, family, or teacher.
#1	Study of teachers and poor classroom management; findings will be shared with school administrators.	No	The study could adversely affect assessments of teacher performance.

No self-determinations where FERPA applies.