

Monmouth University
Normal Educational Practice Guidelines
A School of Education Proposal
in collaboration with
The Monmouth University Institutional Review Board

Contextualization:

The concept of ‘normal educational practice’ is referenced in the federal regulations governing human research protections (45 CFR 46), within a category of research that is exempt from those regulations. Such activities remain subject to the ethical principles of the Belmont Report, and MU policies and procedures governing such exemptions (e.g., the requirement to formally submit, and be granted said exemption, from MU (via the IRB Office). The following is Monmouth University’s Institutional Review Board policy on what does and does not constitute normal educational practice, followed by considerations for the level of IRB review that would be required.

“Normal Educational Practice”:

The regulations do not define “established or commonly accepted educational settings,” or “normal educational practices.” The Office for Human Research Protections (OHRP)’s preamble (accompanying commentary) to this exemption does note that IRB review would be required “for such research activities being conducted in unconventional settings.” [p 7187]. The commentary also explains that the intent is to allow education research “that may contribute to the important public good of improving education, consistent with the [Belmont Report] principle of beneficence.” [p 7186] Further, the regulations specify that the practices under study should not be likely to have a negative effect on students’ opportunity to learn required material, nor on the assessment of instructors and other educators, “an important qualification that should apply to any research activity that is exempt under this provision.” [p 7186]

At OHRP’s request, the [HHS] Secretary’s Advisory Committee on Human Research Protections (SACHRP) has considered what constitutes “Normal Educational Practices” and has offered the definition to include “those activities that are routinely used in similar educational settings and/or are considered proven educational practices within the population under study.”

In the absence of explicit guidance, IRBs and Institutions, rely on ‘plain English interpretation of the regulations. For example:

“Established or commonly accepted educational settings” include those institutions, venues, and sites where training and education normally occur.

“Normal educational practices” include accepted activities that occur during the process of instruction in the educational settings.

The following constitutes Monmouth University’s assessment of these concepts in the context of allowable educational research and consideration by the IRB:

For researchers proposing to work with subjects in an educational setting, the following is a list of potential activities that are recognized as “Normal Educational Practices.” This list is not extensive or finite, as the ever-evolving nature of educational practice would nullify such a list. However, the constant that runs throughout these examples is the professional/academic normalcy which would be consistently present across educational settings.

- Research on instructional methods in a classroom, including comparison of differing (but accepted) teaching methods.
- Faculty experimenting with pedagogical methods
- Surveys with faculty and paraprofessionals
- Interviews with faculty and paraprofessionals
- Journals/logs/observations designed to ascertain data relating to researcher’s questions
- Audio and video recordings of instructional practice
- Student data resulting from teacher-led instruction and/or assessment methods (inclusive of special populations’ data that is procedurally safeguarded under IDEA)
- Diagnostic and post assessments (tests)
- Assessments
 - Designs of said assessments
 - Implementation of a given assessment
 - Short or longitudinal analysis of assessment
- Data on beliefs within an educational setting
 - Qualitative data which can be used in case studies and phenomenological studies
 - Goal to explore potential changes over time given an independent variable
- Program evaluation
- Analysis of school data/records
 - i.e., attendance, disciplinary referrals, health records, grades, standardized test results, IEP’s, 504’s (if FERPA regulations are also met)
- Utilizing student data to help quantify effect of given independent variable/educational initiative
 - This includes aggregate student data NOT disaggregate data
 - i.e., 6th grade Social Studies averages vs an individual student’s identified Social Studies Average
- Research on instructional methods in a classroom
 - Surveys with students
 - Interviews with students

Examples of Educational Practices that are ‘not normal’:

Educational practices that will be defined as “not normal” include those that (1) use machines or procedures that do not occur (or rarely occur) in educational settings, such as MRIs or eye-tracking software, or (2) involve the use of rare interventions that are based on questionable prior research.

- Studies involving medical tests and/or medications that are not part of the school records
 - e.g. analyzing medical data on students clinically diagnosed with a disability as it relates to achievement
 - physiological measures, health measures or invasive tests (height, weight, BMI, blood tests, etc.), where these measures are not acquired per instructional practice.
- Implementation of a punishment-based procedure for research purposes (including corporal punishment procedures)
- Any surveys, analysis, or evaluations falling under the [Protection of Pupil Rights Amendment \(PPRA\)](#), i.e., examining...
 - Political affiliations,
 - Mental or psychological problems potentially embarrassing to the student,
 - Religious practices,
 - Income
- Testing students with *new additional* items for a *longer period* of time that would not be expected in normal educational practice.
- Educational treatments that contradict “best practices,” as assessed by literature review. For example, treatments that do not allow wait time, corporal punishment, or negative (degrading language, humiliation) verbal feedback would fall within this category.

Participants:

Educational research can be broad and multifaceted involving various stakeholders within a given community of learners. Research involving “Normal Educational Practices” may include (but is not limited to) the following populations:

- Students from various institutions
 - P-12, Public, Private, College, University, Religious, Home School
- Teachers
- School Counselors
- Parents/Guardians
- Administrators
- Coaches/Directors
- Staff/Personnel
- Contracted or Volunteering Personnel
 - Resource Officer, Educational Consultants, etc.

All participants in any research study are required to sign any and all necessary consent and/or assent forms before participating in a study. (In some cases, documentation of consent from

participants or parents of K-12 student participants may be waived with acceptable justification within the application.).

Because of their vulnerabilities, research with the following special populations should include considerations for added subject protections:

- Special Populations
 - Students who have been clinically diagnosed (e.g., disability)
 - Students who have been identified as gifted or talented
 - Incarcerated prisoners

Setting:

Given the diverse nature of educational research, the setting for “Normal Educational Practices” may extend beyond the literal classroom. The various stakeholders within a given school or educational environment are not limited to a singular classroom to conduct normal educational responsibilities, and research reflects that reality. Examples of places in which “Normal Educational Practices” includes (but is not limited to) the following:

- K-12 Classroom
 - Includes preschool programs, after-school programs, college/university classrooms, resource rooms, alternative education programs, cyber school, hybrid/online learning, Summer School and/or Extended School Year
- Practices
 - Sports, music, theater, “mock trial,” etc.
- College/University Classrooms
- Professional Development Sessions
 - Faculty, Administrators, personnel
- Offices within a school system
 - Main Office, Nurse’s Office, Athletic Office, etc.

Potential Levels of IRB Review

In addition to determining whether an activity involves normal educational practice, some other variables must be considered by the IRB Office in determining the level of review. These include, (1) whether or not the collected data could be linked back to the subject, (2) involvement of retrospective or prospective data collection, (3) types of questions to be asked in interviews and surveys, and (4) the study population.

If all proposed activities fall into one or more exemption categories, the study can be reviewed for exemption status. If not, then the study is not exempt, and must be reviewed in accordance with all requirements of the federal regulations at 45 CFR 46. Within this option is minimal risk research (qualifying for expedited review), or greater than minimal risk research (requiring

review by the convened IRB). The following discussion addresses the most likely review paths that research involving normal education practices may follow:

I. Exemption Review-Review by IRB staff or an IRB member

1. Exemption #1 (45 CFR 46.104(d)(1))

Any activity described in the first section of this policy, qualifying as ‘normal educational practices,’ could be *considered* for exemption in this category:

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.

What additional aspects of the activity would need to be evident in the research proposal in order for it to be considered for this exemption? Some examples:

- Exemption #1 addresses prospective activities only (so, exemption #1 would not cover accessing of existing data (e.g., school records). See discussion of exemption 4, which could be applied if access to existing data is required for the research.
- In order to consider the research “not likely to adversely impact students’ opportunity to learn required educational content,” the activity should, e.g., not require taking the student out of the classroom during instructional study to conduct the research. Studies that propose use of the homeroom period to conduct research procedures would be acceptable.
- In order to not likely adversely impact the “assessment of educators who provide instruction,” researchers are cautioned regarding proposals where they serve in a position involving, or may be able to influence the, assessment of the performance of teachers who may be subjects, or teach students who will be subjects of the research. One way to mitigate this issue would be to have an alternative study team member (without such authority) be involved in data collection, with the researcher receiving the data in a form where students and teachers would not be identifiable to them.
- Surveys and interviews of children are permitted in this category as long as the questions asked *are related to the educational practice being evaluated*. Note that if the questions are not related, there is no other exemption category that is allowable for surveying or interviewing

children (there is an exception for educational tests in exemption 2, to be discussed), and the proposal would then need to be considered for expedited review. See further discussion below.

Examples of research that would likely be eligible for exemption 1:

- Research on instructional methods in a classroom, including comparison of differing (but accepted) teaching methods
- Faculty experimenting with pedagogical methods (so long as students' ability to learn required material is not adversely affected)
- Research on quiz/testing frequency, lecture vs. section frequency, or availability of assistance outside normal classroom hours (with the same caveat about students' ability to learn required material)

2. Exemption #2 (45 CFR 46.104(d)(2))

(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 certain criteria are met.

Of note is that this exemption cannot apply to children unless the research specifically involves educational tests (cognitive, diagnostic, aptitude, achievement) or the observation of public behavior if the investigators participate in the activity being observed. Further, if the information obtained about the children is identifiable, potential disclosure of that information must not place the children at any risk.

The option to involve children in survey or interview procedures is not permitted under this exemption.

Examples of education research that might be eligible for exemption 2 include:

- Cognitive, diagnostic, aptitude, or achievement testing of subjects of any age
- surveys or interviews of adult subjects
- observation and recording of public behavior (for instance, on a playground or in a school classroom with permission of school authorities, who are responsible for determining whether parental permission is needed) where the investigator does not interact with or otherwise participate with subjects.

3. Exemption #4 (45 CFR 46.104(d)(4)(ii))

Secondary research uses of identifiable private information if...(ii) Information...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, the investigator does not contact the subjects, and the investigator will not re-identify subjects.

The most common applicability of Exemption #4 in research involving normal educational practice is the accessing of data that has been, or will be, collected for another purpose (e.g., school records), for analysis on its own, or to correlate to other aspects of data being collected. The key to having this exemption apply is that, although the researcher may access identifiable data, they must not **record** the data with any link back to the student/subject. If that criterion cannot be met, the study will need to be considered for expedited review. Further, there can be no contact with subjects by the investigator, and the investigator may not later attempt to re-identify subjects.

II. Expedited Review-Review by 1 or more IRB members

If any aspect of the study does not fall under an exemption category, the study will be assessed for expedited review. The IRB office will assist you with compliant documentation, since the study is now ‘nonexempt,’ and is subject to the federal regulations at 45 CFR 46. The most common categories for research involving normal educational practice that does not qualify for exemption are:

#5: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

#6: Collection of data from voice, video, digital, or image recordings made for research purposes.

#7 Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Note, that there are no restrictions for children in these categories, and so, with very limited exception, educational research not qualifying for exemption, will qualify for expedited review.

III. Full Board Review

Any research that does not qualify for exemption, or expedited review, will be placed on the meeting agenda for review by the convened IRB.

IV. FERPA

Researchers who propose accessing student records for research must comply with FERPA. For research involving interaction with parents and/or students, the following information will need to be included in the consent (parent permission, student consent or assent) documents:

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- a) Specify the education records that may be disclosed (GPAs, attendance, number of disciplinary referrals, etc.);
- b) The purpose of the disclosure (study and what you will use it for; example-dissertation);
- c) The party to who the school will make the disclosure (yourself and any other person they may send it to in addition to you (PI, Co-PI, etc.); and
- d) That if they request, the school will provide them with a copy of the records disclosed

Additional information regarding FERPA compliance can be obtained from the Associate General Counsel [Charlene Diana, 304 Wilson Hall, 732-571-3598, <cdiana@monmouth.edu>].

References

Office for Human Research Protections. (11/13/18). *Interpretation revised common rule exemptions (SACHRP)*. Retrieved from www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-b-november-13-2018/index.html

Final Rule for the 2018 Common Rule, with preamble:
<https://www.govinfo.gov/content/pkg/FR-2017-01-19/pdf/2017-01058.pdf>

Federal Regulation for the Protection of Human Subjects at 45 CFR 46 <https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML>

Federal Expedited Categories: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html>

U.S. Department of Health & Human Services (n.d.). *Office for Human Research Protections*. Retrieved from <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/children-research/index.html>

Clemson University (2020). *Guidance on exemption category 1: Normal educational practices*. Retrieved from <https://www.clemson.edu/research/compliance/irb/b1exemption.html>

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