Guidance for Exemption Category D.1: Normal Educational Practices

What type of research qualifies for exemption under this category?

Federal regulations allow specific categories of human subjects research to be exempt from continuing IRB review [45 CFR 46.104(d)]. Exemption D1 applies to research conducted in schools and other educational settings:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices*, such as:
    - research on regular and special education instructional strategies, or
    - research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

*Practices cannot adversely impact students' opportunity to learn required education content or the assessment of educators who provide instruction.

Although the regulations do not address a maximum risk level, it is implicit within the concept of exempt research that there must be very little, if any, associated risk. Protocols qualifying as normal educational practice are not exempt from following the ethical principles set forth in the Belmont Report.

What is an established or commonly accepted educational setting?

The federal regulations do not specify that normal educational practice takes place only in schools. The burden of proof in demonstrating that the proposed research setting qualifies as fitting the category of "established" or "commonly accepted" falls ultimately on the principal investigator.

The broadest definition one could use is that an educational setting is any setting where one would go in order to have an educational experience. For example, a public school would certainly qualify, as would an after-school club or program, a Boy or Girl Scout meeting, or even a professional development seminar for school district personnel. As educational activities expand outside structured institutional settings to include "engaged learning" in applied settings, distance and on-line educational programs, and internships and study abroad programs, the potential for the application of category B1 may expand to include these "educational" settings and activities. Additionally, nontraditional settings may be included in "commonly accepted educational settings," as long as the educational setting is established in the local area. Examples might include a grocery store (e.g., nutrition class) or an automotive garage (e.g., safe driving or how to do preventive maintenance on a car). Finally, international and cultural differences may affect what is considered a "commonly accepted educational setting." For example, if the educational practice is commonly accepted in a specific population such as Amish or Native Americans, it should be considered "commonly accepted" for research within that population.

An educational setting may be considered “established” in a local area if educational activities occur there on a regular basis.

What if a study in an educational setting is not exemptable?

If the protocol does not qualify for exemption yet it poses minimal risk to participants, it may be eligible for expedited review. If the study poses greater than minimal risk to the participants, the protocol will be reviewed at a full board meeting.

What is normal educational practice?

Research involving normal educational practices refers to commonly accepted educational practices. Hence, research involving the use of radically new or innovative practices may not qualify for exemption. The Board recognizes that a variety of activities normally occur in the classroom and that a researcher might propose classroom activities that may not be part of what could normally occur in a particular classroom, but that may be considered “best practice” for a classroom. The addition of these practices in a classroom may benefit the students. In these instances, the Board may determine that implementation of a “best practice” qualifies for exemption under normal educational practice.

What types of studies may qualify for exemption as normal educational practice?

- Test development. Development and pilot testing of new educational assessment tools.
- Experimentation with instructional methods.
- Collecting affective data, specifically attitudes toward learning. The Board recognizes that it is normal for a teacher to assess his or her students’ attitudes regarding learning.
- Assessments related to educational activities. The time commitment required to complete assessments should be described and should not exceed reasonable limits. The protocol design should clearly describe how results will be shared back with the school staff to assist in their instructional decisions as well as potential associated risks (e.g., Will students’ grades be affected by their scores on the assessments? Will results be shared at the individual student level or in aggregate? How will the data be used by the school?).
- Research with instructional methods or classroom/school activities which may include pre- and post-testing, surveys, interviews, and/or observations. For example, if you are studying a new writing technique and you want to ask the students what they think about the writing technique, this could qualify for exemption. In all protocols, it is most helpful to the IRB if you clearly justify the necessity for using the chosen methods for collecting data and specify what data will be collected (via testing or survey instruments, interview questions, and/or observation protocols).
- Collecting data specific to teacher and/or student current knowledge, beliefs, or attitudes towards learning, or data about how these change over time. These studies may be descriptive in nature and may even be longitudinal. Interviews, observations, and surveys must include questions and subject matter that fall within the scope of the educational activity being studied.

- Obtaining samples of student work or scores may be eligible for exemption if FERPA regulations are also met.

Is data collection using videorecording, audiorecording, and/or photography acceptable within an exempted study under B.1?

Yes. Data collection methods must be outlined in the consent process. If the materials will be used in a presentation or publication, it may be necessary to obtain specific permission from parents and/or adult participants to do so.

What research activities may not be considered normal educational practice?

There are studies that may take place in an educational setting that the Board would not consider exemptible because they do not involve normal educational practice. The Board can still approve these studies, but they would require expedited or full board review. Examples of such studies include:

- Interviews, observations, and surveys where the questions and subject matter go beyond the scope of the educational activity being studied.
- Collecting privileged information such as socio-economic status, physical abuse, etc.
- Educational activities involving procedures that are rarely used and are not considered "best practice" in the field.
- Studies that may involve normal educational practice, but pose greater than minimal risk to the students. Such decisions are made by the Board based on possible risks to the participants in the research. The Board may also determine that a study cannot be classified as normal educational practice based on the proposed methodology for the study.

What issues should be addressed when describing proposed research in education settings?

When describing research activities believed to fall under this exemption category, consider the following:

- Will the research activities occur during class time or outside of class time?
- If implementing a novel educational method, describe how it differs from the standard method.
- If conducting educational tests, describe when and how frequently.
- If reviewing and / or collecting student grades and / or standardized test scores, describe what grades or scores will be reviewed and / or collected, and if they will be individually identifiable.
- Identify if observing and recording data on teachers and / or students. If so, describe the activity.
- If reviewing student coursework, describe what coursework will be reviewed, if it will be identifiable, and how subjects' identities will be protected.

- State if the educational activity is solely related to the research OR if the educational activity will occur regardless of whether the research is conducted.
- If extra credit will be offered for participation in the research activity, an alternative activity (involving a comparable amount of time and effort) must be provided to non-participating students for a comparable amount of credit. Such activities must be described.
- If the researcher(s) is not directly involved in the implementation of the intervention, particular attention must be paid to the description of how the surrogate researchers will be trained in the conduct of human subjects research (e.g., obtaining consent, ensuring that those students whose parents do not want them to participate are excluded from the intervention). Describe who is responsible for distribution and collection of signed consent documents. Describe what plan is in place to monitor and manage data collection.
- Describe the plan for accommodating a student who wants to withdraw from the study after permission / consent / assent has been obtained.
- Clearly describe the difference(s) between what would typically occur in class and what will occur related to the research (i.e., Will all students be involved in the same activities or will there be individual students singled out within a classroom?).
- Coercion and undue influence is difficult to avoid in a classroom setting in which activities are determined and implemented by adults. Research designs should include strategies to reduce this risk. For instance, clear procedures should be in place for maintaining the educational activities of students who are not participating in the study in order to minimize interruption to the typical school day. Although students are generally obligated to participate in activity designed for the whole class, activities specifically implemented for the research need to be clearly explained and alternatives be provided for those choosing not to participate. Appropriate alternatives should be provided for those who opt out, and must be described in the protocol as well as the consent documents.
- The risks and inconveniences should be assessed and clearly described in the protocol and consent process. For instance, in studies involving examination of classroom management techniques, will individual students be singled out for use of specific techniques? If so, what risks does that present to that child and to the other students (e.g., possibility of increase in disruptive behaviors)?
- Describe how privacy and confidentiality of all participants (e.g., students, teachers) will be maintained. For example, will study results be shared back with the school on an individual level or in aggregate? Will information about teacher performance be shared with school administration? What risks to participants are presented given how data will be both managed and shared?

Who are the research participants?

The participants should include those involved in the educational experience, and from or about whom data are being collected. This will most likely include the teacher(s), student(s), and possibly the administrator(s). Participants that are indirectly involved in the educational experience may be included in the study.

Participants can include populations with special educational needs, though the IRB will require demonstration of the investigator's credentials to work with these vulnerable populations, as well as a clear explanation of any additional procedures to minimize risks specific to working with this population. For example, if a child is significantly cognitively delayed, obtaining assent may not be appropriate, and the investigator must describe what steps will be taken to ensure that appropriate cues are taken from the child that may indicate an unwillingness to continue with study procedures.

When are research site letters needed?

When researchers propose research activities that occur in public or private schools or other educational institutions (other than colleges or universities), they must submit a letter of permission (i.e., research site letter) from the appropriate school authority allowing the conduct of the research. The IRB strongly recommends contacting the administrative offices of the school/corporation/educational institution proposed to host the research activities in the beginning stages of the research project to identify the authorized school representative to grant such permissions. Additionally, should that representative have a conflict of interest with the research, a different representative should grant the permission (e.g., if a school principal is the authorized individual, but s/he is an investigator on the research project, then the superintendent should grant the permission).

Some school districts have district-wide procedures for granting permission for research in schools, while others allow individual school principals to make decisions about research to take place in the schools they oversee. It is advisable that researchers check with each school district in which they intend to conduct research in order to determine at what level they must obtain permission.

What other factors may be considered in IRB exemption review for this category of research?

The IRB considers educational time to be a valuable commodity, and thus, the design of a research study that will be carried out in an educational setting should be developed with this in mind. At the minimum, the research should not waste student educational time, and may offer benefit to the individual and/or class-wide educational experience. The IRB will consider the proposed methodology for the study in light of both time requirements and likelihood of benefit in order to determine whether it qualifies as normal educational practice. In all cases, the IRB will need to assess risks to all proposed participants in the study to determine the level of review required.

What other regulations may apply to research in educational settings?

Research exempted as normal educational practice is often conducted in public school settings, which may demand that specific steps be followed in order to comply with additional state and federal laws. Although the definition in the regulations is fairly straightforward, it may not address other regulations that the IRB is obligated to follow, such as, FERPA (Family Educational Rights and Privacy Act), and PPRA (Protection of Pupil Rights Amendment).

FERPA restricts researchers' access to student records without written permission from parents (or from the students themselves, if the records are held by a post-secondary educational institution). However, within FERPA (34 CFR 99), there are conditions under which student records can be disclosed without parental / student consent. Investigators must contact each institution and follow that institution's FERPA policy, in addition to the requirements of the CU IRB.

PPRA (34 CFR 98), which applies to Department of Education-funded protocols, outlines eight categories of protected information for survey responses and requires that parents be afforded the right to inspect surveys before they are given to students.