University of Colorado Boulder

Institutional Review Board
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Guidance Document:

Research in Schools

Overview:

This Guidance Document encompasses research projects occurring in schools that are designed to assess curriculum for research purposes as well as studies of the motivations, behaviors and cognition of students, taking place in a classroom setting.

Definitions:

1. “Research” means a systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalizable knowledge.
2. "Schools" in this context generally refers to institutions engaged in primary and secondary education of minor students. However, it can also be interpreted more broadly to any place where educational activities are commonly carried out (see exemption discussion, below).
3. Minors or Children in research are those who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. This is normally 18 years old, but may vary depending on jurisdiction (state-by-state) and specific situation (minors who are otherwise legally able to consent to the proposed procedures on their own).

What kind of review will my education study receive (Exempt, Expedited, or Full Board)?

1. Research Exempt under Category 1 of 45CFR46.101(b):

Federal regulation provides for the Exemption of 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. Research falling under this exemption must be initially reviewed by the IRB to make the Exemption determination. Once determined to be Exempt, the research is no longer under the purview of the Federal Regulation. CU policy requires any changes to the study as well as any unanticipated adverse events be reported to the IRB for evaluation as to impact on the study’s Exemption status.

“Commonly accepted settings” usually involve public schools, but can include nontraditional settings such as an automotive garage (e.g. how to do preventative maintenance on a car) or a teaching kitchen.

The IRB notes that the term "normal educational practice" is not defined, but that the division between "educational practice" and "developmental curriculum" can be blurry. In cases where there may be a question as to whether a practice being studied is a normal educational practice, the research Protocol

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should clearly describe whether and how the practice is normal in the setting being evaluated. Given the examples provided in the Exemption criteria indicating that this Exemption be applied to types or topics of research rather than focus on specific procedures undertaken in the research, the CU Boulder IRB currently applies this Exemption broadly. However, this Exemption does not always apply to research or evaluation of clearly developmental or experimental educational strategies, techniques, curricula, or methodology.

Research of experimental educational techniques, curricula or methodology may be reviewed under Exempt procedure provided the interventions are shown to be mature and are consistent with the techniques, curricula and methodology already in use in the classroom. For example, this would include a program established in one setting being evaluated for use in other contexts. Also included may be some classroom technologies or techniques that build directly on already established techniques.

2. Research involving Immature, New or Experimental Educational Interventions:

Research involving early developmental or immature curricula may be reviewed under either Expedited procedures or by the full IRB. Research involving experimental curricula with the potential to cause academic or developmental harm to students exposed to an unknown or inferior educational technique, curriculum or methodology before it is fully developed will receive the highest scrutiny for Approval. Proposals involving research of this type should provide specific provisions to minimize any such risks to the greatest extent possible and demonstrate a clear potential benefit outweighing these risks. Investigators may be required by the IRB to provide a means to evaluate whether the intervention is resulting in student degradation.

3. Collection of Data from Student Records:

In any research where data are to be recorded from student records, researchers should specifically discuss who will be recording the data and/or in what manner it will be provided to the researchers. The study Protocol and in most cases the Parental Permission form must specifically state what data are to be collected by such procedures.

Research in which identifiable information is obtained from student education records by investigators for research purposes are also covered under The Family Educational Rights and Privacy Act (FERPA). This is the case regardless of whether the investigator would ordinarily have access to this information for educational purposes. Identifiable student data collected in conjunction with other sensitive or protected information (e.g., health information, disability, race, ethnicity, citizenship, legal presence, visas, religion) is viewed by CU Boulder policy as "Highly Confidential". Data Management Plans for such information must be reviewed and approved by the CU Boulder Office of Information Security (OIS), and their Approval Letter included in the study submission. More information about this data management requirement can be found in the IRB's guidance, here: [Data Security Guidance], or the CU OIS website, here: http://www.cu.edu/ois. Contact the CU Boulder OIS office at InfoSec@colorado.edu for more information on data security.

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Who would be considered a research subject in my education study? What are the basic Consent considerations for each?

1. Students:

Generally, research being done in an educational setting involves research about curricular interventions and must involve the students engaged in the curriculum to measure the impact of any changes. As such, these children are subjects involved in an research-based interaction or intervention, and will normally have information collected about them. Researchers conducting studies with child subjects such as students must be cognizant of the requirements of Subpart D of the Federal regulation for non-Exempt research studies. Involvement of students as research subjects will normally require investigators to obtain both Assent and Parental Permission in order for those students to participate. In some special circumstances, the minor students may not be the subjects of the research (that is, no data are being collected *about* the students themselves) even though they may be peripherally involved in the research, for example, a study about mentors of high school students, where data are only collected only about the adult mentors. In these cases, the IRB recommends that students and parents are still informed about the study, but explicit Assent and Parental Permission are not likely to be required.

2. Parents:

If information about parents is collected, or they provide information about themselves, parents may be considered Human Subjects of education research as well. In order to simplify the amount of paperwork required in these cases, Consent forms can be combined with Parental Permission forms, but should clearly indicate what procedures parents will be involved in, and what procedures the students will be a part of.

Another important consideration when conducting research with students is that their parents may not be able to speak or read an English language Permission form. In these cases, a translated Parental Permission form must be submitted and approved by the IRB before being put into use.

3. Teachers/School Staff

In order to measure the effects of interventions such as professional development activities, or how changes in curriculum impact teaching workloads or other factors, teachers and school staff are frequently also subjects of research in educational settings. If data is being collected about teachers as a result of research activities, Informed Consent should be sought from these individuals as well.

Are there any special considerations for recruitment?

1. Students:

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Children are protected as a class per Subpart D of the Federal regulation based on the assumption of a reduced autonomy to consent to research procedures. This consideration extends to recruitment of students into research as well. Even in Exempt research not covered by the regulatory Subpart, care must be taken to avoid undue influence to participate in studies from peers, teachers, and other authority figures. The decision to participate or not must occur in circumstances that minimize the possibilities of coercion or undue influence. Even adult students may view research participation as a requirement or an activity that a teacher/investigator expects all students to take part in. For this reason, a classroom teacher should not be involved in the recruitment of students from his or her own class.

Students should not be presumed to be "recruited" simply because of their presence in a classroom where research may be taking place. Participation in research should generally not be a required part of the curricula, and students should be able to refuse participation. To do otherwise denies a student's autonomy outright.

Recruiting methods such as informational letters sent to parents can often be done through the school by having the administration send the information on behalf of the investigator, or by including recruitment material in information normally sent home with students. When recruiting in this manner, the investigator's contact information should be included in this information. School employees should not act as authoritative representatives of the investigators, as this would result in the school system becoming "engaged" in the research (see the OHRP Guidance Document on Engagement in Research for more on engagement).

2. Teachers:

Care should be taken in the recruitment of teachers both as research subjects and as collaborators. Investigators must be aware of possible undue influences or coercion to participate from sources such as school supervisory staff (principals, superintendents, etc.) as well as from any stipend or compensation provided for participation. Although monetary compensation for teacher activities may be appropriate, the amount must not be so great that it may unduly influence or coerce teacher participation. This includes stipends for any training that a teacher must attend in order to be a participant in the research. This does NOT includes stipends for professional development that teachers are attending independently of research participation, which are not under the IRB's purview.

What Consents are required for conducting Education Studies, and may I have Consent Waived?

1. General:

Prior Informed Consent of research subjects is one of the fundamental principles of ethical conduct in the use of human subjects. It is also mandated by Federal regulation (45CFR46.116). Assent of minors is required per 45CFR46.408. Except in rare circumstances as described below, provisions must be made to

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obtain the Informed Consent of adult research participants, as well as the Assent of, and Parental Permission for, child participants in research.

The language used in these forms must be appropriate for the audience for which it is intended. Templates are available on the IRB website for Consent Forms, and should be followed as much as appropriate. In most cases, the IRB recommends that the reading level of adult Consent forms not be higher than an 8th grade reading level. (The reading level of a document can be estimated in MS Word by going to the Review Tab, and selecting the Check Spelling and Grammar button. Ensure that "Show readability statistics" is selected under options. Once the spell check is completed, a screen will appear showing, among other statistics, the reading level.) The forms should be written in a conversational manner, and should not contain any complex jargon or esoteric information.

Assent forms for children aged 14-17 can use the same format as the adult Consent form, but should keep in mind the reading level of the target audience. Assent forms for younger children ages 7-14 should use a simplified version of the Consent form. The requirement for written Assent of younger children can be waived in certain circumstances due to their inability to read and/or understand the document. With very rare exception, Consent, Assent, and Parental Permission must contain all of the requirements outlined in 45CFR46.116.

2. Waivers of Consent, Assent, or Parental Permission:

"Opt-out" or "passive" consent methods, in which a lack of response is presumed to constitute Consent, Assent, or Parental Permission are not allowable under Federal regulation, and will not be approved by the CU Boulder IRB. In the case of Parental Permission, the more logical presumption is that the forms never made it to the parents.

Whenever possible, students and parents should be able provide Assent and Parental Permission or to refuse participation in research activities. If at all possible, provisions should be made to allow students to decline to participate in any or all of an experimental intervention.

In cases where obtaining Assent or Parental Permission would not be practicable (that is, the research could not possibly be accomplished if affirmative Consent is required), a Waiver of Consent or a Waiver of Written Documentation of Consent may be granted by the IRB. One example of where a waiver may be appropriate is in the case where a school has adopted a new curriculum as the standard for the class, and all students will participate in that curriculum. In this case, a waiver of Consent may be appropriate for the experimental intervention (the new curriculum). However, data collection conducted to assess that curriculum should still be carried out with the Assent of the child and Parental Permission.

Any request for Waiver of Consent or Waiver of Written Documentation of Consent must be made in writing in the research Protocol. The Protocol must specify how the research meets the appropriate criteria for the Waiver. More information on Waivers of Consent can be found at 45CFR46.116(c) and

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(d), .117(c), and in the IRB's Guidance Documents." If questions exist about whether such a waiver would be possible, investigators are also encouraged to contact the IRB office for further consultation.

3. Waivers of Assent, Consent and Parental Permission in Exempt research:

Because the requirement for Assent, Consent and Parental Permission stems from regulatory requirements, it is not necessary to request a formal Wavier of Consent in research that is anticipated to be Exempt as described above. Note that in general, the IRB still expects investigators to make every effort to obtain effective Assent, Consent and Parental Permission, if this is not possible in an Exempt research study, the investigator should describe in the research Protocol alternative procedures as above, but without the formal Waiver information.

4. Provisions must be described in the Protocol for students who do not give their Assent to participate, or for whom Parental Permission has not been obtained. Procedures outlined regarding these students must take into account factors such as peer pressure to participate, possible embarrassment, or teasing from other students.

5. If not obtaining Parental Permission in person, the Protocol must describe specific methods being used to send, return, collect and account for Assent and Parental Permission forms. This should take into account protection of privacy rights, and accounting for who does and does not have Assent or Parental Permission to participate. This can be done by the involvement of a neutral third party, a drop box, and other mechanisms.

Are there any other Submission Requirements for research in schools?

Research in schools must be accompanied by a letter of approval or agreement from the School District in which the research will take place. The letter should be from an officer of the district authorized to commit the district to participation in the research. While letters from specific school principals or classroom teachers are welcomed as well, such letters are not required, and will not suffice for a letter from the School District. In some situations, approval from a School District may not be immediately available. If a letter from the District is not available at the time of IRB submission, the Protocol and Initial Application E-Form must specifically describe the reason for this, and state that the research will not commence in that District until the letter of agreement has been obtained. Research must not begin in that District until the IRB has received the letter as an Amendment to the study and the Investigator has received IRB approval of that amendment.

Other Considerations:

The information in this Guidance Document generally pertains only to CU Boulder policy, and the CU-Boulder IRB's interpretation of Federal regulation. Investigators are responsible to be cognizant of and understand the implications of regulation that may impact their research. Specifically impacting

research in school settings are the Family Educational Rights and Privacy Act (FERPA) and the No Child Left Behind (NCLB) Act.

Different school districts may have additional requirements or review procedures. It is highly recommended that investigators contact the school district in which they intend to do the research early, and involve them in the development of any research Protocol. Contact information for several local school districts is below.

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Denver Public School District
Department of Accountability Research & Evaluation
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720-423-3736
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St Vrain Valley School District
Tori Teague
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Aurora Public Schools
Dr. Mya Martin-Glenn
Department of Assessment & Research
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Jefferson County Public Schools
Heather MacGillivary
Director of Assessment & Research
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References:

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US Government Publishing Office. (12December2016). *Electronic Code of Federal Regulations 34CFR99 - Family Educational Rights and Privacy.* Retrieved from: http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=130c10a869e7dca670cf121bb0860276&rgn=div5&view=text&node=34:1.1.1.1.33&idno=34.