Introduction

Conducting research in the public schools is a complex endeavor. Researchers need to be aware of the following:

- The federal regulations for protecting human research subjects identify children as a vulnerable population and thus include special rules for their protection (Subpart D of 45 CFR 46).
- Federal laws protect information in students' educational records and under some circumstances give parents authority over the kinds of questions researchers may ask their children.
- Multiple levels of protection for children exist in the schools which means that there are multiple systems for investigators to navigate. Authority structures vary from district to district. Investigators may need to confer with teachers, principals, district supervisors, and school boards, all of whom are responsible for the children in their care and all of whom must work under various
political and community pressures.

- Practical constraints on time and resources limit school hours available for research that does not directly address problems identified by the schools.
- Securing parental permission can be very difficult and may place researchers in the position of not being able to understand and possibly serve children in the greatest need.
- School hierarchical structures and relationships among students create special vulnerabilities for some children.
- Researchers may come into contact with children who are abused and neglected, raising both legal and ethical concerns.

In this module, we will examine some of the regulatory, ethical, and practical concerns faced by researchers.

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1.0 Types of Public School Research

Research conducted in the public schools falls into two broad categories. The first is research designed to have immediate, practical implications for improving educational outcomes for children. This research may be related to curricula or to social dynamics that affect student performance. In recent years there has been an increased interest in evidence-based education using randomized trials of educational interventions.

Most research in the public schools falls into the second category: research designed to answer a basic research question of interest to an investigator, but which does not have immediate educational relevance. Such research may ultimately improve young people’s lives and their success in school, but that is not its immediate goal. Of course there are some studies that have both practical and theoretical applications.
2.0 Overview of Regulations that Apply to Research in the Public Schools

In addition to the general provisions of the **Common Rule** (the Federal Regulations for protecting research subjects) the following regulations also govern research in the public schools:

- **The Family Education Rights and Privacy Act (FERPA)**, sometimes referred to as the Buckley Amendment, gives parents certain rights over the content of their children's educational records. See section 3 for more information.

- **The Protection of Pupil Rights Amendment (PPRA)**, amended by the "No Child Left Behind Act" of 2001, is designed to provide parental control over the content of surveys, instructional materials, analyses, and evaluations of minor students. Two levels of control are provided, based upon how the research is funded. See section 4 for more information.

- **Subpart D of the federal regulations, "Additional DHHS Provisions for Children Involved as Subjects in Research,"** when applicable: Some federal agencies that have adopted the Common Rule have not adopted the other subparts to the DHHS regulations. For example, while the Department of Education has adopted Subpart D; the National Science Foundation has not. Thus, when research is funded by the Department of Education, the provisions of the subpart apply. They do not apply when research is funded by the National Science Foundation.

Institutions are free to choose to apply Subpart D to all research, regardless of the source of funding.
3.0 The Family Education Rights and Privacy Act

The Family Education Rights and Privacy Act (FERPA) gives parents certain rights with respect to their children's education records. The rights transfer to the student, or former student, who has reached the age of 18 or is attending any school beyond the high school level. Generally, schools must have written permission from the parent or eligible student before releasing any identifiable information from a student's record. Information in school records may include religious affiliation, citizenship, disciplinary status, attendance, gender, ethnicity, grades/exam scores, test scores (for example, the SAT), and progress reports.

FERPA does allow schools to disclose records without consent to certain parties, including organizations conducting research. Such disclosures may be used by researchers only when invoked by a school, school district, or state department of instruction initiating a study. Schools may disclose, without consent, "directory" information such as a student's name, address, telephone number, date and place of birth, honors and awards, and dates of attendance. However, schools must tell parents and eligible students that directory information is not protected, and they must allow parents and eligible students a reasonable amount of time to request that the school not disclose directory information about them.

Researchers beginning a study may need to get a school to start the notification process for directory information ahead of time. Then when they are ready to send a request to parents for permission to allow students to participate in a study, the school will be in a position to provide names and addresses. Researchers who themselves are employed by the schools, such as teachers returning for graduate degrees, must be aware of their dual roles. As researchers, they do not have legitimate access to information that they may consult daily as teachers.

4.0 The Protection of Pupil Rights Amendment

Protection of Pupil Rights Amendment (PPRA) gives parents some level of control over their child's participation in third-party survey research or exposure to instructional materials developed by researchers. PPRA identifies eight sensitive topics and includes two provisions for parental approval of surveys and materials that cover any of the eight topics. Each provision is associated with a Department of Education funding mechanism: 1) direct funding of a particular
research topic by the Department, or 2) general school funding from the Department.

The eight topics are:

- Political affiliations or beliefs of the student or the student's parent.
- Mental and psychological problems of the student or the student's family.
- Sexual behavior or attitudes.
- Illegal, anti-social, self-incriminating, or demeaning behavior.
- Critical appraisals of other individuals with whom respondents have close family relationships.
- Legally recognized privileged or analogous relationships, such as those with lawyers, physicians, and ministers.
- Religious practices, affiliations, or beliefs of the student or student's parents.
- Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program).

4.1 Research Funded Directly by U. S. Department of Education Programs

If research conducted under an applicable program of the Department of Education asks students to provide information about any of the eight topics listed above, parental permission for the students to participate cannot be waived.

(An "applicable program" means "any program for which the Secretary or the Department has administrative responsibility as provided by law or by delegation of authority pursuant to law." This means any survey that is funded in whole or in part by any program administered by the U.S. Department of Education.)
4.2 Research in Schools Receiving Any Funding from the U. S. Department of Education

Under the "No Child Left Behind Act" of 2001, parents were given additional rights with regard to the content of surveys administered in public schools, not just those funded directly through a Department of Education program. Every public school system that accepts money from the Department of Education (all public elementary and secondary schools) must develop a policy that informs parents of their rights to inspect third-party surveys and related instructional materials and to ask that their children not participate.

PPRA does not require written parental permission for the use of surveys and related instructional materials when such use is not funded directly by the Department of Education. However, the Common Rule does require that parental permission be either secured or waived in accordance with criteria established in the Rule. (See below.) Note that even if an IRB waived the requirement to secure parental permission in accordance with the Common Rule, PPRA requires that, in accordance with school system procedures, parents must be notified about the research to take place and given the opportunity to ask that their children not participate.

5.0 FERPA and PPRA in Private Schools

If research is conducted under an applicable program of the U. S. Department of Education in a private school, PPRA applies. A private school that does not receive any federal funding is not subject to the provisions of FERPA and PPRA.

6.0 Subpart D, Additional Safeguards for Children as Research Subjects.

Subpart D includes:

- Restrictions on the applicability of the criteria for exemption when children are the subjects.
- A hierarchy of four levels of risk and associated benefits, with specifications for parental permission and child assent requirements at each level.
- Criteria for waivers of parental permission and child assent.

Some institutions have chosen not to apply the provisions of the subpart unless
required by a funding agency, so its provisions do not apply universally.

With regard to social and behavioral research, salient portions of Subpart D include 1) limits on the use of exemptions when children are research subjects and 2) an additional provision for waivers of parental permission when it is not a reasonable requirement, for example, when the children are neglected or abused. (Note: Such a waiver cannot violate PPRA, when applicable.)

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### 7.0 Activities That May Qualify for Exemption in Accordance with the Common Rule

The Common Rule describes activities that do meet the definition of research with human subjects, but are not subject to the provisions of the rule. These activities pose little or no risk to the potential subjects and are called "exempt." Consult your IRB about your institution's exemption policies and procedures.

Subpart D limits the use of exemption criteria for research involving children. The following activities likely to take place in the public schools may qualify for exemption:

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."

   *It is important to note that the definition of a normal educational practice varies over time and from community to community. For example, many school districts have adopted programs designed to improve interpersonal skills, such as the widely used "Second Step" curriculum. In those schools, role-playing to explore conflict resolution strategies may be considered a normal educational strategy. Therefore, the application of the exemption criteria regarding classroom activities will be affected by local context.*

2. Research using educational tests (unless an inadvertent disclosure of identifiable data would create the potential for harm).

3. Observation of public behavior in which the researchers do not participate in the activities being observed, for example, playground activities.
4. Research involving the collection or study of existing data or records if the data are publicly available, for example, aggregate system-wide data about student or school performance, or data recorded without identifiers.

5. Food and taste test studies.

The following activities with school children will not qualify for exemption under Subpart D:

1. Research involving surveys.
2. Research involving interviews.
3. Observation of public behavior when the researcher participates in the activities being observed.
The following two case studies will illustrate how the exemption criteria can be applied.

**Case Study 1: Reading Comprehension**

Elementary school teachers are interested in whether they can improve students' comprehension by teaching them how fiction and non-fiction texts are organized. Rising third-graders at schools A and B are tested for reading comprehension in their school district. Before the new school year begins, teachers at school A participate in a developmental workshop where a widely available program of instructional strategies for teaching students about fiction and non-fiction text structures is presented. Teachers at school A implement the new strategies in their classrooms. School A outcomes for reading comprehension will be compared with a comparable population in school B at the end of the third grade year. Teachers from school B will participate in the same workshop the following year if reading comprehension increases for the third-graders at school A.

**Does this study meet the exemption criteria?**

*Yes, because it involves commonly accepted educational practices in a commonly accepted educational setting.*

**Case Study 2: Coping with Grief**

A researcher wants to study how guided writing and drawing help elementary school children cope with divorce. She wants to interview children as part of the study.

**Does this study qualify for an exemption?**

*No, because Subpart D states that interviews with children cannot be exempt.*

**8.0 Parental Permission and Child Assent**

The consent paradigm for research with children requires that parents or legal guardians give permission for their children to become research subjects. The children, when appropriate for their developmental stage, provide assent.

**8.1 Obtaining Parental Permission**

One of the most confounding issues for researchers in the public schools is the
difficulty of securing parental permission. Sending home permission forms is unreliable. The forms may never make it out of the students' packs or may end up in stacks of papers for busy parents to get to later. And forms mailed to parents may not be read. Investigators report response rates as low as 50%. Without a high response rate, it may be impossible to obtain scientifically valid results or to assess treatment effects.

These difficulties create tension between the ethical principle of respect for persons, manifested in obtaining parental permission, and the ethical principle of beneficence. Benefits to both individuals and communities can only occur if research results are meaningful. There is also tension between the ethical principles of respect for persons and of justice. It is possible that those families who already are burdened by poverty or lack of education are less likely to provide permission for their children to be involved in research that might provide some direct benefit to them. If that is the case, there may not be enough of their children enrolled to get data that are meaningful for those children.

**Investigators may use various strategies to increase response rates from parents, such as:**

1. Get the school involved. If teachers and principals buy into the study, they will encourage students to return parental permission forms.
2. Use multiple strategies, such as sending materials home with students and mailing them to parents. Use postcard reminders.
3. Make use of publicly available directory information as permitted by FERPA and local school policy to telephone parents, either as follow up or initial contact.
4. Solicit community involvement in the research.
5. Consult with your IRB about the possibility of securing a waiver of parental permission (see section 8.2).
8.2 Waivers of Parental Permission

Because some institutions have requirements for these waivers that are stricter than the federal regulations, investigators should consult their IRBs for guidance. The Common Rule provides four criteria for waivers of any or all of the elements of informed consent. The same criteria apply to waivers of parental permission.

Subpart D allows waivers of parental permission in accordance with the four criteria of the Common Rule. In addition, the subpart also allows for waivers when parental or guardian permission is not a reasonable requirement to protect subjects (for example, neglected or abused children). In order to waive any or all of the elements of informed consent in accordance with the Common Rule, an IRB must find and document that the following criteria have been met:

1. **The research involves no more than minimal risk to the subjects.**

   "Minimal risk" means that "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." Research with more than minimal risk would introduce risks not normally part of the daily experience of school children.

2. **The waiver or alteration will not adversely affect the rights and welfare of the subjects.** Some parental rights are defined by law, including FERPA and PPRA, as described above. But neither "rights and welfare" or "adversely affect" is defined in the regulations protecting research subjects, so an IRB must interpret what they mean in the local context. As always, the IRB may consult with the investigator, the schools, or other experts.

**Consider the following scenario:**

*A research study has no direct benefit to any of the children participating in the research, but has the potential to benefit a category of children they represent, fourth graders. The researchers can obtain valid results only if all children in each classroom being studied participate. The researchers are requesting a waiver of parental consent, maintaining that the rights and welfare of the children will not be violated. The school*
district has indicated that a waiver would be acceptable.

Reasonable IRBs may come to differing conclusions. One IRB might conclude that it is not a violation of children's rights or welfare to participate without parental permission in studies that have significant potential to help other children, as long as the children may choose not to be in the study. Another IRB might conclude that a waiver, even when there is no more than minimal risk, is a violation of parental rights to approve any activities that do not directly relate to their children's education.

3. The research could not practicably be carried out without the waiver or alteration. The researcher must explain the reasons why the waiver is essential to the study. Inconvenience and expense are not acceptable factors in making a determination about "practicability".

4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation. This process is usually referred to as "debriefing".

Many IRBs require that investigators tell parents about a study, even when it has approved a waiver of parental permission. In essence, parents may be offered the option of entering into a permission process even though it is not required. They may be given the option to get more information and the option to take their children out of the study.

8.3 Child Assent

Even when parents have provided permission for their children to participate in research, children must be allowed to provide assent in a manner appropriate for their age and maturity. Care should be taken so that children do not feel pressured into participating in research. Younger children may need to be reassured that their teacher will not be mad at them if they choose an alternate activity provided by the researcher rather than participating in the research. Adolescents, who might be vulnerable to peer pressure either to participate or not participate, may need privacy to make their decisions..

9.0 Research-Related Harms to Children

If children have been selected to participate in a study based on certain
characteristics or problem behaviors, care should be taken that their participation does not subject them to ostracizing by their peers. For example, folders with written materials or activities could be prepared for all children in a classroom, and only the researcher or teacher will know which students have received research-related materials to complete.

10.0 Child Abuse and Neglect

Researchers must be aware of their state and local reporting requirements when they suspect child abuse and neglect. They must also inform parents and older children that the confidentiality they can provide may be limited by the reporting requirements. While researchers need to alert subjects that they will make reports as required, they may wish to find ways to do so that will not discourage children from talking about their experiences.

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