There are pending regulatory changes that have a general compliance date of 21 January 2019. This module will be updated in January 2019 to reflect these changes. We invite you to review the CITI Program's Final Rule Resources for information on the changes to the Common Rule.

INTRODUCTION

Conducting research in public schools is a complex endeavor. Researchers must contend with a wide range of issues, including the availability of school time and resources for research and the difficulty of securing parental permission. They also must contend with a number of federal regulations and laws that govern research in
the schools. This module will outline those regulations and laws and their implications for researchers.

The regulations governing parental permission and child assent, described in the CITI Program module *Research with Children - SBE*, apply to research conducted in public schools. This module will review the regulations with examples focusing on school-based research.

**Learning Objectives**

By the end of this module, you should be able to:

- List the federal regulations and laws that apply to research in the public schools.
- Discuss the impact on research of the Family Educational Rights and Privacy Act (FERPA) and the Protection of Pupil Rights Amendment (PPRA).
- Give examples of research eligible for exemption in the public schools.
- Identify state and local reporting requirements.

**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 Educational 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.
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.

Subpart D of the federal regulations, "Additional Protections 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 U.S. Department of Health and Human Services (HHS) regulations. For example, while the Department of Education (ED) has adopted Subpart D, the National Science Foundation (NSF) has not. Thus, when research is funded by the ED, the provisions of the subpart apply. They do not apply when the NSF funds research. Institutions, however, may choose to apply Subpart D to all research, regardless of the source of funding.

THE FAMILY EDUCATIONAL RIGHTS AND PRIVACY ACT (FERPA)
FERPA gives parents certain rights with respect to their children's educational records. The rights transfer to students, or former students, who have reached the age of 18 or are 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 allows schools to disclose identifiable records without permission to certain parties, including organizations conducting research initiated by a school district or a state department of public instruction.
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 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 might consult daily as teachers.

THE PROTECTION OF PUPIL RIGHTS AMENDMENT (PPRA)

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 an ED funding mechanism: (1) direct funding of a particular research topic by the department, or (2) general school funding from the department. The following sections explain how PPRA is applied based on the funding mechanism.

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 programs)

DIRECT FUNDING OF RESEARCH BY THE DEPARTMENT OF EDUCATION

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" (General Education Provisions Act 2012). This means any survey that is funded in whole or in part by any program administered by the department.

GENERAL FUNDING FROM THE DEPARTMENT OF EDUCATION

In 2001, parents were given additional rights with regard to the content of any surveys administered in public schools, not just those funded directly through a
program of the ED. Every public school system that accepts money from the department (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. However, the Common Rule requires that parental permission be either secured or waived in accordance with criteria established within the regulation. Note: Even if an Institutional Review Board (IRB) waived the requirement to secure parental permission in accordance with the Common Rule, PPRA requires that, in accordance with school system procedures, parents be notified about the proposed research and be given the opportunity to ask that their children not take part.

FERPA AND PPRA IN PRIVATE SCHOOLS

If research in a private school is directly funded by the Department of Education, PPRA applies. A private school that does not receive any federal funding is not subject to the provisions of FERPA or PPRA.

SUBPART D, ADDITIONAL PROTECTIONS FOR CHILDREN AS RESEARCH SUBJECTS

Subpart D includes sections applicable to research in schools, including: (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.
The Common Rule describes activities that although meet the definition of research with human subjects, are not subject to the provisions of the rule, including the criteria for approval and the required elements of consent. These activities pose little or no risk to potential subjects and are called "exempt." Because exempt research is not covered by the rule, institutional policy will dictate how determinations are made about whether research is eligible for exemption and how exempt research is reviewed. Subpart D limits the use of exemptions for research involving children. The following activities likely to take place in public schools may qualify for exemption (Protection of Human Subjects 2009):
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.

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.

- Research using educational tests (unless an inadvertent disclosure of identifiable data would create the potential for harm).
- Observation of public behavior in which the researchers do not participate in the activities being observed, for example, playground activities.
- 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.
- Food and taste test studies.

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

- Research involving surveys
- Research involving interviews
- Observation of public behavior when the researcher participates in the activities being observed
The following two examples illustrate the application of the exemption criteria to research in the schools.

### EXAMPLE 1: READING COMPREHENSION

Elementary school teachers are interested in whether they may improve students' reading comprehension by teaching them how fiction and non-fiction texts are organized. Students entering third grade 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.

*This study involves commonly accepted educational practices in a commonly accepted educational setting and is therefore eligible for exemption.*

### EXAMPLE 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 before and after they participate in the study activities.

*This study does not qualify for exemption Subpart D states that interviews with children cannot be exempt.*
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.

A challenging issue for researchers in the public schools is the difficulty of securing parental permission. Sending home permission forms is an unreliable method. The forms might never make it out of the students' packs or might end up in stacks of papers for busy parents to get to later. Forms mailed to parents might not be read. Without a high response rate, it might be impossible to obtain scientifically valid results or to assess interventions.
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 occur only if research results are meaningful. There also is tension between the ethical principles of respect for persons and 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.

The Common Rule provides four criteria for waivers of any or all of the elements of informed consent. Subpart D allows waivers of parental permission and child assent in accordance with the four criteria of the Common Rule. In addition, the subpart allows for waivers of parental or guardian permission when permission is not a reasonable requirement to protect subjects, for example, neglected or abused children, provided an appropriate mechanism for protecting the children is substituted.

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. As defined in 45 CFR 46.102 (Protection of Human Subjects 2009), "minimal risk" means "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. Laws, including FERPA and PPRA, as described earlier in this module, define some parental rights. However, neither "rights or welfare" nor "adversely affect" are 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 researcher, the schools, or other experts.

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." There may be studies in which the participation of all students in a classroom is needed in order to obtain valid scientific results. If all other criteria are met, such studies may qualify for a waiver of parental permission.

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 researchers 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.

## CHILD ASSENT

"The federal regulations give IRBs the responsibility to decide whether child assent is required and whether assent must be documented. Factors to be considered include the age and maturity of the children as well as cultural factors in the communities in which the research will take place (OHRP 2011)."

Care should be taken so that children do not feel pressured into participating in research. When research is conducted in the schools, younger children may need to
be reassured that their teacher will not be mad at them if they don't want to take part in the research activities. Alternative activities should be made available that do not single out children who choose not to take part. Adolescents who might be vulnerable to peer pressure may need privacy to make their decisions.

School is a place where children are encouraged to give the right answers to questions. Depending on the age of the children, it may be appropriate to tell them that there are no right or wrong answers to the researcher's questions.

### SUMMARY

Research in public schools is covered not only by the federal regulations for protecting human subjects, but also by additional federal acts and regulations that define students' and parents' rights in educational settings. Nonetheless, there are flexibilities in the regulations that make it possible to conduct research in the schools while ensuring the protection of students' rights and welfare, such as waivers of parental permission for some kinds of research.

### RESOURCES

- Family educational and privacy rights, 20 USC § 1232g (2013).


REFERENCES


- U.S. Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP). 2011. "What is child assent, and how do the requirements vary with the age of the research subjects?"

Original Release: March 2004
Last Updated: September 2014

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