

Institutional Review Board (IRB) Policies & Procedures Manual



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Research Funded by Department of Education and School-Based Research

Purpose

This policy provides guidance when research is funded by the Department of Education and other school-based research procedures.

Policy

Any research that is to be conducted by staff or employees of Boston Children's Hospital with Department of Education funding and/or in a school setting must be submitted and reviewed in accordance with the Boston Children's Hospital Institutional Review Board policies and procedures.

Upon submission it may be determined that a protocol is exempt from review or requires expedited or full committee approval. In reviewing research, the committee will require that a letter of approval from the school or school system be obtained.

In addition, when appropriate, investigators must comply with the Protection of Pupil Rights Amendment (PPRA, 20 U.S.C. § 1232h; 34 CFR Part 98) which is part of the *No Child Left Behind Act of 2001* (Public Law 107-110 which is summarized below, as well as the Family Educational Rights and Privacy Act (FERPA 20 U.S.C. § 1232g; 34 CFR Part 99).

For research sponsored by the Department of Education, 34 CFR Part 97 for research funded by the National Institute on Disability and Rehabilitation Research, when an IRB reviews research that purposefully requires inclusion of children with disabilities or individuals with mental disabilities as research subjects, the IRB will include at least one person primarily concerned with the welfare of these research subjects.

Procedures

Researchers frequently wish to conduct research in schools. Some of this research may be funded by the Department of Education, which has specific requirements when using education records according to the Family Educational Rights and Privacy Act (FERPA).

Research may consist of observation in classrooms, interviews with teachers, questionnaires given to students, video or audio taping of classrooms, focus groups or interviewing parents about their children. Schools may also be used as a recruitment site for posting notices of research activities. Any research that is to be conducted in a school setting must be submitted and reviewed in accordance with the Institutional Review Board policies and procedures. Upon submission it may be determined that a protocol is exempt from review or requires expedited or full committee approval.

Approval by the Schools:

The IRB will request a copy of an approval notification from authorized individuals within the school or school district. Investigators are required to comply with a school's policies and procedures for all proposed research. These may differ between schools and the investigator is obligated to contact the school district and develop their protocol accordingly.

For any research conducted by BCH that involves a request for access to educational institution student records without parental permission/student consent, responsibility for complying with FERPA specific parent/student consent exception requirements, including requirements for removal of all personally identifiable information, will be the responsibility of that educational institution

Is the School Engaged in Research?

If school staff, teachers or personnel perform research procedures or release private identifiable information about students, the school may be considered engaged in research. This may include active recruitment, obtaining consent, performing research assessments or interventions. If a school is engaged in research, special considerations will need to be made as to whether the school must obtain their own IRB review or whether the school signs an agreement to work under the jurisdiction of the Boston Children's Hospital IRB. Schools that are only used as a site for research and permit the Boston Children's Hospital investigators to perform all the research procedures, including recruitment and obtaining consent would not be considered engaged in research.

US Department of Education/Protection of Pupil Rights Amendment (PPRA): School Based Surveys and Informed Consent Requirements and Access to Instructional Material used in a Research or Experimentation Program

The Protection of Pupil Rights Amendment (PPRA) which is part of the *No Child Left Behind Act of 2001 (Public Law 107-110)* specifies eight categories of protected information in surveys of minors in schools. It also gives parents rights with regard to the surveying of minor students, the collection, disclosure, or use of information from students for marketing purposes, and certain non-emergency medical examinations.

PPRA has two sets of requirements for surveys:

1. Requirements that apply to "protected information" surveys that are funded in whole or in part by the U.S. Department of Education.
2. Requirements that apply to "protected information" surveys that are funded by sources other than the U.S. Department of Education and that are administered or distributed by education institutions that receive funds from any Department of Education program (i.e. public elementary and secondary schools and some private schools).

Under PPRA no student shall be required, as part of any research project, to submit without prior consent to surveys, psychiatric examination, testing, or treatment, or psychological examination, testing, or treatment, in which the primary purpose is to reveal information concerning one or more of the following categories which are considered protected information:

1. political affiliations of student or student's parent;

2. mental or psychological problems of student or student's family;
3. sex behavior or attitudes;
4. illegal, anti-social, self-incriminating or demeaning behavior;
5. critical appraisals of others with whom students have close family relationships;
6. legally recognized privileged or analogous relationships;
7. religious practices, affiliations or beliefs of student or student's parent;
8. income.

In this context prior consent means:

- Prior consent of the student, if the student is an adult or emancipated minor; or
- Prior written consent of the parent or guardian, if the student is an un-emancipated minor. Schools and contractors obtain prior written parental consent before minor students are required to participate in any ED-funded survey, analysis, or evaluation that are considered protected information in the categories listed above.

PPRA has implications for applying the criteria for waiving informed consent (in section 116(d) of the Common Rule). Specifically, the second IRB criterion: "research does not adversely affect the rights and welfare of subjects" is impacted because of the "rights" that PPRA gives parents.

First Set of Requirements: US Department of Education Funded Protected Information Surveys

- Does the research involve "protected information" surveys?
- Are the surveys U.S. Department of Education funded, in whole or part?
- Are the surveys "required"?

If the answer is yes to the three questions, PPRA affords parents the right to provide active consent. Under the circumstances, it would be difficult to determine that the "rights and welfare" criterion for waiving informed consent entirely could be met; therefore, prior written parental consent would be required, even if the IRB determined that some of the basic elements of informed consent specified in section 116(a) could be waived as inappropriate to the activity.

The U.S. Department of Education has not written regulations providing guidance about some of the key terms in the current law. For example, the Department has not taken a position about whether the word "required" should be interpreted to mean that surveys that are clearly voluntary are exempt from PPRA requirements. Also, the law does not directly address the question of whether anonymous surveys are exempt from PPRA because anonymous surveys do not provide individually identifiable information about students or their families. Until the Department issues revised regulations implementing PPRA, the IRB will need to use judgments in complying with the first set of requirements.

Second Set of Requirements for Protected Information Surveys that are funded by sources other than the U.S. Department of Education and that are administered or

distributed by education institutions that receive funds from any U.S. Department of Education administered program (i.e., public schools and some private schools)

1. Do the surveys include protected information?
2. Are the surveys being administered or distributed by schools that receive any U.S. Department Education funds?

If the answer is yes to both questions, PPRA affords parents the right to inspect the surveys before they are administered or distributed and to opt the student out of the surveys.

PPRA requires schools to develop and adopt policies, in conjunction with parents, regarding six areas, some of which are relevant to surveys:

1. Right to inspect a survey before administered or distributed;
2. Arrangements to protect student privacy in the administration of a survey;
3. Right to inspect any instructional material used as part of educational curriculum;
4. Administration of physical examinations or screenings;
5. Collection, disclosure or use of personal information for purposes of marketing or selling;
6. Right to inspect any instrument in the collection of information for marketing or selling the surveys.

PPRA also requires local educational agencies to notify parents of the policies and to offer parents the opportunity to opt out of (remove child from) participation in third-party surveys involving protected information. These requirements suggest that local schools have the discretion to set up their own individual policies for non-US Department of Education protected information surveys.

For example, local schools can choose whether to have an active written consent policy or some other policy such as passive consent. The IRB will have to decide how they will handle these requirements in those protocols where the investigators are requesting passive consent.

For example, the IRB might require that if an investigator asks for passive consent procedures, that he/she must also document that the procedures are consistent with the policy of the local school(s) to be included in the research sample. The IRB then can use that information in determining if the "rights and welfare" criterion for waiving informed consent has been met.

PPRA Provision: When accessing instructional material used in research or experimentation program

PPRA (34 CFR Part 98.3) specifies:

- All instructional material—including teachers' manuals, films, tapes, or other supplementary instructional material—which will be used in connection with any research or experimentation program or project shall be available for inspection by the parents or guardians of the children engaged in such program or project.
- Research or experimentation program or project means any program or project in any program or project that is designed to explore or develop new or unproven teaching methods or techniques.

- Children are persons enrolled in a program not above the elementary or secondary education level, as determined under State law.

US Department of Education Contact: The Family Policy Compliance Office is the office charged with administration of PPRA. There are PPRA resources including FAQs, model consent and notices, and contact information on the Offices website at <http://familypolicy.ed.gov/ppra>.

Research Sponsored by the Department of Education Involving Student Education Records

For research sponsored by the Department of Education involving student education records the following the research must be conducted in accordance with Family Educational Rights and Privacy Act (FERPA). The following guidelines must be followed:

If consent is not obtained from the parent/student to release the records to a BCH investigator, the IRB will require that a component of the educational organization (e.g., a FERPA committee) will grant an exception. It is acknowledged that an educational agency or institution may disclose personally identifiable information from an education record of a student without consent if the disclosure is to organizations conducting studies for, or on behalf of, educational agencies or institutions to

- Develop, validate, or administer predictive tests.
- Administer student aid programs.
- Improve instruction

If this exception is granted Boston Children's Hospital must enter into a written agreement with the educational agency or institution that specifies the following:

- The determination of the exception.
- The purpose, scope, and duration of the study.
- The information to be disclosed.
- That information from education records may only be used to meet the purposes of the study stated in the written agreement and must contain the current requirements in 34 CFR 99.31(a)(6) on re-disclosure and destruction of information.
- That the study will be conducted in a manner that does not permit personal identification of parents and students by anyone other than representatives of the organization with legitimate interests.
- That the Organization is required to destroy or return all personally identifiable information when no longer needed for the purposes of the study.
- The time period during which the Organization must either destroy or return the information.

Education records may be released without consent under FERPA if all personally identifiable information has been removed including:

- Student's name and other direct personal identifiers, such as the student's social security number or student number.
- Indirect identifiers, such as the name of the student's parent or other family members; the student's or family's address, and personal characteristics or other information that

would make the student’s identity easily traceable; date and place of birth and mother’s maiden name.

- Biometric records, including one or more measurable biological or behavioral characteristics that can be used for automated recognition of an individual, including fingerprints, retina and iris patterns, voiceprints, DNA sequence, facial characteristics, and handwriting.
- Other information that, alone or in combination, is linked or linkable to a specific student that would allow a reasonable person in the school community, who does not have personal knowledge of the relevant circumstances, to identify the student with reasonable certainty.

Related Content

Federal Guidance

US Department of Education: Family Policy Compliance Office: [PPRA Guidance](#)

Document Attributes

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