



## Guidelines for Research Funded by Department of Education and School Based Research

### Policy

Any research that is to be conducted by staff or employees of Children's Hospital in a school setting must be submitted and reviewed in accordance with the Committee on Clinical Investigation 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) which is part of the *No Child Left Behind Act of 2001 (Public Law 107-110)* which is summarized below. 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. 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 Committee on Clinical Investigation 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 Committee on Clinical Investigation will request a copy of an approval notification from authorized individuals within the school or school district. Investigators are required to comply with a schools policies and procedures for all proposed research. Different school systems may have different procedures and the investigator is obligated to contact the school district and develop their protocol consistent with the school policies.

## **Is the School Engaged in Research?**

If school staff, teachers or personal 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 Children’s Hospital IRB. Schools, that are only used as a site for research and permit the 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**

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 t 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.

[Since the PPRA amendments were added fairly recently, the U.S. Department of Education has not yet 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 committee 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)**

- Do the surveys include protected information?
- 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 6 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 Committee on Clinical Investigation will have to decide how they will handle these requirements in those protocols where the investigators are requesting passive consent. For example, the Committee 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.

**US Department of Education Contact:** The Family Policy Compliance Office is the office charged with administration of PPRA. Note as of March 18, 2003, the web page has the old version of PPRA. However, the Family Policy Compliance Office has released guidance documents about how No Child Left Behind revises PPRA which are on the web site. <http://www.ed.gov/offices/OM/fpc/ppra/parents.html>

### **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: in order to obtain records Children's Hospital, Boston must enter into a written agreement with the educational agency or institution that specifies the following:

- The purpose, scope, and duration of the study and the information to be disclosed.
- That the hospital uses personally identifiable information from education records only to meet the purpose or purposes of the study as stated in the written agreement.
- 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 hospital with legitimate interests.

- That the hospital is required to destroy or return all personally identifiable information when no longer needed for the purposes of the study and specifies the time period in which the information must be returned or destroyed.

This document is partially based on materials provided by Ada Sue Selwitz MA, University of Kentucky, March 2003

## Document Attributes

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<b>Author</b>	<b>Susan Kornetsky</b>	<b>Dates Reviewed/ Revised</b>	03/09/2007
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<b>Approved</b>	_____ Susan Kornetsky Director of Clinical Research Compliance _____ Carleen Brunelli, MBA, PhD Vice President for Research Administration		