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	Title: Research Conducted in Schools	

I. PURPOSE

This policy is to ensure that human subjects research conducted in a school setting complies with federal, state and local laws, regulations, directives and instructions.

II. POLICY STATEMENT

All human subjects research that is to be conducted with Department of Education (DoE) funding or that takes place in a school setting must be submitted and reviewed in accordance with the Children's Hospital of Philadelphia Institutional Review Board policies and procedures. In addition to the federal research regulations and CHOP IRB SOPs, the investigators must also comply with the requirements of 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) and the Family Educational Rights and Privacy Act (FERPA (20 U.S.C. § 1232g; 34 CFR Part 99), when applicable.

III. SCOPE

This policy applies to all research conducted in school settings where the CHOP IRB serves as the Reviewing IRB.

IV. DEFINITIONS


Consent: For the purposes of this policy, consent includes parental permission and student consent, when permitted under state law.

DoE: Department of Education.

FERPA (Family Educational Rights and Privacy Act): A Federal law that protects the privacy of student education records. In general, schools must have written permission from the parent or eligible student in order to release any information from a student's education record.

Investigator: An individual at the institution who participates in the design, conduct, analysis, or reporting of research activities.

PPRA (Protection of Pupil Rights Amendment): Federal regulation which is part of the No Child Left Behind Act of 2001(Public Law 107-110) which specifies eight categories of protected information in surveys of minors in schools. There are two sets of requirements for surveys applying to protected information: for surveys funded by the US DOE and 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).

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V. PROCEDURES

A. Review of research conducted in a school setting

All human subjects research that will be conducted in a school setting must be submitted and reviewed in accordance with the CHOP IRB policies and procedures (described in **SOP 105**, **SOP 302**, **SOP 401** and **SOP 402**). The IRB may determine that the research meets the criteria for exemption or that it requires either expedited or full committee review and approval.

B. Approval by the school

The investigator must obtain approval notification from the authorized individual(s) within the school or school district where the research will take place prior to initiating study activities within the school. Investigators must comply with each school's applicable policies when conducting the research.

C. School engagement in human subjects research

If agents of the school are engaged in human subjects research as defined by OHRP's 2008 Guidance on Engagement in Human Subjects Research, the school must either (a) obtain approval/exemption determination from their own IRB and privacy board review (when applicable) or (b) the school must sign an agreement to work under the jurisdiction of CHOP's IRB. For example if school personnel are collaborators (do not meet the definition of an investigator), if school personnel are not performing any research procedures, or if the school is just providing the venue, then the school would not be considered to be engaged in the research.


D. Ensuring Adherence to FERPA Requirements

FERPA protects the privacy of student education records. Schools must have written permission from the parent or eligible student in order to release any information from a student's education record. However, FERPA allows schools to 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; or improve instruction.

Exception to Written Permission for Records Release under FERPA

Requests for exception (waiver) to consent for student education records release are reviewed by the CHOP IRB. A school district or postsecondary institution that uses this exception is required to enter into a written agreement with CHOP or with the investigator conducting the research that specifies:


1. The determination of the exception.
 - (a) Education records may be released without consent under FERPA if

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all personally identifiable information has been removed including:

- (1) Student's name and other direct personal identifiers, such as the student's social security number or student number.
 - (2) 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.
 - (3) 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.
 - (4) 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.
2. The purpose, scope, and duration of the study.
 - (a) 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.
 - (b) That CHOP is required to destroy or return all personally identifiable information when no longer needed for the purposes of the study.
 - (c) The time period during which CHOP must either destroy or return the information.
 3. The information to be disclosed.
 - (a) 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 university with legitimate interests.

For research accessing educational institution student records without consent, the responsibility for complying with FERPA-specific consent exception requirements, including requirements for removal of all personally identifiable information, will be the responsibility of the investigator in conjunction with the educational institution.

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E. Ensuring Adherence to PPRA Requirements

The PPRA gives parents rights with respect to surveying minor students, the collection, disclosure or use of information.

Under this law no student shall be required, as part of any research project, to submit without consent to protected information surveys, psychiatric examination, testing, or treatment, or psychological examination, testing, or treatment. Protected information includes the following categories:

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 (such as those of lawyers, physicians and ministers);
7. religious practices, affiliations or beliefs of student or student's parent;
8. income.


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.

VI. APPLICABLE REGULATIONS AND GUIDELINES

2008 OHRP Guidance on Engagement of Institutions in Human Subjects Research	PPRA: 20 U.S.C. § 1232h; 34 CFR Part 98):
FERPA: 34 CFR Part 99	

VII. REFERENCES TO OTHER APPLICABLE SOPS

SOP 105 : IRB Review Processes	SOP 401: Expedited Review Procedures
SOP 302: Research Exempt from IRB Review	SOP 402: Criteria for Intial IRB Approval

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VIII. RESPONSIBILITIES

Title	Responsibility
Director, HSR	Responsible for ensuring that research conducted in schools meets the unique requirements as outlined in the regulations.
Chair, CPHS	Responsible for ensuring that the IRB makes all additional determinations and ensuring that the unique requirements are included when reviewing research.

IX. ATTACHMENTS

X. REVISIONS:

Initial Approval Date: 03-26-2018

XI. APPROVAL

 Director, Human Subjects Research

 Date

 Chair, Committees for the Protection of Human Subjects

 Date