

G-002 – Guidance on Conducting Research in Schools

Purpose:

The purpose of this document is to provide guidance regarding the requirements for research and advertisement in schools and other educational institutions.

- Researchers must follow HRPP policy 16.0 Research Conducted by the Department of Education.
- The IRB requires written permission from an appropriate authority (school principal, headmaster, or a high level administrator who has the authority to make decisions for the entire school or a designee of this authority). For a school that is under a Superintendent or other oversight body, the written permission from the Superintendent or oversight body will suffice. For a school that is not under a Superintendent or oversight body, the written permission should be obtained from the school principal or other individual with appropriate authority.

The following scenarios will meet IRB requirements for recruitment in schools:

- If the Superintendent or other oversight body has given written blanket approval for recruitment in their jurisdiction:
 - The blanket approval must be approved by the IRB
 - It is the Principal Investigator's responsibility to obtain permission to participate at each school within the approved jurisdiction. Approvals can be verbal or written and both types should be tracked in a spreadsheet and should include the following information:
 - School name
 - School contact providing the approval and their title
 - Date approval was obtained
 - Any relevant notes, including which studies the approval applies to
 - You do not need to notify the IRB after every individual school approval; however, the spreadsheet must be kept up to date at all times and submitted at continuing review. The IRB may randomly audit this spreadsheet to ensure it is being kept up to date.

- In the event that a school rejects the request, this should also be tracked in the spreadsheet and include the same information listed above for approvals, including the reason for disapproval.
- **EXAMPLE:** Written approval from EBRP Superintendent's office for PBRC to recruit in all schools within its jurisdiction has been approved by the IRB. Investigators contact each school they intend to recruit from within EBRP and keep track of these approvals in a spreadsheet. At continuing review, spreadsheet is submitted to IRB.
- If the target school does not fall within the jurisdiction of an obtained blanket approval:
 - An email or signed letter of permission from an appropriate authority at each school is required prior to starting any recruiting efforts, verbal approval will not be sufficient. The following information must be included:
 - School name
 - School contact providing the approval and their title
 - Date of approval
 - Study names included in the approval
 - In the event that a school rejects the request, this should also be tracked in the spreadsheet and include the same information listed above for approvals, including the reason for disapproval.
 - **EXAMPLE:** Investigator intends to recruit at a charter school that does not have an oversight body. Written approval (email or writing) must be obtained from the proper school authority prior to starting any recruiting efforts and submitted to the IRB at continuing review.
- Once the appropriate permissions have been obtained and documented, a study specific, IRB-approved 'permission to contact' form may be given to schools to be sent home with students. A template of this form can be found at the end of this document.
- In regards to advertisement, all recruitment materials given to prospective subjects are considered to be part of the research and must have IRB approval prior to their use.

For your convenience, a template example of a letter of support can be found at <http://www.pbrc.edu/HRPP/forms>.

Steps to Consider When Conducting Research in Schools:

1. Obtain appropriate documentation from each school or superintendent/oversight body as detailed above.
2. Train personnel and educate all staff conducting research in the school facilities and with children. See FERPA and PPRA guidelines below.
3. Ask teachers to send the consent to parents. Researchers may want to consider sending an informational letter before sending the consent home so parents will understand what the research entails.
4. Parental information - parental permission form, information about the research – should be readable (6th grade reading level preferred). Letters should be no more than 1 page long.
5. In cases where research data are being collected in the school:
 - a. Obtain child assent. Minors are considered a protected class of participants in research and are afforded additional protections in the Common Rule under 45 CFR 46 Subpart D – “Additional Protections for Children Involved as Subjects in Research.” For additional information on research involving children, refer to HRPP policy 6.0 Vulnerable Subjects in Research.
 - i. If an assent waiver is applicable and approved by the IRB, the researcher must retain such documentation and provide it to the school where the research will be conducted
 - b. Investigators must provide a copy of all surveys and instructional material used in the research study to the school and parents. Parents of children involved in the research must be able to inspect these materials upon request within a reasonable amount of time.

Regulations and Policies:

- 45CFR46.401 (Subpart D – Additional Protections for Children Involved as Subjects in Research)
- Family Educational Rights and Privacy Act (FERPA)
- The Protection of Pupil Rights Amendment (PPRA) (20 U.S.C. § 1232h; 34 CFR Part 98)
- PBRC HRPP Policy 16.00, which enacts Element III.1.F of the AAHRPP submission packet which states that we abide by FERPA and PPRA and outlines our consent process
- PBRC HRPP Policy 16.00, which enacts Element III.2.C of the AAHRPP submission packet which states the IRB requirement of a school letter of permission for research conducted in schools.

Definitions:

Department of Education research – Any research conducted in a school that accepts federal funds is subject to Department of Education research. (i.e., federal funds for school lunches, playground equipment, etc.).

Family Educational Rights and Privacy Act (FERPA) – a Federal law that protects the privacy of student education records. If you plan to conduct research that will involve collecting data in schools and/or accessing information from education records, you should be aware of laws that can impact your data access and collection procedures and also limit the IRB's ability to waive consent. FERPA is a federal law administered by the U.S. Department of Education; 34 CFR Part 99.

Protection of Pupil Rights Amendment (PPRA) – is intended to protect the rights of parents and students in seeking to ensure instructional materials are available for inspection to parents and to ensure schools obtain written parental consent before students participate in research.

Association for the Accreditation of Human Research Protection Programs (AAHRPP) – the PBRC HRPP program is accredited by AAHRPP, therefore we must abide by the elements stated in our initial submission packet.

[Study Name] Study

Permission for Pennington Biomedical to Contact You

Dear Parent or Legal Guardian:

Your son/daughter may be eligible to participate in a research study at Pennington Biomedical Research Center called [study name]. A brief description of the study is below. If you would like your child to participate in this study, please complete, sign, and return the form by [date] to [insert where to return form to] which will allow a Pennington Biomedical recruiter to contact you to discuss further your child's participation in the study.

[Description of study including number of participants, purpose of the study, age range of participants, duration of study, location study will take place, and compensation (if applicable)]

By signing below, I authorize Pennington Biomedical to contact me about my child participating in [study name]:

Child's name/age

Parent or Legal Guardian (Print)

Parent or Legal Guardian (Signature)

E-mail address

Phone number

Preferred method of contact: E-mail Phone

Best day/time to be contacted