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Conducting Research in Children and Schools

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6.0 Vulnerable Populations and 16.0 Research Conducted by the DOE

Policy is available at
www.pbrc.edu/hrpp/policies

Training Slides will be posted at:
http://www.pbrc.edu/hrpp/resources

6.0 Research in Children

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Definitions

- **Assent -** means a child's affirmative agreement to participate in research. Mere failure of a child to object may not, absent affirmative agreement, be construed as assent.
- **Children -** are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.
- **Guardian -** means an individual who is authorized under applicable state or local law to consent on behalf of a child to (a) general medical care when general medical care includes participation in research; or (b) to participate in research.
- **Health Agent -** is an authorized representative legally acting for a person pursuant to a Durable Power of Attorney for Health Care (Medical Power of Attorney) or other legal document permitted within a jurisdiction that allows a person to appoint another person(s) to make medical decisions for the patient if the patient should become temporarily or permanently unable to make those decisions for himself/herself. Any adult (18 or older) can be granted this power.

6.0 Research in Children, cont.

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Definitions to Know, cont.

- **Legally Authorized Representative -** is an individual, judicial, or other body authorized under applicable law to consent or otherwise provide permission on behalf of a subject, either prospectively or during the course of research, to the subject's participation in the procedure(s) involved in the research.

  Order of Priority
  - Health Agent
  - Legal Guardian
  - Spouse
  - Adult Children
  - Grandparent
  - Adult Grandchildren

- **Minor -** means any person under the age of 18 years. Do not confuse the definitions of minor (pertaining to a person's age) with child/children (pertaining to a person's ability to consent).

- **Parent -** means a child's biological or adoptive parent.

IRB Review of Research with Children

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IRB Classifications as per Subpart D

- Minimal Risk vs. Not a Minimal Risk
- Direct Benefit vs. Not a Direct Benefit

Risk	Benefit	One or Two Parent Signature
Minimal Risk	Not Applicable	The IRB can decide that only one parent is sufficient
More than Minimal Risk	Direct Benefit	The IRB can decide that only one parent is sufficient **
More than Minimal Risk	Not a Direct Benefit	Must be two parents (as available)
Research Not Approval Under Permitted Categories	Not Applicable	Must be two parents (as available)

** Parent's wishes prevail

Waiver of Parental Permission

- Minimal Risk Research – Must meet ALL requirements
  - No more than minimal risk to subjects
  - Doesn't affect the rights and welfare of subjects
  - Research could not practicably be carried out without the waiver or alteration
  - As appropriate, subjects will be provided with additional pertinent information after participation
  - Research is not FDA regulated
- Research designed to study conditions in children
- Public benefit programs
  - Research could not practicably be carried out without the waiver or alteration
  - The research is not FDA-Regulated

Age of Assent

- Assent – can be oral or written
- The IRB guidelines are vague on the age of assent because it depends on the maturity of the child, nature of the study and ability to comprehend the research.
    - 0-7 – The IRB will waive the assent and parental permission will prevail; however, an oral script can be useful.
    - 7-9 – Some children in this age group can sign or listen to assent. This is up to the investigator and the maturity of the child.
    - 9-11 – The IRB expects at a minimum an oral assent will be provided and depending on the maturity of the child a signed assent.
    - 11-17 – Most children in this age group can sign the assent document.

Documentation of the Assent is critical

16.0 Conducting Research in Schools

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Definitions

- **FERPA -** The Family Educational Rights and Privacy Act
    - Gives the parents of the student, or the student's themselves (if student is age 18), rights regarding the student's educational records.
    - Schools must have written permission from the parent or eligible student in order to release any information from a student's education record.

16.0 Conducting Research in Schools

Definitions, cont.

- **PPRA -** The Protection of Pupil Rights Amendment
  - ❑ Schools must notify parents that they can inspect student surveys and make these materials available to parents to review
  - ❑ The researcher must obtain parental consent before minor students are allowed to participate in any survey, analysis or evaluation that covers the following:
    - Political affiliations or beliefs of the student or the student's parent
    - Mental and psychological problems potentially embarrassing to the student and his/her family
    - Sex behavior or attitudes
    - Illegal, anti-social, self-incriminating and demeaning behavior
    - Critical appraisals of other individuals with whom the participants have close family relationships
    - Legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers
    - Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program)

IRB Requirements for School Research

- Permission from the school's principal to conduct the research.
- In the permission letter the school must assure the IRB that the FERPA act will be followed.
- Parental permission must be given before a student can participate, this includes recruiting.
- If research is being conducted in the classroom or outside the classroom the protocol should explain how this will not affect the student's educational progress.

Additional Considerations

- Reporting of Abuse and Neglect
- Background checks of researchers/staff
- Pregnancy testing for minors
- Payments to Children
- Re-consenting Children when they reach 18

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