Vulnerable Populations: Children (Subpart D)

FEBRUARY 2025 CONTINUING EDUCATION

Policy (HRPP 8.5)

- The IRB will consider:
  - The potential benefits, risks, and discomforts of research involving children
    - Is the inclusion of the children in research justified?
  - The circumstances of the children to be enrolled in a study
    - Ex. health status, age, and ability to understand their involvement
  - The potential benefit to the subjects, other children with the same disease/condition, or society as a whole

Guidance on Additional Requirements of Federal Funding Agencies

- Additional operational and review requirements are required for all protocols conducted by MUSC and sponsored by:
  - Department of Defense (DOD)
  - Department of Education
  - Department of Energy
  - Department of Justice (DOJ)/ National Institute of Justice (NIJ) and Bureau of Prisons (BOP)
  - Environmental Protection Agency (EPA)
- Information is available on MUSC IRB Resource & Guidance Webpage: https://research.musc.edu/resources/ori/irb/resources

Who are Children?

- Persons who have not attained the legal age for consent to treatment or procedures involved in the research or clinical investigations, as determined under the applicable law of the jurisdiction in which the research will be conducted.
- South Carolina - Children are individuals less than 18 years of age.

Research Categories

- The IRB will decide which of 4 risk categories apply to any study enrolling children other than exempt research.
- For a child to be enrolled in research:
  - An adult parent with legal custody of a child or an adult awarded legal custody of a child must give informed consent
  - A child 12 years of age or older must give documented "assent“
    - unless the IRB provides a waiver of assent
    - assent will be documented on the informed consent document
  - An “emancipated minor” must provide documentation of his/her financial independence
    - Ex. rental lease, marriage certificate or court document in his/her name proving emancipation
- If the research is assessed by the IRB to be category 3 or higher, both parents must give informed consent for the child to enroll
  - Exceptions:
    - One parent is deceased, unknown, incompetent, or not reasonably available
    - When only one parent has legal custody of a child
- Under certain circumstances, the IRB may choose to waive parental consent

Children Research - Category 1

- Research not involving greater than minimal risk to the children
- To approve this category, the IRB must make the following determinations:
  - 1) the research presents no more than minimal risk to the children; **and**
  - 2) adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians

Children Research - Category 2

- Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual child subjects involved in the research
- To approve this category, the IRB must make the following determinations:
  - 1) the risk is justified by the anticipated benefits to the subjects;
  - 2) the relation of the anticipated benefit to the risk presented by the study is at least as favorable to the subjects as that provided by available alternative approaches; **and**
  - 3) adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians

Children Research - Category 3

- Research involving greater than minimal risk and no prospect of direct benefit to the individual child subjects involved in the research, but likely to yield generalizable knowledge about the subject's disorder or condition

- To approve this category, the IRB must make the following determinations:
  - 1) risk of the research presents a minor increase over minimal risk;
  - 2) the intervention or procedure presents experiences to the child subjects that are reasonable commensurate with those inherent in their actual, or expected medical, dental, psychological, social, or educational situations;
  - 3) the intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition which is of vital importance for the understanding or amelioration of the disorder or condition; **and**
  - 4) adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians.

Children Research - Category 4

- Research that the IRB believes does not meet the conditions of the other categories but finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children.
- This category of research requires a federal level of review by the Secretary, Health and Human Services, or designee and the Commissioner of FDA who will request the review by a panel of experts in pertinent disciplines and call for public review and comment.

Procedures

- The “Special Subject Populations - Children” checklist will be used as a guide for IRB evaluation
  - Completed by the designated reviewers
- During the initial review of a protocol involving children, the IRB assigned designated reviewers will designate the appropriate risk category and give a brief rationale for the category selected
- The Board determines the appropriate research category as part of the motion after discussion at the convened meeting
- If the research is determined to fit category I or II, the IRB will decide if the consent of one parent is adequate or if the consent of both parents is required
- If the research is determined to fit category III or IV, the documented consent of both parents will be required unless the Board stipulates documented consent from one parent is acceptable
- The IRB will make protocol-specific determinations regarding whether adequate provisions should be made for soliciting the assent of the children younger than 12-years old, when in the judgment of the IRB members, the children are capable of providing assent
- Each determination/decision will be documented in the meeting minutes
- For expedited protocols - the IRB chair or chair’s designee will make this determination
  - This determination will be documented in the IRB expedited initial application checklist

Family Education Rights and Privacy Act (FERPA) and Protection of Pupil Rights Amendment (PPRA)

- Family Educational Rights and Privacy Act (FERPA)
  - Federal law that protects the privacy of student education records
  - Applied to all schools that receive funds under an applicable program of the U.S. Department of Education (ED)
  - Regulates the disclosure of Personally Identifiable Information from youth Education Records in all public elementary and secondary schools, school districts, intermediate education agencies, state education agencies, and any public or private agency or institution that uses funds from ED
  - Purpose: To protect all student and parent information maintained in an Education Record
- The protection of Pupil Rights Amendment (PPRA)
  - a.k.a. “Student Rights in Research, Experimental Programs, and Testing”
  - Applies to programs and institutions that receive funding from the U.S. Department of education (ED)
  - Purpose: To protect the rights of parents and students
- When reviewing research involving students, the convened IRB or the reviewer for expedited procedure will determine and document that the regulatory criteria allowing approval based on the “Protection of Pupil Rights Amendment (PPRA)” and/or “Family Educational Rights Protection Act (FERPA)” have been met.

Wards of the State

- Children who are wards of the State or any other agency, institution, or entity can be included in research that presents minimal risk (Category 1 above) or greater than minimal risk with a prospect of direct benefit (Category 2 above)
- Children who are wards of the State or any other agency may participate in research under Categories 3 and 4 above only if the convened IRB finds and documents that such research is:
  - Related to their status as wards; **or**
  - Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as participants are not wards
- If Category 3 or higher and approved by the convened IRB
  - Appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis is required
    - Advocate – must be an individual who has the background and experience to act in, and agrees to act in, the best interest of the ward for the duration of the child's participation
    - Advocate – must not be associated in any way with the research, the investigator, or the guardian organization

What questions do you have?