MUSC
Medical University of South Carolina

I. Policy

A. The IRB will consider the potential benefits, risks, and discomforts of research involving children within the context of the justification for inclusion of children in the research. The IRB will consider the circumstances of the children to be enrolled in a study, e.g. their health status, age, and ability to understand their involvement, as well as potential benefit to the subjects, other children with the same disease/condition, or society as a whole. (OHRP Guidance, 2005).

B. The IRB will decide which of four risk categories defined by federal regulations [45CFR 46(d) and 21CFR 50.51-50.54] apply to any study enrolling children other than exempt research.

C. Minimally, an adult parent with legal custody of a child or an adult awarded legal custody of a child must give informed consent for a child to be enrolled in research. A child 12 years of age or older must give documented "assent" to be enrolled in research unless the IRB provides a waiver of assent. The assent will be documented on the informed consent document. An "emancipated minor" may only give informed consent when there is documentation that the minor is "emancipated", i.e. the minor is married (a marriage certificate) or becomes self-supporting, as determined by the court [45 CFR 46 Subpart D Additional DHHS Protections for Children Involved as Subjects in Research]

D. Minimally, an adult parent with legal custody of a child or an adult awarded legal custody of a child must give informed consent for a child to be enrolled in research. A child 12 years of age or older must give documented "assent" to be enrolled in research unless the IRB provides a waiver of assent. The assent will be documented on the informed consent document. An "emancipated minor" must provide documentation of his/her financial independence such as a rental lease, marriage certificate or court document in his/her name proving emancipation before consenting as an adult to participate in research [45 CFR 46 Subpart D Additional DHHS Protections for Children Involved as Subjects in Research]

E. The IRB may decide that both parents must give informed consent for a child to be enrolled in research. The IRB will require that both parents must

give informed consent for a child to enroll in research if the research is assessed by the IRB to be category 3 or category 4 unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal custody of a child [45CFR 46.408(c)]. The regulations make two parents the default and one is appropriate if the IRB determines it is so and the research falls into the first two "categories".

F. Under certain circumstances, to protect the welfare of the minor, the convened IRB board may chose to waive parental consent. An example would be a study involving child abuse in which parental consent would be ill-advised. In circumstances where parental consent is waived, a child subject advocate must be assigned to protect the children who would participate as participants in the research.

G. Guidance on Additional Requirements of Federal Funding Agencies

Please note that protocols conducted by MUSC and sponsored by any of the following federal agencies

- the Department of Defense (DOD),
- Department of Education,
- Department of Energy,
- Department of Justice (DOJ) / National Institute of Justice (NIJ) and Bureau of Prisons (BOP) or
- Environmental Protection Agency (EPA)

have additional operational and review requirements. Further information available on the MUSC IRB Resources & Guidance Webpage <http://research.musc.edu/ori/irb/resources.html>)

H. ICH – Good Clinical Practice (GCP)

The MUSC IRBs operate in accord with ICH-GCP guidelines only to the extent that they are compatible with FDA and DHHS regulations. CGP standards contained in the ICH document are not regulatory requirements in the United States and vary from FDA and DHHS regulations. As such, the MUSC IRBs do not voluntarily agree to comply with all of the GCP statements unless requested to do so by sponsors as documented in contractual agreements. The MUSC IRBs comply with most aspects of ICH-GCP, and the MUSC policies, procedures and forms require investigators to com ploy with most ICH-GCP guidance. In addition, protocols following the International Committee on Harmonisation – Good Clinical Practices (ICH-GHP) have additional requirements. Further information available on the MUSC IRB Resources & Guidance Webpage <http://research.musc.edu/ori/irb/resources.html>).

II. Definitions

Definitions for the following terms used in this section may be found in HRPP Guide Section 1.3 Definitions Terms:

A. Children

III. CHILDRENS RESEARCH CATEGORIES

A. Category I [45 CFR 46.404 and 21 CFR 50.51] = 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.

B. Category II [CFR 46.405 and 21 CFR 50.52] = 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.

C. Category III [45 CFR 46.406 and 21 CFR 50.53] = 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.

D. Category IV [45 CFR 46.407 and 21 CFR 50.54] = 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.

IV. Procedures

A. The "Special Subject Populations - Children" checklist will be used as a guide for IRB evaluation and will be completed by the primary reviewer.

B. During the initial review of a protocol involving children, the IRB assigned primary reviewers will designate the appropriate risk category as defined above and give a brief rationale for the category selected.

C. The Board will determine the appropriate research category as part of the motion relative to approval of a protocol involving children; the rationale for this categorization will be documented in the Board meeting minutes.

D. 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. This decision will be documented in the IRB meeting minutes.

E. 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 rationale for this decision will be documented in the IRB meeting minutes.

F. 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. This determination will be documented in the IRB minutes.

For expedited protocols, the IRB chair or chair's designee will make this determination. This determination will be documented in the IRB expedited protocol checklist.

G. Family Educational Rights and Privacy Act (FERPA) and Protection of Pupil Rights Amendment (PPRA)

1. Family Educational Rights and Privacy Act (FERPA) (20 U.S.C. § 1232g; 34 CFR Part 99) is a Federal law that protects the privacy of student education records. The law applied to all schools that receive funds under an applicable program of the U.S. Department of Education (ED). FERPA 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. The purpose

of FERPA is to protect all student and parent information maintained in an Education Record.

2. The protection of Pupil Rights Amendment (PPRA) (20 U.S.C. § 1232h; 34 CFR Part 98), 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). PPRA is intended to protect the rights of parents and students.

3. When reviewing research involving students, the convened IRB or the reviewer for expedited procedure will determine and document that the regulatory criteria allowing approval under 34 CFR 98 "Protection of Pupil Rights Amendment (PPRA)" or 34 CFR 99 "Family Educational Rights Protection Act (FERPA)" have been met.

II. References

A. Special Subject Populations Checklist – Children