Subject: Procedure for Special Categories of Research: Children

Procedure:
This procedure provides guidance on the special ethical and regulatory considerations of children involved in human subjects research under the jurisdiction of the Human Research Protections Program (HRPP).

I. Investigator Responsibilities.
   A. The Investigator will submit supplemental information with any new study submission in which children will be a target population for research activities.
   B. Plans should be described regarding if and how assent and dissent will be obtained and documented for IRB review and approval.
      1. An Investigator must take into account the ages, maturity, and psychological state of the children involved when planning methods to obtain and document assent. The IRB recommends the following:
         a) Parental permission utilizing an informed consent document
         b) Ages less than 7 years: An oral script in very simple language appropriate for children less than 7 years of age;
         c) Ages 7 to 12 years: An assent form written simply and at a comprehension level appropriate for a child 7 years of age; and
         d) Ages 13 to 17 years: An assent form which may be in the same language as the adult consent document.
      2. An Investigator should not solicit a child’s assent without intending to take his or her wishes seriously. In situations where the potential benefits of the study are such that the physicians and parents will enroll the child regardless of the child’s wishes, the child should simply be told what is planned and should not be deceived. In such cases, the Investigator should request a waiver for assent from the IRB.
      3. Once a waiver of assent has been approved, the Investigator will obtain parental permission unless waiver from parental permission has been granted (See HRPP Policy IV.C).
      4. The Investigator may not approach the child to assent to the research study until the parents or legal guardians have given written permission.

II. IRB Committee Responsibilities.
   A. The IRB Committee must review the proposed research taking into consideration all applicable HRPP policies as well as the degree of risk and discomfort involved in the research in relation to the direct benefits it offers to the child before it can determine whether or not the IRB has authority to approve the study.
   B. When determining whether children are capable of assenting, the IRB shall take into account the age, maturity, and psychological state of the children targeted for the study population. This determination may apply to all children involved in the study, or on a case-by-case basis, as deemed necessary by the IRB.
   C. The IRB must determine the appropriate ages for assent and the method of documentation of assent.
   D. The IRB must assure that special protections afforded to children found in 45 CFR 46, Subpart D have been met for this population. The Primary Reviewer must complete the “Reviewer Comment Form” for children.
   E. The Committee may not review or make a determination regarding studies.
involving children as a target population, unless it has sufficient expertise in pediatric ethical, clinical, and psychosocial issues. Therefore, a Committee member or an ad hoc member must be in attendance at the convened meeting or experts who have this knowledge must be consulted by the IRB. When the IRB Committee renders its determination, it will include:

1. The children’s category and corresponding rationale under which the proposed research qualifies (e.g., 45 CFR 46.404-46.407); and
2. Adequate provisions for obtaining assent and dissent from the children and how such assent and dissent will be documented. If assent and dissent is waived by the Committee, the rationale for such determination must be provided.
3. Federally-funded studies determined by the IRB Committee to meet 45 CFR 46.407 for children, will be given a “pending approval” status until a determination by the Secretary of the Department of Health and Human Service (DHHs) is received. The HRPP Director will be promptly notified when the IRB determines a study meets 45 CFR 46.407. Documentation sent to the Secretary include:
   a) IRB minutes from the convened meeting documenting the IRB findings
   b) The complete IRB application and informed consent documents;
   c) The relevant protocol and/or grant application; and
   d) Any supporting material including the Investigator’s Brochure, if applicable.
4. If OHRP grants approval under Category 46.407, then the IRB may grant final approval.
5. If OHRP requires changes in the process of approval, or any other changes are made after the IRB “approved pending” modifications, an amendment must be submitted for review and approved by the IRB Chairperson or his or her designee, unless the IRB Chairperson determines the changes submitted are major, which require IRB Committee review (See HRPP Procedure III.J.1).
6. At any time, the Chairperson may refer the study to the IRB Committee for further review.

F. Non-Federally funded studies determined by the IRB Committee to meet 45 CFR 46.407 for children, and meet all criteria for approval under 45 CFR 46.111, will be given a “pending approval” status until the research proposal is reviewed by both an expert panel and a community panel, for recommendations (See HRPP Procedure IX.A.2).

G. When children as wards of the State are involved in research under 45 CFR 46.407, the required additional individual acting on behalf of the child as guardian or in loco parentis may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interest of the child for the duration of the child’s participation in the research and who is not associated in any way with the Investigators, or the guardian organization.

III. Regulatory Compliance Analyst (RCA) Responsibilities.

A. The RCA will verify that the supplemental information for the inclusion of children is completed as part of the initial study documents.
B. The RCA will conduct a pre-review and take into consideration the type of research and verify the appropriate category of research under Subpart D.
C. The RCA takes into consideration the age, maturity, and psychological state of the children targeted in the proposed research when pre-reviewing the assent and informed consent documents.
D. Requests of pre-review changes to the informed consent documents are to be sent to the Investigator by the RCA.
E. Once the pre-review revisions are received from the Investigator, the RCA will place the new study on the next available Committee agenda assign Reviewers with appropriate expertise in children and assure appropriate materials are available. Reviewers are electronically notified once assigned.