Title: SPECIAL CATEGORIES OF RESEARCH: CHILDREN

1.0 Purpose:

The purpose of this Standard Operating Procedure (SOP) is to provide guidance on the special ethical and regulatory considerations of children involved in human participant research under the jurisdiction of the Syracuse University (SU) Institutional Review Board (IRB).

2.0 Policy:

It is the policy of the SU IRB to review, approve, and provide guidance on the special ethical and regulatory considerations when children are involved in human participant research.

The IRB provides extra scrutiny of research involving vulnerable populations who, by virtue of their situations, are susceptible to exploitation or may have difficulties exercising informed consent. The IRB pays special attention to the risks and benefits of research, incentives for participation, and the informed consent process on research involving vulnerable populations. (*See SOP 016).*

The special vulnerability of children makes consideration of involving them as research participants particularly important. To safeguard their interests and to protect them from harm, special ethical and regulatory considerations apply for reviewing research involving children. The IRB may approve research involving children only if special provisions are met. The IRB must classify research involving children into one of four categories and document their discussions of the risks and benefits of the research study. The four categories of research involving children that may be approved by the IRB are based on degree of risk and benefit to individual participants.

2.1 The IRB may approve research involving children by following the "Checklist for Studies Involving Children".

3.0 References and Reference Documents:

45 CFR 46.116
45 CFR 46 Subpart D
SOP 014, Amendments to Previously Approved Applications or Claims for Exemption.
SOP 016, Legally Effective and Prospectively Obtained Informed Consent
SOP 017, Documentation of Informed Consent
SOP 018, Waiver of Informed Consent
SOP 019, Assent/Dissent by Children

4.0 Procedure:

4.1 Investigator Responsibilities.

4.1.1 The Investigator will submit the initial application including the explanation for including children in the selection of participant section.

4.1.2 Plans should be described regarding if and how assent and dissent will be obtained and documented for IRB review and approval.

4.1.2.1 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 SU IRB recommends the following:

4.1.2.1.1 Parental permission utilizing an informed consent document;

4.1.2.1.2 Ages less than 7 years: An oral script in very simple language appropriate for children less than 7 years of age;

4.1.2.1.3 Ages 7 to 12 years: An assent form written simply and at a comprehension level appropriate for a child 7 years of age; and

4.1.2.1.4 Ages 13 to 17 years: An assent form which may be in the same language as the adult consent document.

4.1.2.2 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.

4.1.2.3 Once a waiver of assent has been approved, the Investigator will obtain parental permission unless waiver from parental permission has been granted. (*See SOP 018 Waiver of Informed Consent).*

4.1.2.4 The Investigator may not approach the child to assent to the research study until the parents or legal guardians have given written permission.

4.2 IRB Responsibilities.

4.2.1 The IRB must review the proposed research taking into consideration all applicable SU 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 will approve the study.

4.2.2 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.

4.2.3 The IRB must determine the appropriate ages for assent and the method of documentation of assent.

4.2.4 The IRB must assure that special protections afforded to children found in 45 CFR 46, Subpart D have been met for this population. The IRB Chair or designee must complete the Review of Research Checklist.

4.2.5 The IRB may not review or make a determination regarding Full Board studies involving children, as a target population, unless it has sufficient expertise in pediatric ethical, clinical, and psychosocial issues. Therefore, an IRB 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 renders its determination, it will include:

4.2.5.1 The children's category and corresponding rationale under which the proposed research qualifies (e.g., 45 CFR 46.404-46.407); and

4.2.5.2 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 IRB, the rationale for such determination must be provided.

4.2.5.3 Federally-funded studies determined by the IRB 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 Services (DHHS) is received. The ORIP Director will be promptly notified when the IRB determines a study is determined to meet 45 CFR 46.407. Documentation sent to the Secretary include:

4.2.5.3.1 IRB minutes from the convened meeting documenting the IRB findings;

4.2.5.3.2 The complete IRB application and informed consent documents;
4.2.5.3.3 The relevant protocol and/or grant application; and
4.2.5.3.4 Any supporting material including the Investigator's Brochure, if applicable.

4.2.5.4 If OHRP grants approval under Category 46.407, then the IRB may grant final approval.

4.2.5.5 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 Chair or his or her designee, unless the IRB Chair determines the changes submitted are major, which require IRB review. (*See SOP 014*).

4.2.5.6 At any time the IRB Chair may refer the study to the IRB for further review.

4.2.6 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.

4.3 ORIP Responsibilities.

4.3.1 The ORIP Director or designee will verify that the supplemental form for "Vulnerable Populations: Children" is completed as part of the initial study documents.

4.3.2 The ORIP Director or designee will verify that the Committee reviewing the research involving children has at least one member who is a child representative in attendance.

4.3.3 To adequately document the IRB review of the research:

4.3.3.1 The curriculum vitae of the child representative serving on the IRB will be on file in the IRB;

4.3.3.2 The "Checklist for Studies Involving Children" will be placed in the IRB file; and

4.3.3.3 The discussion and determinations of the IRB regarding the findings required under HHS regulations at 45 CFR 46.403 will be documented in the minutes.

4.3.3.4 The "Checklist for Studies Involving Children as Wards" will be placed in the IRB file;
and

4.3.3.5 The discussion and determinations of the IRB regarding the findings required under HHS regulations at 45 CFR 46.409 will be documented in the minutes.

SOP 021: SPECIAL CATEGORIES OF RESEARCH: CHILDREN

Approved by: BR Ware 7-20-08

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