1. PURPOSE

This procedure describes the requirement for assent of children, permission of parents or legal guardians, and/or waiver of assent or waiver of parental consent.

2. PROCEDURE

The principle of respect for persons requires that the choice of an autonomous person be respected. Under the usual conditions of clinical research, this is accomplished by soliciting the informed consent of the prospective human subject. In the case of a child, applying the principle of respect for persons may be problematic. Any individual capable of some degree of understanding (generally, a child of seven or older) should participate in research only if they assent. When assent is required by the IRB, however, the decision of the individual assenting is binding.

In all cases, regardless of whether the IRB requires assent, the IRB expects investigators to provide children with developmentally appropriate information about their diagnosis, treatment, and proposed research participation, when appropriate. In particular, investigators should explain the purpose as well as the incremental procedures, risks and benefits of the clinical trial, and offer an opportunity to ask questions.

3. SPECIFIC PROCEDURES

3.1 Use of Assent

In instances in which the human subject is not legally capable of giving informed consent (*e.g.*, children), the IRB must find that adequate provisions are made for soliciting the assent of the human subject when, in the judgment of the IRB, the human subject is capable of providing assent.

- Assent means a child's affirmative agreement to participate in research. Mere failure to object may not, absent affirmative agreement, be construed as assent.
- For children under 7 years of age, the assent of the child is not a necessary condition for participating in a research protocol.
- Children age 7 through 13 vary considerably in their development and cognitive capacity. Many of these children have limited ability to participate in decision making, and a formal request for assent will not be appropriate. Nonetheless, for all protocols, the IRB expects investigators to provide to children in this age range developmentally appropriate information in the form of an age-appropriate assent (whether verbal or written) about the proposed research participation. In particular, investigators should explain the purpose as well as the incremental procedures, risks and benefits of the clinical trial, and offer an opportunity to ask questions.
- For children 14 years of age or older, the assent of the child is a necessary condition for participating in the research, unless this approval is waived by the IRB. Investigators, however, may request that assent be waived *for an individual child*, because the capability of that child is so limited that they cannot reasonably be consulted [45 CFR 46.408(a)].
- In determining whether human subjects are capable of assenting, investigators and the IRB shall take into account the age, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted, or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or

well-being of the child and is available only in the context of the research, the assent of the human subject is not a necessary condition for proceeding with the research. Even when the IRB determines that the children are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with 45 CFR 46.116 Subpart A.

- When the IRB determines that assent is required, it shall also determine whether and how assent must be documented. For protocols not involving greater than minimal risk (45 CFR 46.404 and 21 CFR 50.51), or involving greater than minimal risk and no prospect of direct benefit to the human subjects, but likely to yield generalizable knowledge about the human subject's disorder or condition for which there is no expected direct therapeutic benefit (45 CFR 46.406 and 21 CFR 50.53), adequate provisions should be made for soliciting the assent of children and permission of their parents or guardians, as set forth in 45 CFR 46.408.
- For protocols involving greater than minimal risk but presenting the prospect of direct benefit to the human subjects (45 CFR 46.405 and 21 CFR 50.52), the formal assent of children is not a necessary condition to proceeding with enrollment. Adequate provisions need to be made for soliciting the assent of children and permission of their parents or guardians, as set forth in 45 CFR 46.408. Investigators may decide that assent is appropriate for an individual child, based on an individual assessment of capacity.
- For protocols involving greater than minimal risk but not presenting the prospect of direct benefit to the human subjects (45 CFR 46.406 and 21 CFR 50.53), the formal assent of children is a necessary condition to proceeding with enrollment, and adequate provisions need to be made for soliciting the assent of children and permission of their parents or guardians, as set forth in 45 CFR 46.408.

3.2 Waiver of Assent

In order for the IRB to waive or alter consent/assent, the IRB must find and document that:

- The research involves no more than minimal risk to the subjects;
- The research could not practicably be carried out without the waiver or alteration;
- If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
- The waiver or alteration will not adversely affect the rights and welfare of the human subjects; and
- Whenever appropriate, the human subjects or legally authorized representatives will be provided with additional pertinent information after participation, per 45 CFR 46.116 of Subpart A and 21 CFR 50.55(d).

In addition to the above provisions for waiver of consent/assent, assent can be waived under 46.408 if "the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research." Even where the IRB determines that the human subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with 45 CFR 46.116.

3.3 Permission by Parents or Guardians
The IRB requires the permission of a child's parent(s) or legal guardian(s) based on the risk level of the research as described in 45 CFR 46.408 and, when applicable, 21 CFR 50.55.

Permission of one parent is sufficient for research to be conducted under 45 CFR 46.404 (Research not involving greater than minimal risk) or 45 CFR 46.405 (Research involving greater than minimal risk but presenting the prospect of direct benefit to the human subjects), and, when applicable, 21 CFR 50.51 and 50.52.

Permission of both parents is required for research to be conducted under 45 CFR 46.406 (Research involving greater than minimal risk and no prospect of direct benefit to the human subjects, but likely to yield generalizable knowledge about the human subject's disorder or condition) and 46.407 (Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children), and, when applicable, 21 CFR 50.53 and 50.54, unless one parent is deceased, unknown, incompetent, not reasonably available, or in the case where only one parent has legal responsibility for the care and custody of the child.

3.2 Waiver of Parental or Guardian Permission
If the IRB determines that a research protocol is designed for conditions or for a human subject population for which parental or guardian permission is not a reasonable requirement to protect the human subjects (for example, neglected or abused children), it may waive the consent requirement, provided an appropriate mechanism for protecting the children who will participate as human subjects in the research is substituted, and provided that the waiver is not inconsistent with Federal, state or local law.

4. RESPONSIBILITY
IRB Chair or IRB member(s) are responsible for determining whether assent is indicated.
IRB Chair or IRB member(s) are responsible for review of the assent document.

5. APPLICABLE REGULATIONS AND GUIDELINES
45 CFR 46.116 Subpart A
45 CFR 46 Subpart D
21 CFR 50 Subpart D
21 CFR 50

6. REFERENCED DOCUMENTS
Assent Template

REVISION HISTORY

Revision Number	Version Date	Approved By	Date Approved
2.0	8/4/2020	Avera Institutional Official	9/24/2020
• Reference to cognitively impaired adults is already in SOP 502, so removed it from this particular SOP. • Added in language regarding the permission of parents or legal guardians, and waiver of assent or waiver from parental consent. • Added that the IRB expects investigators to provide children with developmentally appropriate information about the proposed research, when applicable.			
1.0	August 2016	Director HSRP / August 2016	