Guideline (3): Requirements for Permission by Parents or Guardians and for Assent by Children (or Subjects).

The following requirements must be provided to IRB office:

- In addition to determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions have been made to solicit child participants' assent when it ascertains that the children are capable of providing assent. In making this determination, the IRB will take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children who may be involved in research under a particular protocol, or for each child, as deemed appropriate by the IRB. If the IRB determines that some or all of the children have sufficiently limited capacity to understand assent/consent and will benefit from the procedure involved in the research, children's assent may not be a necessary condition for proceeding with the research. If the IRB determines that subjects are capable of assent, the assent requirement may still be waived in accord with IRB Policy V and if procedures for this policy are met.

- In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by IRB Policy V, that adequate provisions have been made to solicit permission from each child's parents or guardian. If parental permission is needed, the IRB may determine that obtaining permission from one parent is sufficient under IRB Policy V. Where research is covered by IRB Policies (II, III, & IV) and parental permission must be obtained, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

- In addition to the waiver provisions in IRB Policy V, the IRB may waive requirements in subpart A of this part and paragraph (b) of this section if it determines parental or guardian permission is not a reasonable requirement to protect subjects in a participant population (e.g., neglected or abused children), provided that an appropriate protective mechanism is substituted, and that the waiver is not inconsistent with existing laws. The choice of an appropriate mechanism depends on the nature and purpose of activities described in the protocol, risk and anticipated benefit to research subjects, and their age, maturity, status, and condition.

- Permission by parents or guardians will be documented in accordance with and to the extent required by IRB Policy V.
- When the IRB determines that assent is required, it shall also determine whether and the manner in which assent must be documented.