CHILD ASSENT

IRB Member Continuing Education

AAHRRP Element 1I.4. B.

The IRB or EC has and follows written policies and procedures requiring appropriate protections for prospective participants who cannot give consent or whose decision-making capacity is in question.

HRPP 8.6
Research Involving Children

- *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.*

ASSENT

- A child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.
  - This means the child must actively show his or her willingness to participate in the research, rather than just complying with directions to participate and not resisting in any way.

45 CFR 46.408(a)

Requirements for permission by parents or guardians and for assent by children

- The IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent.
- 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.

CHILD ASSENT

When judging whether children are capable of assent, the Institutional Review Board (IRB) is charged with taking into account the ages, maturity, and psychological state of the children involved.

Waiver of Assent

- The regulations at 45 CFR 46.408(a) identify three types of circumstances where the IRB may determine that waiver of children's assent is appropriate:
  - if the capability of some or all of the children is so limited that they cannot reasonably be consulted;
  - if the intervention or procedure involved in the research holds out the prospect of direct benefit to the health or well-being of the children and is available only in the context of the research.
  - if the research meets the same conditions as those for waiver or alteration of informed consent in research involving adults, as specified in the regulations at either 45 CFR 46.116(c) or 45 CFR 46.116(d).

Documentation of Assent

- The HHS regulations do not require documentation of assent.
- Institutional Review Board (IRB) has the discretion to determine the appropriate manner, if any, of documenting child assent.
- If young children are involved who are as yet unable to read, documentation should take a form that is appropriate for the purpose of recording that assent took place. The IRB may also decide that documentation of assent is not warranted.