Assent Age Ranges

I. Statement

Research involving children requires that adequate provisions are made for soliciting the assent of the child and the permission of their parents or guardians consistent with the standards described in 45 CFR 46.408. In limited circumstances, the IRB may determine that assent is not a requirement with respect to some children involved in research for one of the following reasons:

- The capability of the children is so limited (based on an assessment of their age, maturity, or psychological state) that they cannot reasonably be consulted;
- 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; or
- The assent can be waived using the criteria described in 45 CFR 46.116(e)(f) for waiver of consent.

The assent process will be determined by when children are capable of assent based on age and maturity of the children, psychological state of the children, and nature of the proposed research activity. 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.

Children who reach the age of majority while participating in a study must be consented if continuing interventions or interactions are planned (including collection or analysis of identifiable private information), as described in 45 CFR 46.116. The IRB may grant a waiver of consent under 45 CFR 46.116 (e), if it finds that required conditions are met, but must document its decision and rationale for doing so.

II. Considerations of Age for Obtaining and Documenting Assent

Though children do not have the legal capacity to consent to participate in research, they should be involved in the process if they are able to assent by having a study explained to them and/or by reading an age-appropriate form that

contains simplified content about the study, and then giving their verbal or written choice (as appropriate) about whether they want to participate or not. Documentation of assent should be captured by the person obtaining assent or by the child signing an assent form using the age ranges below. The process by which assent is documented should take into consideration the age of the participant, the complexity of the research, as well as the setting. These guidelines are not requirements, and study-by-study evaluation is important. IRB staff should refer to the below assent ranges when reviewing research applications involving children.

The IRBs use their best judgment, on a study specific basis, to ensure that the assent is tailored to the level of comprehension of the prospective participants. General guidelines include:

A. IRB-HSBS

- Under age 4, assent is not generally sought
- Ages 4-7, simplified verbal assent
- Ages 8-12, simplified verbal or written assent
- Over age 12, comprehensive verbal or written assent, mirroring the parental permission document may be appropriate

B. IRBMED

- Under age 7, assent is not generally sought
- Ages 7-9, verbal assent using a simplified oral assent script or form
- Ages 10-14, comprehensive verbal or written assent
- Ages 15-17, comprehensive written consent document. Child and parent/s sign the informed consent to document assent and parental permission.

The assent process should consider risk level, prospect of benefit, and whether the research involves sensitive situations. Refer to Common IRB Determinations Regarding Appropriate Provisions for Assent by Children.

III. Resources

- 45 CFR 46, Subpart D
- 21 CFR 50, Subpart D