Guidelines for Use by the IRBMED in Determining When Assent of Children Should be Waived or Required [1]

*In the chart below—blue fields indicate when **waiver of assent** is generally recommended; yellow fields indicate when **assent** should generally be **required**.*

The IRB must make an assent determination **for each protocol** that includes children. The IRB must require child assent unless it can be appropriately waived; which waiver and the reasons for it should be clearly articulated and recorded. There are no strict age criteria in the regulations.

Age Ranges[2]	Risk and Benefit Assessment of the Study or Study Arm					
	Potential of Direct Benefit ***Unavailable*** Outside of the Research[3]		Potential of Direct Benefit that ***is Available*** Outside of the Research		**No** Potential of Direct Benefit	
	No more than minimal risk	Greater than minimal risk	No more than minimal risk	Greater than minimal risk	No more than minimal risk	Greater than minimal risk
0-6	WAIVE					
7-13			Require or waiver **#3**	≤ 9 Require or waiver **#1** ≥9 Require		
14-17		Waive or Require depending on the nature of the research[4]	REQUIRE			
Incapacitated children who cannot be consulted,, regardless of age[5]			**If capabilities of minors change such that they could later assent during the course of the research (including long-term follow-up) the IRB must determine if assent should be required at that point in time.**			

Waiver Options

The IRB may waive assent when **one** or more of the following applies (convened meeting minutes/reviewer worksheet/IRB application must reflect IRB determination of which waiver(s) applies to each study **and why**):

(1) Capabilities of children is so limited they cannot be consulted

(2) Study offers important benefit **unavailable** outside of the research.

(3) Under the same criteria as waiver of consent (minimal risk, assent is not practicable, waiver will not adversely affect rights and welfare of the child, pertinent information will be provided after the research).

When assent is waived the IRB may still require that researchers to explain to children that they are involved in research, what that means, and provide some explanation of the research procedures.

Assent Options

When the IRB determines that assent is required it must also determine if assent must be documented, and if so, how.

Oral Assent Script and Process:	Written Child Assent Document:	Child Signature on Parent Form
Require a copy of general script. Visual aides may be used. o *Recommended for research subjects ages 7 to 9.* o For older children, oral assent may be appropriate for simple studies like a blood draw where there are no special child confidentiality issues. o *Documentation:* Not more than minimal risk:--Waive documentation; Greater than minimal risk--Document via a note in the study record that includes time, date, and who conducted the assent process **OR** child signs a one page form or the parental permission form.	Require a copy of an age appropriate written document. Augment the document orally, with visual aides as needed. o *Strongly recommended for ages 9-17 when research involves drug or pregnancy testing and/or birth control.* o *Recommended for ages 10 to ~14.* o *Documentation:* Subject signs the assent form. Document should be dated and indicate who conducted the process.	Require assent; document on the ***S**tandard* IC document—minor signs in subject box, permitting parent(s) sign in LAR box. Augment the document orally, with visual aides as needed. o *Recommended for ages ~14 to 17—Note, if study involves **drug or pregnancy testing and/or birth control,** recommend either a written assent form **or** require an oral script for information that will be presented privately to subject.*

Requirements for assent by children 45 §46.408 and 21 § 50.55	**Considerations IRB should use to determine if minors are capable of assent:**
"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." **OHRP Guidance:** "Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent. 45 CFR 46.402(b). 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. Assent is a reasonable effort to enable the child to understand, to the degree they are capable, what their participation in research would involve, an ongoing, interactive conversation between the research team and the child. **When the IRB requires assent, the child's decision must be honored**. Although the regulations do not articulate age criteria, the Belmont Report and federal guidance state the age of seven as the age where children gain capabilities that could permit them to assent.	• Age, maturity and psychological state of the children • The nature of the proposed research activity Regulations give IRBs flexibility in deciding which minors the investigator must assent: • A judgment may be made for all children to be involved in research under a particular protocol, or for each child. o Within one study the IRB could waiver assent for younger children and require assent for mature adolescents. o The IRB could require assent but allow the investigator to appeal on a case-by-case basis. o The IRB could waive assent for those that the investigator and/or parents judged incapable of assenting based on criteria submitted to and approved by the IRB. o The IRB could require that someone not involved in the research make the determination.

References: 45 CFR 46, 21 CFR http://www.hhs.gov/ohrp/panels/407-01pnl/riskcat.htm, http://www.hhs.gov/ohrp/irb/irb_chapter6.htm. http://www.cancer.gov/clinicaltrials/understanding/childrensassent0101 and http://www.hhs.gov/ohrp/faq.html

[1] When the IRB requires assent and (1) the parents agree to the research and the child dissents, the child's decision is the one that must be honored; (2) the child agrees to the participate in the research and the parent does not give permission, the parent's decision is the one that must be honored.
[2] Age ranges in left column reflect the range options in eResearch Q.33.1.
[3] The "benefit unavailable outside of the research study" should be such that it is attributable to the scientific question itself. Examples: IND/IDE studies
[4] Consider how the research impacts mature minors and how likely the direct benefit actually is. Also consider: "When research involves the provision of experimental therapies for life-threatening diseases such as cancer . . . IRBs should be sensitive to the fact that parents may wish to try anything, even when the likelihood of success is marginal and the probability of extreme discomfort is high. . . In general, if the child is a mature adolescent and death is imminent, the child's wishes should be respected (OHRP IRB Guidebook)."
[5] Examples: Disease/condition of subjects is such that they lack adequate verbal skills or cognitive capacity to permit assent; e.g., all children are comatose at the time research commences.