Common IRB Determinations Regarding Appropriate Provisions for Assent by Children[1]

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

There are no strict age criteria in the regulations. Determinations are made for each protocol, taking into account the mental capacity and cognitive functioning of subjects, and the complexity of the research at hand.

Age Ranges	Risk and Benefit Assessment of the Study or Study Arm					
	Prospect of direct therapeutic benefit available **only** in the research context		Therapeutic options that offer the prospect of direct benefit **are** available **outside** of the research		No prospect of direct benefit	
	Minimal risk	Greater than minimal risk	Minimal risk	Greater than minimal risk	Minimal risk	Greater than minimal risk
0-6	**WAIVED**					
7-13			**Required** or **Waived** per situation #3	≤ 9 **Required** or **Waived** per situation #1 ≥ 10 Require		
14-17		**Waived** or **Required** depending on the nature of the research[2]	**REQUIRED**		**REQUIRED**	
Incapacitated children who cannot be consulted, any age[3]			If capabilities of minors change such that they could later assent during the course of the research (including long-term follow-up) assent may be required later.			

Waiver Options

The IRB may waive assent when one or more of the following applies:

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

(2) Study offers important health/wellbeing benefit that is **unavailable** outside of the research.

(3) Nature of the research is such that waiver of consent would be appropriate if participants were adults.

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

Options for Making a Record of Assent

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 aids may be used. ○ *Recommended for research subjects ages 7 to 9.* ○ For children 10 and older, oral assent may be appropriate for simple studies like a blood draw where there are no special child confidentiality issues. ○ *Documentation:* Not more than minimal risk -- Board may decide that documentation is not required; Greater than minimal risk--Record 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 to be used to conduct the assent process and to obtain written documentation of assent. Augment the document orally, with visual aids as needed. ○ *Strongly recommended for ages 9-17 when research involves drug or pregnancy testing and/or birth control.* ○ *Recommended for ages 10 to ~14.* ○ *Documentation:* Subject signs the assent form. Document should be dated and indicate who obtained assent.	Require assent; record on the ***S**tandard* IC document—minor signs in subject box, permitting parent(s) sign in LAR box. Augment the document orally, with visual aids as needed. ○ *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 "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." 45 CFR 46.408 and 21 CFR 50.55

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. OHRP FAQs on research with children**.**
The assent process requires a reasonable effort to enable the child to understand, to the degree they are capable, what their participation in research would involve as a way of including them as an active participant in the decision-making process, and would involve an ongoing, interactive conversation between the research team and the child. **When the IRB requires assent, a child's dissent 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 when children gain capabilities that could permit them to assent.

Considerations IRB uses to determine if minors are capable of assent:

- Age, maturity and psychological state of the children
- The nature of the proposed research activity

Regulations give IRBs flexibility in deciding from which minors the investigator must ask for assent. A judgment may be made for all children to be involved in research under a particular protocol. Other options include:

- Within one study, the IRB could waive assent for younger children and require assent for mature adolescents.
- The IRB could require assent but allow the investigator to appeal on a case-by-case basis.
- 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.
- The IRB could require that someone not involved in the research make the determination.

References: OHRP (FAQ, Guidances, and Education & Outreach Archived Materials); NCI (Children's Assent); 45 CFR 46 Subpart D, 21 CFR 50 Subpart D

[1] When the IRB requires assent and (1) the parents agree to the research and the child dissents, the child's decision is final; (2) the child agrees to the participate in the research and the parent does not give permission, the parent's decision is final.
[2] Consider how the research impacts mature minors and how likely the direct benefit actually is. Also consider (from OHRP IRB Guidebook 1993, archived): "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."
[3] Examples: Disease/condition of subjects is such that they lack adequate verbal skills or cognitive capacity to permit assent; all children are comatose at the time research commences.