



# MUSC-IRB EDUCATION: CHILD ASSENT

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# Child Assent

The IRB/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 8.5 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 judgement of the IRB members, the children are capable of providing assent. This determination will be documented in the IRB minutes.





# UNDERSTANDING CHILDREN'S ASSENT IN RESEARCH



## SIMPLE COMPLIANCE (NOT ASSENT)



Child is complying with directions and not resisting, but not actively showing willingness.

## ACTIVE WILLINGNESS (TRUE ASSENT)



Child actively shows their desire and willingness to participate.

*Mere failure to object or absent affirmative agreement, should not be construed as assent.*



# Requirements for permission by parents/guardians and for assent:

45 CFR 46.408 (a)

Determines that adequate provisions are made for soliciting the assent of children, when in the judgement of the IRB the children are capable of providing assent.



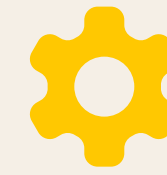
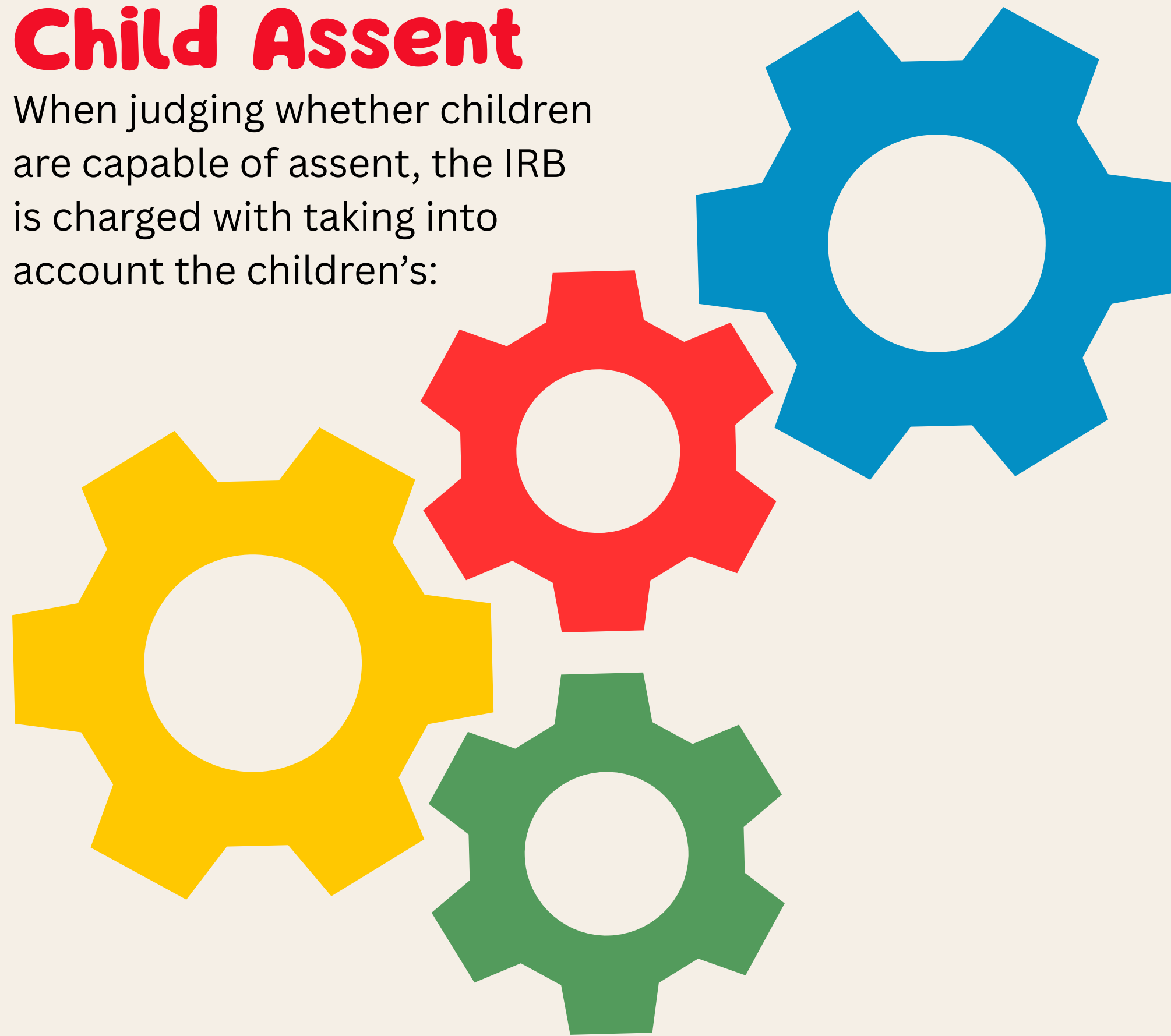
IRB



This judgement 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

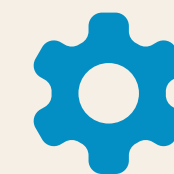
When judging whether children are capable of assent, the IRB is charged with taking into account the children's:



**Ages**



**Maturity**



**Psychological  
State**

# 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:



## Limited Capability

If the capability of some or all of the children is so limited that they cannot reasonably be consulted.



## Direct Benefit

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.*



## Regulations

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



## Young Children

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.



## IRB

The IRB has the discretion to determine the appropriate manner, if any, of documenting child assent.



## HHS Regulations

The HHS regulations do not require documentation of assent.

# Questions

