

## GUIDELINES FOR PROCESS OF INFORMED ASSENT

**ASSENT** is the term used to describe a child's affirmative agreement to participate in research. Researchers should obtain both assent and parental consent when a child does not have the capacity to consent. The **PAeDS-MoRe** process below provides a general framework to develop a protocol for the process of informed assent.

### Prepare for Assent

- Include a process to prepare prospective participants for the assent discussion
- Explain how research differs from clinical care (if relevant)
- Explain what free, informed assent means

### Assess Readiness

- Present assent disclosures in a manner that is appropriate for each child
- Include methods to assess capacity (where relevant) and readiness for assent discussion

### Discuss Study

- Make assent disclosures available before the consent/assent discussion
- Discuss the study with both parent and child to promote understanding of the elements of assent

### Seek Decision

- Be confident about the participant's level of understanding before seeking a decision
- Have a process to assess both verbal and nonverbal **DISSENT**

### Monitor Decision

- Ensure **ONGOING** informed assent by reconfirming agreement to participate throughout the study
- Make relevant new information known and reassess capacity changes

### Respect Role

- Consider how to acknowledge the child's contribution (e.g. post-study meeting, letter of thanks, etc.)

- Identify and respect signs of **DISSENT** or a lack of agreement except in cases where REB has approved exceptions to the assent process (e.g. research involving infants or toddlers).
- Ensure that the assent process is documented.
- Involve children in the decision making process as much as possible. It is the responsibility of the local principal investigator to ensure assent processes and disclosures meet applicable regulations, guidelines, and institutional policies.

### **OTHER ADVICE FOR OBTAINING AN ASSENT DECISION**

- Use warm-up activities to increase comfort and readiness
- Be conscious of language levels and body language while discussing
- Be aware of any vulnerabilities
- Be observant during discussions
- Do not rush
- Consider different approaches to share information about what a research study involves (e.g. pictures, video)

**See REB-704 (Elements of Informed Assent) and REB-705 (Process for Informed Assent) for further details:**

<http://research.hollandbloorview.ca/researchethicsboard/standardoperatingprocedures>