Assent is defined as “a child’s affirmative agreement to participate in research,” and should be sought in addition to parental permission when the minor is sufficiently mature to understand the nature of his or her participation in a research study. While children are legally incapable of providing informed consent, they nevertheless may possess the ability to assent or dissent from participation. The assent process assures the elements of understanding and cooperation, and provides a feeling of inclusion on the part of the child. The process also illustrates the investigator’s respect for the rights and dignity of the child in the context of research. In recognition of children’s differing rates of intellectual and emotional development, regulations do not specify the age from which assent is required. They also do not state what form the assent process should take. Rather, these determinations are left to the judgment of the principal investigator and the REB. In making such assessments, the principal investigator and the REB are obligated to examine the ages, maturity and psychological state of the children involved.

While many children under the age of 7 may not be sufficiently mature to assent to participate in research, young research participants exhibit a broad range of cognitive abilities. Assessing children’s maturity based solely on chronological age may not provide an accurate picture of their capacity to understand the research or to give assent. An assessment of children’s intellectual or developmental ages will more accurately predict whether they can comprehend and appreciate what it means to be in a research study.

**REB Procedures**

The REB has determined that the policy for obtaining assent will apply to children between the ages of 7 and 15 years of age.

From the age of 16 to 17 years of age consent may be obtained from the participant alone or the parent/guardian may be asked to provide consent also.

From the age of 18 the participant will provide consent.

Exceptions to the above policy may be allowed with provisions. For instance, if someone under the age of 16 is pregnant, or is receiving treatment for STDs, or is considered to be independent and/or is living on their own, or is considered to be an ‘adult’ for reasons of consent processes, then consent will be obtained.

If in doubt about procedures or special considerations, please seek the advice of the REB and maintain a written policy for your procedures for assent/consent for your research trial. (Consult the Research Ethics Officer, Alison van Nie: vanniea@mcmaster.ca)
The crafting of an assent process should be viewed as a collaborative effort between the investigator and the REB. Although the REB determines what type of assent is required, researchers are often in the best position to assess the capabilities of their potential participant population. This assessment may even need to be made on a case-by-case basis.

The Application for REB Review form should therefore contain a thorough description of the proposed procedures that will be used to obtain parental permission and child assent. This description should include information such as:

- How potential participants’ maturity will be assessed;
- Who will obtain assent;
- Where and when parental permission and child assent will be obtained;
- What type of assent documents will be used;
- Whether signed assent will be requested;
- How the child’s assent or lack of assent will be documented by the researcher;
- How it will be determined whether the child/parents understand the research;
- Justification of a waiver of parental permission or child assent, if such a waiver is requested.

Copies of all parental permission and assent forms should be appended to the protocol.

**Writing the Assent Form**

The Assent Form should be brief and study specific, and should explain the research procedures, risks and benefits in language that is appropriate to the child’s maturity. The assent form should have a simple format that is easy to read and when possible, should be limited to one to two pages. The use of larger type, simple schema, and pictures can facilitate the child’s understanding of the text. Below is a suggested assent form template to be used by investigators as a guide; however, use of this template is not required. Investigators are encouraged to develop assent forms that they feel will most effectively present information about the research to participants.

The assent form does not replace a thoughtful discussion with the child regarding participation in the research. The assent process, or discussion with the child, is more important than the document. Investigators should remember that the assent process should take into account, in both oral and written communication, the child’s experience and level of understanding. Ultimately, the assent process should illustrate respect for the child and convey the essential information the child requires, in a manner the child can understand, in order to make a decision about participating in the research. The assent process should be well documented.
SAMPLE ASSENT FORM FOR CHILDREN 7 – 15 years of age

Assent Form Template: Wording should be very simple. A larger font is recommended, as well as simple schema and pictures to facilitate a child’s understanding of the text. The length should be limited to one or two pages maximum. If the child is not able to read, procedures may be used to present the information verbally to obtain verbal assent. This must be documented in source and in study records.

- **Title of Study**
- **Investigator(s)**
- **Research Staff**
- **Why are we doing this study?**
  We are doing a research study about (purpose in simple language). A research study is a way to learn more about people.
- **Why am I being asked to be in the study?**
  We are inviting you to be in the study because….
- **What if I have questions?**
  You can ask questions if you do not understand any part of the study. If you have questions later that you don’t think of now, you can talk to me again or ask your nurse to call me (include phone #).
- **If I am in the study what will happen to me?**
  If you decide that you want to be part of this study, you will be asked to (description, including time involved).
- **Will I be hurt if I am in the study?**
  There are some things about this study you should know. There are (procedures, things that take a long time, other risks, discomforts, etc.)
- **Will the study help me?**
  If you are in the study it may not help you to get better or benefit you. The study may help us to understand…..
**Do I have to be in this study?**
You do not have to be in this study, if you do not want to be. If you do not want to be in this study, we will tell you what other kinds of treatments there are for you. If you decide that you don’t want to be in the study after we begin, that’s OK too. Nobody will be angry or upset. We are discussing the study with your parents and you should talk to them about it too.

**What happens after the study?**
When we are finished this study we will write a report about what was learned. This report will not include your name or that you were in the study.

**Assent:**
If you decide you want to be in this study, please print/write your name. If you decide that you don’t want to be in the study, even if you have started in the study, then all you have to do is tell: …………

I,__________________________ (Print your name) would like to be in this research study.

__________________________ (Date of assent)

__________________________ (Name of person who obtained assent)

__________________________ (Signature of person who obtained assent and Date)

__________________________ (Local Principal Investigator name)

__________________________ (LPI signature and Date)