

ASSENT FORM (For CHILDREN 7-15 YEARS of AGE):

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. 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. 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.

As a general rule, assent should be obtained from children between the ages 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 rules may apply. 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

The TAHSN Application Form for REB Review should 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, study specific, and should explain the research procedures, risks and benefits in a simple language that is appropriate to the child’s maturity level. Larger font is recommended. Below is a suggested assent form template to be used by investigators as a guide. Please remember the assent form does not replace a thoughtful discussion with the child regarding participation in the research.

[ONTARIO SHORES' LOGO or ABILITIES CENTRE'S LOGO]

SAMPLE ASSENT FORM FOR CHILDREN 7 – 15 years of age

(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):

Institutional Affiliation and Phone #:

Why are we doing this study?

We want to tell you about a research study we are doing. A research study is a special way to find out about new things that may benefit people. We are doing a research study about (***Describe purpose of the research in simple language***).

Why am I being asked to be in the study?

We are inviting you to be in the study because (***insert the name of medical condition or other reasons for inclusion***)

What if I have questions?

You can ask questions if do 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 (***Name of PI***) (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 (***describe procedures like blood withdrawal, giving medications etc.***), in words a child would know and understand. ***Include number of visits and time frame.***

Will I be hurt if I am in the study?

We want to tell you about some things that might hurt or upset you if you are in this study. There are (***procedures, things that take a long time, other risks, discomforts, etc.***) ***For example: The needle we use to take the blood may hurt and cause a bruise on your arm.***

Will the study help me in anyway?

We do not know if being in this study will help you to get better or benefit you in anyway. But we hope to learn something that will help other people someday.

Do I have to be in this study?

You can choose to be or not to be in this study. It is entirely up to you. If you say yes now, but change your mind later, that is okay too. All you have to do is tell us. Nobody will be angry or upset. If you decide not to be in the study, we will tell you what other kinds of treatments are there for you. We are discussing

the study with your parents/guardians and you should talk to them about it too. Whatever you decide, we will still take care of you.

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.

Signature Section for Assent:

If you decide you want to be in this study, please sign and/or print/write your name below to affirm your decision to participate.

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

If the child not able to read/write, verbal assent received: Yes No Not Applicable

_____ (Date of assent)

_____ (Name of person who obtained assent)

_____ (Signature of person who obtained assent and Date)

(This form has been adapted from Hamilton Integrated Research Ethics Board)