

ASSENT FROM CHILDREN

When appropriate, investigators are encouraged to fully involve children in the consent process for studies in which they will be participating. Include an assent form only if it will enhance a child's understanding of what they will have to do. It must be written in very simple language. While children are often not in a position to 'consent' to the research (i.e. they are not capable of making a truly informed decision), especially in the case of a therapeutic treatment, they should be told what is happening and what their rights are. In lieu of 'consent', minor children may sign documents indicating that they 'assent' to the research. This can be accomplished in two ways: a) they may sign the regular study consent document agreeing to be in the study or b) a separate assent document with wording more appropriate to their age and comprehension level.

Assent forms ***should be written in very simple language*** geared to the appropriate educational and maturity level of the youngest prospective subject in the age range. Techniques such as the use of larger type, simple words, simple schema, and pictures may help boost a child's understanding of the text. Depending on the age range of the minors to be involved, the Lead Researcher may want to consider submitting 2 different assent forms at different reading comprehension levels (e.g., one assent form written for young children between the ages of 7 and 12 years or age, and one assent form written for teenagers between the ages of 13 and 18 years).

An assent form should contain the child's name, the date and signature lines for the child, and the person obtaining consent. The assent form should cover the following points:

- ❑ what the study is about,
- ❑ why the child is eligible to participate for the study,
- ❑ what procedures will be performed,
- ❑ potential risks and discomforts to the child,
- ❑ potential benefits to the child or society,
- ❑ for non-therapeutic research, a statement that the child can choose whether to participate and may withdraw at any time without negative consequences,
- ❑ an invitation to ask questions any time, and
- ❑ indication of whom to contact with questions.

See next page for an example of an Assent Form. Please note: the sample is ***not meant to serve as a template***. Assent forms must be tailored to the reading and comprehension level(s) of the subject populations to be enrolled and will vary widely from study to study.

UWO – HSREB GUIDELINES (January 2003)

GUIDELINE 2-G-006 (formerly APPENDIX 5)

SAMPLE ASSENT FOR CHILDREN 7-10

Study title

Investigators

Why you are here.

The doctors want to tell you about a study about children with cancer. They want to see if you would like to be in this study. Dr. Kate Miller and some other doctors are doing this study.

Why are they doing this study?

They want to see how your treatment is working.

What will happen to you?

If you agree to be in the study two things will happen:

1. Every 3 months a small amount of your blood will be taken. It will be taken by a needle in your arm.
2. The doctors will study a piece of your brain tumour that was removed when you had your surgery.

Will the study hurt?

The stick from the needle will hurt but the hurt will go away after awhile. It will not hurt for the doctors to study the part of your brain tumour.

Will you get better if you are in the study?

This study won't make you feel better or get well. But the doctors might find out something that will help other children like you later.

What if you have any questions?

You can ask questions any time, now or later. You can talk to the doctors, your family or someone else.

Do you have to be in the study?

You do not have to be in the study. No one will be mad at you if you don't want to do this. If you don't want to be in this study, just say so. Even if you say yes now you can change your mind later. It's up to you.

I want to participate in this study.

Print name of Child

Signature of Child

Age

Date

Signature of Person Obtaining Assent

Date