

## ASSENT FROM CHILDREN

When appropriate, investigators are encouraged to fully involve children in the consent process for studies in which they will be participating. 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 or b) a separate assent document with wording more appropriate to their age and comprehension level.

Assent forms should be written at the appropriate educational and maturity level of the youngest prospective subject in the age range. Techniques such as the use of larger type, 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 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.

**SAMPLE ASSENT FOR CHILDREN 7-10**

**Study title**

**Investigators**

**Why you are here.**

The researchers want to tell you about a study about to help children who do not like school. They want to see if you would like to be in this study. Dr. Kate Miller and some other researchers are doing this study.

**Why are they doing this study?**

They want to see if certain things, more than others, make you like going to school.

**What will happen to you?**

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

1. Every 3 months while you are in grade 4 you will be asked some questions by the researcher about how you like school.
2. You will go on a field trip to the museum.

**Will there be any tests?**

No there will not be any tests or marks on the report card.

**Will the study help you?**

No, this study will not help you directly but in the future it might help children who are having trouble with their math.

**What if you have any questions?**

You can ask questions any time, now or later. You can talk to the teachers, 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