Consent and Authorization Documents
Information Sheet and Assent

When appropriate, investigators are encouraged to fully involve children in the consent process for studies in which they will be participating. The nature of this involvement will depend on the developmental level of the child and the characteristics of the study. It is possible that a relatively young child would be capable of understanding a simple study and providing informed consent. For children who are incapable of giving informed consent, they nevertheless may still possess the ability to provide or refuse assent to participation in research. Out of respect for children as developing persons, children should be asked whether or not they wish to participate in the research, particularly if the research:

1) does not involve interventions that may be of benefit to the subjects and

2) the children can comprehend and appreciate what it means to be a volunteer for the benefit of others.

The process of obtaining assent may proceed in variety of ways. One option is to provide an information form that explains the research procedures in a language that is appropriate to the child's age, experience, maturity and condition. This explanation should include a description of any risks, discomforts and inconveniences the child may experience if he or she agrees to participate. Provision of an information form for the child is considered to be an expected part of the assent process. An information form should be used when it will enhance a child's understanding of their participation in research.

An alternative to providing an information form for the child is to have a well-documented and explicit process to provide the same information that would be contained in an information form. In order for the REB to judge whether appropriate assent is being obtained, it is important that the process of providing information to the child is described in detail. The REB may also require an opportunity to observe this process. Justification for not using an information form must be provided.

Information forms used must include the following headings to ensure that the relevant information is clearly conveyed to participants. Ensure that the information form is written at an appropriate level for study participants (assents should be at Grade 2-3 reading level).

Title of Study (simplified)

Investigators

Why are we doing this study?
Describe the rationale for the study. Include, if appropriate, the reason why this child is being approached for the study.

What will happen during this study?
Describe all interventions and testing that participation in this study will require. Also describe anything that will be required of the child and his/her family (completion of forms, visits to the health centre, etc.) over the course of the study. Also describe how long the study will last, and how much time will be required for all study procedures.

Are there any good or bad things about this study?
Describe any benefits or risks associated with participation in this study.

Who will know about what I did in this study?
Describe who may have access to the study records, or results of testing done during the study. The following text may be used if appropriate: “No one except the researchers will know you are taking part in this study unless you want to tell them. Your name, your study forms and your chart will only be seen by people involved in the study, <possibly funding agency or regulatory bodies>”

Do I have to be in this study?
Suggested text is as follows: “You do not have to be in this study. No one will be mad at you and it will not affect how your doctors look after you. If you don’t want to be in this study, tell us. Even if you say yes now, you can change your mind later. Being in this study is totally up to you.”

What if I have any questions?
Suggested text is as follows: “You can ask questions about the study any time, now or later. You can talk to your parents about things in the study you don’t understand. You can also ask <study doctor, Dr. X, study nurse>. You can call him/her at XXX-XXXX”.

Signature Page
Must be dated and signed by research participant, the person providing the information and person obtaining consent. The date must be entered at the time of signature.