**ASSENT FORM TEMPLATE FOR CHILDREN AGED 7-13**

This assent form template is intended to assist researchers to develop assent forms that meet the FHREB’s requirements. This template is primarily intended for children who are not legally competent to consent on their own behalf, but have the capacity to assent to participation and who are between the ages of 7 and 13. This age range, however is not fixed.

This template is a guide only, and it expected that it will be adapted for other populations as necessary according to the nature of the study. For example, it may be adapted for adult participants who are legally incapable of consent.

In cases where the child is not able to read, this form may be used as a guide for the assent discussion. The assent form should be:

* written in first person,
* at a grade 2 reading level.
* in minimum 12 point font,
* not exceed 2 pages.

**STUDY TITLE**

*If the title is long and/or overly complicated, please use a simplified, shortened title that is easy to understand, e.g., “Assent Form – Hematoblastoma Biology Study”*

**INVITATION**

Include an invitation to participate. The assent form must invite, not ask, the participant to participate in the study. Any phrases that may unduly influence the participant into the study must be omitted. E.g., “The study doctors want me (need me) to help…”

**Sample wording**

*I am being invited to be part of a research study because I have a disease called [disease name]. This disease affects many other children. This study is trying to find out [anticipated results] so that scientists can [anticipated benefits/results]. A research study tries to find better treatments for children like me.*

**DO I HAVE TO JOIN THE STUDY**

This section must explain in brief, simple terms what the study is about and why it is being done. All acronyms, drug and disease names must be spelled out and explained in simple terms. A statement that the participant can ask their doctor or parents about other treatments or therapies can be included here, if applicable.

**Sample wording**

*It is up to me if I want to be in this study. No one will make me be part of the study if I don’t want to. Even if I agree now to be part of the study, I can change my mind later and stop the study at any time. If I join the study, but later decide that I want to stop, I can just tell my parents or guardian that I want to stop. No one will be mad at me if I choose not to be part of this study.*

**WHO IS DOING THIS STUDY?**

Include the name of the principal investigator and they and their colleagues will be available to answer questions or deal with problems that may arise. There is no need to mention the funder or sponsor of the study.

**Sample wording**

*Dr. [****Name in bold****] and other doctors from [name of hospital] will be doing this study. They will answer any questions I have about the study. I can also call them at [****phone number in bold****], if I am having any problems or if there is an emergency and I cannot talk to my parents/guardian.*

**WHAT WILL HAPPEN TO ME IF I AM IN THIS STUDY?**

Explain what will happen to the participant in simple terms, including:

* Any therapies or interventions that will be administered to the participant, and how;
* How much time the participant will spend in the study, and how many visits the study will involve;
* If applicable, how much tissue will be taken from them; how and when it will be taken, and what will be done with it (e.g. “kept frozen for many years”), including any future uses such as tissue banking.

**Sample wording**

“*I agree to be in this study, I will go to see the doctor one time each week for 4 weeks (4 visits. The third time I go see them (my third visit), they will give me medicine to take home and start taking the next morning. The medicine that I will take home is called [medicine name]. During my fourth (last) visit, the doctor will use a needle to take blood from my arm for some tests, and I will give a sample of urine (pee) for other tests. If it does not look like the medicine is helping me, or if it makes me feel bad, then the doctor will ask me to stop taking the medicine.*

**CAN ANYTHING BAD HAPPEN TO ME?**

Explain very simply the possible side-effects, discomfort or harm that the participant might experience from the study procedures. The frequencies of the risks can be referenced, but are not required to be included. If this is a minimal risk study, this section may be omitted.

**Sample wording**

*Sometimes medicines make people not feel very good. The scientists do not know very much about [name of drug] compared to many other drugs that people take. They do know that some people who have taken [name of drug] in other studies have told them they had headaches and stomach aches, or that they were dizzy, had a dry mouth, or had trouble falling asleep.*

*Even though medicine is being tested for the treatment of ADHD, I might not actually feel better during the study. It is possible I might feel worse. I should tell my parents right away if I feel worse.*

**COULD I GET BETTER BY BEING IN THIS STUDY?**

Explain that no one knows whether the participant will feel any better during or after the study, and that they may even feel worse. If this is a study with no prospect of therapeutic benefit, this section may be omitted.

**Sample wording**

*No one knows whether or not I will get better by being in this study, and I may get worse. The study doctors hope that I will get better, but they cannot tell me that I will get better.*

**WHO WILL KNOW I AM IN THIS STUDY?**

Instead of the standard FHREB wording for confidentiality, use simpler wording that conveys the core ideas. Explain that any information collected about the participant will be kept private and that only their parent(s)/guardian(s) and study doctor(s)/investigator(s) will know they took part.

**Sample wording**

*All information collected about me in this study will be kept secret, and only my study doctor and parents/guardians will know I am in it. When the study is finished, the doctors will write a report about what was learned. This report will not say my name or that I was in the study.*

**WHAT IF I HAVE QUESTIONS?**

Include a statement that the participant has been given time to think about the study, that they have had the opportunity to ask any questions they like and have heard satisfactory answers, and they understand they are encouraged to ask questions at ANY time. Clarify who they may ask and how.

**Sample wording**

*Before I say yes or no to being in this study, the study doctor has to answer any questions I have. If you join the study, I can ask questions at any time. All I have to do is tell the study doctor or my parents/guardian that I have a question. I can also call the study doctor at [****phone number in bold****] if I have questions or if this medicine makes me feel bad.*

**SIGNATURES**

* Include a statement that the participant will receive a signed copy of the assent form;
* Include an assent statement, such as "I*f I put my name at the end of this form, it means that I agree to be in the study called [Study Title]*”;
* Include a line for the participant’s printed name, signature, and date. No additional signatures from the Principal Investigator, parent/guardian, etc., are required, as they will have signed the consent form.
* The participant must be given a signed copy of the assent form.

In cases where the Assent Form is used as a discussion guide by the study team, but the participant is unable to sign the form, the signature page may be used by the study team to document the assent discussion did take place. The following section may be included for that purpose, but is not required if the participants will sign the form:

**Assent (for study team to complete)**

*I have discussed this research study with [Name of participant] using language which is understandable and appropriate. I believe that I have fully informed the participant of the nature of the study and its possible risks and benefits. I believe the participant understood this explanation and assented to participant in this study.*

*Person obtaining assent Signature Date*