Please note that this is a SAMPLE assent form. You must modify this form to ensure that it is applicable to your study. Assent should be about 2 pages with font size 12-14 point.

**TITLE OF YOUR STUDY**

**Assent Form for Children 7-17 Years Old** *[update the age range as appropriate]*

*First Name Last Name, Degree*, Principal Investigator (Researcher)
*Institution/Organization Name*

**Why are we meeting with you?**

We are doing a research study. A research study is when researchers/scientists collect a lot of information to learn more about something. *First Name Last Name, Degree* and some others are doing a study to learn more about *[state reason participant is being approached here]*.

* You can say "Yes" or "No" to being in this study.
* You can ask as many questions as you like before making a decision.

**Why is the study being done?**

The researcher wants learn more about *[explain the reason for the study here in simple terms – add a concise description of the study as needed to facilitate the child’s understanding]*.

**What will happen if I am this study?**

*NOTE TO INVESTIGATOR: Sample text appears below. Customize for your study. Be sure to:*

* *Describe what the child will be expected to do.*
* *Describe which part of the study is experimental.*
* *Describe all procedures using simple terms and explain any medical terms.*
* I will be in the study for *[state duration – e.g., 5 weeks, about 2 months, about 1 year)]*.
* I will come to the clinic *[or office]* about *[state number of study visits or encounters – e.g., 5 times].*
* The researcher will ask me about how I am feeling and *[describe other types of questions child may be asked here].*
* I will have a check-up. My heart, breathing, temperature and weight will be checked.

**Can anything bad happen to me the study?**

*NOTE TO INVESTIGATOR: Sample text appears below. Customize for your study. Be sure to:*

* *Explain any possible risks/discomforts to the child, using simple terms.*
* *State if something might be painful.*
* *Explain that if the child feels any discomfort or pain as a result of being in the study, they should inform their parents/guardians.*
* Answering some of the questions maybe upsetting to me, but the researcher expects that this would not be different from the kinds of things I discuss with family or friends.
* I may skip any questions I don’t want to answer, and I may end the interview at any time.
* I should tell the researcher or my parent or guardian anytime I feel sick or if any of the study tests hurt me.

**Will this study help me?**

Being in this study might not help me. But the researcher hopes to learn more about *[state what you hope to learn from the study]* so that it might help other children in the future. *[--OR—describe the possible direct benefit to the child, when applicable.]*

**Will anyone know I am in the study?**

*NOTE TO INVESTIGATOR: Sample text appears below. Customize for your study. Be sure to:*

* *Explain using simple terms that the child’s participation in the study will be kept secret, but if applicable, also explain that the researcher may share information about them with the study sponsor.*
* *For assent forms for very young children, this information may not be applicable.*

The researcher, my parents or guardians, and I will know that I am in this study. The researcher will share information collected about me during this study with the study sponsor and the people who help to make sure the study is being run according to plan. The study sponsor is the company helping to pay for this study. No one else will be told that I am in this study.

**What happens if I get hurt?**

*NOTE TO INVESTIGATOR: Sample text appears below. Customize for your study, and only include if there is greater than minimal risk. Be sure to:*

* *Explain using simple terms that the child’s parents or guardians have been told what to do if the child in injured during the study.*
* *For assent forms for very young children, this information may not be applicable.*

My parents or guardians have been given information about what to do if the I am injured during the study.

**Do I have to be in this study?**

* I do not have to be in this study, even if my parent or guardian wants me to be.
* I can say "No." No one will be mad at me. The researcher or my parents or guardians will still take care of me.
* If I say “Yes” now, I can change my mind at any time. I just have to tell the researcher or my parent or guardian that I want to stop. I don’t have to say why.

**Who can I talk to about the study?**

I can talk to my parents and the researcher about the study at any time and ask them questions at any time.

*For older children and/or adolescents add the following:*

If you have any questions about the study or any problems to do with the study you can contact the researcher: *[name of Principal Investigator]*. You can call them at [Principal Investigator’s phone number]. You can also call *[name]* at *[phone number]*.

If you have questions about the study but want to talk to someone else who is not a part of the study, you can call the Institutional Review Board (IRB) at 516-318-6877.

**YES**, I want to be in the study. (Fill in your name below.)

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Child: Print your name Sign your name (if able) Date

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Witness\*: Print Name Signature Date

Witness must be a third party unrelated to the subject
(\*Witness is only needed for greater than minimal risk study)

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Person Obtaining Assent: Print Name Signature Date