**Children’s Healthcare of Atlanta
Assent to be in a Research Study**

**Title:**

**Principal Investigator:**

Research Participant Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Research Participant Age: \_\_\_\_\_\_\_

Should the assenting child decline participation in this study, they the parent(s), legal guardian(s) cannot force the child to participate.

**1. Please select one:**

**☐ (< 6 years) NO ASSENT REQUIRED**
*Stop here -- completion of this form is not required.*

**☐ (ages 6-10) VERBAL ASSENT**
*The study and the treatment have been explained to this child in an age-appropriate manner. The child has asked questions, verbalizes understanding of the information, and provides verbal assent. Children ages 6-10 should not sign the assent document. The person obtaining assent should sign this form (page 2) to document that assent was obtained.*

**☐ (ages 11-17) WRITTEN ASSENT See attached Written Assent document.**
*Once the study and treatment have been explained to the child, he or she should be asked to sign the written assent document. If the process of signing is too intimidating, the consenter may document (here and in the medical record) that the assent as been obtained verbally. It is suggested that the written assent document be read to the child as part of this age-appropriate discussion.*

**☐ (any age) UNABLE TO PROVIDE ASSENT**
*If a child age 6 or older is too immature or otherwise unable to give informed assent, it is the investigator's prerogative to state the following:*In my opinion, this child cannot give informed assent. Reason(s):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Printed Name of Person Soliciting Assent:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_**

**Signature of Person Soliciting Assent Date Time**

**2. ALL SUBJECTS: Is subject postpubertal? Yes No Unsure**
Include any reproductive risks in the Risks section of the written assent document.
Initial here to indicate you discussed any reproductive risks with the subject \_\_\_\_\_\_\_, or initial here if there are no reproductive risks whatsoever for this study:\_\_\_\_\_\_

**Written Assent Document**

 (Limit to 1 page) REMOVE ALL THE INSTRUCTIONS IN RED BEFORE SUBMITTING
Required Language (In black; Do not alter or remove)

We are asking you to volunteer to be in a medical research study. The study is about briefly outline the purpose of the study. We are inviting you to be in the study because state why the child is being asked to participate.

Explain KEY study elements in BASIC language. The goal is to provide information that the child is interested in (usually what will hurt/feel bad, what is expected of them, GENERAL risks/benefits) and including them in the decision-making process. Detailed discussion of risks and potential benefit as would be done in the consent document is usually not appropriate, nor is discussion of issues of confidentiality, cost/compensation, disclaimers, contacts, etc.
You can refuse (say no) to be in this study. Your doctors or your parents cannot make you be in the study if you don't want to be in it.

The assent document should serve as a launch-pad for age-appropriate question/answer dialogue, with ample opportunity for the minor to ask questions and have them answered. Example language indicating this:

Your doctor will talk to you about what it means to be in a research study. You should ask your doctor all of the questions you have. You can ask any questions that you have about the study. If you have any questions later, you can call [insert study doctor’s telephone number] or ask next time. You can also talk to your parents about the study.

Be sure to address any reproductive risks (including infertility risks, risks to fetus, etc). Example language may include (modify to fit the study as appropriate. If there are no reproductive risks, you may remove the following paragraph): The treatment on this study could cause problems if you get pregnant (girls), or get somebody pregnant (boys). The treatment could/is likely to make it hard for you to get pregnant (girls) or get somebody pregnant (boys), even if you are trying to have children later. You should talk to your doctor/nurse/etc about these things too. While you are on this study you must not get pregnant or get somebody pregnant. Talk to your doctor about the different ways to prevent pregnancy.

Writing your name on this page means that you agree to be in the study, and you know what will happen to you. You can change your mind and stop being part of this study at any time. Even if you write your name on this paper, you can say no later. All you have to do is tell a parent or the doctor.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_
**Participant Signature/Printed Name Date Time**

***Only the child should write/sign name. If the assenting child is 10 years old or younger, the child should not sign this form.***

**Printed Name of Person Obtaining Assent:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_**

**Signature of Person Obtaining Assent Date Time**