Name of participant Age ­­­­

*Guidance for investigator (delete this section prior to use):*

* *This assent form is recommended for children ages 7-12 and/or cognitively impaired adults; however, it is the responsibility of the investigator to utilize the assent form that best facilitates understanding of the research for an individual participant.*
* *Delete all instructional text in red. Example language is included in this template, but the investigator should write this form in a way that best facilitates understanding for their participant population.*
* *Assent is not Consent, which means the federal regulations do not require all of the elements of consent be included in the form.*
* *It is acceptable to use pictures along with the text in this assent form.*
* *Please refer to the Children in Research FAQ page on the HRPP website for additional information and guidance.*

Below are the answers to some of the questions you may have. If you have any questions, please ask. You will be given a copy of this assent form.

1. **Who are we and what are we doing?**

*Example*: We are [ex: doctors, researchers] and we want to tell you about a research study we are doing. A research study is a way to learn information about something. We would like to find out more about [insert purpose of study in simple language]. We want you to be in the study because [insert name of medical condition or other reasons for inclusion].

1. **What will we do and how long will it take?**

*Describe the procedures and the duration of participation. Describe what will take place in a language that is both appropriate to the assenting individual’s maturity and age or comprehension.*

*Example*: If you decide to be in this research study and your [insert “parent or guardian” for children or “legally authorized representative” for adults with impaired decision-making capacity] agrees, this is what will happen [insert simplified explanation of study procedures].

*These are prompts that you can choose to include, if applicable*:

• We will [insert procedure(s) the study team will do].

• We will ask you to [insert procedure(s) the study team will ask the participant to do].

• You will be in the study for [insert amount of time].

1. **Do you have to be in this research study and can you stop if you want to?**

*Explain that the study is voluntary.*

*Example*: You do not have to be in this study if you don’t want to. Being in this study is up to you. No one will be upset if you don’t want to do it. You can take your time to decide. You can talk to your [insert “parent or guardian” for children or “legally authorized representative” for adults with impaired decision-making capability] before you decide. Even if you say yes now, you can change your mind later and tell us you want to stop.

1. **Will any part of this study hurt you?**

*Describe any risks to the assenting individual that may result from participation in the research. Risks should be explained in a language understandable to the assenting individual. However, the investigator should not minimize the actual risk by using simple language. For example, a bone marrow aspiration should not be described as a “poke”.*

*Example*: There is a chance that during this research study you could feel afraid, uncomfortable, or hurt.

*Example (additional text if applicable):*

• You could [insert risk, e.g. get a bruise, get an upset stomach, throw up, feel dizzy, etc.].

• The questions we ask might make you feel [insert risk, e.g. embarrassed, sad, uncomfortable, etc.].

• The [insert procedure] may hurt.

We will try to help you feel better if any of this happens. You can stop at any time if you want to.

1. **Will anyone know that you are in this research study?**

*Explain how the records will be kept confidential.*

*Example*: People doing this research will be able to see the information about you from this research study. We will talk about this information with you, your doctors, and your parents.

*Optional Language For instances where the child may harm him/herself*: If you tell us that you want to hurt yourself, we will tell other adults who may be able to help you feel better.

1. **How will this research help you or other people?**

*Describe any benefits to the assenting individual from participation in the research. Describe any benefits to society from the research.*

*Example for studies with the prospect of direct benefit:* We think being in this study may help you. It is possible that we could learn something to help other children with [insert subject matter of study or medical condition] some day.

*Example for studies with no prospect of direct benefit:* This study may not help you. Your being in this study may help us learn something to help other children with [insert subject matter of study or medical condition] some day.

1. **What if you have questions?**

*Example:* It is okay to ask questions. If you don’t understand something, you can ask us. We want you to ask questions now and anytime you think of them.

Date Signature or printed name of patient/volunteer

Assent obtained by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature Printed Name and Title