**INSTRUCTIONS FOR DRAFTING AN ASSENT FORM FOR MINOR PARTICIPANTS**

This Assent form template is designed for studies that will obtain oral or signed assent from minor participants.

This is a Word Document; remove this instruction page and the all the instruction language as you complete your form. **When you type, choose black as your font color.**

As you draft your language, consider the following:

* Use simple words and short sentences. It’s easier for participants to digest single concepts than multiple concepts in a string. Itemizing using bullet points, images, or tables may also be helpful to the person obtaining the consent and to the potential participant.
* The language we’ve used is suggested, not mandated. Use language appropriate for your study population. Consider the age, maturity, and psychological state of the children you approach and adapt your language to their needs and abilities.
* Do not present information as a list of isolated facts.
* Think about what you, or one of your family members, would like to know if he or she considered joining the study.
* If your study involves study drugs, consider taking out the drug risks from the consent form and describing them on a separate form.
* Use good document control practices to identify your document and its current version.

**JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH**

**ASSENT FORM**

**Study Title:**

**Principal Investigator:**

**IRB No.:**

**PI Version Date:**

[Greeting/Personal introduction.] I am [Data Collector Name] from [Johns Hopkins/Collaborating Organization] and would like to talk to you about [topic of the study].

* We want to tell you about a research study we are doing. Research allows us to collect information from people to help us answer questions about health. We would like to find out more about <<insert purpose of study in simple language>>.
* You are being asked to join the study because you have/are <<insert name of medical condition or other reasons for inclusion>>. We hope to include about << insert number>> of other <<children/young people>> like you in this study.
* If you agree to join this study, you will be asked to << describe the study procedures in words a child would know and understand. Include number of visits and the time frame, if applicable.>>
* << Describe the risks of the study procedures in simple terms. Include all risks, including risk of pain (from a blood draw, for example), physical discomfort, emotional or psychological discomfort or distress, etc., and how you will try to minimize those risks. If you are collecting sensitive personal information that an adolescent’s parent might not know, assure the child that you will not share that information with the parent. Make clear in the parental permission form that you will not disclose to the parent information you may collect from the child.>>

For example, include language like the following if you are collecting sensitive information:

Some of the questions we will ask may make you uncomfortable. We will ask about <<insert description of questions that will give a good idea of the sensitivity of the topics.>> You may skip any questions you want or take time thinking about your responses. We will keep your answers private and will not share them with your parent/guardian.

* <<Describe any direct personal benefit a participant may get from participation, and other reasons why a child might want to participate. If no direct personal benefit is possible, use something like the following language: This study will not help you, but we hope to learn something that will help other children with [insert name of medical condition or subject matter of study]>>.
* You do not have to join this study. It is up to you. You can say okay now, and you can change your mind later. All you have to do is tell us. No one will be mad at you if you change your mind.
* Do you have any questions?
* Would you like to join the study?

<<Include if you want the minor participant to sign the Assent Form>>

If you want to join this study, please sign your name. We will give you a copy of this form to keep for yourself.

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