**LSUHSC-NO ASSENT FORM (Ages 7-12) TEMPLATE**

**Instructions for Using the Template**

ONLY USE THIS TEMPLATE WHEN RESEARCH **IS NOT** TAKING PLACE AT CHNOLA. IF CHNOLA IS INVOLVED, USE THE JOINT ASSENT TEMPLATE.

Assent is required to provide potential participants between the ages of 7 and 12 with the information necessary for them to make a decision about participating in research. Use of this template, and the instructions provided below, will help you create an assent document that is organized and written to facilitate comprehension by potential participants. It also will speed up IRB review and approval of your assent form. If you submit a new or revised assent form that does not comply with these instructions, your submission may be returned without review.

**General Instructions**

* Unless otherwise indicated, all sections of this template are required. If necessary, you may insert additional sections not included in this template.
* **DO NOT** change existing text of title, header & footers, headings, subheadings, signature blocks, and the information for contacting the Office of the Chancellor.
* Specific instructions for completing the form are in **blue** or **red** text. In general, **blue** text references required information. **Red** text references information that may or may not be applicable to your study or is otherwise optional.
* In each section, **black** text is suggested language. While not mandatory, we highly recommend using this language to maintain consistency across assent forms. This text is optimized for readability and grade-level comprehension.
* Insert the LSUHSC IRB # for the study and your assent version date in the header. Assent forms must have the IRB #, a version date, and page numbers.
* Before you submit your assent document to the IRB, delete the instruction pages.Delete all **blue,** **red** and yellow-highlighted text before finalizing the document. The font color of the finished consent document should be black. The finished document should reflect what you will give to the subject.

**DELETE THE INSTRUCTION PAGES FROM THE CONSENT FORM PRIOR TO SUBMITTING TO THE IRB**

Louisiana State University Health Sciences Center - New Orleans

Research Assent Form

**STUDY TITLE:**

**RESEARCHER:**

****What is a research study?

A research study helps us learn new things. Research helps us test new ideas. First we ask a question, and then we find an answer.

This paper will tell you about the research study and the choice you have to take part in it. You can ask questions at any time.

**Important things to know**:

* You get to decide if you want to take part
* You can say “No” or you can say “Yes”
* No one will be upset if you say “No”
* If you say “Yes” now, you can say “No” later
* You can say “No” at any time

****Why are we doing this study?

[Insert name and degrees of the Principal Investigator] is doing this study to find out more about [briefly explain in lay language of why the study is being conducted].

****Why should I be in this study?

We are asking you if you want to be in this study because you have [insert disease or disorder]

****What will I have to do if I join this study?

**INSTRUCTIONS:** Create a list of items in age-appropriate terms. Only list procedures/items for which assent is required.

If you decide to be in the study, we will ask you to do the following:

* [a brief description of what will happen to the study participant]

****Could bad things happen if I join this study?

Some of the tests might make you uncomfortable or the questions might be hard to answer. We will try to make sure nothing bad happens.

**[Include if a blood draw will occur]** You might feel a pinch when we test your blood. Sometimes the needle can leave a black and blue mark called a bruise.

Remember, you can say “no” when we ask you to do something and we will stop.

****Could the study help me?

**INSTRUCTIONS:** Include one of the two following statements.

We think being in this study may help you because [provide a fair, reasonably detailed and easily comprehensible description of any potential direct benefits to participants from taking part in this study; use bullets and numbering where appropriate. Incentives such as monetary compensation should not be mentioned here].

**[OR]**

This study will not help you. We do hope to learn new things from this study that may someday help other kids who have [insert disease or disorder] like you do.

****What else should I know about this study?

If you do not want to be in the study, you do not have to be.

It is ok to say “yes” now and say “no” later. You can stop being in the study at any time. If you want to stop, please tell the researcher.

You can ask us any questions at any time. You can talk to [list research team contact name]. Take the time you need to make your choice.

Your Assent

If you want to be in the study after we talk, you will write your name below. We will write our name, too. This shows we talked about the study and that you want to be in the study.

A copy of this paper will be given to you and your parents or legal guardian after you write your name.

We will continue to take care of you if you say “yes” or “no.”

**Name of Participant:**

Being in this study is up to me. Whatever I decide, no one will be upset with me. I can tell my parents or the researcher “no” at any time.

(*To be written by child/adolescent*)

**Signature of Person Obtaining Consent:**

*I have explained the research to the subject and answered all his/her questions. I will give a copy of the signed assent form to the subject.*

Signature of Person Obtaining Assent Printed Name Date

**INSTRUCTIONS:** Include this signature block when you anticipate enrolling subjects who do not cannot read. **Otherwise, delete.**

**Signature of Reader & Witness to Assent of Subjects Who Cannot Read:**

*The study subject has indicated to me that he/she is unable to read. I represent that the assent form was presented orally to the subject in the subject’s own language, that the subject was given the opportunity to ask questions, and that the subject has indicated his/her assent for participation by completing the signature line above.*

Reader Signature Printed Name Date

Witness Signature Printed Name Date