**LSUHSC-NO ASSENT FORM (Ages 13-17) 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:**

**PRINCIPAL INVESTIGATOR:**

**EMERGENCY CONTACT:**

What is a Research Study?

A research study is a scientific way to test new ideas or improve current methods. Studies are designed to answer specific questions on how to prevent, diagnose, or treat diseases and disorders.

**Research studies are voluntary and include only people who choose to take part.** The researchers will explain this study to you and this form will help you decide if you want to take part in this study.

**Important things to know**:

* You get to decide if you want to take part in this study.
* You can say “No” to taking part or you can say “Yes”
* Even if you say “Yes” to being in the study now, you can decide to say “No” at any time.
* No one will be upset with you if you say “No”
* If you have any questions, you can ask the researchers for more information.

Why is this study being done?

**INSTRUCTIONS:** Insert a concise (1-2 paragraphs) explanation of why the study is being conducted.

Why should I be in this study?

The research team is asking you to be in this study because you [describe in one sentence why the potential participant qualifies for this study].

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

**INSTRUCTIONS:** Provide a concise description of study procedures in enough detail to give a clear picture of what the subject will experience during the study.

**Before you begin the study**

Before you begin the study, you will be asked to:

* [explain any exams, tests, procedures, etc. that are required for screening or determining eligibility. Use bullets or numbering where appropriate].

**During the study**

If you say “Yes” to taking part in this study, you will be asked to:

* [provide a detailed description of what the subject will be asked to do in chronological order (what, when, where, how)].

Will it hurt me to be in 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 or hurts you.

**[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.

**[Include if treatment is involved]** Sometimes when a treatment is being tested, it can make people feel better or worse or just the same. Some of the ways the treatment might make you feel worse are:

* [provide a detailed description of known, possible side effects]

If any of these things happen, tell your parents or guardians right away. You or your parent or guardian should contact the research team.

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

Could it help me to be in this study?

**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 if I don’t want to be in this study?

**INSTRUCTIONS:** Use one of the three options below.

**OPTION 1**

The alternative is not to take part in the study.

**OPTION 2:** For studies that involve an intervention that might treat or improve a condition or a disease, include one of the following statements.

You do not have to take part in this study. At this time, however, there are no other options for treating [medical condition being studied].

**[OR]**

You do not have to take part in this study to be treated for [medical condition being studied]. Other treatments available for your condition include: [state other available treatments; use bulleted list when appropriate].

**[OR]**

There may be other ways of treating your condition if you do not want take part in this study. Check with your doctor to talk about other options.

**OPTION 3:** For non-clinical protocols where alternative actions are available:

You do not have to take part in this research study. Other options for you include [state other options such as private weight loss clinics, private counseling, special courses, etc.].

What else should I know about this study?

Taking part in this study is your choice. You are free to say “no” now or to at any time for any reason or no reason. If you want to stop, please tell the researcher. No matter what you decide, no one will be upset with you, and you will not lose any care you would normally have.

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

A copy of this form will be given to you and your parents or legal guardian after you sign your name. Your parents or legal guardian will also have to sign a form that explains the study. You doctor will continue to care for you whether or not you are in this study.

*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 research team “no” at any time.*

* *I have read this Assent Form*
* *I have been allowed to ask questions about the study and all my questions have been answered.*
* *I will be given a signed copy of this form.*

**Signature of Participant:**

*I agree to take part in this study.*

Participant Signature Printed Name Date

**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 consent form to the subject.*

Signature of Person Obtaining Consent Printed Name Date

 Time

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

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

*The study subject has indicated to me that he/she is unable to read. I represent that the consent 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 consent for participation by completing the signature line above.*

Reader Signature Printed Name Date

Witness Signature Printed Name Date