***Note (REMOVE THIS TEXT BEFORE SUBMITTING):***

* *Note: this template can be used in paper form or made into an e-consent document.*
* *Grey boxes with black text in brackets are to be completed.*
* *Red, italicized text in brackets is help text and/or a prompt for information that also must be included.*
* Orange text is optional, sample wording.
* *Do NOT delete the paragraph headings.*
* *Edit this document to reflect changes to research participant and relevant IRB requirements.*
* *If you are only notifying participants, remove the signature line. If you are reconsenting currently enrolled participants, include the signature line.*
* *With the guidance language removed, this template has the following readability scores:*
	+ *Flesch Reading Ease: 65.3*
	+ *Flesch-Kincaid Grade Level: 7.4*

# **Research Consent Addendum**

*[If for Parental/Guardian Permission]:*

“I/my/you/your” mean your child [the child].

*[If use of an LAR]:*

“I/my/you/your” mean the participant you are giving permission to join the study.

You have joined the research study titled,  [Study title] , by  [PI name] . You previously signed a consent form describing the goals of the study, what you are expected to do in the study, how long the study will last, risks/discomforts, benefits of participating, how your data will be used and protected, and contact information. Please refer to the copy of your originally signed consent form to review this and other research study information.

This form outlines the changes that have been made since you joined the study.

The decision to continue participating in this study is yours. You do not need to continue in the study and you may also leave the study at any time. If you choose not to continue or leave the study, there will be no penalty to you.

The changes are:  [outline all changes] .

**Signature**

I agree to continue participating in this research and allow my information to be used in this research. My questions have been answered. I will get a signed copy of this form.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_

Name of Adult Participant Signature of Adult Participant Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_

Name of Parent/Guardian Signature of Parent/Guardian Date

**Legally Authorized Representative**

I am making a decision on behalf of the research participant who signed above whether to participate in this research. My questions have been answered. I will get a signed copy of this form.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Signature of legally authorized representative (LAR) or healthcare proxy |  | Print Name and relationship to participant (when appropriate) |  | Date |

**Participant Medical Record Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Researcher Signature**

I confirm that the above information was thoroughly explained to the participant. I reviewed the information and answered all questions.  The participant appeared to have understood the information.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_          \_\_\_\_\_\_\_

Name of Research Team Member Signature of Research Team Member Date