# **Revised – March 01, 2021**

Patient name:

DOB:

MRN:

Physician:

TEMPLATE: Assent Form (For Children)

***Instructions:***

*“Italicized red writing” provides instructions and guidance on how to complete this template; it should be removed from the final documents*. *All studies should start with this template. If a sponsor or another entity has provided a template for multiple sites, the content is to be merged into this form and carefully revised/written for ease in reading, reading level, and comprehension. Do not duplicate content and all header sections are to be included in the final consent form(s).*

“Black writing**”** *is required language to be included in final documents.*

# **Adolescent Assent to Take Part in a Research Study**

**Title of research study:** *(insert title of study)*

**Principal Investigator:** *(insert name of Principal Investigator)*

**Sponsor:** *(insert name of Sponsor or, if no sponsor, insert Spectrum Health)*

This form is to tell you about a research study. Research studies help us learn more about conditions and develop new treatments. Taking part in a research study is your choice.

**Why is this research study being done?**

*Describe the main purpose of the study in simple terms.*

We are asking you to be in this research study because you have (*insert name of condition or other reason(s) for inclusion*).

*OR/And*

 We would like to find out more about (*insert topic and describe goals in simple language*).

**If I decide to join this research study, what will I have to do and what will happen to me?**

*Describe procedures in words a child would know and understand. Include the key research tests/procedures, the number of visits and overall time/duration of participation, Include a brief description of any optional procedures.*

If you join this study, you will be asked to:

* *Use of a bullet-list is encouraged.*

**Will anything good happen to me if I join this study?**

*Use any of the following statements that are appropriate:*

* We do not know if being in this study will help you.
* We expect that the study will help you by *(describe how).*
* We may learn something that will help other children with *(insert name of condition or topic under investigation)* some day.
* This study will help us learn more about *(topic under investigation).*

**What are the bad or harmful things that could happen to me if I join this study?**

*Outline the main risks or discomforts in simple language*.

*Include verbatim:* If you feel sick or are afraid that something is wrong when taking part in this study, tell your study doctor, nurse or an adult right away.

**Will I be paid if I join this study?**

*Use the appropriate statement below:*

If you decide to join this study, you will get $\_\_\_\_\_\_\_ (or get a \_\_\_\_\_\_\_\_) *insert the frequency and timing of all payments, gifts, or other compensation. If this compensation will be going to the parent, be sure to state this information.*

No, you will not be paid for your participation in this study.

**Do I have other choices for treatment than being in this study?**

*Describe any alternative procedures or treatments that might be available to other than this study*

*If treatment is included in this study, you may use:*

You do not have to be in this study if you do not want to. You may be able to have other treatments outside of this study. These treatments may be: *(list these other treatment options, in simple terms).* Your doctor will talk to you about these other choices for treatment.

**Will people know I am in this study or see my information?**

*Include the following information verbatim:*

Your family and your doctor, nurse and research staff will know that you are in this study.

We will do everything we can to make sure that your information collected about you during this study, and your medical records, are kept private. *Insert is applicable:* Some or all of the research information may be added to your medical record.

We may also share your research and health information collected during this study with other researchers. If anyone else is given information about you, we will not share any information that can identify you directly, such as your name. A number *(or initials*) will be used instead of your name. When we are finished with this study we might write a report about what was learned during this study. This report will not include your name or that you were in the study.

**What if I do not want to be in this study?**

*Include the following verbatim:*

It is your choice to join this study. If you say yes now, you can still change your mind later. No one will be mad at you if you don’t want to be in the study or if you join the study and change your mind later and stop. The doctor will tell you about new information that may make you change your mind about being in this study.

Before you say yes or no to taking part in this study, we will answer any questions you have. If you join the study, you can ask questions at any time. Just tell the doctor or nurse you have a question.

If you want to talk to someone else about this study, you can call the IRB office at (616) 486-2031 or email irbassist@spectrumhealth.org.

I have read about this research study and my questions have been answered.

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|  |  |  |
| Printed Name of Child |  |  |
|  |  |  |
| Signature of Child (printed name only is acceptable)  |  | Date of Assent |
|  |  |  |
| Printed Name of Person Obtaining Assent |  |  |
|  |  |  |
| Signature of Person Obtaining Assent |  | Date |