CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title ________________________________

Principal Investigator _______________________

IRB number ________________________________

“You” refers to you, your child, or someone who you are acting in their best interest.

Before you agree, the researcher(s) must tell you about:

1. Why they are doing the study
2. How long will the study take
3. About all of the procedures you would have
4. About the procedures that are experimental
5. Any risks or discomforts they know about
6. Any benefits (good things) for you or other people
7. Any other procedures or treatments you could try instead
8. How they will keep your information private and safe

When it applies, the researcher(s) will also tell you:

1. Any plans for payments and/or medical treatments if you are hurt because of the study
2. There could be risks to you that the researchers don’t know about
3. That the main researcher could take you out of the study even if you want to stay in it
4. Any extra costs to you for being in the study
5. Any new information that could change your mind about wanting to be in the study
6. How many people will be in the study
7. Who will use and share your information
8. What happens if you stop being in the study
9. About optional sub-studies
10. Any plans to use or share your health information

If you have questions about your rights as a study volunteer, or are unhappy at any time with any part of the study, you can call the Spectrum Health Institutional Review Board at (616) 486-2031. You do not have to give your name if you don’t want to. You may also contact __________________________ (study doctor) at ______________________ (office number) at any time if you have questions about the study or think you have been hurt by the study.
CONSENT TO PARTICIPATE IN A RESEARCH STUDY (CONTINUED)
Taking part in the study is voluntary. You have the right to refuse to volunteer for the study. There will be no penalty or loss of benefits to which you are entitled. You have the right to withdraw your consent and stop being in the study at any time. You will still have all the benefits that you normally would as a patient. If you agree to this study, we will give you a signed copy of this form. We will also give you a copy of the English version of the consent form.

STATEMENT OF SUBJECT OR SUBJECT’S LEGALLY AUTHORIZED REPRESENTATIVE
I agree that this research study and the above information have been verbally explained to me in my language and I willingly agree to take part in this research study.

DATE
Signature of Subject or Subject’s Legally Authorized Representative

Printed name of Subject or Subject’s Legally Authorized Representative

STATEMENT OF INTERPRETER
I declare that, to the best of my ability, I have accurately interpreted to/from the participant’s (study subject’s) stated primary language, __________________________ (specify language), everything said during the informed consent discussion.

TIME ______ DATE ______ Interpreter signature __________________________

Interpreter name (print) __________________________

STATEMENT OF WITNESS TO THE INTERPRETATION
I declare that I was present for the entire informed consent discussion and that, to the best of my ability, everything said during this discussion was accurately interpreted by the Spectrum Health-appointed interpreter to/from the participant’s (study subject) stated primary language: __________________________ (specify language).

DATE
Signature of Witness to the Interpretation

Printed name of Witness to the Interpretation

NOTE: Reference the English version of the informed consent form to see documentation of “person obtaining consent”.

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