**St. Luke’s University Health Network**

**Informed Consent Document for Human Subjects Research**

**Parental Permission**

**Department**:

**Principal Investigator**:       **Telephone**:

**Co-Investigator(s)**:       **Telephone**:

**Medical Study Title**:

**Lay Study Title**:

**Sponsor:**

**Instructions (REMOVE HIGHLIGHTED SECTION AFTER READING):** The revised Common Rule requires that consent forms contain a concise presentation of key information. The intention of this section is to provide potential research participants with a better understanding of the project’s scope, including major risks and benefits, so they can make a more fully informed decision about whether to participate. This section should include a summary of the purpose of the study, duration of participation, major requirements of the study and any potential benefits. This section should also contain any significant risks of participating in the study. The information presented in this section may be discussed in greater detail later in the consent form.

Highlighted text in this template is intended to be edited or removed depending on the needs of an individual study. Please ensure all highlighted text has been addressed and the formatting is removed in the final version of your consent document. Submit the final consent as a word document to the IRB with a submission application.

This table has information about this research. Where it says “See Below”, there is more complete information later in this form. You and the research personnel will discuss this information so you can decide whether or not to take part in this research. Make sure you discuss your concerns and have all your questions answered before deciding to take part in this research.

**CONCISE SUMMARY**

|  |  |
| --- | --- |
| **Purpose** | The purpose of this research is explain the purpose of the study using conversational language. This should be a brief summary of the purpose of the study phrased so that the subject will be able to understand why they are a candidate for the study |
| **Voluntary Participation** | Your Child’s participation in the research is voluntary. You can consider how this research differs from standard medical care as well as the risks and possible benefits of participating. If you choose not to participate, there is no penalty and we will continue to treat you. |
| **Number of Participants** | About       (**add recruitment goal number**) people will take part in this research. |
| **Duration** | Your Child will be in this research study for about       (**insert duration of study**). |
| **Procedures (See Below)** | While your child is in the study, they will have different evaluations, tests and/or procedures which involve certain risks. These are described in more detail below this table.   * List the most significant research procedures that would affect willingness to participate * For most investigational product trials, the procedures listing can be limited to the use of/implantation of the investigational product (i.e. the element of the research that carries the most risk) |
| **Drugs/Devices (See Below)** | The drug(s) used in this study is/are:       (**insert drug name(s).** The device(s) used in this study is/are:       (**insert device name(s).** These drugs/drugs (choose one) involve certain risks. |
| **Risks**  **(See Below)** | Taking part in this study involves certain risks. There may be more or less risks depending on what group you are assigned to. In addition to the risks described in more detail below this table, there may also be risks that are not known at this time. |
| **Benefits** | (Describe the possible benefits. Do not overstate them).  -OR-  You may not personally benefit from taking part in this research, but other people may be helped by what is learned. |
| **Alternatives (See Below)** | Your child may have other options than taking part in this study. If the alternatives are brief, they may be included here, otherwise include them in the separate section for alternatives below.  -OR-  The alternative to being in this study is to not take part. |

**What Is Parental Permission?**

Your child is being asked to take part in a medical research study. As required by federal regulations, this research study has been reviewed and approved by an Institutional Review Board (IRB), a committee that reviews, approves and monitors research involving humans. Before you and your child can make a decision about whether to participate, your child should understand the possible risks and benefits related to this study. This process of learning and thinking about a study before you and your child make a decision is known as *informed consent* and includes:

* Receiving detailed information about this research study;
* Being asked to read, sign and date this consent form, once your child understand the study and have decided to participate. If your child doesn’t understand something about the study or if you have questions, your child should ask for an explanation before signing this form;
* Being given a copy of the signed and dated consent form to keep for your own records.

**What is the purpose of this study?**

***(Please be as brief as possible, use lay language, and do not cut and paste from the investigator brochure.)***

**How many individuals will participate in the study and how long will the study last?**

     patients will participate nationally/worldwide ***(delete the irrelevant one)*.**  We hope to enroll     patients at St. Luke’s University Health Network. Your child’s involvement in the study will last about      weeks.

**What will my child have to do during the study?**

***(Please be brief. Unless standard of care treatment/procedures are an integral part of the study, provide only brief descriptions of them and that the subject will be asked to sign a separate consent regarding standard tests/procedures if that is the case).***

**What are the risks or discomforts involved?**

***(If only risk is loss of confidentiality or psychological discomfort, indicate that and delete the remainder of this section***

**Are there alternatives to being in the study?**

Your child does not have to participate in this study.

# **HIPAA Authorization: How will privacy and confidentiality (identity) be protected ?**

Federal regulations require that certain information about individuals be kept confidential. This information is called “protected health information” (PHI). PHI includes information that identifies your child personally such as name, address and social security number, or any medical or mental health record, or test result, that may have this sort of information on it. The laws state that your child may see and review his/her St. Luke’s University Health Network medical records at any time. However, in a research study, your child may not see the study results or other data about the study until after the research is completed unless the study doctor decides otherwise.

If your child joins this study, the following individuals or entities may have access to your child’s PHI and by law must protect it. These include investigators listed on this consent form and other personnel of St. Luke’s University Health Network involved in this specific study, including the Institutional Review Board (IRB), and your child’s health insurance company (if necessary for billing for standard medical care). It may also be provided to other people or groups as follows: ***(Follow the instruction, and then delete all italicized language along with this prompt)***

* ***(If this is a study where PHI will be shared with researchers at other institutions, add “Researchers at (name of institution).” This applies to collaborative research and not to multi-center commercially sponsored clinical trials.)***

Your child’s PHI may also be shared with the following entities that, while not obligated by law to protect PHI, will protect it to the best of their ability: ***(delete any entities below that are not relevant and add any entities necessary)***

* ***(Insert name of sponsor)*** which is providing funds to St. Luke’s University Health Network to conduct this research
* The Food and Drug Administration (FDA)
* A Contract Research Organization (CRO) or other designated entity which has been hired by the sponsor to coordinate and/or monitor the study
* Sponsor collaborators and/or sponsor business partners
* A Data and Safety Monitoring Committee (DSMC),
* Research Monitors hired by the sponsor to oversee the study and review medical records to ensure study-related information is correct,
* With any person or agency required by law.

The following information will be provided to the study sponsor and other entities noted above:

##### **Study data for analysis:** *list any study data that may be shared**(e.g., lab results, imaging studies, questionnaire results)*

**Demographic data:** ***list any demographic data that may be shared*** ***(e.g. Race and Ethnicity if federally funded and include any other information that is relevant) )***

**Other:** ***(describe or delete if none– include photo, audiotapes, etc. if applicable)***

If your child develops an illness or injury during the course of your participation in this study, other PHI about treating and following the condition may be generated and disclosed as it relates to this study. Your child’s PHI may be used/disclosed 1) until the end of the research study **OR** 2) indefinitely. ***(Choose appropriate option.)***

Your child may quit the study and revoke permission to use and share your PHI at any time by contacting the principal investigator, in writing, at:       **(*insert name and address of PI*)**. If your child quits the study further collection of PHI will be stopped, but PHI that has already been collected may still be used.

The results of clinical tests and procedures performed as part of this research may be included in your child’s medical records. The information from this study may be published in scientific journals or presented at scientific meetings but your child will not be personally identified in these publications and presentations.

After your information is shared with others, like the sponsor, it may no longer be protected by the Privacy Rule. The people who receive this information could use it in ways not discussed in this form and could disclose it to others. The sponsor will use and disclose information about you only for research or regulatory purposes or to prepare research publications. In addition to using it for this study, the sponsor may reanalyze the study data at a later date or combine your information with information from other studies for research purposes not directly related to this study. When using the information in these ways, the sponsor may share it with other researchers, its business partners, or companies hired to provide research-related services. However, your name will never appear in any sponsor forms, reports, databases, or publications, or in any future disclosures by the sponsor.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, this Web site will include a summary of the results. You can search this Web site at any time.

# **Will my child benefit from being in this study?**

Your child may/may not ***(choose one)***benefit from being in this research, but we hope that what we learn may be helpful to future patients or society in general. Possible benefits from being in the study may include: ***(Please list additional benefits or delete the last sentence)***

# **Will my child be paid for being in this study?**

Your child will/will not ***(choose one)*** receive payment for your participation in this study. **(*If payment is involved, indicate how much for each visit and the total amount at the end of the study)***

You will be asked to provide a completed W-9 Form in order to receive payment. A blank W-9 will be provided to you along with this consent form to complete should you decide that you would like to participate in this trial and receive reimbursement. Your completed W-9 will be maintained by the St. Luke’s University Health Network Accounting Department as required by the IRS and our internal policies to release any payments.

Should study payments meet or exceed $600 in one calendar year, you will be issued a 1099 Form to report study payments as taxable income as required by the IRS. ***We do not foresee your participation falling under the reportable income parameters as there are only a total of***      ***study visits, thus the maximum you will be paid for your participation is $***

In addition, you will not be paid if inventions and/or patents are developed from the study results.

**Will my child be told about any new findings?**

Anything learned during the study, beneficial or not, that may affect your child’s health or your child’s willingness to continue in the study, will be told to your child and explained.

**Disclosure of Financial Interest**

***(If this is a sponsored study, complete the sentence below. If not, delete this section)***

The sponsor of this clinical study,       (insert sponsor name), is paying St. Luke’s University Health Network to conduct this study.

**Are there costs related to being in this study?**

***(Please list any associated costs.)***

# **Can my child be removed from the study or quit the study?** *(Please adjust wording in the paragraphs below if not a treatment or device study)*

Your child’s decision to participate in this research study is entirely voluntary. You and Your child have been told what being in this study will involve, including the possible risks and benefits.

Your child’s participation in this research project may be terminated by the study doctor or study sponsor ***(delete sponsor if not relevant)*** without your child’s assent for any reason that he/she feels is appropriate.  ***(You may also add specific circumstances for removal of a subject from the study)***

Your child may refuse to participate in this investigation or withdraw consent and quit this study without penalty and without affecting the ability to receive medical care at St. Luke’s University Health Network.

If your child withdraws from this study, your child may continue treatment with his/her St. Luke’s University Health Network doctor, or your child may seek treatment from another doctor of his/her choice.

Should your child decide to withdraw from the study, please be sure to inform the study doctor. Additional tests or procedures may be needed to ensure your safety. The study doctor will explain why these tests or procedures are necessary.

**CONTACT INFORMATION**

|  |  |  |
| --- | --- | --- |
| Telephone number for questions about your rights as a research participant | St. Luke’s University Health Network Institutional Review Board | ***610-776-4832*** |
| For questions, concerns or complaints about the research, or if you suspect a research-related injury | The Principal Investigator,  Dr.       (insert PI)  or any co-investigator listed at the beginning of this form | ***Insert telephone number*** |

**If your child experiences a medical emergency, go to the nearest emergency room or call 911. You may also contact your child’s own doctor or seek treatment outside of St. Luke’s University Health Network. If your child is having a non-emergency medical issue after normal business hours, you may contact (XXX-XXX-XXXX) and the 24/7 nursing care staff will assess your child’s situation. Please be sure to tell the doctor or his/her staff that your child is in a treatment protocol at St. Luke’s University Health Network.**

By your permission to allow your child to participate in this study, and by signing this consent form, you are not waiving any of your or your child’s legal rights.

**You affirm that you have read this consent form and have been told that you will receive a copy.**

**You also authorize the use and disclosure of your health information to the parties listed in the HIPAA authorization section of this consent for the purposes as described.**

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

Printed Parent’s Name Printed Childs Name

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

Signature of Parent Date

Name of Person Conducting

Consent

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

Signature of Person Conducting Date

As defined in [SLUHN Policy IC 604](https://sluhn-my.sharepoint.com/personal/jayne_silva_sluhn_org/Documents/Documents/Desktop/Main_ICF_Template_%20Parental%20Permission_Assent%207-2025.doc#PolicyIC604) Child Assent for Participation in Research, “assent" means a child's affirmative agreement to participate in research. Failure to object without affirmative agreement cannot be construed as assent. The child must actively show his or her willingness to participate in the research rather than just complying with directions to participate and not resisting in any way. The IRB shall make certain that adequate provisions are made for soliciting the assent of the child when in the judgment of the IRB the child is capable of giving it. When the child is judged intellectually capable of understanding the parental permission form, the child should read the parental permission form and sign it rather than signing the Child Assent form. The child’s signature on the parental permission will then indicate his/her assent.

*(Delete paragraph and signature lines if the child will sign assent)*

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

Printed name of child Date

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

Signature of child

As defined in SLUHN Policy IC 604 Itis acknowledged that some children who are adolescents (15-17 years of age) should be able to adequately comprehend the information in the Parental Permission Form for the study, and so with the concurrence of the parent(s) may also sign and date that document. The child’s signature and date on the parental permission would then indicate his/her assent.

*(Delete paragraph and signature lines if the child will sign assent)*

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

Printed name of child

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

Signature of child Date