PURPOSE:

The ethical conduct of clinical investigations is based upon the voluntary consent of the subject who has been appropriately informed about a study's risks and benefits. It is the responsibility of the investigator to ensure that all federal and state regulations have been met through the language of the informed consent document, and that informed consent itself has been properly obtained from the subject or the subject's legal representative. Documentation of the informed consent process is required to establish that the subject was accurately and adequately informed and that no study-related procedures were initiated prior to obtaining informed consent.

This standard operating procedure (SOP) describes the steps for fulfilling the regulatory and ethical requirements for appropriately obtaining the subject's informed consent. It applies to obtaining consent under general requirements or routine circumstances, as well as identifies the specialized procedures for obtaining informed consent from subjects who do not speak English and from children. This SOP also specifies the conditions for exceptions from the general requirements for obtaining informed consent and for emergency research, as well as reconsenting already enrolled subjects.

DEFINITIONS/ABBREVIATIONS:

- **Central Institutional Review Board (CIRB):** The CIRB Initiative is a partnership between the NCI CIRB and local institutions based on the signed Authorization Agreement and Division of Responsibilities document. The CIRB conducts all IRB reviews of selected NCI-sponsored trials.
- **Clinical Research Nurse/Coordinator (CRC):** Clinical Trials staff responsible for oversight and coordination of assigned protocols
- **Clinical Research Organization (CRO):** An organization that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.
- **Clinical Trials Office (CTO):** Centralized clinical trials staff, responsible for the conduct and support of SLUHN clinical trial functions
- **Electronic Medical Record (EMR):** A digital/electronic version of a paper chart and documents that contain all of the patient's medical history.
- **Epic:** An integrated electronic health record system utilized by St Luke's University Health Network (SLUHN) to support functions related to patient care.
- **Good Clinical Practice (GCP):** A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of research that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of subjects are protected
- **Health Insurance Portability and Accountability Act (HIPAA):** A rule that provides subjects with federal protection and rights with respect to their individually identifiable health information while permitting entities the disclosure of health information needed for patient care.

- **Informed Consent Form (ICF):** IRB approved form outlining all aspects of a clinical trial in lay language, signed by the subject consenting to participate.
- **Institutional Review Board (IRB):** Independent ethics committee formally designated to approve, monitor, and review biomedical and behavioral research involving human subjects.
- **Legally Authorized Representative (LAR):** Legally authorized representative (LAR) means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research (45 CFR 46.102(c)).
- **National Clinical Trials Network (NCTN):** A group sponsored by the National Cancer Institute to allow members to participate in large national studies.
- **Principal Investigator (PI):** Lead investigator, responsible for the sound conduct of the project in accordance with the protocol and regulations.
- **Research Finance Compliance Analyst (RFCA):** Clinical Trials Office staff member responsible for the overall day to day pre and post-award financial operations of SLUHN industry or grant funded clinical trials.
- **Standard Operating Procedures (SOPs):** Detailed, written instructions to achieve uniformity of the performance of a specific function.
- **St. Luke's University Health Network (SLUHN)**

SCOPE:

This SOP applies to those members of the clinical research team involved in obtaining informed consent from research subjects, and those responsible for the oversight of the policy. This includes the CRC, Sub-Investigators, Clinical Trial Managers, Director of Clinical Trials and Research, and Principal Investigator.

This policy describes the process:

- Starting from the time that a patient may be eligible for a clinical trial
- Ending after a patient signs informed consent and all proper documentation has been completed

This policy is applicable to:

- Industry Funded clinical trials
- NCTN clinical trials
- Government funded clinical trials

PERSONNEL RESPONSIBLE:

This SOP applies to the CTO personnel involved in the informed consent process of clinical trial subjects, as well as clinicians and the PI.

ROLES:

The following information describes which areas and associated roles that shall adhere to this policy:

- **PI:** The PI shall be responsible for the overall oversight of the trial.
- **Clinical Research Nurse/Coordinator (CRC):** The CRC shall be responsible for providing thorough study information both verbally and written to the patient and/or LAR, and consenting study subjects utilizing the current IRB approved ICF.
- **Clinical Trials Manager:** The Clinical Trial Manager shall be responsible for oversight of the informed consent process as it pertains to this SOP.
- **Director of Clinical Trials and Research or designee:** The Director of Clinical Trials and Research shall be responsible for the oversight of the CTO staff as it pertains to this SOP.
- **Sub-Investigator(s):** The Sub-investigators shall be responsible for the consenting of subjects as delegated.

PROCEDURES:

- All research personnel shall maintain integrity and compliance with all regulations and GCP guidelines.
- The CRC or designee shall provide subjects with the informed consent document(s), and any other pertinent study material approved by the IRB.
- The CRC or designee shall have a detailed conversation and review the ICF thoroughly with subject and/or LAR in the appropriate language and comprehension level, and answer an questions.
- The CRC or designee shall ensure all proper information is collected and documented in the study record and medical record ***(See Attachment C)***, and provide the subject with a signed copy of the ICF.
- The CRC or designee shall make a copy of the ICF for the medical record for upload to EPIC, and maintain the original signed copy in the research shadow chart.

INFORMED CONSENT PROCESS

Role	Step	Activity
CRC or designee	1.0	Review the current IRB approved informed consent form with the subject, in the subject's primary native language, by discussing all of the elements: provide an overview of the study, explain its purpose, procedures, risks and benefits, drug and comparative agent (if applicable), alternatives, research-related procedures, etc. so the subject is able to make an informed decision about participation.

		NOTE: ICF shall contain all required elements per FDA regulations, and shall utilize the SLUHN ICF template (***See Attachment A***). *Exception:* CIRB studies will utilize the NCI consent and HIPAA. **NOTE:** If the subject does not speak English, please either have the entire ICF translated into the subject's native language using the current SLUHN translation service, or utilize the SLUHN Short Form Consent as referenced in Steps 2.0 through 2.9. **NOTE:** If the subject is unable to give written informed consent, provide the above information to the subject's LAR per local law, and utilize the Surrogate Consent ***(See Attachment B)*** in addition to the main study consent. **NOTE:** Subjects shall be reconsented once able to provide informed consent on their own behalf. If they decline, they shall be withdrawn from the study.
CRC or designee	1.1	Allow the subject or LAR sufficient time to read the document and ask questions. Encourage input from family members and other care providers, if appropriate. **NOTE:** This process shall be documented in the patient's research shadow chart (***Attachment C***)
CRC or designee	1.2	Ensure that the subject or LAR signs and dates all pertinent ICF(s), as well as the person obtaining consent.
CRC or designee	1.3	Review Teach-Back questions with subject or LAR and document responses.
CRC or designee	1.4	Provide the subject or LAR with a copy of the signed informed consents.
CRC	1.5	Maintain the original signed/dated ICFs in the research shadow chart.

CRC	1.6	Make a copy of the ICF with the patient's printed name and birthdate in the medical records bin for scanning into EpicMaintain the original signed copy in the research shadow chart.
CRC or designee	1.7	Obtain a signed and dated W-9 from the subject if payment during study duration is provided to the patient from SLUHN. **NOTE:** A signed copy of the W-9 is given to the RFCA, the Director of Clinical Trials and the manager along with the Requisition for Check.

INFORMED CONSENT USING THE SHORT FORM

Role	Step	Activity
CRC	2.0	Develop a summary of the study outlining all of the elements of informed consent: provide an overview of the study, explain its purpose, procedures, risks and benefits, drug and comparative agent (if applicable), alternatives, research-related procedures, etc.
CRC	2.1	Send the Short Form Consent template ***(See Attachment D)*** to the current SLUHN translation service provider for translation into the subject's native language if not already available.
CRC or designee	2.2	Obtain the translated Short Form Consent Step 2.1, along with a Letter of Authentication, and add study specific information (e.g. IRB # and PI info) to the translated Short Form Consent.
Regulatory Coordinator	2.3	Submit the study summary from Step 2.0, the translated Short Form Consent, and the Letter of Authentication to the IRB for approval.
CRC	2.4	Provide the current SLUHN translation service provider with the IRB approved study summary from Step 2.3
CRC	2.5	Utilize the language line phone to have the current SLUHN translation service provider verbally review the study summary provided to them in Step 2.4 in the subject's native language, allowing ample time for questions.

		NOTE: This process shall be documented in the patient's chart ***(See Attachment C)***
CRC	2.6	Ensure that the subject or LAR, as well as the person obtaining consent, signs and dates the short form, ensure that an impartial witness sign both the study summary sheet and the short form to document that the informed consent process was properly implemented, and ensure that the person obtaining informed consent signs the summary.
CRC	2.7	Provide the subject or LAR with a copy of the signed informed consent documents.
CRC	2.8	Maintain the original signed/dated ICFs in the research shadow chart.
CRC	2.9	Make a copy of the ICF for the medical record with the patient's printed name and birthdate, and place in the medical records bin for pick-up and scanning into Epic. **NOTE:** Maintain the original signed copy in the research shadow chart.
CRC	2.10	Obtain a signed and dated W-9 from the subject if payment during study duration is provided to the patient from SLUHN **NOTE:** A signed copy of the W-9 is given to the RFCA, the Director of Clinical Trials and the manager along with the Requisition for Check.

EXCEPTION FROM INFORMED CONSENT FOR EMERGENCY RESEARCH

Role	Step	Activity
Not Applicable	---	Exception from informed consent shall only be applicable to life-threatening conditions or emergency research and be approved by both the FDA and IRB.
PI or designee	3.0	Establish that a licensed physician not participating in this study, who is an IRB member or a consultant to it, determines that the clinical investigation cannot be conducted with prior informed consent from subjects for

		all the following reasons: • The subjects are in a life-threatening situation, where available treatments are unproven or unsatisfactory, and scientific knowledge gained from the study will be used to determine the efficacy and safety of the test article, • Informed consent cannot be obtained from the study subjects or LAR prior to initiating the experimental treatment, • The clinical investigation could not be carried out without waiver of consent.
PI or designee	3.1	Assure that risks to the study subjects are reasonable and subjects may directly benefit from the research study
PI or designee	3.2	Obtain community input prior to initiating the study.
PI or designee	3.3	Ensure there is an independent data monitoring committee to oversee the study.
PI or designee	3.4	Make every attempt to obtain informed consent from the subject or LAR, when feasible, and document all attempts to do so.
PI or designee	3.5	Ensure that family members have been afforded the opportunity to object to the subject's participation
PI or designee	3.6	Provide public disclosure of summarized results of study at the conclusion of the study.

WAIVER OF INFORMED CONSENT IN EMERGENCY SITUATIONS

Role	Step	Activity
PI or designee	4.0	Establish that informed consent cannot be obtained from the subject for ***all*** the following reasons: • The subject is in a life-threatening situation requiring the use of the test article, • Informed consent cannot be obtained from the study subject, • There is insufficient time to seek consent from the subject's legal

		representative, • No appropriate alternative therapy is available or recognized as being effective.
PI or designee	4.1	Obtain documentation from an independent second physician that the life of the subject is at stake and above requirements for Waiver of Informed Consent from Step 4.0 are applicable. **NOTE:** If time does not permit the independent judgment of a second physician and the life of the subject is at stake, administer the test article.
CRC	4.2	Provide the IRB with documentation from the investigator and the second physician from Steps 4.0 and 4.1 within 5 working days of the emergency use of the test article.
CRC	4.3	Notify the sponsor as soon as possible of the above actions.
CRC	4.4	Document all information in the subject's medical record and research shadow chart.

AMENDED INFORMED CONSENT PROCESS

Role	Step	Activity
CRC	5.0	Make a determination as to whether reconsenting of enrolled patients is necessary based on the revisions to the protocol/consent per institutional and IRB policies. **NOTE:** The SLUHN IRB requires reconsenting of patients only when the updates affect the risk versus benefit in the study and/or the changes affect the currently enrolled patients or their decision to continue with their participation ***(See SLUHN IRB Policies and Procedures: Policy IC 602)***. **NOTE:** If the updates are no longer relevant to patients then reconsenting is not required (e.g. if the patient is in survival follow-up). **NOTE:** If reconsenting is not necessary, any

		new information should be relayed to the patient and documented in the research chart at next patient contact.
CRC	5.1	Contact all subjects enrolled in the study to request that they sign the revised informed consent form, if applicable.
CRC	5.2	Review all changes to the study with the subject or LAR and allow sufficient time for them to carefully read the updated ICF and ask questions.
CRC	5.3	Review Teach-Back questions with subject or LAR and document responses **NOTE:** This process shall be documented in the patient's research shadow chart ***(See Attachment C)***.
CRC	5.4	Ensure that the subject or LAR, as well as the person obtaining informed consent, has signed and dated the revised informed consent. **NOTE:** Repeat Steps 1.3 through 1.6

INFORMED CONSENT OF MINORS

Role	Step	Activity
Not Applicable	---	In patients less than 18 years old, informed consent of the one or both of the subject's parents, or the subject's legally authorized representative, shall be obtained before enrollment.
CRC	6.0	Determine whether the study has the potential to enroll minors.
Regulatory Coordinator	6.1	Ensure the Informed Consent is written accordingly (e.g. in the format of Parental Permission) and that it contains the Children's Assent signature line for IRB approval.
CRC	6.1	Utilize the Surrogate Consent Form ***(See Attachment B)*** and follow all Steps outlined for obtaining Informed Consent ***(See Steps 1.0 through 1.6)***
CRC	6.2	Obtain the assent of the child if they possess the intellectual and emotional ability to

		comprehend the concepts involved in the study utilizing the assent signature line of the Main ICF.

RESOURCES:
45 CFR 46.102(c)
21 CRF 50.24
21 CFR 50.25
21 CFR 312.54
45 CFR 46.116
21 CFR 312.60
FDA Internal Compliance Program Guidance Manual, 1994; 7348.811: Clinical Investigators
FDA Information Sheets, October, 1998 Frequently Asked Questions, A Guide to Informed Consent Documents, Informed Consent and the Clinical Investigator, The Belmont Report and Declaration of Helsinki
May 9 1997 International Conference on Harmonisation; Good Clinical Practice: Consolidated Guideline

Endorsed by: SOP Committee (5/15/15; 4/8/16)
Approved by: Tracy Butryn, Director of Clinical Trials and Research (5/28/15; 6/29/16)

ATTACHMENT A

St. Luke's University Health Network
Principal Investigator:
Abbreviated Title:
Telephone:
IRB Control #:
Sponsor:
Page 1 of 12

St. Luke's University Health Network
Informed Consent/Assent Document for Human Subjects Research

Department:_____

Principal Investigator:_____**Telephone:**_____

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

Medical Study Title:_____

Lay Study Title:_____

Sponsor: _____

What Is Informed Consent / Parental Permission? ***(delete one or the other)***

You/Your child are/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/your child can make a decision about whether to participate, you/your child should understand the possible risks and benefits related to this study. This process of learning and thinking about a study before you/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 you/your child understand the study and have decided to participate. If you/your child don't/doesn't understand something about the study or if you have questions, you/you and/or 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.

(Delete the paragraph below if there is no therapeutic intervention or if only recruiting healthy controls)
You/Your child should understand that your/your child's relationship with the study doctor is different than your/your child's relationship with your/your child's treating or personal doctor. The treating doctor treats a specific health problem with the goal of improving a medical condition. A study doctor treats all subjects according to a research plan to learn about the experimental drug, device or procedure being studied and with the understanding that you/your child may or may not benefit from being in the study. You should ask questions of the study doctor and/or study team if you want to know more about this.

Version Number:
Version Date:

This prompt and the following section should be deleted for non-drug studies

The type of study you are being asked to join is known as a Phase _____ study. ***Insert 1, 2, 3 or 4 and pick the appropriate description. Delete the rest).***

A Phase 1 research study is one that determines the safe dose range and side effects of a new drug and how the body absorbs and gets rid of the drug. Phase 1 studies are done on small numbers of individuals, usually fewer than 30. Phase 1 studies are usually done on healthy individuals. Phase 1 studies of anti cancer drugs are nearly always done on patients with cancer. These studies are considered experimental and their treatment value is unknown.

A Phase 2 research study is done to get further information on safety, dosage, and side effects, and to collect preliminary information about how well a drug works for a certain disease. Phase 2 studies usually have very strict rules about who may and who may not be in the study. Phase 2 studies may compare the new drug to a placebo (inactive substance) or to a known treatment and usually enroll about 100 subjects.

A Phase 3 study is done on large numbers of individuals using the best dose as discovered in earlier phase studies. Phase 3 studies may compare a new drug to a placebo (inactive substance) or to other available treatments. There are usually strict rules about who may and who may not participate in the studies. Phase 3 studies may enroll hundreds or even thousands of subjects

A Phase 4 study is done after a drug has been approved by the Food and Drug Administration (FDA). Phase 4 trials find out how the new drug works and what are the side effects when used in the "real world" – that is in patients who may have other medical conditions in addition to the one the drug is designed to treat, and who may be taking other medications for these conditions. Phase 4 studies may enroll tens of thousands of subjects.

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?

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

What will I/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)

(Please ensure that risks are written in lay language and that they are in agreement with those listed in the Investigator Brochure or, if applicable, the package insert. If possible describe risks as "Likely" (10% or greater) "possible" (3-9%) and "Rare" (less than 2%. Please do not describe the risks of standard of care procedures or treatment if subject is signing a separate consent for these procedures).

You/your child should call the study doctor as soon as possible at XXX-XXX-XXXX if, during the course of this study, you/your child develop/develops any of these side effects or symptoms. The study doctor has told you that if your/your child's condition worsens, if side effects become very severe, or if it turns out that being in this study is not in your/your child's best interest, you/your child will be taken out of the study.

(Delete one or the other of the following sections related to pregnancy)

What are the risks to fetuses, infants and pregnant women? *(Delete the section below that does not apply)*

Pregnant women or women who are breast feeding should not be in this study because exposure to investigational drugs may be hazardous to an embryo, fetus or nursing infant. Even medications that are well known and prescribed may have adverse effects on an embryo or fetus. As with any medication, there are unknown risks. To be in this study you and your partner must practice adequate birth control measures. The study doctor will discuss acceptable methods of birth control with you. If you are a woman of childbearing potential, you will have a pregnancy test before making a decision about being in this study. This requires either a urine test or that blood be drawn from a vein in your arm (1-2 tsp.) prior to the start of the study and according to study guidelines. The results of this pregnancy test will be made available to you prior to the start of the study.

If you become pregnant during the course of this study, you should notify the study doctor as soon as possible.

If you are a man participating in this study, you also should practice adequate birth control because investigational drugs may have adverse effects on sperm that could also adversely affect a fetus. If your partner becomes pregnant during the course of the study, the sponsor may want to follow her through the pregnancy and receive information on the pregnancy outcome. She will be asked to sign a separate consent form or a form for release of medical information to collect this information.

If you are a person in a same sex relationship, it is not necessary for you to practice birth control. However, if you are female, you will still have to have pregnancy tests according to the study protocol.

What if my child is pregnant or becomes pregnant?

Pregnant women should not be in this study because exposure to investigational drugs may be hazardous to a fetus. If your child is a female able to have children (your child has menstrual periods), she will have a pregnancy test before making a decision about participating in this study. The pregnancy test requires that blood be drawn from a vein in your child's arm (about 1 tsp.) or that a urine sample be tested one or two days prior to the start of the treatment program. The results of the pregnancy test will be made available to your child prior to the initiation of this study.

Presently, your child is not pregnant and should not plan to become pregnant while participating in this study. Your child has been advised to routinely practice a medically-accepted method of birth control. Such methods will be discussed with your child by the study physician.

If your child is pregnant or breast feeding, she cannot participate in this study. Your child should not plan to become pregnant while participating in this study. If sexually active, your child should use effective birth control to prevent pregnancy while participating in this study. Where appropriate, the study physician will discuss issues regarding sexual activity and the use of effective contraception privately with your child. Results of any pregnancy test conducted during the course of the study will be made available to your child. By law, all minors have a right to confidentiality when discussing issues of pregnancy and contraception with a physician. While a desired outcome of these discussions is the sharing of this information with the family, the decision whether to do so is up to your child and alternative support will be provided to her when necessary.

If your child is a sexually-active male, he should also practice birth control measures since experimental drugs may have an adverse effect on sperm and therefore could also adversely affect a fetus.

(If the study involves a drug with known fetal toxicities (e.g., Thalidomide, Warfarin, Methotrexate, etc.) please list the known risks and also indicate that there are unknown risks to fetal exposure.)

Are there alternatives to being in the study?

You/your child do/does not have to participate in this study. ***(Delete everything that follows in this section if not a device, or therapy study)*** There may be other alternatives that could be considered. These alternatives would include: ***(Describe alternatives, such as standard of care, other experimental protocols, etc.).***

The study doctor will provide information about the study and any alternative treatments available to you/your child.

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 you/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 you/your child may see and review your/his/her St. Luke's University Health Network medical records at any time. However, in a research study, you/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 you/your child join/joins this study, the following individuals or entities may have access to your/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/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/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 you/your child develop/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/Your child's PHI may be used/disclosed 1) until the end of the research study **OR** 2) indefinitely. ***(Choose appropriate option.)***

You/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 you/your child quit/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/your child's medical records. The information from this study may be published in scientific journals or presented at scientific meetings but you/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.

What if I am/my child is injured as a result of being in this study? ***(Delete this section if no intervention and study is truly minimal risk)***

In the event that you/your child experience/experiences a research-related injury, necessary and available medical care (including hospitalization) will be provided. A research-related injury is a physical injury or illness resulting to you/your child that is directly caused by any procedure or treatment used in this study that is different from the treatment you/your child would receive if you/your child were/was not participating in a research study. If you/your child are/is physically injured due to any drug/substance or procedure properly given under the plan for this study, medical expenses for treating the injury will be billed to your insurance carrier. You should be aware that some costs may not be covered by insurance. ***(If a sponsored study, delete the preceding***

sentence and insert the following sentence. If not sponsored or if supported by a grant or NIH, delete the following sentence) Costs not covered by your insurance may be paid for by the sponsor of this study. There is no plan to provide compensation for loss of wages, lost time from work, personal discomfort, or for injuries or problems related to your underlying medical condition(s).

(If sponsored study insert the following sentence, if not delete it) If you have questions about the sponsor's agreement regarding payment for a research-related injury please discuss with the study doctor.

If you/you or your child receive/receives a bill related to a research-related injury that seems wrong, please discuss it with the study doctor or research coordinator.

Will I/my child benefit from being in this study?

You/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 I/my child be paid for being in this study?

You 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, and insert below language)*

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 I/my child be told about any new findings?

Anything learned during the study, beneficial or not, that may affect your/your child's health or your/your child's willingness to continue in the study, will be told to you/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, _____, is paying St. Luke's University Health Network to conduct this study.

Are there costs related to being in this study?

Research Procedures ***(Describe the procedures that are experimental)***

The investigational agent/device (choose one) will/will not *(choose one)* be provided by the sponsor free of charge ***(If not being supplied by sponsor, indicate how it will be paid for).*** ***(Delete the following sentence if it does not apply)*** In some research studies there are costs related to giving a medication or having surgery to implant a device and these may be billed to insurance. If that is the case, the study doctor will discuss this with you/your child before you/your child agree to be in the study. If a study drug or device becomes commercially available while you/your child are/is still in the study, you may be asked to purchase it yourself through insurance until the end of your/your child's participation in the study.

Standard Testing Procedures

Procedures, tests and doctor's charges resulting from being in the study that are considered standard of care will be billed to your/your child's health insurance carrier. These are charges that you/your child would have whether or not you/your child were participating in a research study. It is possible that your/your child's insurance company may deny payment. If that happens you/your child may be responsible for some or all of these charges. The study doctor will explain to you/your child which procedures, tests and doctor visits are considered standard of care.

If you/your child receive/receives a bill that you think is wrong, please discuss it with the study doctor or research coordinator.

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

Your/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/your child's consent/assent for any reason that he/she feels is appropriate. ***(You may also add specific circumstances for removal of a subject from the study)***

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

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

Should you/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	*Insert telephone number*
For questions, concerns or complaints about the research, or if you suspect a research-related injury	The Principal Investigator, Dr. _____ or any co-investigator listed at the beginning of this form	*Insert telephone number*

By your agreement/your permission to participate/allow your child to participate in this study, and by signing this consent form, you are not waiving any of your/ 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.

_____
Your Name *(please print or type)*

_____ _____
Your Signature Date

_____
Name of Person Conducting Consent

_____ _____
Signature of Person Conducting Consent Date

_____
Printed name of child (if "Child Assent")

_____ _____
Signature of child Date

TEACH-BACK FOR INFORMED CONSENT (GREATER THAN MINIMAL RISK STUDIES)

1. Is the drug or device used in this study FDA approved?

   YES _____ NO _____ DON'T REMEMBER _____

2. Do you have to be in this research in order to be able to receive your usual care?

   YES _____ NO _____ DON'T REMEMBER _____

3. Do you understand the risks of being in this study?

   YES _____ NO _____

4. Is there a risk(s) you would like to know more about?

   YES _____ NO _____

   If yes, what risk(s)

5. Is there a benefit to you from being in this study?

   YES _____ NO _____ DON'T REMEMBER _____

6. Are there other treatments you can get for your condition without being in this research study?

   YES _____ NO _____ DON'T REMEMBER _____

7. Will you be paid for being in this study?

   YES _____ NO _____ DON'T REMEMBER _____

8. Can you drop out of this study at any time for any reason and still receive care from the study doctor or your regular doctor?

   YES _____ NO _____ DON'T REMEMBER _____

9. Do you need to tell the study doctor or study staff if you are going to quit the study?

   YES _____ NO _____ DON'T REMEMBER _____

If patient is being reconsented due to changes in the study that may affect participation, please answer below questions in addition to the above:

1. Have the risks changed since your initial consent?

   YES _____ NO _____ DON'T REMEMBER _____

2. Have the requirements of participation changed since your initial consent?

   YES _____ NO _____ DON'T REMEMBER _____

3. Do you understand the changes that have been made since your initial consent?

   YES _____ NO _____ DON'T REMEMBER _____

ATTACHMENT B

St. Luke's University Health Network
Principal Investigator:
Abbreviated Title:
Telephone:
IRB Control #:
Sponsor:
Page 1 of 2

ST. LUKE'S UNIVERSITY HEALTH NETWORK
SURROGATE CONSENT FOR A RESEARCH PROTOCOL

Department: _____

Principal Investigator: _____ Telephone: _____

Co-Investigator(s): _____ Telephone: _____

Medical Title: _____

Lay Title: _____

Name of Subject: _____

COMPLETE SECTIONS "A," "B" AND "C" BELOW.

A. REASON FOR SURROGATE CONSENT:

Reason for Subject's Inability To Give Informed Consent:[1] _____

_____

B. SURROGATE INFORMATION:

_____ COURT ORDER AUTHORIZING GUARDIAN CONSENT

Date of Order: _____ Name of Guardian: _____

_____ POWER OF ATTORNEY Name: _____

_____ SPOUSE Name: _____

_____ PARENT Name: _____

_____ ADULT CHILD Name: _____

_____ ADULT BROTHER/SISTER Name: _____

_____ OTHER ADULT RELATIVE Name: _____ Relationship: _____

C. PATIENT'S ASSENT TO PARTICIPATE:

_____ The subject's assent to inclusion in the study was sought and obtained.

_____ The subject's assent to inclusion in the study was sought and denied.

_____ The subject's assent was not sought.

Reason for Subject's Inability to Assent: _____

_____

_____

Signatures:

_____
Name of Surrogate

_____ _____
Surrogate Signature Date

_____
Name of Person Conducting Consent

_____ _____
Signature of Person Conducting Consent Date

ATTACHMENT C

Documentation of Informed Consent Process for Clinical Research Study

Study title: _____

_____

_____

Patient Name: _____ Date of Birth: _____

This signed and dated document shall serve as certification that all of the below listed required elements of informed consent were provided to the subject or legally authorized representative signing the actual Informed Consent Document, both in written and verbal format.

The HIPAA consent is contained within the Informed Consent document, and has also been discussed.

A copy of the actual signed and dated Informed Consent has also been provided to the subject or legally authorized representative, and the original signed document shall be maintained in the research shadow chart.

Element of Informed Consent Discussed	Date	Initials/Person obtaining consent
A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental		
A description of any reasonably foreseeable risks or discomforts to the subject.		
A description of any benefits to the subject or to others which may reasonably be expected from the research.		
A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.		
A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records		
For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.		
An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.		
A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.		
A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable		
Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.		

Any additional costs to the subject that may result from participation in the research		
The consequences of a subjects decision to withdraw from the research and procedures for orderly termination of participation by the subject.		
A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.		
The approximate number of subjects involved in the study.		

The patient speaks, reads and understands English? ☐ Y ☐ N

If NO, Name of translator:_____

Translator speaks, reads, and understands English? ☐ Y ☐ N

Process utilized to obtain consent:_____

Subject meets eligibility criteria as outline in the current protocol?

☐ Y ☐ N

☐ N/A – Reason: _____

The protocol consent was reviewed with the patient and all questions were addressed and answered?

☐ Y ☐ N

The Informed Consent Teach-back section was reviewed with the subject and all questions and/or lack of understanding were addressed?

☐ Y ☐ N

The subject agreed to participate and the consent was signed and dated?

☐ Y ☐ N

Consent was obtained prior to any research procedures being performed?

☐ Y ☐ N

Date & Time ICF signed _____

Were any recruitment materials or advertisements used/discussed with the subject?

☐ Y ☐ N

If "yes" file a copy with the signed consent form and provide a copy to the subject

Certification of Person Conducting the Consent Process:

_____
Printed Name

_____ _____
Signature Date

ATTACHMENT D

St. Luke's University Health Network
Permission to Take Part in a Human Research Study
Short Form

You are being asked to take part in a research study.

Before you agree to take part, someone will explain to you:

- That the study involves research
- The purposes of the research
- How long you will be in the research
- What will happen to you
- What is experimental
- Risks or discomforts to you
- Benefits to you or others
- Other choices you might have
- Who will see your information
- You volunteer to be in a research study
- Whether or not you take part is up to you
- You can choose not to take part in the research study
- You can agree to take part now and later change your mind
- Whatever you decide it will not be held against you
- If you have questions, concerns, or complaints, or think the research has hurt you, you can talk to the research team at [Insert contact information for the research team]
- This research has been reviewed and approved by an Institutional Review Board. You may talk to them at 484-526-4944or medaffairs@slhn.org for any of the following:
  - Your questions, concerns, or complaints are not being answered by the research team
  - You cannot reach the research team
  - You want to talk to someone besides the research team
  - You have questions about your rights as a research subject
  - You want to get information or provide input about this research

When applicable, someone will explain to you:

- Whether you will get treated or paid if injury occurs
- The possibility of unknown risks
- When you may be taken off the research without your agreement
- Added costs from taking part
- What will happen if you stop taking part
- Steps to safely stop taking part
- When new information will be told to you
- The number of people expected to take part in the research
- That the Food and Drug Administration may inspect the records
- What happens to collected data if you stop taking part
- An explanation of www.ClinicalTrials.gov

[There are two signature pages attached to this template consent. Use the signature page or pages appropriate for your study. The IRB recommends that you make separate consent documents for each signature page to be used.]

St. Luke's University Health Network

Permission to Take Part in a Human Research Study

. Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process	Date
Printed name of person witnessing consent process	

St. Luke's University Health Network

Permission to Take Part in a Human Research Study

Signature Block for Adult Unable to Consent

Your signature documents your permission for the named subject to take part in this research.

_____
Printed name of subject

_____ _____
Signature of legally authorized representative Date

_____
Printed name of legally authorized representative

_____ _____
Signature of person obtaining consent Date

_____
Printed name of person obtaining consent

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

_____ _____
Signature of witness to consent process Date

_____
Printed name of person witnessing consent process