**Project Title:**

**Sponsor:**

**Principal Investigator:**

**KEY INFORMATION**

You are being asked to take part in this research study because you *[insert condition here]*.

* Research studies are voluntary and include only people who choose to take part. The purpose of this research is *[insert purpose here]*.
* The total amount of time you would be in this study is *[insert duration of subject**participation here]*.
* During your participation you will be involved in *[insert procedures participate will be asked to participate in].*
* Taking part in this research involves the following risks or discomforts: *[insert reasonable foreseeable risks or discomforts here]*.
* Taking part in this study includes the following benefits: *[insert reasonable expected benefits here]*OR *there are no benefits to you for taking part in this study****.***
* You have the alternative of not taking part in this study OR the alternative to taking part in this study is *[insert alternative procedures or courses of treatment that might be advantageous to the subject]****.***

Please read this consent form carefully and take your time making your decision. As the researcher(s) discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. Please talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

**Introduction/Purpose**

(Insert Introduction/Purpose Information)

**Study Procedures**

(Insert Study Procedures Information)

**Risks**

(Insert Risk Information)

**Benefits**

(Insert Benefit Information)

**Alternative to Study Participation**

(Insert Alternative Information)

**Financial Information**

(Insert Financial Information)

**Notice Regarding Information/Biospecimens**

This new element requires a notice about whether participants' information or biospecimens collected as part of the current research will be removed of identifiers and used for other research in the future.

**Confidentiality**

(Insert Confidentiality Information)

**Privacy Protected Health Information**

***[Required Language unless there is no collection of Protected Health Information or otherwise waived by the IRB]***

The researchers will protect your information, as required by law. Absolute confidentiality cannot be guaranteed because persons outside the study team may need to look at your study records. Your health information will be protected by a federal privacy law called The Health Insurance Portability & Accountability Act (HIPAA). By signing this consent form, you are giving permission for Saint Luke’s Health System to use and share your health information. If you decide not to sign the form, you cannot be in the study.

The researchers will only use and share information that is needed for the study. To do the study, they will collect health information from the study activities and from your medical record. Your medical records at Saint Luke’s Health System may contain information such as name, address, phone, date of birth, social security number, or other identifiers. Your health information will be used at Saint Luke’s Health System by Dr. \_\_\_\_\_\_\_\_\_\_, members of the research team, Saint Luke’s Health System Medical Record Department, the officials at Saint Luke’s Health System who oversee research, including members of the Saint Luke’s Health System Institutional Review Board and other committees and offices that review and monitor research studies.

By signing this form, you are giving Dr. \_\_\_\_\_\_\_ and the research team permission to share information about you with persons or groups outside Saint Luke’s Health System. Your information will be shared with representatives of \_\_\_\_\_\_\_\_\_\_\_ (*the sponsor of the study*), the monitoring company that inspects study data, the laboratory that processes study lab samples ***[if applicable],*** other business partners of the sponsor who help with the study, the Data Coordinating Center at \_\_\_\_\_\_\_\_\_\_ ***[if applicable],*** the study’s Data and Safety Monitoring Board ***[if applicable],*** the U.S. Food and Drug Administration (FDA) **and similar agencies in foreign countries *[if applicable]*,** and U.S. agencies that oversee human research (if a study audit is performed). These groups or agencies may make copies of study records for audit purposes. The purpose for using and sharing your information is to make sure the study is done properly and to evaluate the safety and effectiveness of [the study drug or device].

The HIPAA privacy law may not apply to everyone who receives your health information. Your information may not be protected by HIPAA if persons outside Saint Luke’s Health System disclose it. In some cases, there may be other laws that protect your information from improper use.

Your permission to use and share your health information will not expire unless you cancel it. Any research information that is placed in your medical record will be kept indefinitely. Your permission to use and share your health information remains in effect until the study is complete and the results are analyzed. However, you have the right to change your mind at any time and revoke your authorization. To revoke your permission, you must do so in writing by sending a letter to Dr.\_\_\_\_\_\_\_\_ at 4401 Wornall Road, Kansas City, MO 64111.

While you are participating in this study, you may see and copy any study information that is placed in your Saint Luke’s Health System medical record. However some study information is kept only by the researcher. The records kept only by the researcher may not be available to you until the end of the study.

***If applicable, include information in this section about any of the following:***

* ***Mandatory reporting of child abuse or neglect***
* ***Protections offered by a Certificate of Confidentiality and the limits of those protections***

The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

**Summary of your rights as a participant in a research study**

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed. In the event new information becomes available that may affect the risk or benefit associated with this study or your willingness to participate in it, you will be notified so that you can decided whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at Saint Luke’s Health System (SLHS) or elsewhere; however, SLHS has no plans to provide free care or compensation for lost wages.

**Disclosure of your study records**

Every effort will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The Saint Luke’s Health System Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possible foreign regulatory agencies may also review your records. If your records are reviewed, your identity could become known.

**Contact Information**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator (Insert Name of Principal Investigator) can also be contacted at (Insert Principal Investigator contact number). If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

If the researchers cannot be reached or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant’s rights; research-related injury; or other human subject issues, please call the Saint Luke’s Health System Institutional Review Board at 816-932-5019. You may also write the Saint Luke’s Health System Institutional Review Board at 4401 Wornall Road, Kansas City, Missouri, 64111.

**Signatures**

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form, will be provided to you.

**[Instructions for signature block: Once you find the signature block that applies to your study, delete the other signature blocks, except for the** *“study personnel”* **block. Be sure to delete the blue text as well]**

**[Use this for studies enrolling adults]**

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Signature of Participant Date

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

Printed Name of Participant

**[Use this for studies enrolling decisionally impaired adults]**

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

Signature of Participant Date

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

Printed Name of Participant

**[If participant does not have the capacity to consent and the protocol was approved for inclusion]**

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

Signature of Legally Authorized Representative (LAR) or next of Kin Date

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

Printed Name of Legally Authorized Representative (LAR) or next of Kin

If Next of Kin, please mark one relationship from list below (in descending order of priority):

Spouse Adult Child Custodial Parent Adult Sibling Adult relative (related by blood or adoption)

**[Use this for studies enrolling minors where the IRB has determined One Parent Signature is sufficient]**

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

Signature of Participant Date

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

Printed Name of Minor if used to obtain assent

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

Signature of Parent/Legal Guardian Date

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

Printed Name of Parent/Legal Guardian

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

If Legal Guardian, indicate relationship to child

**[Use this for studies enrolling minors where the IRB has determined that Two Parent Signatures are required]**

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

Signature of Participant Date

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

Printed Name of Minor if used to obtain assent

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

Signature of Parent/Legal Guardian Date

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

Printed Name of Parent/Legal Guardian

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

If Legal Guardian, indicate relationship to child

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

Signature of Second Parent Date

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

Printed Name of Second Parent

If unable to obtain second parent signature, indicate why: (*mark one*)

Deceased Unknown Legally Incompetent No legal responsibility for care/custody of child

**[Use this when a Witness will be included in the consenting process (Common examples include: inclusion of illiterate individuals or individuals who cannot physically sign but are able to provide informed consent.)]**

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

Signature of Witness Date

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

Printed Name of Witness

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

Signature of Person obtaining informed consent Date

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

Printed name of person obtaining informed consent