**Format**

* Use 10 point or larger font size with no more than 6 lines per inch.
* Use reasonable margins on all sides of the document.
* Include page number and total pages in the center of the footer (e.g., page 1 of 2).
* A “version date” in the bottom right corner is required.
* List only one Principal Investigator.
* HIPAA language (Privacy of Protected Health Information) is required.

**Language**

* Use simple language targeted at an 8th grade reading level.
* Avoid scientific and technical terms. When such terms are used, please be sure to define the terms.
* Define all acronyms prior to use.
* Consent forms written in the second person are preferred but use of first person is allowed.
  + *Pronoun use must be consistent throughout the consent document.*
* For studies enrolling children, please use the second person pronoun and include the statement:
  + “You/Your Child, hereafter referred to as You” at the beginning of the consent form.
* Use more than one consent form, if appropriate, and add a qualification to the title to identify the target population.
* Carefully proofread the consent form for typographical errors.

**Standard Research Consent Language**

The last four paragraphs of the consent document (Summary of Your Rights as a Participant in a Research Study, Disclosure of Your Study Records, Contact Information, Signature Block) is SLHS Standard Research Consent Language (SRCL) and is required on all written consent forms unless waived by the IRB. The **only investigator changes allowed** to the standard research consent language are the following:

* If the rest of the consent is written in first person.
  + *Pronouns must be changed to first person to match the rest of the consent form.*
* In the section “Disclosure of Your Study Records”, if the study is ***not being regulated by the FDA****,* you may delete the sentence:
  + “If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records.”
* In the section “**Contact Information**”, please insert the name and the phone number for the Principal Investigator as instructed in red.
* The signature lines that are appropriate for the consent form need to be selected from the signature block options listed at the end of the consent form.
* If you wish to enroll individuals who do not have the capacity to provide informed consent, please use the appropriate signature block.

Once the IRB has approved your consent document for use, you will receive a “stamped” version that will contain a stamp from the IRB indicating the IRB number and the expiration date of the document. Only a currently approved version will be used when obtaining written consent from subjects. Failure to do so may result in an allegation of non-compliance with human subject protections.

**CONSENT TEMPLATE GUIDANCE BY SECTION**

(Insert Header)

**Saint Luke’s Health System**

**Consent for Research**

**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 reasonably foreseeable risks or discomforts here]*.
* Taking part in this study includes the following benefits: *[insert reasonably 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.

**KEY INFORMATION**

(Insert the following if applicable)

1. *(PI Name)* will conduct the study and it is funded by (*Sponsor Name*). The sponsor of this study, *(Sponsor Name)*, will pay Saint Luke’s Health System (SLHS) to perform this research, and these funds may pay part of *(PI Name’s)*salary.

***OR (if relevant):***

1. A grant from [e.g., the National Institutes of Health (NIH), research foundation like the National Cancer Institute, etc.,] will sponsor this study. Portions of *(PI’s Name)* and his/her research team’s salaries will be paid by this grant.

**WHY IS THIS STUDY BEING DONE?**

(Insert **Introduction/Purpose** Information)

If subjects are to be enrolled, a statement must be included stating the approximate number of subjects to be involved in the study. If this is a multi-center study, indicate how many sites are involved, how many subjects will be included overall and how many will be included at this site.

***Example:***

*You will be one of [INSERT NUMBER OF PARTICIPANTS] participants enrolled in this research which includes [INSERT NUMBER OF SITES] sites in [INSERT LOCATIONS SUCH AS US, SOUTH AFRICA, BRAZIL, ETC]. Approximately [INSERT NUMBER OF PARTICIPANTS] participants from this facility will participate in this study.*

If applicable, the FDA phase of a drug study should be described in lay language. An indication of whether the drug(s)/device(s) used in the study are approved for use or still considered experimental or whether it may be an approved drug/device for an unapproved use.

***Example:***

* *The [INSERT NAME OF DRUG AND/OR DEVICE] being studied is experimental, which means that the U.S. Food and Drug Administration (FDA) has not approved it for use.*
* *The [INSERT NAME OF DRUG AND/OR DEVICE] being studied is approved for other uses but is not approved for use in [INSERT DISEASE/CONDITION]. [INSERT NAME OF DRUG AND/OR DEVICE] is considered experimental in this study.*

This section should also include a statement indicating that if any significant new findings develop during the course of the research, which may relate to the subject’s willingness to continue participation, the subject will be provided this information.

***Example:***

*There is a possibility that the investigators may become aware of new findings that may affect your willingness to continue participation. You will be informed of these new findings so that you may choose to continue or discontinue your voluntary participation.*

**How many people will take part in this study?**

If subjects are to be enrolled, a statement must be included stating the approximate number of subjects to be involved in the study. If this is a multi-center study, indicate how many sites are involved, how many subjects will be included overall and how many will be included at this site.

***Example:***

Approximately \_\_\_ people will take part in this study at \_\_\_ (*if multicenter, add number of hospitals/medical facilities)*different hospitals and medical facilities, and approximately \_\_\_\_ people will take part at [SLHS].

**WHAT IS INVOLVED IN THE STUDY?**

(Insert **Study Procedures** Information)

The Study Procedures section should provide a clear concise statement of what subjects will experience during their participation. All statements should appear in lay language, minimizing the use of medical or scientific terminology unless the sample population can be reasonably assumed to have familiarity with terms (i.e., subjects with recurrent or chronic disease will have greater understanding of medical terms related to that illness.)

Throughout this section a clear distinction should be made between what is standard care and what is added because of research participation. It should also clearly identify which procedures are experimental.

This section should begin with a statement indicating the total duration of the study and, if applicable, the number of visits involved.

***Example:***

* *As a participant in this study, you will be asked to come to the (indicate location) . . .*
* *Your participation in this study will last for . . . and will involve . . . visits.*

This section must include a detailed lay language explanation of the study design*.* Study procedures should be listed in chronological order. For complex studies the clarity of the procedure section can be improved if it is broken down into subsections such as: Screening, Baseline, Washout, Randomization, Study Intervention, and Follow-up Procedures. Review the protocol schema to ensure the consent form and protocol agree.

**Screening** (if applicable):

***Example:***

*At this visit, the following screening procedures will be performed to determine if you can take part in this study.*

**Baseline/Washout** (if applicable)

**Randomization/Study Intervention:**

***Example:***

*If you participate in this study, you will be assigned to a study group by chance using a process similar to the flip of a coin. This process is called randomization. Neither you nor study staff will select the group to which you will be assigned. However, this information can be obtained if you have a medical emergency.*

Explain and clearly describe the groups into which subjects are randomized. If the study involves a placebo or control group, also explain that (select appropriate option).

***Example:***

* *A placebo is an inactive substance containing no medication.*
* *Subjects in the control group will receive no investigational treatment but will be monitored by study staff*
* *Subjects assigned to the control group will receive the standard treatment.*

The consent should also provide an indication of the duration of each phase, visit or procedure of the study. This information should be reported throughout the procedure section as the procedures are described.

***Example:***

*This part of the study, (or this procedure) (this visit) will last approximately….*

When numerous visits are involved, they should be outlined using visit subheadings (e.g., Visit 1 [Pre-Screening], Visit 2 [Randomization] etc.) If the same procedures are repeated across a number of visits, the later visits can reference this by stating:

*The same procedures performed at visit \_\_ will be performed again at this visit.*

If blood is being drawn, include the amount in teaspoons, tablespoons, or ounces (1 teaspoon=5 ml, 1 tablespoon=15 ml, 1 ounce=30 ml). At the end of the Procedures section, list the total number of times blood will be drawn, the frequency of draw (e.g., at each study visit), and total amount.

***Example:***

*You will have (amount) of blood withdrawn (number of times drawn, and frequency). The total amount of blood drawn for the entire study will be (amount).*

**Follow-Up Procedures** (if applicable):

Include number of follow-up visits, (and/or phone calls) frequency, a description of what will occur, and time involved.

**Consequences of withdrawing or being discontinued from the research:**

(When Applicable, Insert Information)

If there are consequences related to a subject’s decision to withdraw from the research, or being withdrawn from the research, this section should include a statement describing the consequences and the procedures for the orderly termination of participation by the subject.

***Example:***

*If you withdraw from the study prior to its completion, you will be asked to return all study medication and, for your safety, come in for a final clinical visit in order to (specify exactly what will happen at this visit, i.e. questionnaire, interview, blood tests, duration, etc.)*

**STUDY PARTICIPATION RISKS**

(Insert **Risks** Information)

This section should include foreseeable risks and discomforts that may occur, as a result of participating in the research.

***Suggestions regarding how to present risks:***

* Use subheadings when there are multiple elements involving risks, (i.e., list the risks of each drug, device, or study procedure separately.)
* The risks of standard of care procedures that would be performed regardless of whether the subject chooses to participate in the study should not be listed in the consent form. However, some protocols intimately link investigational procedures with standard of care procedures. If standard of care risks are appropriate to include, clearly identify these as risks applying equally to standard treatment.
* The risk section should be ordered based on the likelihood of risks or the severity of risks. If the frequency is known for common risks, state the percent.
* Animal study risk findings should normally be excluded from the consent form but may be selectively included when relevant to the subject consent process. For example, when existing data for human studies are not relevant or informative, if the investigational drug or device has had limited exposure in humans, or if a new risk has been identified based on animal data.
* Emotional and psychological risks should also be addressed in the consent form.
* Breach of Confidentiality

The risks section should open with a clear statement of whether the study is associated with risk.

***Example:***

* *Your participation in this study does not involve any physical risk to you.*

***OR***

* *Your participation in this may involve the following risks…*

If there is the possible risk of emotional discomfort from dealing with sensitive issues or answering a questionnaire, this risk should also be included.

***Example:***

*Some of the questions may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and go to the next question.*

For studies involving placebo, discontinuation of current medication, or a washout period, include a statement that the subject’s condition may worsen while taking part in this study.

***Example:***

*Your condition may not improve or may worsen while you are taking part in this study.*

If the risks of an investigational drug are not fully established, or a novel medication combination is being tested, include this statement:

*We cannot predict all risks or potential side effects.*

If the study includes outpatient medications the following can be included:

*The study drug must be taken only by you. It must be kept in a safe place out of reach of children and other people who cannot read well or understand that they should not take it.*

***Use the following text for all studies***:

*Let your study doctor know of any questions you have about possible side effects. You can ask the study doctor questions about side effects at any time.*

Examples of potential risk or discomfort from Research Procedures (only list research-related procedures):

* *Blood Draws:*

*The insertion of the needle to draw blood is painful; however, the discomfort is usually brief. For most people, needle punctures to get blood samples do not cause any serious problems; however, they may cause bleeding, bruising, discomfort, infections, dizziness, or fainting.*

* *Bone Marrow Biopsy:*

*There are also risks associated with taking samples of your bone marrow. Your study doctor will insert a needle into your hip or breast bone to withdraw a sample of fluid containing bone marrow cells. The risks of bone marrow sampling commonly include discomfort, pain, redness, swelling, and/or bruising where the sample is taken from your hip or chest. Sometimes bleeding can occur at the place where the sample is drawn. Fainting and infection can happen, but rarely. Many patients also experience soreness or stiffness in the hips for several days after the procedure.*

* *CT Scans:*

*If you take part in this research, you will have one or more medical imaging studies which use radiation. The radiation dose we have discussed is what you will receive from this study only, and does not include any exposure you may not have received or will receive from other tests. The CT scan that you will receive in this study will expose you to low amounts of radiation. Every day, people are naturally exposed to low levels of radiation that come from the sun and the environment. This type of radiation is called “background radiation.” No one knows for sure whether exposure to low amounts of radiation is harmful for your body. However, scientists believe that being exposed to too much radiation can cause harmful side effects, including causing a new cancer. The amount of radiation that scientists think can cause harmful side effects equals more than 15 times the amount of extra radiation you would receive from being in this study. Also, scientists believe the number of people who would be at risk for developing a second cancer from being exposed to large amounts of radiation to be about 1 out of every 1,000.*

* *MUGA Scan:*

*During a MUGA scan, a small amount of a radioactive substance called a radionuclide (or radioactive tracer) is injected into your bloodstream. The injection of the radionuclide may cause some slight discomfort. Allergic reactions to the radionuclide are rare.*

* *Echocardiogram:*

*Uses sound waves to evaluate your heart. These high-frequency sound waves have not been shown to have nay harmful effects.*

* *Electrocardiogram (ECG):*

*Some people's skin reacts to the sticky patches that attach the electrodes to the chest for the ECG. This skin irritation usually disappears when the patches are removed. Some men may have some chest hair shaved.*

* *Magnetic Resonance Imaging (MRI):*

*If you take part in this research, you will have an MRI (magnetic resonance imaging and/or magnetic resonance spectroscopy). MRI uses a magnet and radio waves to make images (pictures) of the inside of the head and/or body. There have been no ill effects reported from exposure to the magnetism or radio waves used for these studies; however, it is possible that harmful effects could be recognized in the future. A known risk is that the magnet could attract certain kinds of metal that may cause injury to you. We will ask you about metal within your body (this includes certain dyes used in tattoos and body piercings). If there is any question about potentially hazardous metal within your body, you will not be able to participate in this research study. We will also keep the MRI room locked so that no one carrying metal objects enters the room while you are having this scan performed. In addition, the MRI scanner makes a loud buzzing noise that could affect hearing ability. You will be provided with earplugs and assistance in their use in order to protect your hearing. You will be able to communicate with the scanner technologist using an intercom and/or signaling device. The technologist will try to help you feel as comfortable as possible in the scanner. You can ask to stop the scan and be removed from the scanner at any time by using the intercom or signaling device.*

* *Contrast dye is used with MRI:*

*There is a very slight risk of an allergic reaction if contrast material is injected. Such reactions usually are mild and easily controlled by medication. If you experience allergic symptoms, a radiologist or other physician will be available for immediate assistance.*

* *Gadolinium-based:*

*Contrast agents (dyes) may increase the risk of a rare but serious disease called nephrogenic systemic fibrosis in people with poor kidney function. Nephrogenic systemic fibrosis triggers thickening of the skin, organs and other tissues. There is no effective treatment for this debilitating disease.*

* *Bone Scan:*

*A bone scan is a test that helps diagnose and track bone disease. A bone scan will be done when you first start the study. For a bone scan, you will receive an injection of a tracer into a vein in your arm. You will need to lie still on a table while a machine with an arm-like device supporting the camera passes over your body to record the pattern of the tracer being absorbed by your bones. This is painless. A scan of your entire skeleton will take up to 60 minutes. You may find the injection and the need to lie still during the scanning procedure mildly uncomfortable. The risk of an allergic reaction to the tracer is extremely rare.*

* *X-ray:*

*We are all exposed to radiation on a daily basis both from natural (sun and earth) and man-made sources that we call background radiation. The amount of radiation from an x-ray is lower than what you are exposed to through natural sources of radiation in the environment. The x-ray technologists and radiologists use the smallest possible dose of radiation and provide a protective lead apron when multiple x-rays are necessary.*

* *DEXA scan:*

*The amount of radiation from a DEXA scan is lower than what you are exposed to through x-rays.*

* *Biopsies:*

*Risks associated with biopsies include pain, redness, swelling, low blood pressure, excessive bleeding, bruising, or draining at the needle site, abnormal wound healing, fever, infection, and allergic reaction to the medication used to numb the skin over the biopsy site. Two to 3% of patients require hospitalization after a tumor biopsy. Rarely, an infection can occur.*

(If applicable, include: *“You will sign a separate consent form before the biopsy is taken. This will be a standard surgical consent form from the institution where the biopsy procedure takes place.”*)

*Risks specifically associated with lung biopsy are pneumothorax (collapse of lung), air embolus (air in a blood vessel), hemopericardium (blood around the heart), and lung torsion (twisting that interrupts the blood supply to the lung).*

* *HIV testing:*

*As part of this protocol, you will be tested for HIV (human immunodeficiency virus, which is the virus that causes the acquired immunodeficiency syndrome (AIDS). You will be notified of the results of the testing, and counseled as to the meaning of the results, whether they are positive or negative. If the test indicates that you are infected with HIV, you will receive additional counseling about the significance for your medical care and possible risks to other people.*

*We are required to report all positive results to the Missouri State Board of Health. The test results will be kept confidential to the extent permissible under the law. If you do not want to be tested for HIV, then you should not agree to participate in this study.*

* *Hepatitis testing:*

*The state of Missouri and applicable regulations require laboratories to report new cases of Hepatitis B, and Hepatitis C infection to governmental agencies. The reports may include the patient’s name, social security number, and other identifying information. Information about these new infections is used to track these diseases statewide and nationwide. Other than this required reporting, your results will be treated confidentially by the research study staff.*

* *Reproductive risks:*

*(If a subject is or may become pregnant during the course of the research, a statement must be included to inform subjects that the particular treatment or procedure may involve risk to the subject, or to the embryo or fetus, which are currently unforeseeable).*

*Participation in this study may involve risk that are currently unforeseeable due to the nature of this research. However, if any new risks become known in the future, you will be informed of them.*

*You should not get pregnant, breastfeed, or father a baby while in this study. The (specify intervention) used in this study could be very damaging to an unborn baby. Check with the study doctor about what types of birth control, or pregnancy prevention, to use while in this study.*

*(If males are potentially at risk for reproductive effects the following may be appropriate).*

*The treatment used in this study could affect your sperm and could potentially harm a child that you may father while on this study. If you are sexually active, you must agree to use a medically acceptable form of birth control in order to be in the study. Medically acceptable contraceptives include: (1) surgical sterilization, or a (2) condom used with a spermicide.*

*(If a study drug might interact with birth control pills, additional clarification should be provided and alternative birth control methods suggested).*

* *Risks from Pharmacogenetic Testing:*

*Risks of being in genetic testing include the misuse of personal, genetic information. All personnel who will have access to genetic information about you are ethically and legally obligated to maintain the confidence of that information. However, there can be no absolute guarantees. Although rare, misuse of such information has caused problems for persons related to their employment and/or their life and/or health insurance and other benefits or entitlements.*

**BENEFITS**

(Insert **Benefits** Information)

This section should describe any benefits to the subject or to others which may be reasonable expected from the research. This section should open with a clear statement about benefits to the participant. The second choice may be appropriate if the study includes a placebo group.

***Example:***

* *There will be no direct benefit to you by your participation in this research study.*

***OR***

* *There may be no direct benefit to you by your participation in this research in this research study.*

Any benefits that can be reasonably expected should be stated in a way that is not potentially coercive. Exclude any statements indicating that the subject may benefit from closer monitoring of their condition or free treatment. Do not include benefits that presume a positive answer to the study question.

***Example:***

*The potential benefits to you from participation in this study may include…*

Discuss potential future benefit to research/society (do not assume positive benefit).

***Example:***

*Your participation in this study may aid in our understanding of…*

Do not include statements regarding payments or reimbursement to subjects for their participation. This information should only be in the **Financial Information** section.

**ALTERNATIVE PROCEDURES/TREATMENTS**

(Insert **Alternative to Study Participation** Information)

This section should disclose any appropriate alternative procedures or course of treatment, if any, that might be advantageous to the subject. If there are no alternatives to participation this should be stated.

***Example:***

* *Because of the nature of this research the only alternative is to not participate in this study.*

***OR***

* *Currently, there are no other approved treatment/drugs for the treatment of your condition.*

List all alternative procedures or treatments that are currently available. Options should be listed in the consent form; it is not sufficient to say that the study doctor will discuss them with the subject. This section should state what treatments used in the protocol are available without participating in the study.

***Example:***

*If you do not wish to participate in this study, the following alternative treatments are available.*

**PAYMENT/COMPENSATION INFORMATION**

(Insert **Financial Information**)

This section should include a statement regarding any additional costs to the subject that may result from participation in the research. Costs that are research-related and those that are standard of care should be clearly identified. If the research procedures/devices/drugs used in the study might not be covered by a subject’s insurance, a statement should be added that advises subjects to contact their insurance provider to determine their level of coverage. *Payment for specific aspects of the study (i.e. drugs, devices, visits, testing, transportation, and standard care) should be made clear to the subject.* This section should open with one of the following statements:

* *There is no cost to you or your insurance for participation in this protocol.*

***OR***

* *The sponsor will cover the costs of the research that are not part of routine medical care. You or your insurance will be billed for the parts of the study that are standard medical care. Your insurance or government health program may not cover certain items if you are part of a research study. You may want to talk to your insurance company before deciding to participate.*

*Although study funds will pay for certain study-related items and services, we may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care.*

The second part of the Financial Information section should specify if subjects will be paid or reimbursed for their participation in the study.

***Example:***

* *You will receive* \_\_\_\_\_\_\_ *dollars for your participation in this research study. It will be paid (*specify the method of payment and when*). If you withdraw from the study, you will be paid for the portions that you completed, depending upon….*

***AND/OR***

* *You will be reimbursed for your transportation expenses, parking etc…*

If financial compensation is provided, the following ***must be in the consent form***:

*To receive payment you must agree to complete a W-9 form which requires you to provide an address and social security number to the accounting department. This payment to you may be considered taxable income by the IRS.*

If there is no payment for participation the following statement may be included, but is not required:

*You will not be paid for your participation in this study.*

For a research study that involves a reimbursement amount of $600 or greater in a year, insert the following statement:

*You will be issued a 1099-Misc form only if payment exceeds $600 from all studies in which you are participating, in a fiscal year.*

If commercial potential exists from the use of tissues, blood, or DNA, the following information may be appropriate:

*Allowing for the storage and future testing of tissue and blood samples will involve no cost to you. Your tissue will be used only for research and will not be sold. The research done with your tissue and blood may lead to the development of new products in the future. You will not receive, either now or in the future, any compensation, royalty, or any other financial benefit which might result from any product, procedure, or other items that may be developed from studying your \_\_\_\_\_\_\_\_ or any information or data that is derived from such research.*

**BIOSPECIMENS**

(Insert **Notice Regarding Information/Biospecimens**)

A statement that the subjects’ biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.

For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

**Information/Biospecimens Notice** (if applicable):

***Choose the statement that applies:***

* *That de-identified information or biospecimens could be used for future research without additional consent*

***OR***

* *That subjects’ information or biospecimens will not be used for future research*

**Research Results** (if applicable):

A statement regarding whether clinically relevant research results, including if individual research results will be disclosed to subjects, and if so, under what conditions.

**Research-Related Injury:**

Preferred language if the trial is interventional and/or there is a change that a subject may be injured as a direct result of study procedures.

If a study sponsor requests any changes to this Research-Related Injury section, the sponsor should be advised that such changes will delay or prevent approval of the informed consent form. Additional language related to discussion of payment for research related injury may not be added to other sections of the consent form. Injury language directly from a negotiated sponsor contract is not acceptable in this section. ***You must ensure that the option chosen is consistent with contract***.

Option #1 **Use this if any payment for injury will be provided:**

*If you become ill or are physically injured as a result of participation in this study, you should seek prompt medical attention. You may seek treatment at any medical facility. You should also contact the Study Doctor or the Research Nurses at (phone number).*

*If any injury or illness happens to you as a direct result of being in this study, the sponsor of this study will provide medical treatment at no cost to you. Treatment may include hospitalization, first aid, emergency care and follow-up care, as needed. Payments will not be offered for other expenses (such as time off work, lost wages, childcare, etc.) In no way does signing this consent form waive your legal rights nor does it relieve the Study personnel, Sponsor or involved institutions from their legal and professional responsibilities.*

*Option #2* **Use this if no payment for injury will be provided:**

*If you have a bodily injury as a result of participating in this study, treatment will be provided for you at the usual charge. Treatment may include first aid, emergency care and follow-up care, as needed. Claims will be submitted to your health insurance policy, your government program, or other third party, but you will be billed for the costs that are not covered by the insurance. In no way does signing this consent form waive your legal rights nor does it relieve the Study personnel, Sponsor or involved institutions from their legal and professional responsibilities.*

*To help avoid injury, it is very important for you to follow all study directions.*

*Option #3* **Use this for Greenphire payment cards:**

*You will receive ($$$$) per visit for being in the study. The money is to help with the cost of transportation and other expenses due to participation.*

*You will be given a ClinCard, which works like a debit card. After a study visit, payment will be added onto your card by computer. The money will be available within one business day. You can use this ClinCard at an ATM or at a store. No one at Saint Luke’s Health System will know where you spent the money.*

*You will be charged $4.50 per month after 6 months of no activity. No activity means no ATM transactions, no point-of-sale transactions or no funds being posted. \*\*After your participation in a study ends, you may want to use any available funds within 6 months to avoid this fee.*

*You will be given one card during the study. If your card is lost or stolen, please call the study team for information on how to obtain a new card.*

*The Office of Research Services (ORS) will be given your name, address, social security number, and the titles of this study to allow them to set you in the ClinCard system. Study payments are taxable income. A Form 1099 will be sent to you and the Internal Revenue Service if your payments are $600 or more in a calendar year.*

*Your personnel information will be kept one a secure computer. It will be removed from the computer after the study is over and the money on the card has been used. Your information will not be shared with other businesses. Every effort will be made to keep your information confidential.*

**Optional Text Messaging Service:**

This message service is provided by Greenphire. Not required, this would be up to the study team to decide if they wish to offer such to their subjects.

*You can choose to sign up for emails or text messages about the study. The messages will remind you about your study appointments and give you other information that might be helpful during the study. (You will pay your standard texting rate.) This message service is optional. You are not required to give your cell phone or email address in order to be in the study. If you decide to receive messages when the study starts, you can still change your mind later.*

CLINCARD   
I want to receive visit reminders by (check one):

Email\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (your email)

Text message\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (your cell phone number)

Not at all

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

(Clinic ID Number)

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

(Date / Time)

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(Printed Name of Individual Obtaining Consent)

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(Signature of Individual Obtaining Consent)

**GENETIC STUDIES**

(Insert **Genetic Testing** Information, if applicable)

Genetic research studies may create medical, psychosocial, and economic risks to human subjects and their relatives. Genetic studies present a wide range of issues, and the consent form needs to be individualized for each study.

In studies involving genetic testing, the following issues may need to be addressed:

* *Will test results be given to the participant?*
* *Will disease risk be quantified, including the limits on certainty of the testing?*
* *Will any change in a family relationship be disclosed, such as mistaken paternity?*
* *Does the subject or family member have the option not to know the results? How will this decision be recorded?*
* *Could other clinically relevant information be uncovered by the study? How will disclosure of this added information occur?*
* *Do any limitations exist on the subject’s right to withdraw from the research, withdraw data, and/or withdraw DNA?*
* *Is the subject permitted to participate in the study while refusing to have genetic testing?*
* *Will DNA be stored or shared? If shared, will the subject’s identity be known by the new recipient investigator?*
* *Will the subject be contacted in the future by the investigator to obtain updated clinical information?*
* *How can the subject opt out of any distribution or subsequent use of his/her genetic material if they sign the consent and participate in the study?*

The consent should state if the results of the genetic analysis done for the study will or will not be given to the subject.

***Example:***

*The results of the analysis of your DNA done as part of this study will (not will) be given to you.*

In family genetic studies the issues of paternity should be discussed.

***Example:***

*When the DNA is examined from members of a family paternity can be determined. It is the policy of Saint Luke’s Health System that paternity results are not disclosed to study participants. The only exception to this is if a court or other legal authority requires disclosure.*

Unless the samples are anonymous (no possible way to connect identifying data to the sample) or are limited to use only for the specific study question, the ***following options need to be included***:

*Your DNA (genes) or your cells that can be used to make your DNA will be stored for research purposes. Please check one of the following options telling us how your DNA samples may be used.*

* *My samples may be used for this project only. Do not use them for any other project and do not contact me again for permission.*
* *My samples may be used for this project only and for other projects with my permission. If my samples could be used for another project, contact me to ask my permission.*
* *My samples may be used for any scientific purposes involving this or any other project. Do not contact me again for permission.*

For studies where guidance about how to handle future genetic results could be important the following paragraph should be added to the previous paragraph:

*If you choose to allow your samples to be used for future research, please note that a genetic test not related to the current study could be developed and tested on your DNA. It is unlikely, but possible, that this test would give information that is important to your personal health. For example, a result could suggest that you have an increased likelihood of developing a serious disease. If this does occur, please choose one of the options below to tell us what you would like us to do with the information.*

* *Please try to contact me if information is discovered in future studies of my genes that would be important my personal health.*

❑ *Don’t contact me with any information obtained from future studies of my genes. (If a finding is made where we have a legal obligation to try to contact you, we will not be able to honor your request not to be contacted.)*

If the DNA samples are shared with investigators doing other projects (check box 3 above) the following paragraph is appropriate if the subject’s identity is not shared:

*We may share portions your DNA with other researchers working on different projects. If your DNA is shared with other researchers, your identity will remain anonymous to the other investigators.*

If the DNA samples are stored without identifiers but are not anonymous the ***following paragraph must be used***:

*Your DNA sample will be identified by a code number, and all other identifying information will be removed. \_\_\_\_\_\_\_\_\_\_\_ will keep a separate code sheet which links the DNA sample code number with your identity.*

If the DNA samples are stored for a long period of time including the following option may be appropriate:

*Your sample may be stored indefinitely. If in the future if you change your mind and would prefer not to have your DNA used for research you can contact [INSERT CONTACT INFO] and request that any existing samples linked to you be destroyed.*

If you want to make unequivocal that the subject does not have access to the stored sample this may be added to the above paragraph or stated on its own:

*You will not have access to your sample once it is donated.*

If the DNA samples are anonymous the ***following paragraph must be used***:

*Your banked DNA sample will not contain any accompanying information that could reasonably permit anyone to link the sample to you. Because of this, you will not receive any results or information from the research done on your DNA sample. You will not be able to withdraw consent for the use of your DNA sample after the DNA sample has been collected and entered into the DNA storage bank, because it will not be possible to identify your specific DNA sample.*

If the DNA samples are only used for this study and then destroyed or made anonymous the following paragraph may be used:

*Your DNA sample will only be used for the specific purpose described in this consent form. When the study is complete your sample will be destroyed (or, all identifiers connecting your identify to the sample will be destroyed.)*

If genetic studies are optional for study participants, include a yes/no option.

***Example:***

You can participate in this research study even if you do not want to have a sample taken for DNA (gene) studies. Please indicate below your choice.

❑ Yes, I want to have a sample for the DNA (gene) studies.

❑ No, I do not want to participate in the DNA (gene) studies.

For studies that focus on identifying abnormal genes that are clinically significant:

***Example:***

* Through this research, we may find that you have an abnormal gene which puts you at risk for developing [INSERT DISEASE OR CONDITION] at some time in the future. These results may also provide information about your entire family. Some people involved in genetic studies have felt anxious about the possibility of carrying an abnormal gene that places them at risk or that can be passed on to their children. If you have these feelings at any time during the study, you may contact the investigator(s) who will arrange for you to speak with a genetic counselor.

***AND/OR***

* The information obtained as a result of your participation in this research will not be included in your medical record. Information from which you may be personally identified will be maintained in a confidential, locked file at [INSERT LOCATION] and will not be disclosed to third parties except with your permission or as may be required by law.

If samples will be submitted to the National GWAS Repository for Genome Wide Association Studies, *use the following*:

***GENOME-WIDE ASSOCIATION STUDIES:*** *In addition to the use described here, coded information about your DNA (phenotype and genotype) will also be submitted to a national database maintained at the National Institutes of Health (NIH) by the study researchers. These coded samples will be shared with other investigators for future research purposes as part of this database. Neither NIH nor other researchers using the coded information will not be able to identify you.*

*If, at a future date you wish to withdraw your consent to allow use of your DNA information in this NIH GWAS database, you can contact [INSERT LOCAL OR COORDINATING RESEARCHER CONTACT- NOT NIH GWAS] to withdraw your information. This will remove your information for any future research. Any research that was conducted with your data prior to this request will be unable to be withdrawn and may still be utilized.*

*It is unlikely at this stage that any future use of your DNA would give the researchers any information about you or your specific condition. Therefore, there are no plans for you to receive any individual results from any future tests. If a future researchers find something very important about you or your condition, they may contact this study investigator with your code number and the results. The study investigator would then contact you regarding the results.*

**IN ADDITION:** Any study that is conducting genetic testing must include information about the provisions applicable under GINA. ***The information in the paragraph below must be included verbatim*.** If the information is not applicable, this justification must be included in the research protocol.

***(Information on Genetic Studies)***

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), effective May 21, 2010, generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

* Health insurance companies and group health plans may not request your genetic information that we get from this research.
* Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
* Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009.

Be aware that this new Federal law does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

***(Information on NIH Funded Genomic Data Repository)***

Information from analyses of your coded samples and your coded medical information will be put into one of the National Institutes of Health (NIH) databases along with information from the other research participants and will be used for future research.

There databases will be accessible by the internet. Only anonymous information from the analyses will be put in a completely public database, available to anyone on the internet.

No traditionally-used identifying information about you, such as your name, address, telephone number or social security number, will be put into the public database. While the public database will not contain information that is traditionally used to identify you, people may develop ways in the future that would allow someone to line your genetic or medical information in our databased back to you. For example, someone could compare information in our databases with information from you (or a blood relative) in another database and be able to identify you (or your blood relative). It also is possible that there could be violations to the security of the computer systems used to store the codes linking your genetic and medical information to you.

However, your privacy is very important to us and we will use safety measures to protect it. Despite all of the safety measures that we will use, we cannot guarantee that your identity will never become known.

**CONFIDENTIALITY**

(Insert **Confidentiality Information**)

(Note: this is not the same as HIPAA Authorization)

This section should include a statement describing the extent to which confidentiality of records identifying the subject will be maintained. Review the Saint Luke’s Health System standard research consent language and **DO NOT** include issues that are already covered. Use this section for issues required by the protocol as appropriate from the suggestions below. If any data have identifiers removed and use a code to link to the identifiers, describe who has access to the codes and how the codes are kept secure.

**Centralized data collection or registries:**

(Note: Also indicate if the results will be stored by an identifier or code, and protections in place for privacy of records.)

***Example:***

The results of your examinations will be collected in a centralized computer or data registry at the (name the facility and give the location – the city and state).

**Storage of tissues for the purposes of this study:**

***Example:***

After tissues are collected for study, they will be identified by a study number and not by your name or identifying information.

**Dealing with video or audio records upon completion of the study:**

***Example:***

* We may publish or present photographs, audio recordings, and videos of you (including or not including, specify one) your face. No other personal information about you will be included in the presentation.

**OR**

* All videotapes, audiotapes, and photographs will be destroyed at the end of the study.

**When subjects are likely to reveal reportable activities:**

(Note: In studies in which researchers think it is likely that subjects will reveal actions that the researchers are obligated to report to authorities, these statements, if applicable, should be added explaining that such circumstances may arise.)

***Example:***

* *If the study personnel find evidence that suggests that you have been physically or sexually abused, they are required by law to report this to local law authorities.*

***OR***

* *The only exception to this promise of confidentiality is that we are legally obligated to report evidence of child abuse or neglect.*

***OR***

* *We will not ask you about child abuse, but if you tell the interviewers about child abuse they are required by law to report your name to the state authorities.*

**When subjects are likely to reveal illegal activities but acquiring a Certificate of Confidentiality would be excessive or is not possible:**

***Example:***

*In this study, you will be asked about illegal activities [specify]. The researchers will keep information about you as confidential as possible, but complete confidentiality cannot be guaranteed. On rare occasion, courts have required the disclosure of research records.*

**When Certificate of Confidentiality has been obtained:**

(Note**:** Research subjects are placed at risk when they are asked about possible illegal drug use or other illegal activities. In order to protect the subject, you may wish to ask your federal-funding agency to issue a certificate of confidentiality, which prevents courts from compelling researchers to reveal information about their subjects.)

***Example:***

*In this study, you will be asked about illegal activities or highly personal behavior. The principal investigator has obtained a Certificate of Confidentiality from the federal government. Your study records cannot be subpoenaed (released to courts as required by a court order), and we will only release your study records if you ask us in writing.*

*You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research.  Note however, that if an insurer or employer, learns about your participation, and obtains your consent to receive research information, then the Certificate of Confidentiality cannot used to withhold this information.  This means that you and your family must also actively protect your own privacy.*

**IN ADDITION:** Any study that is considered an “[applicable clinical trial](http://clinicaltrials.gov/ct2/info/results)” by the FDA and required to be registered in the Clinicaltrials.gov database ***must also include the following paragraph verbatim*:**

**U.S. NATIONAL INSTITUTES OF HEALTH (NIH) CLINICAL TRIAL DATABASE:** A description of this clinical trial will be available on <http:///www.clinicaltrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time to find out information about the trial and basic results.

**STUDENT/EMPLOYEE RIGHTS**

(Insert **Student and Employee Rights** Information)

This section is required if students or employees of the health system are included as research subjects.

***Example:***

*Choosing not to participate or withdrawing from this study will not affect your employment or class standing, nor the will results be shared with your supervisor.*

**STUDY TERMINATION/WITHDRAW**

(Insert **Termination of Participation** Information)

This section should include any anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent. Include this section if there are conditions for involuntary withdrawal (sponsor closes study, etc.).

**Example:**

*Your participation in this study may be discontinued by the sponsor or investigator without your consent if (specify conditions).*

**REQUIRED HIPAA LANGUAGE**

(Insert **Privacy Protected Health** **Information**)

In the section “Privacy Protected Health Information”, you may remove the HIPPA language below ***only if you are not collecting PHI:***

**Privacy of 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 is 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 might 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 disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to [***insert name and mailing address for Principal Investigator***].

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 otherwise 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 not will 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 and possibly 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

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Printed Name of Participant

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

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Signature of Participant Date

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

Printed Name of Participant

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

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

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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 in 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 Two Parent Signature are required]**

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Signature of Participant Date

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

Printed Name of Minor if used to obtain assent

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Signature of Parent/Legal Guardian Date

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

Printed Name of Parent/Legal Guardian

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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 is 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

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Printed Name of Witness

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Signature of Person obtaining informed consent Date

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

Printed name of person obtaining informed consent