Saint Luke's HEALTH SYSTEM

Instructions for Informed Consent Guidance

The information presented in this tutorial is designed to act as a general guide for developing and effective research consent document

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 footer (e.g., page 1 of 2).
- A type of version control 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.
- If your study includes multiple groups/arms, consider using more than one consent form. For example, if optional procedures/genetic study, then use a separate consent form to provide the information to those participants. This can help reduce the length and amount of information being conveyed in the main consent form.
- Carefully proofread the consent form for typographical errors.

STANDARD RESEARCH CONSENT LANGUAGE

The last four sections of the consent document (Summary of Your Rights as a Participant in a Research Study, Disclosure of Your Study Records, Contact Information, Signatures) 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 SRCL 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 phone number for the Principal Investigator as instructed in red.
- Keep the signature lines that are appropriate for the consent form and delete those that are not 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, IRB effective date and IRB expiration date of the consent document. Only a currently approved version will be used when obtaining written consent from participants. Failure to do so may result in an allegation of non-compliance with human participant protections.

CONSENT TEMPLATE GUIDANCE BY SECTION

(Insert Header)

Saint Luke's Health System

Consent for Research

Project Title:

Sponsor:

Principal Investigator (PI):

PI Address:

PI Phone Number:

KEY INFORMATION

(Required for all research subject to the Common Rule (45CFR46) and recommended for all research subject to FDA (pending finalization of FDA's proposed rule)

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 participant involvement here]*.
- During your participation you will be involved in *[insert procedures participant 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 participant].*

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.

FUNDING 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):

2. 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 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 research, which may relate to the participant's willingness to continue participation, the participant will be provided with 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 participants are to be enrolled, a statement must be included stating the approximate number of participants to be involved in the study. If this is a multi-center study, indicate how many sites are involved, how many participants 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.

WHAT IS INVOLVED IN THE STUDY?

(Insert **Study Procedures** Information)

The Study Procedures section should provide a clear concise statement of what participants 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., participants 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 the standard of care and what is research. It should also clearly identify which procedures/treatments 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 like flipping a coin. This process is called randomization. Neither you nor the 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 participants 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.*
- *Participants in the control group will receive no investigational treatment but will be monitored by study staff*
- *Participants assigned to the control group will receive 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 <u>discontinued</u> from the research:

(When Applicable, Insert Information)

If there are consequences related to a participant'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 involvement by the participant.

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 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.

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

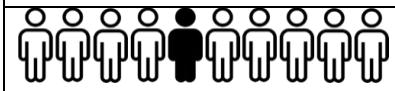
- *Your participation in this may involve the following risks…*

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 participant chooses to participate in the study should not be listed on 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 percentage.

Very common side effects

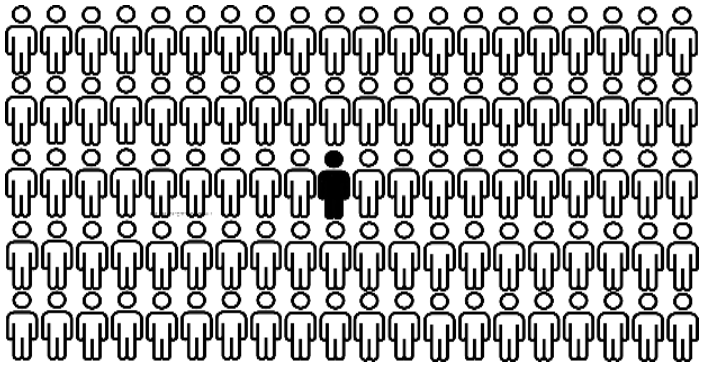
More than 1 in 10 people may have these side effects (**more than 10%** of people)



- Anemia: Low red blood cell counts, which may make you feel tired or worn out and may require blood transfusions
- Neutropenia: Decrease in a type of white blood cell called a neutrophil, that may affect the body's ability to fight infection. You may need extra medicine(s) to increase your cell counts.
- Thrombocytopenia: A decrease of platelets in your blood, which can increase bleeding and bruising
- Nausea: Feeling like you have to throw up, with or without actually throwing up
- Vomiting: Throwing up
- Diarrhea: Loose or watery stool (poop)
- Constipation: Trouble passing stool (poop)

Common side effects

More than 1 in 100 people may have these side effects (**more than 1%** of people)



• Interstitial Lung Disease or Pneumonitis: Scarring, inflammation, or swelling of your lungs that might make it hard for you to breathe, dry cough (or make an existing cough worse), chest pain, or fever. Call your study doctor right away if you have symptoms listed above. You may need scans and treatment for this condition. • Corneal events: Some patients experienced blurry vision, dry eyes, increased tearing or watery eyes, or eye pain. • Peripheral neuropathy: Tingling, numbness, pain or weakness that might make you feel like something doesn't feel right about your senses like touch • Infusion Related Reaction and Hypersensitivity (allergic reaction): such as a fever, warmth and redness (flushing) of your skin, itching, rash, feeling dizzy, or a decrease in blood pressure during or after the infusion.
Uncommon side effects **Less than 1 in 100 people** may have these side effects (**less than 1%** of people)
• Infertility (difficult becoming pregnant or fathering a child)

- Animal study risk findings should normally be excluded from the consent form but may be selectively included when relevant to the participant's 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

If there is a 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 participant'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:*
  Using a needle to draw blood may be 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 breastbone to withdraw a sample of fluid containing bone marrow cells. The risks of taking bone marrow samples 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.

  Radiation Risks:
  Very Low Dose – Effective Dose <3 mSv
  If you take part in this research, you will have tests that use very small amounts of radiation. These tests are: **(indicate types of examinations: x-ray examinations, DXA scans, etc.)**. This radiation is in addition to what you may get as part of your regular medical care. Everyone gets low levels of natural radiation, called 'background radiation.' This comes from outer space and from rocks and minerals in the soil. The average yearly background radiation in the United States is 3 mSv. The amount of additional radiation you will get by participating in this study will be <3 mSv.

  Low-to-Moderate Dose – Effective Dose Between 3 and 50 mSv
  If you take part in this research, you will have tests that use small to moderate doses of radiation. These tests are: **(indicate types of examinations: x-ray examinations, CT scans, nuclear medicine studies, PET scans, etc.)**. This radiation is in addition to what you may get as part of your regular medical care. Everyone gets low levels of natural radiation, called 'background radiation.' This comes from outer space and from rocks and minerals in the soil. The average yearly background radiation in the United States is 3 mSv. The amount of additional radiation you will get will be approximately [**specify here**] mSv. This is less than the maximum amount a person working with radiation is allowed to get in 1 year.

  Moderate Dose – Effective Dose Between 50 and 100 mSv

  If you take part in this research, you will have tests that use moderate doses of radiation. These tests are: **(indicate types of examinations: x-ray examinations, CT scans, nuclear medicine studies, PET scans, FGI procedures, etc.)**. This radiation is in addition to what you may get as part of your regular medical care. Everyone gets low levels of natural radiation that comes from outer space and the Earth called 'background radiation.' The average yearly background

radiation in the United States is 3 mSv. The amount of additional radiation you will get will be ~[**specify here**] mSv.

- *CT Scans:*
  A CT scan uses computers and rotating x-ray machines to create cross-sectional images of the body. These images provide more detailed information than typical X-ray images. They can show soft tissues, blood vessels, and bones in various parts of the body. During a CT scan, you lie in a tunnel-like machine while the inside of the machine rotates and takes a series of X-rays from different angles.

- *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 radionuclide may cause some slight discomfort. Allergic reactions to radionuclide are rare.

- *Echocardiogram:*
  Uses sound waves to evaluate your heart. These high-frequency sound waves have not been shown to have any 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 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. Some people may feel claustrophobic, so tell the study staff if you are claustrophobic. 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/CT:*

  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.

- *Biopsies:*

  Risks associated with biopsies include pain, redness, swelling, low blood pressure, excessive bleeding, bruising, or draining at the collection site. Abnormal wound healing, fever, infection, and allergic reaction to the medication used to numb the skin over the biopsy site may also occur. 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:*

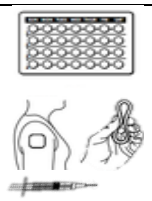
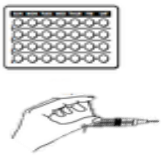
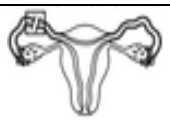
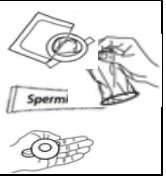
  As part of this protocol, you will be tested for HIV (human immunodeficiency virus), which is the virus that causes the acquired immunodeficiency syndrome (AIDS). We will collect [identify specimen type and amount] from you to test for HIV. You will be notified of the results of the testing, and counseled 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:*

  We will collect [identify specimen type and amount] from you to test for Hepatitis. 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:*
- *The consent must list out the specific types of acceptable methods of birth control*

Method	What it includes	
Combined hormonal birth control with estrogen and progestogen that stops ovulation when started at least 30 days before day 1 of the study (baseline)	Birth control: • Taken by mouth (orally) • Placed in the vagina (intravaginal) • Placed on the skin (transdermal) • Taken as a shot (injectable)	
Hormonal birth control with only progestogen that stops ovulation when started at least 30 days before day 1 of the study (baseline)	Birth control: • Taken by mouth (orally) • Placed in the body (implantable) • Taken as a shot (injectable)	
Bilateral tubal occlusion/ligation or Bilateral tubal occlusion/ligation by hysteroscopy with a hysterosalpingogram to confirm the procedure's success	A surgery that blocks or cuts the fallopian tubes to prevent the egg from being fertilized (also called having the "tubes tied")	
Intrauterine device (IUD) or Intrauterine hormone-releasing system (IUS)	A small device inserted into a woman's uterus to prevent pregnancy	
Vasectomized partner	An operation to make a man permanently unable to get a woman pregnant (as long as the partner confirms the medical success of the surgery and is the sole sexual partner of the participant).	
True Abstinence	Not having sex at all (as long as this is a part of the participant's long-term life choice). This doesn't include periodic abstinence (such as the calendar, ovulation, symptothermal, or post-ovulation methods) or the withdrawal method.	
If required per local practices, male or female condom with or without spermicide OR cap, diaphragm or sponge with spermicide should be used in addition to one of the birth control methods listed above (excluding true abstinence).		
Barrier	• Male or female condoms with or without spermicide • Cap, diaphragm, or sponge with spermicide (items placed in a woman's vagina that contain spermicide to block and kill sperm before it reaches an egg)	

If a participant is or may become pregnant during the research, a statement must be included to inform participants that the treatment or procedure may involve risk to the participant, or to the embryo or fetus, which are currently unforeseeable.

- *Participation in this study may involve risks 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. You must agree to use birth control while in the study and for [x] days after the last dose of the study drug. Your study doctor will talk to you about your options and which method may be right for you.*

  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 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 genetic Testing:*

  The 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 guarantee. Although rare, misuse of such information has caused problems for people 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 participant or to others which may be reasonably expected from the research. This section should open with a clear statement about the benefits to the participants. The second choice may be appropriate if the study includes a placebo group.

Example:

- *There will be no direct benefit to you by participating in this research study.*

OR

- *There may be no direct benefit to you by participating 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 participant 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 benefits 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 participants for their involvement. 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 available to the participant. 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 participant. 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 participant 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 participant's insurance, a statement should be added that advises participants 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 participant.* This section should open with one of the following statements:

- *There is no cost to you or your insurance for participating 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 participants 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 participants' biospecimens (even if identifiers are removed) may be used for commercial profit and whether the participant 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 participants' 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 participants, and if so, under what conditions.

Research-Related Injury:

Required language if the trial is interventional and/or there is a chance that a participant 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 the 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 payment cards:**

  To compensate you for time and expenses for participating in this study, you may receive XXX per study visit and up to $XXX for meals. There will be no compensation provided for randomization and follow-up visits. If you do not complete all the study visits, you will only be paid for those visits you complete.

  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 reloadable debit card. Once you have completed a study visit, the amount of money you are to receive for that visit will be added to the card three to five business days (Monday-Friday, excluding holidays) after the visit.

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. If your card expires with a balance remaining, a new card will automatically be issued to you within 10 days of expiration.

The Office of Research Services will be given your name, address, social security number, and the title of this study to allow them to set you up in the payment system. Study payments are taxable income. A Form 1099 will be sent to you and the Internal Revenue Service if your payments are $600.00 or more in a calendar year.

Your personal information will be kept on 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. It will be kept completely confidential.

GENETIC STUDIES

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

Genetic research studies may create medical, psychosocial, and economic risks to participants 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 participant 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 participant's right to withdraw from the research, withdraw data, and/or withdraw DNA?*
- *Is the participant permitted to participate in the study while refusing to have genetic testing?*
- *Will DNA be stored or shared? If shared, will the participant's identity be known by the new investigator?*
- *Will the participant be contacted in the future by the investigator to obtain updated clinical information?*
- *How can the participant 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 participant.

Example:

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

In family genetic studies, the issue of paternity should be discussed.

Example:

When 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.*

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

We may share portions of 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.

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 that information.

- ❑ *Please try to contact me if information is discovered in future studies of my genes that would be important to 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 stored without identifiers but are not anonymous (coded) the ***following paragraph must be used***:

Your DNA sample will be identified by a code number, and all other identifying information will be removed. [Insert who will keep the code sheet… for example the research team, honest broker, etc.] 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, 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 it unequivocal that the participant 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 you 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 your choice below.

- ❑ Yes, I want to have a sample for DNA (gene) studies.
- ❑ No, I do not want to participate in 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). 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 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 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 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 will 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 out 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.

These databases will be accessible online. 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 the database back to you. For example, someone could compare information in one database with information from you (or a blood relative) in another database and be able to identify you (or your blood relative). It is also possible that there could be violations of 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 participant 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 has 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: 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 participants are likely to reveal reportable activities:

(Note: In studies in which researchers think it is likely that participants 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 participants 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 occasions, courts have required the disclosure of research records.

When Certificate of Confidentiality has been obtained:

(Note**:** Research participants are placed at risk when they are asked about possible illegal drug use or other illegal activities. To protect the participant, 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 participants).

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 be 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" by the FDA and required to be registered in the Clinicaltrials.gov database ***must also include the following paragraph verbatim*:**

> 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 Saint Lukes Health System are included as research participants.

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

STUDY TERMINATION/WITHDRAW

(Insert **Termination of Participation** Information)

This section should include any anticipated circumstances under which the participant's involvement may be terminated by the investigator without regard to the participant'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 people 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 records. Your medical records at Saint Luke's Health System may contain information such as name, address, phone number, 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 people 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 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 decide 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 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 participant issues, please call the Saint Luke's Health System Institutional Review Board at 816-932-5019. You may also write to 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]

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

[Use this for studies enrolling decision impaired adults]

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

[If participant does not have the capacity to consent and protocol is 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 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]

_____ _____

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 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

_____

Printed Name of Witness

[*Study Personnel* – This block must be included in all consent forms. Do not delete.]

_____ _____

Signature of Person obtaining informed consent Date

_____

Printed name of person obtaining informed consent