**Project Title:**

**Sponsor:**

**Principal Investigator:**

***\*\*\*It must be clear that you are inviting potential participants to consider taking part in your research and that participation is entirely voluntary.***

Example:

*You are being invited to take part in our research study. Before you decide, it is important that you understand why the research is being done what it would involve for you. Please take time to read this information, and discuss it with other if you wish. If there is anything that is unclear, or if you would like more information, please ask us.*

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

(Provide a brief outline of the purpose of your study in lay language. Do not cut and paste directly from the protocol).

**Why have I been invited?**

Explain specifically why the participant has been invited (e.g. because they have a specific condition, or because they are healthy individuals, also state how many participants you are intending to involve and their characteristics (e.g. healthy volunteers, people with x condition)).

**What will happen to me if I decide to take part?**

(This section details what will be involved in your research study from a participant’s point of view, and in the order they will experience it. If there are multiple study visits, describe them in turn. If research is taking place in the context of clinical care, make clear which parts are research and which standard care. A table or flow chart can provide clarity when describing a complex series of interventions).

*Consider:*

* *How long the participant will be involved in the research; how often they will need to attend a research session; and how long visits will be. If you will be allocating participants randomly to study medication(s) and/or placebo, describe what it means in lay terms.*
* *If you will be collecting samples, give an idea of amounts. Blood volume may be more meaningfully expressed in tablespoons: 5ml is equivalent to 1 teaspoon, 15ml is 1 tablespoon. Biopsies may be compared to grains of rice.*
* *If you will be using tissue samples, state whether the tissue will already be collected as part of clinical care. Are you requesting use of tissue surplus to diagnostic need, or collecting additional samples?*
* *If you will be collecting data, state how much and how often you will collect their information.*
* *Outline any plans for long-term monitoring/follow-up.*
* *If the study involves the use of any ionising radiation (e.g. x-rays) or non-ionising radiation, such as MRI scans, please add template consent form point 10 (appended) to your consent form.*

**Are there any possible disadvantages or risk from taking part?**

(Provide a fair and honest evaluation of the possible consequence of key research procedures for example:

* Questions or interview questions that may cause distress: give indication of kinds of questions you will be asking, and outline would happens if a participant becomes upset.
* Potential breach of confidentiality).

**What are the possible benefits of taking part?**

(Sometimes participants can benefit directly or indirectly. If this is so, be clear; if not, be equally clear that there is no benefit. Ensure that potential participants are aware that you do not know what the outcome will be, and this is why you are conducting the research).

**Will my General Practitioner/family doctor (GCP) be informed of my participation?**

* GPs should be notified if study participation could affect clinical care of participants. (GPs should be provided with a letter and the study information sheet.)
* There may also be instances where GPs will be contacted to follow up incidental findings that may be of clinical significance, such as high blood pressure or indications of depression.
* If the GP will be informed of participation or may be notified of findings requiring follow up, make this clear in your consent form.

**Financial Information**

Make clear whether they will be compensated for their time, inconvenience for having to take part in this study. It should not cost participants to contribute to research; at a minimum, travel should be reimbursed. This expense may sometimes be avoided by having research visits coincide with regular clinical appointments.

**Will my taking part in this study be kept confidential?**

Explain arrangements made to ensure that information is kept secure.

(Explain in what form you will hold information. For example, will participants be identified by study code only? Will you destroy all direct identifiers and store only fully anonymized data? Note that if you anonymize during the study, it will not be possible for participants to withdraw their data. They should be informed of this here.

**What will happen if I don’t want to carry on with the study?**

Make clear that:

* Participation is voluntary and participants may change their minds at a later stage.
* Withdrawal will not affect the care they receive at Saint Luke’s Health System
* What procedure is in place in case of withdrawal?
* Will samples and data collected to point of withdrawal be retained for the study, removed, or
* Will the participant have a choice?
* Provide an opt-out form

Examples:

* *If you withdraw from the study, we will destroy all your identifiable samples, but will use the data collected up to your withdrawal.* Or;
* *If you withdraw from the study, unless you state otherwise, any blood or tissue samples which have been collected whilst you have been in the study will be used for research as detailed in this participant information sheet. You are free to request that your blood or tissue samples are destroyed at any time during or after the study.* Or;
* *You can withdraw from the study but keep in contact with us to let us know your progress.*
* *Information collected may still be used. Any stored blood or tissue samples that can still be identified as yours will be destroyed if you wish.*

**What will happen to the results of this study?**

Reassure potential participants that they will not be identified from any report or publication placed in the public domain. If they will be (for instance, with images of faces) it will be necessary to obtain specific consent for this.

You should inform potential participants of your intentions with respect to:

* Publishing research findings;
* Presenting your findings at conferences*;*

Feeding back findings to participants themselves. Will you provide them with a summary, or add in a link to a website from which they could get the information, or ask them to contact you?

* Indicate whether the study is part of an educational project, such as fulfilment of requirements for a
* DPhil. For example:
* Some of the research being undertaken will also contribute to the fulfilment of an educational requirement (e.g. a doctoral thesis).

**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 816-932-3361. You may also write the Saint Luke’s Health System Institutional Review Board at 4401 Wornall Road, Kansas City, Missouri, 64111.