PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM

*Please see Section 8 of our Health Research Ethics Committee (HREC) Standard Operating Procedures (SOPs) for more detailed information about requirements for Informed Consent (IC). You will find the SOPs here:* [*http://www.sun.ac.za/english/faculty/healthsciences/rdsd/Pages/Ethics/SOP.aspx*](http://www.sun.ac.za/english/faculty/healthsciences/rdsd/Pages/Ethics/SOP.aspx)*.*

*(Please delete this paragraph before submitting your Informed Consent Form (ICF) to the HREC)*

|  |  |
| --- | --- |
| **Title of Research Project:** | |
|  | |
| **DETAILS OF PRINCIPAL INVESTIGATOR (PI):** | |
| **Title, first name, surname:** | **Ethics reference number:** |
| **Full postal address:** | **PI Contact number:** |

We would like to invite you to take part in a research project. Please take some time to read the information presented here, which will explain the details of this project. Please ask the study staff or doctor any questions about any part of this project that you do not fully understand. It is very important that you are completely satisfied that you clearly understand what this research entails and how you could be involved. Also, your participation is **entirely voluntary** and you are free to decline to participate. In other words, you may choose to take part, or you may choose not to take part. Nothing bad will come of it if you say no: it will not affect you negatively in any way whatsoever. Refusal to participate will involve no penalty or loss of benefits or reduction in the level of care to which you are otherwise entitled to. You are also free to withdraw from the study at any point, even if you do agree to take part initially.

This study has been approved by the Health Research Ethics Committee at Stellenbosch University. The study will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki, the South African Guidelines for Good Clinical Practice (2006), the Medical Research Council (MRC) Ethical Guidelines for Research (2002), and the Department of Health Ethics in Health Research: Principles, Processes and Studies (2015).

## What is this research study all about?

* *Where will the study be conducted? Are there other sites? State the total number of participants to be recruited at your site, and the number of participants altogether.*
* *Explain in participant-friendly language what your project aims to do and why you are doing it. Imagine having a conversation with one of your participants. Write in plain English and use the active form; avoid passives as far as possible. This applies to all text that you add to this form.*
* *Explain all procedures.*
* *Explain any randomisation process that may occur.*
* *Explain the use of any medication, if applicable.*

## Why do we invite you to participate?

* *Explain this question clearly.*

## What will your responsibilities be?

* *Explain this question clearly.*

## Will you benefit from taking part in this research?

* Explain all benefits objectively. If there are no personal benefits then indicate who would be likely to benefit from this research, e.g. future patients.

## Are there any risks involved in your taking part in this research?

* Identify any risks objectively.

## If you do not agree to take part, what alternatives do you have?

* *Clearly indicate in broad terms what alternative treatment is available and where it can be accessed, if applicable.*

## Who will have access to your medical records?

* *Explain that the information collected will be treated as confidential and protected. If it is used in a publication or thesis, the identity of the participant will remain anonymous. Clearly indicate who will have access to the information.*

## Even though it is unlikely, what will happen if you get injured somehow because you took part in this research study?

*Background information:*

* *The sponsor of a trial must ensure that the participants in health research are covered by comprehensive insurance in the event of physical (bodily) harm or injury, including death. This means that the insurance company will compensate a participant for medical expenses which may have resulted directly from their participation in research without the participant having to prove that the sponsor was at fault.*
* *Stellenbosch University has insurance to cover participants in all non-industry sponsored research studies that are registered with the HREC.*
* *It is important to explain to each participant that:*
* *By agreeing to participate in this study, he/she agrees that there is a risk that the study medicine(s) or procedure(s) may cause him/her harm. If it does, the sponsor will reimburse him/her for his/her medical expenses without the participant having to prove that the sponsor was at fault.*
* *The participant may, however, still claim for emotional pain and suffering if he/she so chooses. In this event, he/she will have to prove that the sponsor was negligent and did not take all reasonable and foreseeable steps to prevent the injury or emotional trauma. This will be a separate legal matter.*

*For more information, please see Section 9 of HREC SOPs on Participant Insurance.*

*(Please delete this text before submitting your ICF to the HREC).*

*Recommended wording - please use one of the following text excerpts in this section:*

*(Please delete the irrelevant section before submitting your ICF to the HREC).*

*For non-sponsored health research or research sponsored by Stellenbosch University where the*

*principal investigator is a staff member or student of Stellenbosch University; or for NIH/US*

*government funded research:*

* Stellenbosch University will provide comprehensive no-fault insurance and will pay for any medical costs that came about because participants took part in the research (either because the participant used the medicine in this study, or took part in another way). The participant will not need to prove that the sponsor was at fault.

*For industry-sponsored health research:*

* The sponsor will provide comprehensive no-fault insurance and will pay for any medical costs that came about because participants took part in the research (either because the participant used the medicine in this study, or took part in another way). The participant will not need to show that the sponsor was at fault.

Will you be paid to take part in this study and are there any costs involved?

* You will be compensated to take part in the study and your expenses will be reimbursed for each study visit. You will not have to pay for anything, if you do take part.
* *The amount and method of payment to research participants should reflect the following three components:*
  + *Compensation for time;*
  + *Compensation for inconvenience; and*
  + *Reimbursement of expenses.*

*Please see Section 9 of HREC SOPs on Participant Insurance, Appendices IX and X on Compensation for Injury.*

Is there anything else that you should know or do?

* You should tell your family practitioner or usual doctor that you are taking part in a research study. (Include if applicable)
* You should also tell your medical insurance company that you are participating in a research study. (Include if applicable)
* You can phone Dr [insert PI’s name here] at [insert PI’s tel number here] if you have any further queries or encounter any problems.
* You can phone the Health Research Ethics Committee at 021 938 9677/9819 if there still is something that your study doctor has not explained to you, or if you have a complaint.
* You will receive a copy of this information and consent form for you to keep safe.

### Declaration by participant

By signing below, I …………………………………..…………. agree to take part in a research study entitled (insert title of study here).

I declare that:

* I have read this information and consent form, or it was read to me, and it is written in a language in which I am fluent and with which I am comfortable.
* I have had a chance to ask questions and I am satisfied that all my questions have been answered.
* I understand that taking part in this study is **voluntary,** and I have not been pressurised to take part.
* I may choose to leave the study at any time and nothing bad will come of it – I will not be penalised or prejudiced in any way.
* I may be asked to leave the study before it has finished, if the study doctor or researcher feels it is in my best interests, or if I do not follow the study plan that we have agreed on.

Signed at (*place*) ......................…........…………….. on (*date*) …………....……….. 2015.

Signature of participant Signature of witness

### Declaration by investigator

I *(name)* ……………………………………………..……… declare that:

* I explained the information in this document in a simple and clear manner to …………………………………..
* I encouraged him/her to ask questions and took enough time to answer them.
* I am satisfied that he/she completely understands all aspects of the research, as discussed above.
* I did/did not use an interpreter. (*If an interpreter is used then the interpreter must sign the declaration below.)*

Signed at (*place*) ......................…........…………….. on (*date*) …………....……….. 2015.

Signature of investigator Signature of witness