

PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM

Please see Section 8 of the 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>. (Please delete this paragraph and any irrelevant information before submitting your Informed Consent Form (ICF) to the HREC).

N.B. Please note that this is a template that is meant as guidance, so researchers need to edit content to reflect the circumstances of the specific study and its ethical considerations.

TITLE OF RESEARCH PROJECT:	
DETAILS OF PRINCIPAL INVESTIGATOR (PI)/RESEARCHER(S):	
Title, first name, surname:	Ethics reference number:
Full postal address:	PI Contact number:

We/I would like to invite you to take part in a research project. [Kindly provide details: state who 'we' relates to, that is, whether you are a student registered at Stellenbosch University for a specific degree or part of a research team (names of the team members) and so forth.]

Please take some time to read the information presented here, which will explain the details of this project. Please ask the researcher/study staff or doctor [Delete what is not relevant to your study] 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. You are also free to withdraw from the study at any point, even if you do agree to take part initially. [Please edit according to the context of your project]

The Health Research Ethics Committee at Stellenbosch University has approved this study. 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?

- What is the aim/focus of the study?
- 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.*
- *Clearly differentiate between what is standard of care/practice, and what is specific/additional to this research study.*

Why are you invited to participate?

- *Explain this question clearly.*

What will your responsibilities be?

- *Explain this question clearly, making the participant's role in the study procedures as simple as possible for the lay person to understand what is expected and how much time activities are estimated to take.*
- *Please bear in mind that the recommended language level is a Grade 6 to 8.*

Will you benefit from taking part in this research?

- *Explain all direct 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 and do not overstate risks.*

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

- *Retain this section only if applicable.*
- *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?

- *Retain this section only if applicable.*
- *Explain that the information collected will be treated as confidential and protected. Please consider compliance to POPIA. 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?

- *Retain this section only if applicable & remove references to 'the sponsor' if there is no sponsor involved in the 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/UREC.*
- *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/researcher 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.

Are there any costs involved if I decide to participate/take part?

- The researchers are responsible for all direct study-related costs.
- If the study uses information based on Standard Operating Procedures or standard clinical treatment practices, clearly differentiate between who is responsible for the treatment costs (the patient or the study team).
- You will be compensated for your time in taking part in the study and your expenses will be reimbursed for each study visit. You will not have to pay for anything related to the research 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 14 of HREC SOPs on Compensation of Research Participants. Please refer to SAHPRA (2022) GUIDELINE FOR CLINICAL TRIAL PARTICIPANT TIME, INCONVENIENCE AND EXPENSE (TIE) COMPENSATION MODEL as a point of reference for determining fair TIE for participants. Please visit the HREC website by clicking [here](#)

For health and student projects kindly reflect on how respect for participants can be demonstrated by acknowledging participants in a meaningful way be this in the form of a token of appreciation, data vouchers (especially in the case of studies where online platforms are used), a grocery voucher, refreshments, and so forth. It is not a justification to simply state that the project is self-funded as the research is not possible without participants.

Is there anything else that you should know or do?

- *Include if applicable:* 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.)

- You can phone [insert PI's name here] at [insert PI's telephone 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 the researcher 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 understand that research is separate to my medical care or treatment and that refusing to take part in research does not mean I will no longer receive medical care. *[Please delete if not applicable to your study]*
- 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. *[Where this is not relevant, please delete]*

Signed at (place) on (date) 2022.

.....
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) 2022.

.....
Signature of investigator

.....
Signature of witness

Permission to have all anonymous data shared with journals:

Please carefully read the statements below (or have them read to you) and think about your choice. No matter what you decide, it will not affect whether you can be in the research study, or your routine health care.

When this study is finished, we would like to publish results of the study in journals. Most journals require us to share your anonymous data with them before they publish the results. Therefore, we would like to obtain your permission to have your anonymous data shared with journals. In accordance with the POPI Act, the researchers will take care to ensure that you are not identifiable (all personal information is not linked to the data shared).

Permission for sharing samples and/or information with other investigators:

Please carefully read the statements below (or have them read to you) and think about your choice. No matter what you decide, it will not affect whether you can be in the research study, or your routine health care.

In order to do the *research* we have discussed, we must collect and store [describe the samples that are going to be collected e.g. blood/tissue/urine etc. and volume of blood/tissue/urine etc.] and health information from people like you with [disease X]. We will do some of the tests right away. Other tests may be done in the future. Once we have done the research that we are planning for this research project, we would like to store your sample and/or information. Other investigators from all over the world can ask to use these samples in future research [please indicate if the samples will be shipped from South Africa, where the samples will be stored and who will have access to these samples]. To protect your privacy, we will replace your name with a unique study number. We will only use this code for your sample and information about you. We will do our best to keep the code private. It is however always possible that someone could find out about your name but this is very unlikely to happen. Therefore, we would like to ask for your permission to share your samples and information with other investigators.

Permission to store samples and/or information for future studies:

Please carefully read the statements below (or have them read to you) and think about your choice. No matter what you decide, it will not affect whether you can be in the research study, or your routine health care.

As you are aware technology is constantly changing and so tests that may not be available at the time of this research may be possible in the future. As researchers learn more about illnesses or diseases, new research can be done using existing samples instead of returning to participants to ask for additional samples.

In order to do further *research* in the future, we would like to ask your permission to store [describe the samples that are going to be collected e.g. blood/tissue/urine etc. and volume of blood/tissue/urine etc.] and health information from people like you with [disease X]. Any future studies or reuse of samples or data will need to be approved by the Stellenbosch University Health Research Ethics Committee.

Tick the Option you choose for anonymous data sharing with journals:

I agree to have my anonymous data shared with journals during publication of results of this study

☐

Signature_____

OR

I do not agree to have my anonymous data shared with journals during publication of results of this study

☐

Signature_____

Tick the Option you choose for sharing samples and/or information with other investigators:

I do not want my sample and/or information to be shared with other investigators

☐

Signature_____

OR

My sample and/or information may be shared with other investigators who are able to conduct further analysis in ... *[describe the field of your study, e.g., diabetes research]*

☐

Signature_____

Tick the Option you choose for storage and reuse of samples/data for studies in the future:

I do not want my sample(s) and/or information (data) to be stored for reuse for future studies

☐

Signature_____

OR

I hereby agree that my sample(s) and/or information (data) may be stored for future research in a field related to ... *[describe the field of your study, e.g., diabetes research]*

☐

Signature_____