SAMAREC PRO FORMA: PARTICIPANT INFORMATION AND INFORMED CONSENT DOCUMENT

(Each participant must receive, read, and understand this document before the start of the study. Furthermore, this document should be translated into local language of where the study is going to take place).

PROTOCOL NUMBER: .....

PROTOCOL TITLE: .....

INVESTIGATOR OR INSTITUTION:

ETHICS CLEARANCE REFERENCE NUMBER:

INTRODUCTION

We obtained your contact details from … *[Explain how contact details were obtained].* You are invited to take part in a research study. This document is needed to help you decide if you would like to participate. You should fully understand what is involved before you agree to take part inthis study. If you have any questions that are not fully explained in this document, do not hesitate to ask the researcher. You should not agree to take part unless you are completely happy about all theprocedures involved and possible risks.

THE PURPOSE OF THE RESEARCH STUDY:

I am conducting this research to *[Include a brief explanation of what your study is about in terms that can be understood by a general audience.]*

THE DURATION OF THE RESEARCH STUDY

[Provide details of duration of the study and the duration of the participant's involvement. Explain what will be required of the participant in this study, e.g. will they be completing questionnaires, interviews, audio or video recording…?]

If you decide to take part in this study, you will be one of approximately ..... participants. The study is estimated to last for up to..... (days/weeks/months/years). You will be asked to….

ETHICS APPROVAL OF RESEARCH STUDY

The Protocol of this study was submitted for approval to the South African Medical Association Research Ethics Committee (SAMAREC), a research ethics committee registered with the National Health Research Ethics Council. Written approval has been granted by SAMAREC for the conduct of the study. The study has been structured in accordance with the 'Ethics in Health Research: Principles, Processes and Structures' Guidelines, published by the Department of Health, as well as the Declaration of Helsinki (updated October 2024), adopted by the World Medical Association (WMA), which deals with the recommendations for biomedical research involving human participants. Copies of these guidelines may be obtained from the researcher should you wish to review it.

YOUR RIGHTS AS A PARTICIPANT IN THIS RESEARCH STUDY

Your participation in this research study is entirely voluntary and you can refuse to participate, or you can stop at any time without stating any reasons whatsoever. If you choose to withdraw from this study, you will not face any penalty

or loss of benefit for non-participation.

POPI ACT - DATA PROTECTION

POPIA (POPI Act) stands for the Protection of Personal Information Act (2013). The act was introduced to promote the protection of personal information (e.g. race, gender, address, telephone number – to name a few) collected and processed by public and private bodies, amongst other reasons. The researcher/research institution is required to follow POPIA (POPI Act of 2013), for the processing of data collected for this research study.

Consent to use and share personal data

By signing this consent document, you consent to the use and sharing of your personal data for the purposes of this study. You are not obliged to give this permission. However, if you do not consent,you will not be able to participate in the study.

Will your consent ever expire?

This permission has no expiry date.

Can you withdraw your consent?

You have the right to withdraw your consent and participation at any time and you will not be held liable for termination. To withdraw, you may inform a member of the study team at
<Insert address with telephone number / e-mail address>

What happens if you leave the research study prematurely?

Any information collected about you prior to your early withdrawal may be used and shared in accordance with this participant informed and informed consent document. However, you may request that the data collected may be destroyed and / or records of your personal information must be deleted (in terms of Section 24 (1) of POPIA). *[Do not mislead your potential participants by stating that they can withdraw from a research project at any time if the project involves the submission of non-identifiable material such as questionnaires. Explain clearly to them that it will not be possible to withdraw once they have submitted the questionnaire. Please note that this will depend on the nature of the questionnaire. Some questionnaires may clearly indicate the identity of the participant, but the researcher may have agreed to anonymise personal data. Thus, it may be possible to withdraw the data provided].*
The researcher will retain your personal data for …. years after the study has ended (After this ….-year period the data will be destroyed). During this entire period,you may always:

- Ask for additional information about the processing of your personal data.
- Request access to the personal data held about you if this does not impede the scientific integrity of the study.
- Ask for corrections if the personal data is incorrect or incomplete.
- Ask to transfer study related personal data relating to you in a common format to yourself or someone else.
- If you feel any of your rights related to the collection and processing of your data have been violated, you should contact a member of the study team. If your concerns cannot be resolved to your satisfaction you can lodge a complaint in writing with the Information Regulator (South Africa), by writing to:

  The Chief Executive Officer Information Regulator (South Africa)
  P.O Box 31533,Braamfontein, Johannesburg, 2017
  Tel: +27 (0) 10 023 5200
  Email: complaints.IR@justice.gov.za
  General enquiries Email: inforeg@justice.gov.za.

Organisational and technical security measures

The researcher has taken appropriate security measures to prevent accidental loss of your personal data,unauthorised use or access, changes, or disclosure. For example, your personal data will be de-identified (data will be processed in a way that cannot be tracked directly back to you) before it is stored, analysed, or transferred. The researcher has also

established procedures on how to deal with a suspected breach of data protection and will notify you and all designated supervisors of a suspected breach if it is required by law to do so.

Transfer of your data outside South Africa *[Only include if applicable]*

It is important to emphasise that some of the authorised users of your data may be located in countriesthat do not have the same standards as South Africa when it comes to the legal protection of personal data. Although the researcher, as the party responsible for the processing of personal data, makes every effort to respect the provisions of South African legislation on protecting privacy, transferring personal data to a country outside South Africa may pose a security risk. In addition, there is a risk thatyou may not be able to exercise certain rights or that it may be more difficult to exercise such rights against these recipients. To the extent possible, international recipients of your personal data will sign special contracts to ensure the security and protection of your rights. If the security and protection of your rights cannot be guaranteed if personal data is transferred to a country outside South Africa, yourexplicit consent for such transfers will be requested below. In all cases, all parties involved in the investigation are obliged to respect the confidentiality of your personal data.

Where will my personal data be processed and who will have access to my personal data?

The researcher will be responsible for collecting personal data, as required, for you to take part in the study. Your personal data related to your participation in the study will be replaced by a code so that you cannot be identified directly. Only the research team *[Explain who is part of this team]* will be able to identify you from the code.
The researcher will be responsible for processing the information which will be stored under the code allocated to you and is responsible for ensuring your data remains confidentialas required by the law in your country. Data collected about you for the purposes of this study will be transferred to a central location.
Your answers may be reviewed by people responsible for making sure that research is done properly, including the transcriber, external coder, and members of the Research Ethics Review Committee. Otherwise, records that identify you will be available only to people working on the study, unless you give permission for other people to see the records. Anyone outside of the study panel and the Research Ethics Committee needs to sign a third-party confidentiality agreement with the researchers.
Some authorized Sponsor representatives (including the contract research organization working with the researcher, monitors, auditors), National Health Authorities, Regulatory Authorities and Ethics Committees will have limited but direct access to your personal data held by the researcher when required to check study procedures have been performed and data has been captured correctly. The information will remain confidential as required by the law in your country and remain the responsibility of the researcher.
This access may include viewing your data remotely
Once the study has been completed results of the study may be published. At no point will any personal information that can identify you be included in the results.

STUDY PROCEDURES MAY RESULT IN DISCOMFORT OR INCONVENIENCE

[Explain any discomforts or inconveniences i.e., sensitive information, questions that may trigger uncomfortable memories, etc]

THE RISKS INVOLVED IN THIS STUDY

[Describe any risk, harm, or discomfort participants may experience. Explain measures that will be taken to minimize or prevent any harms from occurring.]

[Technical terminology and jargon should be explained in layperson's language in brackets.]

COSTS AND FINANCIAL ARRANGEMENTS

[Any costs incurred by the participant should be explained and justified in adherence with the principle of fair procedures (justice)].

You will not be paid for participation in this study. However, a reasonable amount to cover your travel expenses will be paid out to you. Please discuss further details in this regard with the researcher before commencement of the research study. There will be no costs to you or your loved ones.

[Although the participant may consider financial compensation a desirable outcome this fact will not be used in the risk benefit analysis and should not be mentioned in the PID. For example, the fact that participant may receive a certain sum of money per visit to defray travel expenses, cannot be reflected as a benefit. Please note that it may be stated in the protocol document that the participant would receive an exact amount fortravel and / or other costs. However, the exact amount of money must not appear in the Participant Information and Informed Consent Document (PID) as this could be seen as coercive.
It should also be noted that participants will not be promised any form of compensation including employment as a token of appreciation]

SOURCE OF ADDITIONAL INFORMATION

Your participation in the study will be supervised by the researcher (name)..... If at any time between your visits you have anyquestions during the study, please do not hesitate to contact him/her. The telephone number through which you can reach him/her, or another authorised person is …….. and/or……

CONFIDENTIALITY

All information obtained during the course of this study is strictly confidential and will be maintained as such. Data that may be reported in scientific journals will not include any information that identifies you as a participant in this study.

Any information uncovered regarding your test results or state of health as a result of your participationin this study will be held in strict confidence. You will be informed of any finding of importance to your health or continued participation in this study, but this information will not be disclosed to any other thanthose mentioned above without your written permission. The only exception to this rule will be in caseswhere a law exists compelling us to report incidences of communicable diseases. In this case, you will be informed of our intent to disclose such information to the authorised state agency.

The results of this research study may be presented at meetings or in publications. However, you will not be personally identified in any presentations or publications.

The information collected during this study may be added to research databases and used in the future by the researcher or research institution and their affiliated companies to study better measures of safety and effectiveness, studyother therapies for subjects, develop a better understanding of disease included in the study or improvethe efficiency, design, and study methods of future studies. Such information will not identify youby name.

INFORMED CONSENT

- I hereby confirm that I have been informed by the researcher about the nature, conduct, benefits, and risks of this research study.
- I am aware that the results of the research study, including personal details regarding my sex, age, date of birth, initials and diagnosis will be anonymously processed into a research study report, but that some of my health information may be reasonably disclosed to the research institution and/or affiliated companies and/or authorities under certain circumstances.
- I may, at any stage, without prejudice, withdraw my consent and end my participation in the research study.
- I have had sufficient opportunity to ask questions and (of my own free will) declare myselfprepared to participate in the research study.
- I have read and understood the contents of the document.

- I understand that I shall receive a signed copy of this document.

(If the study uses an online questionnaire /survey in which the PID forms the cover page, then this signed section can be removed from the document, as online participants will consent by clicking a "consent" button, or signing in to proceed with questionnaire /survey)

Participant:

Printed Name	Signature	Date

I, (researcher name)..... herewith confirm that the above participant has been informed fully about the nature,
conduct and risks of the above study.

Researcher:

Printed Name	Signature	Date

Witness:

Printed Name	Signature	Date

VERBAL PARTICIPANT INFORMED CONSENT

(This section is applicable when participants cannot read or write and should replace the previous InformedConsent section)

I, the undersigned researcher, ... , hereby confirm that:

- I have read and explained fully to the participant, named.....as well as the witness who signed below, with the consent of the participant, the content of this document, indicating the natureand purpose of the research study in which I have asked the participant to participate.
- I have explained both the possible risks and benefits of the research study associated with participation in this study
- The participant has indicated that he/she understands the contents of the document and that he/she will be free to withdraw from the research study at any time without giving any reason and will not face any penalty or loss of benefit for non-participation.
- I have informed the participant on the existence of relevant compensation for participation in the research study.
- The participant has had sufficient opportunity to ask questions.
- The participant has voluntarily agreed to participate in this research study.

Participant:

Printed Name	Signature or mark	Date

Researcher:

Printed Name Signature Date

I, the witness who signed below, confirm that the researcher has explained fully the content of this document to the participant.

Witness:

Printed Name Signature Date

(Witness' signature confirms that he/she has witnessed the relevant signatures at the time of signing. Witness name, signature and date must be completed by the witness at the same time that this document is signed and dated by the participant and the researcher. A competent witness is a person 16years or older and of sound mind and not involved with research study).

INFORMED CONSENT FOR PARENTS/LEGAL GUARDIANS

(This section must be used where parents/legal guardians give consent on behalf of minors under 18 years old. The PID can be worded to include reference to the parent(s)/legal guardian and the child, or **it can be stated at the beginning of the PID that: "You" will read "you/your child".)**

I/we, the parent(s)/legal guardian of.....hereby confirm that:

- I/we have also been given an opportunity to discuss the possibility of my/our child's/ward's participation in the research study.
- The researcher has given me/us the opportunity to ask any questions concerning both data collection methods and the research study.
- It has been explained to me/us that I/we will be free to withdraw my/our child/ward from thetrial at any time, without facing any penalty or loss of benefit for non-participation.
- I/we have understood everything, including the nature, risks, benefits, and purpose of the research study, that has been explained to me/us and I/we give consent for my/our child/ward to participate in this research study.
- The researcher will provide me/us with a copy of this signed document.

Participant:

Printed Name Signature (where child can write) Date

Parents/Legal Guardian:
1. Mother:

Printed Name Signature Date

2. Father:

Printed Name Signature Date

(The Research Ethics Committee will indicate whether one parent may give consent on behalf of the participant who is younger than 18 years, or both parents must give consent)

3. Legal Guardian (in cases where one has been appointed by the court)

Printed name Signature Date

(Minors competent to understand must participate as fully as possible in the entire procedure)

Researcher:

Printed Name Signature Date

Witness:

Printed Name Signature Date

(Witness's signature confirms that he/she has witnessed the relevant signatures at the time of signing. Witness name, signature and date must be completed by the witness at the same time that this document is signed and dated by the participant and the researcher)

THIS PRO FORMA SHOULD BE USED TOGETHER WITH THE PID FOR THE PARENT(S)/LEGAL GUARDIAN)

PARTICIPANT INFORMATION AND ASSENT DOCUMENT
(Minor participant under 18 years of age, who can understand the nature and extent of the research must receive, and sign a copy of this document)

PROTOCOL NUMBER:

PROTOCOL TITLE:

INVESTIGATOR OR INSTITUTION:

INTRODUCTION

You are invited to participate in a study to evaluate *[mention the aim of the study in layman terms]*
You will be one of ……..participants participating in the study The length of
your participation in the study will be ..... (Days/weeks/months/years).
If you decide to participate in this study, you will be required to ..... *[Explain nature of study in simple Terminology]*

You may have some discomfort due to the questions we may ask *[describe any potential discomforts]*.

You may ask any questions about the study and should you wish to ask more questions in future pleasedo not hesitate to call the researcher on .....or ask her/him next time you visit her/him.

You understand that you do not have to agree to participate in this study and that your parents/legal guardian cannot force you to be in the study. Your parents/legal guardian will have to give consent on behalf of you to participate in this study to make it legal. They are also being informedby the researcher about the study before they will give consent. However, their consent will be worthless if you do not agree to participate in the study.

If you change your mind in future and you do not wish to continue to participate in the study, you maywithdraw without any penalty or loss of benefits. Please also discuss this with your parents/legal guardian.

All information collected about you for this study will be kept confidential (will not be told to anyone not involved in the study) and your name will not be used in study reports. Persons working on the study may look at your personal records collected during the study, but they will not share your name with anyone. When the studyis finished the researcher will write a report about what was learned. The report will not name you orsay that you were in the study.

If you sign this document, you agree/assent to be in the study. You will be a given copy of this documentto keep after you signed it. Your parent(s)/legal guardian will also sign this document in addition to theParticipant Information and Informed Consent document that they will sign to give consent on behalf of you to participate in this study.

Participant:

Name	Signature	Date

Parent(s):Mother:

Name	Signature	Date

Father:

Name	Signature	Date

Legal Guardian:

Name	Signature	Date

Researcher:

Name	Signature	Date

Witness:

Name	Signature	Date

*(**Witness's signature confirms that he/she has witnessed the relevant signatures at the time of signing. Witness name, signature and date must be completed by the witness at the same time that this document is signed and dated by the participant and the researcher***