SAMAREC SOP ANNEXURES JULY 2026, V6

Research Ethics Committee

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Final Version	Reason for Amendment	Effective Date
3	Updated and published for implementation	October 2023
	Administrative changes. Content was not changed	March 2024
4	Fee Update	June 2024
5	Fee Update, NDOH 2024 Updates	July 2025
6	Fee Update, Minor Administrative	July 2026

ANNEXURE 1: SCHEDULED SAMAREC MEETING DATES 2026/2027

Submission Date:	Meeting Date:
29 July 2026	12 August 2026
28 August 2026	09 September 2026
25 September 2026	14 October 2026
30 October 2026	11 November 2026
27 November 2026	09 December 2026
06 January 2027	20 January 2027
27 January 2027	10 February 2027
24 February 2027	10 March 2027
31 March 2027	14 April 2027
28 April 2027	12 May 2027
26 May 2027	09 June 2027
30 June 2027	14 July 2027

NOTES:

- *Meeting dates may change at the discretion of the Chairperson and unforeseen circumstances e.g., load shedding*
- *Please expect a response to your application within 10 days of meeting dates.*

ANNEXURE 2: SAMAREC APPLICATION FORM, V5

SAMAREC APPLICATION FORM, V5

Protocol Number		
Protocol Title		
Study Phase		
Invoicing Details		
PO Number if applicable		
VAT Number		
Contact Person		
Contact Number		
Email Address		
Postal Address		
Clinical Trial Submission: (Section A)		
New Protocol	☐	
Major Amendment	☐	Protocol or Informed Consent Document – Ethical Changes to patient facing documentation/Additional Documents, Reimbursements Etc..
Minor Amendment	☐	Administrative Changes, e.g., Address
Annual Renewal	☐	
Additional Site	☐	
Rapid Review	☐	Subject to Committee Approval, Public Importance, Additional 30% on fee
Expedited Review	☐	Subject to Committee Approval, Minimal Risk Only, Major Public Importance
Is the Study Low, Medium or High Risk?		High (serious harm/ significant discomfort, vulnerable populations) ☐ Medium (less than serious) ☐ Low (discomfort or inconvenience) ☐
Is the Study Involving Children?		Yes ☐ No ☐

CHECK LIST: (Completion for new protocols only)

(Please note that this list reflects the requirements of the Research Ethics Committee, and the Patient Information and Informed Consent Document (PID) will be weighed against these criteria). Ensure the information below is included in your submission for new protocol submissions.

Section A: CLINICAL TRIAL SUBMISSION (Completion for new clinical trial protocols only)		
Is the following Information Included in Application:	**Yes**	**No**
1. Is the trial going to be conducted in the Private Sector?	☐	☐
2. Do you wish to make a presentation?	☐	☐
3. Have you submitted all the requested documentation electronically, and clearly labelled, listed all the documentation submitted? Ensuring no long file names of over 200 characters.	☐	☐
4. Is the protocol number clearly visible on all the documentation?	☐	☐
5. Have you included details of the financial arrangements with investigators and confirmed that patients will be reimbursed for expenses incurred?	☐	☐
6. Will patients be expected to pay for anything? If so, elaborate on reimbursements as per the latest SAHPRA TIE and SAGCP 2020 Requirements	☐	☐
7. Placebo Justification – where applicable the placebo justification must be included in the cover letter.	☐	☐
8. Are there any potential additional risks or discomfort in respect of patients?. Is the Study High	☐	☐

	Risk? (research involving highly sensitive topics and/or the participation of very vulnerable and marginalised individuals/groups/research involving procedures that may cause harm). If yes, please elaborate in your Covering Letter		
9.	Are all relevant details (names of Investigators, Declarations of Trialists, etc.) filled in?	☐	☐
10.	Do the Investigators' CVs include the following information? • Name and Practice address • Qualifications and tertiary institutions • Clinical trials experience: Details of previous and current trials, dates, and whether completed or ongoing • Conferences and/or Congresses attended – if applicable • Proof of personal indemnity insurance cover, i.e., MPS or other valid insurance membership number • Health Professions Council of SA (HPCSA) registration number • Date and signature • Good Clinical Practice Training (GCP) • Dispensing Licence • An outline of additional Research Ethics Training other than GCP Training	☐	☐
11.	Does the protocol clearly stipulate that the investigator may independently publish his or her results?	☐	☐
12.	Have you included a Data Management Plan for the study?	☐	☐
Information concerning the Patient Information and Informed Consent Document (PID)		**Yes**	**No**
1.	Have all applicable PIDs been included (i.e., HIV, Pregnancy, Pregnant Partner, Assent, Future Research, Optional Genetic Research PIDs etc.)?	☐	☐
1.	Does the PID indicate that the principles enunciated in the Declaration of Helsinki (update: October 2024) are complied with?	☐	☐
2.	Does the PID state that neither the patients nor their medical schemes must pay for trial related expenses?	☐	☐
3.	Does the PID state that compensation for trial related injury will be paid in accordance with the NDOH no fault compensation principles.	☐	☐
4.	Is the PID one continuous document? • Please ensure no gaps in the document e.g., signature pages, paragraphs, headings etc. • Please ensure that the footers indicate the relevant information "Protocol number/ Participant Information and Informed Consent Document, SAMAREC Version XX dated XXX"	☐	☐
5.	Does the Informed Consent paragraph provide for names of the patients, study doctor and witness to be both printed and signed?	☐	☐
6.	Have you fully complied with the details in the latest versions of SA GCP, SAHPRA and NDoH Research Ethics guidelines?	☐	☐
7.	Have you structured your PID around the SAMAREC "ideal" example/template? (refer to Annexure 4)	☐	☐
8.	When you refer to the PID, do not refer to it as the *Informed Consent "Form"*, as this is a legal document, the word "*document*" must be used throughout.	☐	☐
9.	Please refer to the participant as "*patient*" when they have a particular disease entity.	☐	☐
10.	Study Doctor/Principal Investigator should undertake the consent process and therefore sign the consent section.	☐	☐
11.	Is the Informed Consent Process done in a confidential setting?	☐	☐
12.	Are the relevant translation documentation being considered, e.g., Afrikaans, Sotho	☐	☐
13.	Has this application been denied by another Research Ethics Committee?	☐	☐

SITE STAFF:

Please complete the attached table for study staff and ensure all documentation is submitted:

SITE ADDRESS	SITE STAFF: Name & Designation	CV	DECLARATION	HPCSA/SANC REGISTRATION	MALPRACTICE INSURANCE	DISPENCING LICENCE	GCP/RESEARCH ETHICS TRAINING

Any queries relating to the functioning of the SAMA Research Ethics Committee may be addressed to the SAMAREC Officer of the SAMA Research Ethics Committee:

Telephone: 012 481 2082
Email Address: samarec@samedical.org
Postal Address: P O Box 74789, Lynwood Ridge 0040
Physical Address: Castle Walk Corporate Park, Block F Nossob Street, Erasmuskloof Ext 3, Pretoria, 0183

ACCESS TO AND PROTECTION OF INFORMATION

Protocol and trial information and documentation are regarded as confidential and are treated as such by SAMAREC and SAMA. In terms of the Guidelines for Ethics in Health Research, published by the National Department of Health, all records and documentation relating to the functioning of SAMAREC are open to the National Health Research Ethics Council. All other requests for access must be done in terms of the Promotion of Access to Information Act. All personal information is treated as confidential and shall be processed in accordance with the Protection of Personal Information Act, 2013 (POPIA).
All documents are stored electronically for record keeping and are accessible only to current SAMAREC members.

REIMURSEMENTS AND INDUCEMENTS FOR PARTICIPANTS

Participants should not have to incur expenses to take part in research. Consequently, researchers should budget to reimburse expenses incurred by participants for travel, refreshments and for inconvenience, depending on the circumstances. If no travel or other expenses are incurred, reimbursement is not required unless an inconvenience reimbursement is justifiable.
A fair rate of reimbursement should be calculated using the latest SAHPRA Time, Inconvenience and Expenses (TIE) method to determine the cost to participants for time expended, inconvenience and refreshments associated with research participation. This method costs expenses at the current hourly rate for unskilled labour in the marketplace, regardless of whether the participant is employed. Researchers must submit planned payment schedules and amounts together with a justification to SAMAREC when making application for ethics review.. The protocol and the informed consent documentation should indicate whether reimbursements are pro rata if the participant does not complete the study, i.e., whether only some of the offered reimbursement is available if participation is stopped before the anticipated end of the study. Where minors are the participants, their accompanying parent or guardian should also receive reimbursement for travel costs and refreshments.
Inducements encourage participation. They may be offered in some circumstances where e.g., recruitment, especially of healthy participants, is anticipated to be difficult. However, a justification for this tactic should be provided and the inducement or reimbursement should not unduly influence an informed choice about participation. In particular, an inducement should not undermine a potential participant's assessment of risk of harm. All should be clearly explained and justified to SAMAREC.

Noted and Accepted by Applicant: _____

Print Name

_____

Signature

_____

Date

ANNEXURE 3: SAHPRA FORMAT FOR CV'S OF INDIVIDUALS PARTICIPATING IN THE CONDUCT OF CLINICAL TRIALS IN SOUTH AFRICA.

Trial:

Protocol:

Designation: (e.g., National Principal Investigator, Investigator (Principal, Co- or sub-), Associate Investigator, Study Co-Ordinator, Regional Monitor, Local Monitor, Contract Research Affiliate)

1. Personal Details Name: Work Address:
   Telephone Number:
   Fax Number:
   Cell-phone Number:
   E-mail address:
2. Academic and Professional Qualifications
3. Health Professions Council of South Africa (HPCSA) registration number if applicable (or other health professions body registration particulars if applicable – e.g., Nursing Council)
4. Current personal medical malpractice insurance details [medical and dental practitioners]
5. Relevant related work experience (brief) and current position
6. Participation in clinical trials research in the last three years (title, protocol number, designation) [If multiple trials, only list those with relevance to this application, or in the last year.]
7. Peer-reviewed publications in the past 3 years
8. Date of last GCP training (as a participant or presenter)
9. Outline of research ethics training in past three years
10. Dispensing Licence Registration number (if applicable)
11. Any additional relevant information supporting abilities to participate in conducting this trial [briefly].

Name: _____

Signature: _____

Date: _____

ANNEXURE 4: GUIDELINES PERTAINING TO SAMAREC PATIENT INFORMATION AND INFORMED CONSENT DOCUMENT (PID)

(Including various consent annexures to be used as relevant to a particular clinical trial)

1. It must be clearly indicated in the PID that the principles contained in the Declaration of Helsinki (updated October 2024) and the National Dept of Health (NDoH) South African Ethics in Health Research Guidelines: Principles, Processes and Structures, v3.2, 2024 are complied with, and that the study has been approved by the SAMAREC. The latest approved version of the Declaration of Helsinki and NdoH guidelines is always applicable.
2. The PID must be written in layperson's language appropriate to the target population (with attention to grammar and South African English spelling).
3. Wherever patients are expected to consider or sign documents, and the age group involves minors, parents/legal guardian involvement, this must be clearly mentioned in the PID.
4. Where patients are *non-compos mentis*, the involvement and capacity of the person who may legally consent on behalf of the patient must be clearly mentioned in the PID.
5. The PID is ONE continuous document, and may not be presented separately – i.e., INFORMED CONSENT is merely another sub-heading in the document, in the same format as all other sub-headings, and does not start on a new page.
6. Kindly ensure that the approved SAMAREC PID version and date details are included in the footer of the PID together with page numbering ideally in the format "page 1 of 2".
7. In the Informed Consent section of the PID, names of patients, study doctor, parents/legal guardians and witnesses must be printed as well as signed. If someone other than the study doctor explains the informed consent, i.e., an interpreter, he/she must also sign a Declaration to this effect at the same time.
8. Based on the risk/benefit ratio of each study, SAMAREC may require a witness in the Informed Consent Process. This will be assessed on a case-to-case basis – therefore the requirement for a witness for a literate patient may be waived for all studies unless specifically requested by SAMAREC.
9. Whenever generics are mentioned, please insert examples of South African trade names as well in brackets. This is useful information for patients reading the PID.
10. Reference to "clinic" or "hospital" is unacceptable and should read "study doctors' rooms" or "- facilities", in accordance with Health Professions Council of SA (HPCSA) rules.
11. All trial related injuries must be covered, and a copy of the certificate of insurance must be furnished.
12. Arrangements for compensation and insurance must be included in the PID, and it must be stated clearly that compensation to patients is of no fault principles
13. All tests done on blood, urine and other samples taken from patients must be specified, and the nature and purpose of such tests explained in layperson's terminology in the PID e.g. urine sample for pregnancy test or for kidney functions and to advise if samples will be kept for future use.
14. It should be stated that there will be no trial-related costs to the patient or his/her medical scheme. Any costs to be borne by the patient must be clearly stated in the PID.
15. Once the full term "The Patient /Participant Information and Informed Consent Document" (PID) has been used, it can thereafter be referred to as "this document.
16. Tick boxes– the use of tick boxes is not encouraged, and participants should rather sign their initials when they have to reflect a choice.
17. Please ensure that no product logos appear on any patient facing material (including recruitment material) as this is considered advertising.

PRO FORMA

PATIENT INFORMATION AND INFORMED CONSENT DOCUMENT

(Each patient must receive, read, and understand this document before the start of the study)

PROTOCOL NUMBER: .....

PROTOCOL TITLE: .....

SPONSOR: .....

INTRODUCTION

You are invited to take part in a research study. This document is needed to help you to decide if you would like to participate. You should fully understand what is involved before you agree to take part in this study. If you have any questions that are not fully explained in this document, do not hesitate to ask the study doctor. You should not agree to take part unless you are completely happy about all the procedures involved and possible risks. In the best interests of your health, it is strongly recommended that you discuss with or inform your personal doctor (general practitioner) of your possible participation in this study. The study doctor will also be notifying your personal doctor in this regard, unless you disagree that notification takes place.

THE PURPOSE OF THIS TRIAL

You have been diagnosed as suffering from.....and the study doctor would like you to consider taking part in the research of a new drug/intervention (delete which is not applicable), called (***Where possible, include the trade name and/or examples of the drug in brackets after the word. Details of the study population and age must also be furnished).***

During the study you will receive …… (Explain the intervention), e.g. ..... either the active drug or a placebo. A placebo is an inactive substance; it does not contain any of the drugs which are to be used in this trial).

THE DURATION OF THIS TRIAL

If you decide to take part in this trial, you will be one of approximately ..... patients. The study will last for up to..... (days/weeks/months/years). You will be asked to visit the study doctor.....times as per the following schedule:.....
At each visit you will undergo the following examinations and tests:

Visit 1 – (week?):
Visit 2 – (week?):

<u>(Give the exact reasons for the blood, urine and other tests, electrocardiograms (ECG), and all other tests must be stated, indicating what tests will be done and why it is necessary to do them, in layperson's terms)</u>

It is important that you let the study doctor know of any medicines (both prescriptions and over-the-counter medicines), alcohol or other substances that you are currently taking.

ETHICS APPROVAL

The Protocol of this clinical trial 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 trial. The study has been structured in accordance with the National Dept of Health (NDoH) South African Ethics in Health Research Guidelines: Principles, Processes and Structures, v3.2, 2024 , published by the Department of Health and the Declaration of Helsinki (updated October 2024), adopted by the World Medical Association (WMA), as well as the Guidelines for Good Clinical Practice in the Conduct of Clinical Trials with a Human Participant in South Africa (Third Edition, 2020), which deals with the recommendations guiding doctors in biomedical research involving human participants. Copies of these documents may be obtained from the study doctor should you wish to review it.

If you have any questions about the study or your rights, at any time, or think you have experienced an injury or reaction to the study medication, you should contact your study doctor.

Study doctor/Principal Investigator: Dr [insert PI name and contact information].
If you have questions about your rights as a research participant, you may contact: The South African Medical Association Research Ethics Committee (SAMAREC)
PO Box 74789
Lynwood Ridge 0040
Tel: 012 481 2082
Email: samarec@samedical.org

YOUR RIGHTS AS A PARTICIPANT IN THIS TRIAL

Your participation in this trial is entirely voluntary and you can refuse to participate, or you can stop at any time without stating any reasons whatsoever. Your refusal to participate in or your withdrawal from this clinical trial will not affect your access to other medical care. The study doctor, however, retains the right to withdraw you from the study if it is considered to be in your best interest, in which event reasons will be provided for withdrawing you from the study. If it is detected that you did not give an accurate history or did not follow the guidelines of the trial and the prescriptions of the trial facility, you may be withdrawn from the trial at any time.

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 Sponsor is required to follow POPIA , 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 clinical trial. You are not obliged to give this permission. However, if you do not consent, you will not be able to participate in the clinical trial.

Will your consent ever expire?

Your personal information will be retained only for as long as necessary to fulfil the purposes of the research study and applicable legal/regulatory retention requirements

Can you withdraw your consent?

You have the right to withdraw your consent at any time by informing a member of the study team at *<Insert address with telephone number / e-mail address>*

What happens if you leave the clinical trial prematurely?

If for any reason you terminate your participation in the clinical trial, site staff will inform the sponsor that you are doing so. The site staff will ask you to return for a closing visit and if you agree, the site staff will also send the sponsor details of that visit. Any information collected about you prior to your early withdrawal may be used and shared in accordance with this patient 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)

In the interest of your safety, the investigator can inform your personal general practitioner as indicated by you that you are participating in this clinical trial.

The sponsor and / or the clinical trial site will retain your personal data for 15 years after the investigation has ended (After this 15-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 clinical trial. To guarantee the scientific integrity of the clinical trial, you may only have access to certain personal data when the clinical trial has ended.

Ask for corrections if the personal data is incorrect or incomplete

Ask to transfer clinical trial 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 sponsor 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 and anonymised (data will be processed in a way that cannot be tracked directly back to you) before itis stored, analysed, or transferred. The sponsor 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

It is important to emphasise that some of the authorised users of your data may be located in countries that do not have the same standards as South Africa when it comes to the legal protection of personal data. Although the sponsor, as the party responsible for the processing of personal data, makes every effort to respect the provisions of South African legislation on the protection of privacy, a transfer of personal data to a country outside South Africa may pose a security risk. In addition, there is a risk that you 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, your explicit 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?

Your study doctor and study staff will be responsible for collecting personal data, as required, for you to take part in the study. Along with medical data, including data from laboratory samples, other data collected may include your sex, age or date of birth, ethnicity, body weight and height. Your personal data related to your participation in the study will be replaced by a code so that you cannot be identified directly. Only your study doctor and study staff will be able to identify you from the code. The Sponsor and the other companies collaborating with the Sponsor on the study (the Sponsor representatives) will not be able to identify you directly. The Sponsor and their representatives will be responsible for processing the information which will be stored under the code allocated to you and are responsible for ensuring your data remains confidential as required by the law in your country. Data collected about you for the purposes of this study will be transferred to a central location.

Some authorised Sponsor representatives (including the contract research organisation working with the Sponsor, laboratories testing your samples, monitors, auditors), National Health Authorities, Regulatory Authorities and Ethics Committees will have limited but direct access to your personal data(medical records and genetic data) held by the study site 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 study doctor.

This access may include viewing your medical records remotely, from a location outside of the study site.

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.

ALTERNATIVE TREATMENT

Alternative treatment in the form of..... is often used to treat (this condition). ..... If you decide not to take part in this study it is possible that your personal doctor may treat you with this, or another suitable treatment. ***(If the option of "no treatment" is an alternative, this should be stated.)***

TRIAL PROCEDURES MAY RESULT IN DISCOMFORT OR INCONVENIENCE

(**Example)**: Venipunctures (i.e., drawing blood) are normally done as part of routine medical care and presents a slight risk of discomfort. Drawing blood may result in a bruise at the puncture site, or less commonly fainting, swelling of the vein, infection, and bleeding from the site. Procedures are performed under hygienic conditions by experienced personnel. A total of ml of blood (i.e. tablespoon) will be collected over the course of the entire study.

THE RISKS INVOLVED IN THIS TRIAL

All medicines carry some risk, however small. In previous studies some patients have reported experiencing side effects which included ....., ..., and..... **(Medical terminology should be explained in layperson's language in brackets.) PREGNANCY / BIRTH CONTROL** Safety of the study medication in pregnancy and lactation as well as the effects during fertilisation of the egg cell has not been established. There might be unknown risks to the unborn child if a female patient is pregnant, or becomes pregnant during the study or if a male patient fathers a child whilst on study medication

MALE PATIENTS

If you are a man who can father a child, suitable contraceptive measures should be used during the study.

FEMALE PATIENTS

If you are a woman of child-bearing potential:

- You must not participate in this study if you are pregnant, or plan to become pregnant during the research study period or are breastfeeding.
- You must use acceptable methods of birth control during this study (for example, a condom or a diaphragm plus spermicide; hormonal contraceptives that are injected, implanted, or taken orally, or an intrauterine device.
- A pregnancy test will be done to confirm that you are not pregnant before your participation in this study.
- By signing this document, you confirm to the best of your knowledge that you are not pregnant now, breastfeeding and you do not intend to become pregnant during this study.

If at any time during this study you think you might be pregnant or later learn during the study that you are pregnant, you must contact the study doctor immediately for further instructions regarding your participation in this study and follow-up.

DISCONTINUATION OF TRIAL TREATMENT

Uncontrolled discontinuation of trial medication is not advisable. Special care needs to be taken for the discontinuation of this trial medication. The study doctor will supervise any discontinuation with your health as first priority. In the event of withdrawal from the study-by-study doctor, the study doctor will provide you with reasons.

COSTS AND FINANCIAL ARRANGEMENTS

Neither you nor your medical scheme will be expected to pay for any study medication, study-related visits, or trial procedures. **(If it is a requirement that a patient is responsible for any non-trial related costs, i.e. for usual treatment costs, this must be indicated clearly, giving details of what these responsibilities are and the estimated amount(s)**).

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 study doctor before commencement of the trial. There will be no costs to you or your medical scheme.

(All informed consent documents submitted for review must clearly outline any participant reimbursement. This includes reimbursement for time, inconvenience, and out-of-pocket expenses related to study participation. Reimbursement details must specify what is covered, the method of calculation, and confirmation that payments will be provided regardless of study outcome or early withdrawal. Including this information ensures transparency, supports voluntary and informed decision-making, and allows the ethics committee to assess that reimbursements are appropriate and not coercive, in line with South African Good Clinical Practice (SA-GCP) requirements and the latest SAHPRA TIE requirements.)

Participant Reimbursement for Time, Inconvenience, and Expenses (TIE)
Participation in this study is voluntary, and you will be reimbursed for your Time, Inconvenience, and Expenses (TIE) as per the SAHPRA TIE latest guidelines, directly related to your study visits, as mandated by the SA-GCP-2020 guidelines. This payment is a reimbursement for costs such as transport and refreshments and is not an incentive to participate.

Should the participant be a minor or require a caregiver/escort, the same reimbursement scheme will apply to the parent or legal guardian accompanying them.

INSURANCE AND COMPENSATION

The Sponsor has obtained insurance for you and the study doctor in the event of trial related injuries. The Sponsor assumes no obligation to pay for the medical treatment of other injuries or illnesses not related to the studies. Further detailed information on the payment of medical treatment and compensation due to injury can be obtained from the study doctor should you wish to review it. Any compensation will be paid in accordance with the NDOH no fault compensation principles, cover the compensation aspects relating to clinical trials.

Your medical scheme should receive pre-notification of your possible participation in the trial and provide clarity on non-trial-related costs to be borne by them.

(This sentence is applicable where study doctors initiate studies or for studies where the patients' medical scheme will be expected to pay for certain costs. All costs to be borne by the patient or the medical scheme should be specified, and the patient should be made aware of it).

You must notify the study doctor immediately of any research or other related complications, side effects and/or injuries resulting from the trial, and the nature of the expenses to be covered.
By signing this document, you do not waive any of your legal rights should a research-related injury occur.
Please note that if you have a life insurance policy you should enquire whether your insurance company requires notification of your intention to participate in a clinical trial. Our information to date is that it should not affect any life insurance policy taken out. Nevertheless, you are strongly advised to clarify this with the insurance company concerned.

SOURCE OF ADDITIONAL INFORMATION

For the duration of the trial, you will be under the care of the study doctor, Dr.....If at any time between your visits you feel that any of your symptoms are causing you any problems, or you have any questions during the trial, 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 trial 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 patient in this trial.

In connection with this trial, it might be important for domestic and foreign regulatory health authorities, such as the Department of Health (DoH), the National Health Research Ethics Council (NHREC), the Food and Drug Administration of the United states of America (FDA), the South African Medical Association Research Ethics Committee (SAMAREC), the South African Health Products Association (SAHPRA), as well as authorised persons on behalf of the Sponsor, to be able to review your medical records pertaining to this trial. Therefore, by signing this document, you authorise your study doctor to release your medical records in appropriate circumstances to the Sponsor, its employees or agents, domestic and foreign regulatory health authorities, the SAHPRA and the SAMAREC. You understand that these records will be utilised within reason by them only in connection with conducting their obligations relating to this clinical trial.

Any information uncovered regarding your test results or state of health as a result of your participation in this trial will be held in strict confidence. You will be informed of any finding of importance to your health or continued participation in this trial, but this information will not be disclosed to any other than those mentioned above without your written permission. The only exception to this rule will be in cases where 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 sponsor and its affiliated companies to study better measures of safety and effectiveness, study other therapies for subjects, develop a better understanding of disease included in the study or improve the efficiency, design, and study methods of future clinical trials. Such information will not identify you by name.

INFORMED CONSENT

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

Patient:

Printed Name	Signature	Date

I, Dr .....herewith confirm that the above patient has been informed fully about the nature, conduct and risks of the above trial.

Study Doctor:

Printed Name	Signature	Date

Witness:

Printed Name	Signature	Date

VERBAL PATIENT INFORMED CONSENT

(This section is applicable when patients cannot read or write and should replace the previous Informed Consent section)

I, the undersigned study doctor, Dr..... , hereby confirm that:

- I have read and explained fully, to the patient, named..... as well as the witness who signed below, with the consent of the patient, the content of this document, indicating the nature and purpose of the trial in which I have asked the patient to participate.
- I have explained both the possible risks and benefits of the trial and the alternative treatments available for

his/her illness.

- The patient has indicated that he/she understands the contents of the document and that he/she will be free to withdraw from the trial at any time without giving any reason or jeopardising his/her subsequent treatment.
- I have informed the patient on the existence of relevant compensation arrangements in case of an injury attributable to the drug(s) used in the clinical trial, to which he/she agrees.
- The patient has had sufficient opportunity to ask questions.
- The patient has voluntarily agreed to participate in this trial.

Patient:

Printed Name	Signature or mark	Date

Study Doctor:

Printed Name	Signature	Date

I, the witness who signed below, confirm that the study doctor has explained fully the content of this document to the patient.

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 patient and the Study Doctor. A competent witness is a person 16years or older and of sound mind and not involved with trial).

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 trial.
- The study doctor has given me/us the opportunity to ask any questions concerning both the medicine and the trial.
- It has been explained to me/us that I/we will be free to withdraw my/our child/ward from the trial at any time, without any disadvantage to future care.
- I/we have understood everything, including the nature, risks, benefits, and purpose of the trial, that has been explained to me/us and I/we give consent for my/our child/ward to participate in this clinical trial.

- The study doctor will provide me/us with a copy of this signed document.

Patient:

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 patient 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)

Study Doctor:

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 patient and the Study Doctor)

PATIENT INFORMATION AND ASSENT DOCUMENT

This Pro Forma should be used together with the PID for the parent(s)/legal guardian)

(Minor patients under 18 years of age, who can understand the nature and extent of the research/treatment, must receive, and sign a copy of this document)

TRIAL NUMBER:……..

TRIAL TITLE:

SPONSOR:

INTRODUCTION

You have been diagnosed with…… a disease of the……., and are invited to participate in a study to evaluate the effect of (the drug) on your disease.
The purpose of the study is to find out what effects the drug has on people like you and to learn more about how to treat your illness. This treatment may or may not help you.
If you are not completely truthful with your study doctor about your health history, you may harm yourself by participating in this study.
You will be one of ……..patients participating in the study in ……centres world-wide. 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 treated…… ***(Explain nature of study in simple terminology)***

If you choose to participate in this study you will need to visit the study doctor's rooms for……..times which visits will take about ……hour each.
There will also be tests that you must undergo and for these tests it will be necessary to draw blood from a vein and to obtain urine. The study doctor will explain these tests to you.

Phase 1 Studies: (Optional paragraph – include if applicable:
This study is a Phase-1 ('first-in-human') study and is the first time this medicine is being tested in people. The aim is to understand this medicine's safety, how the body processes it, and what dose levels can be used safely. It is not expected to provide medical benefit to participants. If you choose to take part, you will attend scheduled visits, take the study medicine as instructed, and undergo safety checks such as blood tests, vital-sign measurements, and monitoring for any side effects. You may need to stay in a hospital or research facility for several days, so the study team can closely monitor your response during and after dosing. Because this is the first use in humans, there may be unknown or unexpected side effects, including serious ones, and the study doctor may pause or stop dosing at any time if needed for your safety.'

(Optional paragraph – include if applicable:
If it is possible for you to become pregnant, a urine/blood pregnancy test will be done before receiving the first doses of medication. As it is not known what effects the medicine you will be taking could have on an unborn baby, it is important to find out whether you are pregnant or not before you start taking the medication. Should you be pregnant or become pregnant during the course of the study, you will be taken off the study.)

You may have some side effects from the medicine you will be taking. These effects may make you feel ill. You must tell the study doctor of any side effects. The study doctor will then stop the medication if indicated. The most common side-effects are…….

You may ask any questions about the study and should you wish to ask more questions in future please do not

hesitate to call the study doctor 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 or study doctor 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 informed by the study doctor 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 may withdraw, and usual medical care will be given to you. Please also discuss this with your parents/legal guardian.

The study doctor will tell you if they find new information (good or bad) that they did not know about when they first explained this study to you.

This research study is covered by an insurance policy taken out by [name of institution] in the event that you suffer a bodily injury as a result of taking part in the study. The insurer will pay for all reasonable medical costs required to treat your bodily injury, in accordance with the latest SA Good Clinical Practice Guidelines.. The insurer will pay without you having to prove that the research was responsible for your bodily injury. The insurer will not pay for harm if, during the study, you

- Use medicines or other substances that are not allowed
- Do not follow the study doctor's instructions
- Do not tell the study doctor that you have a bad side effect from the study medicine
- Do not take reasonable care of yourself and your study medicine

If you are harmed and the insurer pays for the necessary medical costs, usually you will be asked to accept that insurance payment as full settlement of the claim for medical costs.
However, accepting this offer of insurance cover does not mean you give up your right to make a separate claim for other losses based on negligence, in a South African court.

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 medical records, but they will not share your name with anyone. When the study is finished the study doctor will write a report about what was learned. The report will not name you or say 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 document to keep after you signed it. Your parent(s)/legal guardian will also sign this document in addition to the Patient Information and Informed Consent document that they will sign to give consent on behalf of you to participate in this study.

Patient:

Name	Signature	Date

Parent(s): Mother:

Name	Signature	Date

Father:

Name	Signature	Date

Legal Guardian:

Name	Signature	Date

Study Doctor:

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 patient and the Study Doctor

ANNEXURE 5: MEMBERS OF SAMAREC

Committee Members

NAME OF MEMBER	FIELD OF INTEREST	DESIGNATIONS FOR REC
Dr N Naidoo BSc, BMedSc, MBBCh, MPH, MMed (Clin Path), FC Path(SA) Clin	Clinical Pathologist	Chairperson Medical Professional, Indian, Male
Ms. T Coetzee PG Dip (Health Res Ethics); M Phil (Applied Ethics)	Health Research Ethics	Vice Chairperson Health Research Ethics Expert, White, Female
Ms N Madolo BHSc Biomedical Science	Quantitative Research	Quantitative Research, Black, Female
Mr R Masemola BCom (Law), LLB, Cert. in Corp Governance	Legal Advisor	Legal Representative, Medico Legal Advisor, Black, Male
Ms M Raitsu Dip. Biomedical Sciences, BSc, Hons Epidemiology & Biostatistics, MSc Epidemiology & Biostatistics	Epidemiology & Biostatistics	Biostatistician, Black, Female
Ms K Ledibane BA in Communications, Hons Psychology, MA Forensic Psychology	Psychologist	Counsellor, Community Representative, Black, Female
Dr S Nyamathe MBChB, Dip Public Health, MSc Child Health	Public Health Clinician	SAE Officer Medical Professional, Qualitative Research, Black, Female
Dr C Khoza MBChB, MPH	Public Health Clinician	Medical Professional, Black, Male,
Dr Z Mafika MBChB, MMED (HAEMATOLOGY), FCPATH(SA) HAEM	Haematopathologist	Medical Professional, Black, Male
Dr L Pillay MBChB, MSc (Med) Sports Medicine, PhD Candidate	Sport Medicine	Medical Professional, Indian, Male
Ms S Abdurahman LLB, LLM	Legal Advisor	Legal Representative, Coloured, Female
Prof NJ Mekwa Ph. D (Psychosocial Nursing), M Soc. Sci. (Nursing), B Cur, Hons, B Sc. Nursing (I et A)	Professor Emerita	Layperson Representative, Black, Female

Administrative Support

Mrs L Reid Bachelor of Business Administration, CRA Cert. Diploma in IT Support	SAMAREC Officer, White, Female
Ms M Snijder BHSc Biomedical Science, BHSc (Hons) Bioethics & Health Law, MSc Epidemiology & Biostatistics	SAMAREC Assistant, Coloured, Female

ANNEXURE 6: FEE STRUCTURE FOR PROTOCOLS 2026

Please request an invoice accordingly. (Excluding VAT) – Rates to be updated annually each July

APPLICATION:	RATE:
New Protocol (Full Review – Committee Meetings, response 10 days from meeting date)	R 26 500
Rapid Review - only applicable to clinical trials (10 Working Days) Subject to approval	Additional 30%
Expedited Review – (3 Working Days) a) New Protocol (minimal risk) b) Amendment (minimal risk) Subject to approval, 10 days from meeting date	a) R17 250 b) 14 400
Major Amendment - (Ethical Changes) e.g., Protocol or PID, Changes in patient recruitment (Full Review – Committee Meetings) Response, 10 days from meeting date	R12 700
Minor Amendment – Sponsor Name Changes, Addresses, Administrative not involving ethical concerns (5 Working Days)	R6 200
Annual Review (5 Working Days) a) Clinical Trial b) Non-clinical study	a) R7 200 b) R 2 890
Additional Sites – after initial application. (5 Working Days)	R2 065 per site
Student/Doctor Unsponsored Study/Surveys (Full Review – Committee Meetings, response 10 days from meeting date)	R5 721
Auditing Fee – When required (SAMAREC is mandated by the NHREC to conduct random audits or as the need arises)	R5 500
Ethics Waiver	R2 000 Administration Fee

SAMAREC prefers response to Committee queries within 30 days

If a protocol submitted for review is of a unique, complex, or highly specialised nature that requires consultation with external subject-matter experts or specialist reviewers, additional costs may be incurred beyond the standard protocol review fee. In such instances, the Ethics Committee reserves the right to obtain appropriate expert input to ensure a thorough and competent scientific and ethical review of the study. Any such additional costs will be reasonable and directly related to the specialist consultation required, and the applicant will be informed in advance where applicable.

Banking Details: Name of Account Holder: The South African Medical Association **Account Number**: 011933615 **Bank Name:** Standard Bank **Branch Code:** 011545 **Reference:** Invoice Number. Please include a purchase order number with the application if required.

Proof of payment to be sent through to samarec@samedical.org .

ANNEXURE 7: SAMAREC GUIDELINES FOR CLINICAL STUDY ADVERTISEMENTS AND NOTIFICATIONS IN HEALTH RESEARCH

PART A

ADVERTISEMENT AND NOTIFICATION TO THE PUBLIC INTRODUCTION

In terms of the Standard Operating Procedures (SOPs) of the South African Medical Association Research Ethics Committee (SAMAREC):
All advertisements and notifications to the general public and prospective research participants, or other persons or organisations, must be approved by SAMAREC. In assessing such advertisements, SAMAREC will consider the Guiding Principles enunciated hereunder.

PURPOSE

The purpose of these Guiding Principles is primarily to protect the fundamental rights of persons participating or considering participation in health research by providing guidance and governance in respect of advertisements and notifications relating to such health research.

Persons experiencing health problems are often particularly vulnerable to persuasive influence such as unprofessional advertising and are, therefore, entitled to protection from misleading or promotional advertising, or improper competitive actions.

It should also be noted that advertising in an unprofessional manner or canvassing and touting for research participants is, generally, regarded as unethical behaviour by health care personnel and health establishments, and could constitute a breach of professional conduct.

GUIDING PRINCIPLES

In light of the above, the following principles are hereby published to assist health care workers, researchers, health establishments, as well as sponsors, when compiling advertisements and notifications relating to health research:

1. It is generally permissible for sponsors undertaking health research, as well as health care providers and researchers participating therein, to advertise such research. However, the advertisements for recruiting research participants should be evaluated and approved by the same Research Ethics Committee (REC), such as SAMAREC that evaluates and approves the health research protocol.
2. Researchers intending to promote their participation in health research shall do so in a professional manner and always subject to the rules and ethical considerations of the statutory body with whom they are registered or the entity governing their specific profession.
3. The name of a sponsor company or individual researcher may not appear on advertisements and notices. However, the particulars of an independent person from the sponsor company may be stipulated as a contact person.
4. The telephone number stated on the advertisement should be that of an independent person or independent call centre and must not belong to any researcher participating in the health research, or to any health research site.
5. The contact details must be that of a person able to respond to questions related to the study and may also be the person engaged to undertake screening for the health research.

6. The person engaged to screen the phone calls may be reasonably reimbursed.
7. The advertisements and notifications may be published in any medium, printed, or electronic, including the internet and television.
8. There are no limitations on the size or number of times an advertisement or notice may be published.
9. Factual information of the health research may be published e.g. “A Phase III Clinical Trial on Type 2 Diabetes...”
10. The selection / inclusion criteria may be mentioned e.g. “Are you between 18 and 70 years and suffering from Type 2 Diabetes?”
11. Any reference to drugs, which contain a substance appearing in Schedule 2 and above as defined in the Medicines and Related Substances Act (as amended from time to time), may be included in the advertisement, provided that the reference or sentence construction is not tantamount to promotion or advertisement of such drug.
12. Advertisements or notifications may be made available for distribution to existing patients of health care providers, at consulting rooms, clinics, hospitals, health establishments or at local information centres such as libraries and museums.
13. Graphics and photographs (even of an anatomical structure) on advertisements and notices are permissible but must not be indecent, deceptive, misleading or bring any profession into disrepute.
14. Payment details or reimbursement to research participants may not appear in the advertisement or notice for research participants.
15. All advertisements and notifications to be used for or in health research, must be approved by the relevant REC or by SAMAREC.

PART B

ADVERTISEMENTS AND NOTIFICATIONS AMONGST HEALTH CARE PERSONNEL

INTRODUCTION

It is common practice and should be encouraged amongst health care providers, to communicate the setting up of a practice or practice address changes to colleagues and in these communications to colleagues they may include information on their field of practice, e.g. “treatment of patients with AIDS”. It is likewise permissible for a health care provider or researcher engaging in health research to advise colleagues, other health care providers and health establishments, that they are involved in health research and that they are looking for suitable research participants.

In the best interests of research participants, only health care personnel and researchers with demonstrable research capabilities should be recruited to conduct the required research. The health care personnel and researchers to be recruited would be held accountable, and could be convicted, for unprofessional and unethical behaviour on their part during health research.

PURPOSE

The purpose of these further Guiding Principles is to ensure that health care personnel and researchers intending to promote their participation in health research do so in a regulated and professional manner.

GUIDING PRINCIPLES

1. Health care personnel and researchers participating in clinical trials may communicate such information to colleagues, other health care providers and health establishments or relevant persons and entities, with the aim of obtaining referrals of potential research participants.
2. The advertisements and notifications may be published in any medium, printed, or electronic, provided that

all relevant ethical rules and guidelines of the statutory body with whom they are registered or the entity governing their specific profession, are complied with.

3. Any further detailed or information on the health research, selection / inclusion or exclusion criteria may be included in the notification, to enable appropriate referral of potential research participants for screening.
4. It should be specifically mentioned in the advertisements or notification letter that the research participant referred for participation in the health research will remain the *bona fide* patient (person) of the referring health care provider i.e. as soon as the health research has been completed / or is terminated for whatever reason, such research participant would be referred to the referee.
5. Health care providers or researchers who are liable for and incur advertising costs for recruitment of research participants in health research, may be reimbursed.
6. The Guiding Principles enunciated in paragraphs 8, 9, 10, 11, 12, 14, and 16, of Part A above, shall apply *mutatis mutandis* to this Part B.

PART C

EXAMPLE OF ADVERTISEMENT/ NOTIFICATION

(Picture)

ADVERTISEMENT/ NOTIFICATION:

A Phase III Clinical Trial on Type 2 Diabetes

(NO RESTRICTION ON SIZE OR TYPESTYLE OR NUMBER OF TIMES PUBLISHED)

ARE YOU BETWEEN 18 AND 45 YEARS OLD? ARE YOU SUFFERING FROM TYPE 2 DIABETES?

DO YOU HAVE THE FOLLOWING SYMPTOMS..... ?

IF SO, PLEASE PHONE THE FOLLOWING NUMBERS SHOULD YOU BE INTERESTED IN PARTICIPATING IN HEALTH RESEARCH WHEREIN A NEW DRUG WILL BE TESTED FOR THE CONDITION / DISEASE YOU HAVE

ANNEXURE 8: DECLARATION BY PRINCIPAL INVESTIGATOR

Name:

Title of Trial:

Protocol:

Site:

1. I have read and understood Item 1.5.5 on page 5 and Section 3 (pages 14-20) 'Responsibility of the Principal Investigator (PI) and Participating investigators 'of the *Clinical Trials Guidelines of the Department of Health: 2000.*
2. I have notified the South African regulatory authority of any aspects of the above guidelines with which I do not
   / am unable to comply. (Details of non-compliance must be attached to this declaration.)
3. I have thoroughly read, understood, and critically analysed (in terms of the South African context) the protocol, and all applicable documentations, including the investigator's brochure, and the Patient/Participant Information and Informed Consent Document(s).
4. I will conduct the trial as specified in the protocol.
5. To the best of my knowledge, I have the potential at the site(s) I am responsible for, to recruit the required number of suitable participants within the stipulated time period.
6. I will not commence with the trial before written authorisations from the relevant ethics committee(s) as well as the South African Health Products Regulatory Authority (SAHPRA) have been obtained.
7. I will obtain informed consent from all participants, or if they are not legally competent, from their legal representatives.
8. I will ensure that every participant (or other involved persons, such as relatives) shall at all times be treated in a dignified manner and with respect.
9. I declare that I have no financial or personal relationship(s) which may inappropriately influence me in conducting this clinical trial. All conflicts of interest have been declared by me.
10. ***Delete the inapplicable option below:***
    I have not previously been the Principal Investigator at a site which has been closed due to failure to comply with Good Clinical practice.

OR

    I have previously been the Principal Investigator at a site which has been closed due to failure to comply with Good Clinical practice and attach the relevant explanatory documents to this declaration.

11. ***Delete the inapplicable option below:***
    I have not previously been involved in a trial which has been closed as a result of unethical practices.

OR

    I have previously been involved in a trial which has been closed as a result of unethical practices and attach the relevant explanatory documents to this declaration.

12. I will submit all required reports within the stipulated timeframes.

Printed name of Principal Investigator | Date | Principal Investigator's signature

ANNEXURE 9: DECLARATION BY SUB- AND CO-INVESTIGATORS AND OTHER STUDY

Name:

Title of Trial:

Protocol:

Site:

Designation:

1. I will conduct my role in the trial as specified in the protocol.
2. I will not commence with my role in the trial before written authorisations from the relevant ethics committee(s) as well as the South African Health Products Regulatory Authority (SAHPRA) have been obtained.
3. If applicable to my role, I will ensure that informed consent has been obtained from all participants, or if they are not legally competent, from their legal representatives.
4. I will ensure that every participant (or other involved persons, such as relatives) shall at all times be treated in a dignified manner and with respect.
5. Using the broad definition of conflict of interest below, I declare that I have no financial or personal relationship(s) which may inappropriately influence me in conducting this clinical trial.
6. *[Conflict of interest exists when an investigator (or the investigator's institution) has financial or personal relationships with other persons or organisations that inappropriately influence (bias) his or her actions.]* **Modified from: Davidoff, F. Et al Sponsorship, Authorship and Accountability. (Editorial) JAMA Volume 286 number 10 (September 12, 2001)
7. ***Delete the inapplicable option below:***
   I have not previously been the Principal Investigator at a site which has been closed due to failure to comply with Good Clinical practice.
   OR

   I have previously been the Principal Investigator at a site which has been closed due to failure to comply with Good Clinical practice and attach the relevant explanatory documents to this declaration.
8. I will submit all required reports within the stipulated timeframes.

Printed Name	Date	Signature

ANNEXURE 10: EXAMPLE OF LIST OF STUDY STAFF AND THEIR SUBMITTED DOCUMENTATION

Protocol number:_____

Table indicating the staff members who are requesting approval for participation in the trial and a record of their submitted documents.

Name and address of site:_____

Name	Position	CV	Declaration	MPI	GCP	HPCSA or other professional body	Dispensing licence
Dr A	Principal Investigator	✓	✓	✓	✓	✓	n/a
Dr B	Sub-investigator	✓	✓	✓	✓	✓	✓
Ms C	Co-ordinator	✓	✓	n/a	✓	n/a	n/a

ANNEXURE 11 SAMAREC DATA MANAGEMENT PLAN TEMPLATE

GENERAL CONSIDERATIONS

- A Data Management Plan (DMP) is a living document that should be adjusted throughout the research process as methods change.
- SAMAREC does not provide a word count or limit the number of pages for the DMP. The length of your DMP should align with the complexity of your research while ensuring that the purpose of the DMP is maintained - to ensures transparency, reproducibility and reusability of data.
- Your DMP should flow from your research proposal, thus ensure congruency between these documents.

PROJECT DESCRIPTION

Provide a brief description of the aim and purpose of your research project.

DATA LIFECYCLE

Complete the table below:

Lifecycle Stage	Responsible Individual/s	Description of Activities
Collection		This section should clearly outline the process of collecting the data (will you search the literature, rely on an existing database, conduct interviews etc).
Processing		Describe the data cleaning and data verification process. Describe any other processing that the data will undergo (i.e., transformation, encryption, compression etc.) If new variables will be generated (i.e., scores, dichotomising variables etc.) describe how this new variable will be created.
Storage		Describe how and where the data will be stored. If data will be stored on multiple platforms, clearly describe where each variable will be stored.
Analysis		Describe how the individual conducting the data analysis will access and/or receive the data.
Archive and Destruction		Describe how the data will be archived, for how long it will be archived and how the data will be destroyed (if necessary)

DATA DESCRIPTION

Complete the table below for each variable:

Variable	Type (survey, health record, interview, lab result etc.)	Data Format (i.e., .csv, .txt, MP3, jpeg etc.)	Meta Data (file size, date created date modified etc)	Storage (on which platform will the data be stored)	Data Collection Method (including whether the data will be collected from a primary or secondary source)	Notes

DATA PROTECTION

Describe the measures put in place to ensure confidentiality of the data (i.e., protection of physical data collection devices, cybersecurity measures, access controls etc.). Should your Organisation hold to specific safety standard (i.e., ISO/IEC 27001), please provide the Organisation's registration number.

Provide justification for collecting any personal information. Specify which parties will have access to personal information and include the following wording: *"All other requests for access must be done in terms of the Promotion of Access to Information Act. All personal information is treated as confidential and shall be processed in accordance with the Protection of Personal Information Act, 2013 (POPIA)."*

DATA SHARING

Describe the procedures for sharing data. If applicable, provide a Data Sharing Agreement.

DATA LIMITATIONS

Describe any limitations with the data (study design limitations, a lack generalisability etc).

ANNEXURE 12: SAMAREC MATERIAL TRANSFER AGREEMENT 2026

(To remove all SAMA branding when submitting for approval, as this is a template)

SAMAREC MATERIAL TRANSFER AGREEMENT

Entered into between:

[Company name][Legal address] Represented by:

[Name of PROVIDER representative] (Hereinafter referred to as "**the Provider**")

And

[Company name][Legal address] Represented by:

Name of RECIPIENT representative (Hereinafter referred to as "**the Recipient**")

WHEREAS,

a) the Provider remains custodian of the Materials;
b) the Provider hereby transfers the Materials to the Recipient, and the Recipient accepts the Materials subject to the terms and conditions below; and
c) each Party undertakes to engage with the other in the utmost good faith and to conduct itself in the highest ethical standards and comply with all applicable legislation, including but not limited to the legislative ban on the sale of or trade in tissues, gametes, blood, or blood products;
d) the Recipient shall use the Materials to conduct non-commercial research in relation to the research project;
e) the Parties agree to conduct themselves hereunder in compliance with the SAMAREC Standard Operating Procedures on research on human biological materials; and
f) understanding, therefore, that no Materials can be transferred for purposes of a research project that has not been approved by the SAMAREC.

THE PARTIES THEREFORE AGREE AS FOLLOWS:

DEFINITIONS

1.1 In this agreement the following terms/expressions shall bear the meanings assigned to them below:

"Agreement"	shall mean this agreement and all annexures thereto, which annexures shall also be signed by the parties and shall form an inextricable part of this agreement;

"Benefit"	shall mean the benefit that will be received by the Provider from the use of the Materials by the Recipient. Benefits may include, amongst others, the sharing of information, use of research results, royalties, acknowledgement of the Provider as the source of the Materials, publication rights, transfer of technology or materials, and capacity building;
"Benefit sharing"	shall mean the process or act of sharing in the benefits that derive from the Project in a manner that is fair and equitable;
"Biobank"	shall mean an organised collection of Human Biological Material and associated data from different individuals, which are usually kept for an unlimited period, for the purposes of health research;Must include: storage duration; governance oversight; participant withdrawal procedures; destruction/retention procedures; access control.
"Clinical Research Organisation"	Shall mean a company or organisation contracted by a sponsor to assume various aspects of the human research project.
"Country"	shall mean the Republic of South Africa;
"Custodian"	shall mean a person or entity entrusted by the Donor(s) with safeguarding and protecting the Materials;
"Data"	shall mean any information, including personal information in any form, derived directly or indirectly from Human Biological Materials, which will be used for research purposes;
"Donor"	shall mean a person who has donated Materials to be used for health research purposes;
"Effective date"	shall mean_____2025 irrespective of the date when the parties have signed the agreement;
"Human Biological Materials"	shall mean material from a human being, including but not limited to Deoxyribonucleic Acid (DNA), Ribonucleic Acid (RNA), blastomeres, polar bodies, cultured cells, embryos, gametes, progenitor stem cells, tissues and growth factors and any modifications or derivatives thereof;
"Intellectual Property"	shall mean all patents, trademarks, service marks, designs, copyright (including all copyright in any designs and computer software), including source codes, formats, inventions, trade secrets and all other incorporeal property which may be the subject-matter of a right whether registered or capable of registration or not;
"Informed Consent"	shall mean the continuous information sharing process which allows a Donor(s) to consent to participate and determine whether and how their Materials will be utilised in the Project, as approved by SAMAREC;
"Materials"	shall mean Human Biological Materials and Data;

"Party"	shall mean either of the entities that entered into this Agreement as represented by their duly authorised signatories to this Agreement and **"Parties"** means any of them collectively and shall be deemed to mean and include their respective successors and permitted assigns;
"Patient Information and Informed Consent Document"	shall mean the document signed by the Donor(s), confirming their informed consent to participate in the research study, and "**PID**" shall have the correspondent meaning
"Project"	shall mean the health research project for which the Materials will be used hereunder;
"Research Results"	shall mean all products of the research, whether tangible or intangible;
"SAMAREC"	shall mean the South African Medical Association Research Ethics Committee registered with the National Health Research Ethics Council (NHREC), with the purpose of independently reviewing and evaluating the ethical acceptability of health-related research protocols, including but not limited to clinical trials, to be conducted primarily within the private healthcare and education sectors;
"Secondary Use"	shall mean the use of the Materials for health research purposes other than the uses determined in the approved protocol. Secondary uses must be approved by SAMAREC;
"Sponsor"	An individual, company, institution, or organisation which takes responsibility for the initiation, management and /or financing of a health research project. The sponsor in this agreement is: __
"Termination Report"	shall mean a report prepared by the Recipient and submitted to the Provider on termination of the Project. The Termination Report will include, inter alia, the reason for termination, status of Project at termination and current state of Materials.

2. OBLIGATIONS OF THE PROVIDER

2.1. The Provider agrees to transfer to the Recipient the Materials more fully described in **Annexure A**, and in the quantity, packaging and by mode of transport as more fully described in **Annexure A**.
Should the Provider be informed that the Materials have become identifiable for any reason whatsoever, the Provider is responsible for informing SAMAREC and the relevant Donor(s) of same and for obtaining approval from SAMAREC and consent from the Donor(s), where reasonably possible, for any further uses of the Materials.
2.2. This Agreement is subject to the suspensive condition that SAMAREC has approved the study of which this Agreement form's part of and is of no force or effect unless and until such approval has been granted.

3. ACKNOWLEDGMENTS BY AND OBLIGATIONS OF THE RECIPIENT.

3.1. The Recipient acknowledges that the Materials have been obtained and/or developed by the Provider.
3.2. The Recipient acknowledges that the Materials are of health research value.
3.3. The Recipient may only conduct research according to the protocol approved by SAMAREC.
3.4. The Recipient will be responsible for obtaining the necessary permits and authorisations, and for arranging and bearing the costs of the appropriate transport for the Materials to be transferred to the Recipient.

"No transfer or shipment of Human Biological Materials may occur until all applicable REC approvals, SAHPRA approvals (where applicable), Department of Health export permits, import permits, biosafety approvals, and institutional authorisations have been obtained

3.5. The Recipient acknowledges that the Materials may contain sensitive and confidential information, which information the Recipient undertakes to protect and keep confidential.

3.6. Other than those parties stipulated in **Annexure A**, the Provider may not transfer or otherwise provide the Materials to any party without approval of SAMAREC. Such approval will be on such written conditions as the Provider may deem fit in its sole discretion and will be agreed by the Recipient in writing.

3.7. Should the Materials become identifiable for any reason whatsoever, the Recipient must inform the Provider and SAMAREC without delay.

3.8. The Recipient agrees to deliver feedback to the Provider on the development and progress made with regard to the Project by supplying the Provider with updated information, where relevant, and in terms of applicable ethical and legal requirements.

4. USE AND PURPOSE OF MATERIALS

4.1. The Recipient warrants that the Materials will be used only for the purposes of the Project, as set out in **Annexure A**, attached hereto.

4.2. The Recipient agrees that the Materials will be stored at, including any Biobank, the following address:

_____

_____

4.3. The Recipient shall not, use the Materials for any purpose other than that permitted in terms of this Agreement.

5. BENEFIT SHARING

The sharing of benefits should be discussed and negotiated between the Provider, Recipient, the Sponsor and/or the clinical research organisation before Materials are transferred to the Recipient. The Parties agree to Benefit Sharing as detailed in **Annexure B**, attached hereto.

6. TERM AND TERMINATION

This Agreement will commence on the effective date and shall continue until the termination date.

7. TERMINATION OF PROJECT

7.1. In the event that the Project terminates, for any reason whatsoever, the Recipient will provide the Provider **and** SAMAREC with a Termination Report.

7.2. Termination of the Project will occur under one or more of the following circumstances:

7.2.1. the Project reaches completion;

7.2.2. the Project cannot be conducted by the Recipient for any reason whatsoever, including but not limited to the following:

a) the Donor(s) withdraw consent for use as contemplated hereunder, and in such that the numbers render continuation of the Project impracticable or impossible;
b) the Recipient entity dissolves, winds-up or ceases to continue operating;
c) SAMAREC withdraws approval for the Project in its entirety;
d) either Party terminates the Agreement on reasonable notice; or
e) a force majeure makes continuance of the Project impracticable or impossible.

7.3. On termination, the Recipient will immediately discontinue using the Materials for any purpose whatsoever and shall destroy the Materials.
7.4. Destruction, return to the Provider or transfer of Materials will be undertaken, or any other arrangements made, with the express approval of SAMAREC.

8. INFORMED CONSENT

8.1. The Provider has to obtain informed consent from the Donor(s), on the SAMAREC approved PID, to provide Materials to the Recipient to undertake the Project as contemplated. In the event of Secondary Use of the Materials, the Donor(s) must consent thereto, as far as the Secondary Uses have been approved by SAMAREC.
8.2. Secondary use of Materials outside the scope of the original approved protocol and informed consent shall require prior SAMAREC approval and, where applicable, additional participant consent unless a REC-approved waiver of consent applies."
8.3. The Donor(s) must be informed that, where reasonably possible, the Provider will inform them of developments or progress made by the Recipient in the Project, and which is relevant to the Donor(s)' Informed Consent.
8.4. The Donor(s) must be informed and accept that on termination of this Agreement, the Materials will be returned to the Provider or destroyed, or any other arrangements made, as determined by the Provider under clause 7.
8.5. The Donor(s) must be made aware that all Materials and associated data are de- identified.
8.6. In the event that the Recipient wishes to conduct studies or use the Materials for any other purpose either than that approved by SAMAREC, the Provider must be notified in writing and SAMAREC approval must be obtained prior to any other studies or uses.

9. DISPUTE RESOLUTION – NEGOTIATION, MEDIATION AND ARBITRATION

9.1. If any dispute arises out of or in connection with this Agreement, or related thereto, whether directly or indirectly, the Parties must refer the dispute for resolution, firstly by way of negotiation and in the event of that failing, by way of mediation and in the event of that failing, by way of Arbitration. The reference to negotiation and mediation is a precondition to the Parties having the dispute resolved by arbitration.
9.2. A dispute within the meaning of this clause exists once one Party notifies the other in writing of the nature of the dispute and requires the resolution of the dispute in terms of this clause.
9.3. Within 10 (ten) business days following such notification, the Parties shall seek an amicable resolution to such dispute, by referring such dispute to designated representatives of each of the Parties for their negotiation and resolution of the dispute. The representatives shall be authorised to resolve the dispute.
9.4. In the event of the negotiation between the designated representatives not resulting in an agreement signed by the Parties resolving the dispute within 15 (fifteen) business days thereafter, the Parties must refer the dispute for resolution by way of mediation, in accordance with the then current rules of the Arbitration Foundation of Southern Africa ("AFSA").
9.5. In the event of the mediation envisaged in 9.4 failing in terms of the rules of AFSA, the matter must, within 15 (fifteen) business days thereafter, be referred to arbitration as envisaged in the clauses below.
9.6. The periods for negotiation or mediation may be shortened or lengthened by written agreement between the parties.
9.7. Each Party agrees that the Arbitration will be held as an expedited arbitration in _(Insert city), in accordance with the then current rules for expedited arbitration of AFSA, by 1 (one) arbitrator appointed by agreement between the Parties, including any appeal against the arbitrator's decision. If the Parties cannot agree on the arbitrator or appeal arbitrators within a period of 10 (ten) business days after the referral of the dispute to arbitration, the arbitrator and appeal arbitrators shall be appointed by the Secretariat of AFSA, who shall administer and manage the arbitration proceedings.
9.8. The provisions of this clause 9 shall not preclude any Party from access to an appropriate court of law for interim relief in respect of urgent matters, by way of an interdict or mandamus, pending finalisation of this dispute

resolution process for which purpose the Parties irrevocably submit to the jurisdiction of a division of the High Court of the Republic of South Africa.

9.9. The references to AFSA shall include its successor or body nominated in writing by it instead.

9.10. This clause 9 is a separate, divisible agreement from the rest of this Agreement and shall remain in effect even if the Agreement terminates, is nullified, or cancelled for whatsoever reason or cause.

10. INTELLECTUAL PROPERTY

Intellectual property will be dealt with through the relevant laws related to the applicable protocol for the project and underlying third party agreements as far as they are applicable.

11. CONFIDENTIALITY

The Recipient agrees to keep the Materials secure and confidential at all times. Confidentiality includes, but is not limited to the properties, characteristics, content, composition, potential secondary uses, and methods of use of the Material. All information relating to the nature and processes of the research in whatever form, should be treated as confidential. The personal information, including the identity of the Donor(s), must be protected, and kept confidential at all times. Any publications, newsletters or oral presentations must not divulge any details of the Donor(s), unless consent has been obtained for such use from the Donor(s).

"All processing, transfer, storage, sharing, retention, and destruction of associated personal information and coded data shall comply with the Protection of Personal Information Act (POPIA), applicable South African data protection legislation, and institutional data governance requirements. Cross-border transfer of associated data may only occur where adequate data protection safeguards are in place and where such transfer has been approved by SAMAREC and consented to by participants where applicable."

12. PUBLICATIONS AND PUBLICITY

12.1. Publications of any health research results must be in accordance with the updated guidelines laid down by the World Medical Association, in particular, the Declaration of Helsinki (2024), and authorship of the publication emanating from the use of the Materials hereunder must be in keeping with the International Committee of Medical Journal Editors Authorship Guidelines (http://www.icmje.org/icmje-recommendations.pdf) as amended from time to time.

12.2. Where the Recipient wishes to publish any information concerning the Project (in either oral or written form), the Provider must be notified and provided with a copy of the publication, at least ten (10) days prior to submission of the proposed publication. The Provider must inform the Recipient whether any information related to the publication must be removed or included and provide reasons to substantiate the removal or addition of such information.

12.3. The Provider must be supplied with a final copy of the publication before the publication is released by the Recipient. The Recipient must acknowledge the Provider's contribution of the Materials, unless otherwise requested by the Provider.

12.4. Neither Party shall use the name of the other Party or its employees in any advertisement, press release or other publicity without prior written approval of the other Party.

12.5. Notwithstanding the above, and where relevant, publications must be subjected to the applicable protocol and relevant third-party agreements.

13. LIMITED LIABILITY

13.1. The Provider gives no warranty that the Materials are fit for the use and purpose for which they are transferred hereunder, or that they have any qualities or characteristics.

13.2. In no event shall either party be liable to the other or any third party in contract, delictor otherwise for incidental or consequential damages of any kind, including, without limitation, punitive or economic damages or lost profits, regardless of whether either party shall be advised, shall have other reason to know or in fact shall know of the possibility.

13.3. The Provider will not be liable to the Recipient for any claims or damages arising from the Recipient's use of the Materials.

13.4. Should either Party breach the terms of this Agreement, notwithstanding 7 (seven) days written notice to rectify the breach, this Agreement may be terminated by the aggrieved Party on written notice.

14. ENTIRE AGREEMENT

This Agreement sets forth and constitutes the entire agreement and understanding of the parties with respect to the subject-matter hereof. This agreement supersedes any and all prior agreements, negotiations, correspondence, undertakings, promises, covenants, arrangements, communications, representations, and warranties, whether oral or written, of any party to this Agreement. This Agreement is null and void and of no force and effect unless and until SAMAREC has approved the research of which the Agreement forms a part.

15. CONFLICTS

The terms of this Agreement, including the Annexures forming part hereof, shall take precedence over any conflicting terms in any referenced agreement or document.

16. VARIATIONS

No variation or consensual cancellation of this Agreement will be of any effect unless reduced to writing and signed by the parties.

17. NON-WAIVER

The failure or delay of either party to exercise any of its rights or remedies under this Agreement for a breach thereof shall not be deemed to be a waiver of such rights or remedies, and no waiver by either party, whether written or oral, express or implied, or any rights or remedies under or arising from this Agreement shall be binding on any subsequent occasion, and no concession by either party shall be treated as an implied modification of this Agreement, unless specifically agreed in writing, duly executed by authorised representatives of the parties. Similarly, the rights and remedies of parties arising in common law shall not be capable of being waived or varied otherwise than by an express waiver or variation in writing duly executed by authorised representatives of the parties.

18. CESSION AND ASSIGNMENT

No rights, duties or liabilities under this Agreement may be ceded, assigned, transferred, conveyed, or otherwise disposed of by either party without the prior written consent of the other party and the approval form SAMAREC, which consent shall not be unreasonably withheld.

19. SEVERABILITY

The terms of this Agreement are severable – if any term or provision of this Agreements is declared to be illegal, void, or unenforceable by a court of competent jurisdiction, the remainder of the provisions shall continue to be valid and enforceable.

20. SIGNATURE AUTHORITY

The individual signing below hereby represents and warrants that he/she is duly authorised to execute and deliver this Agreement on behalf of the party whose name appears beneath his/her signature and that this Agreement is binding upon such party.

Thus, done and signed on this the _____ day of _____ 2025

On behalf of the Provider:

_____
(duly authorised thereto)

As witnesses: The Provider:

1. _____
Signature:
Name:

2. _____
Signature:
Name
:

Thus, done and signed on this the _____ day of _____ 2025.

On behalf of the Recipient:

_____
Name:
Designation:
Developer:
(duly authorised thereto)

As witnesses: the Recipient:

1. _____
Signature:
Name

2. _____
Signature:
Name:

Annexure A

To be completed by the Parties

The details of the entity which will obtain the necessary permits and authorisations and arrange appropriate transport for the Materials to be transferred is:

_____

Description of health research project under which the Materials will be used on transfer:

_____

_____

Details of the Sponsor funding the health research project:

_____

_____

_____

Details of the Clinical Research Organisation conducting the health research project on behalf of the Sponsor (if applicable):

_____

_____

_____

The nature of the Materials requested:

_____

_____

_____

_____

Specific experimental tests that the Materials will be subjected to on transfer:

_____

Parties (except the sponsor and the clinical research organisation) other than the Recipient to whom the Materials might be transferred as required by the Project:

Quantity of Materials required to be transferred:

Preferred method of transfer of Materials:

Period within which Materials will be transferred:

How will confidentiality be maintained should Materials be released into the public domain?

Annexure B

Benefit Sharing Arrangement between the Recipient and Provider.

ANNEXURE 13: NON-CLINICAL 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?

Your personal information will be retained only for as long as necessary to fulfil the purposes of the research study and applicable legal/regulatory retention requirements

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 dataheld by the researcher when required to check study procedures havebeen 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)].

Participation in this study is voluntary, and you will be reimbursed for your Time, Inconvenience, and Expenses (TIE) as per the SAHPRA TIE latest guidelines, directly related to your study visits, as mandated by the SA-GCP-2020 guidelines. This payment is a reimbursement for costs such as transport and refreshments and is not an incentive to participate.

Should the participant be a minor or require a caregiver/escort, the same reimbursement scheme will apply to the parent or legal guardian accompanying them.

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 than those 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 futureby 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 Informed Consent 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 and reimbursement 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)

PARTICIPANT INFORMATION AND ASSENT DOCUMENT

This Pro Forma should be used together with the PID for the parent(s)/legal guardian)

(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 the Participant 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***

ANNEXURE 14: NON-CLINICAL TEMPLATE OF CV FOR RESEARCH ETHICS APPLICATIONS

Research Protocol title:

Protocol number:

Designation: *[e.g., Researcher, Primary or Co-supervisor etc]*

1. Personal Details Name and surname:

Work Address:
Telephone or Cell-phone Number:
E-mail address:

2. Academic and Professional Qualifications
3. Health Professions Council of South Africa (HPCSA) registration number if applicable (or other health professions body registration particulars if applicable – e.g., Nursing Council) *[if obtained from other countries than South Africa, please clarify]*
4. Current personal medical malpractice insurance details *[medical and dental practitioners]*
5. Relevant related research experience (brief) and current position *[Supervisors to describe supervision experience].*
6. Relevant publications and other research outputs in the past 3 years
7. Research ethics training done within the past three years.
8. Date of last GCP training (if applicable)
9. Dispensing Licence Registration number (if applicable)
10. Any additional relevant information you wish to bring under the attention of the reviewers (brief).

I, *[Full name and surname]*, confirm that the information included on this form is accurate and complete, as on *[Date]*.

Signature: _____

ANNEXURE 15: NON-CLINICAL DECLARATION FORMS

DECLARATION BY SUPERVISOR

Name and surname:

Protocol number:

Protocol title:

Designation:

1. I have thoroughly read, understood, and critically analysed (in terms of the South African context) the protocol, and all applicable documentations, including the Patient/Participant Information and Informed Consent Document(s).
2. I have read and reviewed my student's final research draft proposal and supporting documents before submission to SAMAREC. I am satisfied that under my supervision, this proposal meets a high standard of scientific merit
3. I have the relevant research and supervision experience to supervise a student at the respected level of research required to complete this study.
4. I will ensure that the study will not commence with the research study before written authorisations from the relevant ethics committee(s) have been obtained.
5. I declare that I have no financial or personal relationship(s) which may inappropriately influence me in supervising this research study. All conflicts of interest have been declared by me.
6. ***Delete the inapplicable option below:***
   I have not previously been involved in a research study which has been closed as a result of unethical practices.
   OR
   I have previously been involved in a research study I which has been closed as a result of unethical practices and attach the relevant explanatory documents to this declaration.
7. I will ensure that all required reports are submitted within the stipulated timeframes.

I, (Supervisor's full name and surname), the Supervisor of (Student's full name and surname), confirm that the information included on this form is accurate and reliable, as on (Date).

DECLARATION BY RESEARCHER AND OTHER STUDY STAFF

Name and Surname:

Protocol number:

Protocol Title:

Designation:

1. I have thoroughly read, understood, and critically analysed (in terms of the South African context) the protocol, and all applicable documentations, including the Patient/Participant Information and Informed Consent Document(s).
2. I will conduct my role in the research study as specified in the protocol.
3. I will not commence with my role in the research study before written authorisations from the relevant ethics committee(s) have been obtained.
4. If applicable to my role, I will ensure that informed consent has been obtained from all participants, or if they are not legally competent, from their legal representatives.
5. I will ensure that every participant (or other involved persons, such as relatives) shall at all times be treated in a dignified manner and with respect.
6. Using the broad definition of conflict of interest below, I declare that I have no financial or personal relationship(s) which may inappropriately influence me in conducting this clinical trial.
7. *[Conflict of interest exists when an investigator (or the investigator's institution) has financial or personal relationships with other persons or organisations that inappropriately influence (bias) his or her actions.]***Modified from: Davidoff, F. Et al Sponsorship, Authorship and Accountability. (Editorial) JAMA Volume 286 number 10 (September 12, 2001)
8. ***Delete the inapplicable option below:***
   I have not previously been involved in a research study which has been closed as a result of unethical practices.
   OR
   I have previously been involved in a research study I which has been closed as a result of unethical practices and attach the relevant explanatory documents to this declaration.
9. I will submit all required reports within the stipulated timeframes.

I, (Full name and surname), confirm that the information included on this form is accurate and reliable, as on (Date).

Signed By:

Date Signed: