THE SOUTH AFRICAN MEDICAL ASSOCIATION RESEARCH ETHICS COMMITTEE

(SAMAREC)

**STANDARD OPERATING PROCEDURES**

**AND**

**GUIDELINES FOR THE ETHICS EVALUATION OF CLINICAL TRIALS IN HUMANS –**

**ANNEXURES**

#### (UPDATED July 2023; Version 7)

**Registered Address:**

SAMA Research Ethics Committee

P O Box 74789

Lynnwood Ridge

0040

Block F Castle Walk Office Park

Nossob Street Erasmuskloof Ext 3

Pretoria

0183

Tel: (012) 481 2082

[samarec@samedical.org](mailto:samarec@samedical.org)

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# 16. ANNEXURES

The following annexures set out further information and pro-forma documentation, for the guidance of study doctors and sponsors:

* + Annexure 1: SAMAREC Meeting Dates
  + Annexure 2: SAMAREC Application Form
  + Annexure 3: SAHPRA Format of Curriculum Vitae of Trialists
  + Annexure 4: Guidelines Pertaining to the Patient Information and

Informed Consent Document (PID) and SAMAREC Patient Information and Informed Consent Document (PID) (Including various consent

Annexures to be used as relevant to a particular clinical trial)

* + Annexure 5: Members of SAMAREC
  + Annexure 6: SAMAREC Fees
  + Annexure 7: SAMAREC Guidelines for Clinical Study Advertisements
  + Annexure 8: Declaration by Investigators
  + Annexure 9: List of Study Staff and their submitted documents.
  + Annexure 10: Material Transfer Agreement

# ANNEXURE 1: SCHEDULED SAMAREC MEETING DATES 2023

|  |  |
| --- | --- |
| **Submission Date:** | **Meeting Date:** |
| 15 December 2022 | 18 January 2023 |
| 4 January 2023 | 8 February 2023 |
| 1 February 2023 | 8 March 2023 |
| 29 March 2023 | 12 April 2023 |
| 26 April 2023 | 10 May 2023 |
| 31 May 2023 | 07 June 2023 |
| 28 June 2023 | 12 July 2023 |
| 26 July 2023 | 02 August 2023 |
| 30 August 2023 | 13 September 2023 |
| 27 September 2023 | 11 October 2023 |
| 25 October 2023 | 8 November 2023 |
| 22 November 2023 | 6 December 2023 |

##### 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

|  |  |  |
| --- | --- | --- |
| **Protocol Number** |  |  |
| **Protocol Title** |  |  |
| **Invoicing Details** |  |  |
| **VAT Number** |  |  |
| **Contact Person** |  |  |
| **Contact Number** |  |  |
| **Email Address** |  |  |
| **Postal Address** |  |  |
| **Clinical Trial Submission: (Section A)** | | |
| **New Protocol** |  |  |
| **Major Amendment** |  | Protocol or Informed Consent Document Changes |
| **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 |
| **Research Study Submission** |  |  |
| **General Research Submission: (Section B)** | | |
| **New Proposal** |  |  |
| **Amendment of Proposal** |  |  |
| **Annual Renewal** |  |  |

**CHECK LIST:**

(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** | | |
| **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? |  |  |
| 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 costs |  |  |
| 7. Placebo Justification – where applicable the placebo justification must be included in the cover letter. |  |  |
| 8. What is your assessment of any potential additional risk or discomfort in respect of patients? |  |  |
| 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  • GCP and / or Dispensing Licence |  |  |
| 11. Does the protocol clearly stipulate that the investigator may independently publish his or her results? |  |  |
| 12. Is the Study High Risk? |  |  |
| **Information concerning the Patient Information and Informed Consent Document (PID)** | **Yes** | **No** |
| 1. Does the PID indicate that the principles enunciated in the Declaration of Helsinki (last update: October 2013) are complied with? |  |  |
| 2. Does the PID state that neither the patients nor their medical schemes have to pay for trial related expenses? |  |  |
| 3. Does the PID state that compensation for trial related injury will be paid in accordance with the guidelines of the ABPI? |  |  |
| 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 attached guidelines? |  |  |
| 7. Have you structured your PID around the SAMAREC “ideal” example? |  |  |
| 8. When you refer to the Patient Information and Informed Consent Document, do not refer to it as the Informed Consent Form, as this is a legal document, and 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 should undertake the consent process and therefore sign the consent section. |  |  |
| **Section B: RESEARCH STUDY PROPOSAL** | | |
| 1. Covering letter |  |  |
| 1. Research Summary |  |  |
| 1. Research proposal |  |  |
| 1. Participant Information and Informed Consent Document (PID) This document must be submitted in a Word format. |  |  |
| 1. Data collection tools (questionnaires and/or interview guides |  |  |
| 1. Details and breakdown of financial arrangements with researchers if any |  |  |
| 1. Information pertaining to recruitment e.g., advertisements, bulletins and information placed on the Internet. |  |  |
| 1. Curricula Vitae of all study personnel |  |  |
| 1. Declarations by Researchers |  |  |

**SITE STAFF:**

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

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **SITE ADDRESS** | **SITE STAFF:**  **Name**  **Designation** | **CV** | **DECLARATION** | **HPCA/SANCA REGISTRATION** | **MALPRACTICE INSURANCE** | **DISPENCING LICENCE** | **GCP** |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

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](mailto: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 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.

Noted and Accepted by Applicant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Print Name

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date

# ANNEXURE 3: SAHPRA FORMAT FOR CVs 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:

1. Academic and Professional Qualifications
2. Health Professions Council of South Africa (HPCSA) registration number if applicable (or other health professions body registration particulars if applicable – e.g., Nursing Council)
3. Current personal medical malpractice insurance details [medical and dental practitioners]
4. Relevant related work experience (brief) and current position
5. 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.]
6. Peer-reviewed publications in the past 3 years
7. Date of last GCP training (as a participant or presenter)
8. Dispensing Licence Registration number (if applicable)
9. Any additional relevant information supporting abilities to participate in conducting this trial. [briefly]

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 (last updated October 2013) and the South African Department of Health Clinical Trial and Ethics in Health Research Guidelines are complied with, and that the study has been approved by the SAMAREC. The latest approved version of the Declaration of Helsinki 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 insurance certificate must be furnished. Arrangements for compensation and insurance must be included in the PID, and it must be stated clearly that compensation to patients will be in accordance with the ABPI guidelines. A copy of the guidelines must be available.
12. 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.
13. 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.
14. *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.*
15. Tick boxes– the use of tick boxes is not encouraged, and participants should rather sign their initials when they have to reflect a choice.
16. Please ensure the following statement is included in your informed consent document:

*“If you wish to ask questions about your participation in the study to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, you may contact the Research Ethics Committee (REC) for this study, the South African Medical Association Research Ethics Committee (SAMAREC). SAMAREC is a Research Ethics Committee whose committee members provide REC services for participants involved in research studies in the Private Sector in South Africa.*

*The South African Medical Association Research Ethics Committee (SAMAREC)*

*PO Box 74789*

*Lynnwood Ridge*

*0040*

*Tel: 012 481 2082*

*samarec@samedical.org”*

1. Please ensure that no product logos appear on any patient facing 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, 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?):**

***(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 laypersons terms)***

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 OF TRIAL**

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 Guidelines on Clinical Trials and Ethics in Health Research, published by the Department of Health and the Declaration of Helsinki (last updated October 2013), adopted by the World Medical Association (WMA), 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.

**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 (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 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?**

This permission has no expiry date.

**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](mailto:complaints.IR@justice.gov.za)

General enquiries Email: [inforeg@justice.gov.za](mailto:inforeg@justice.gov.za).

**Organizational and technical security measures**

The sponsor has taken appropriate security measures to prevent accidental loss of your personal data, unauthorized use or access, changes or disclosure. For example, your personal data will be de-identified and anonymized (data will be processed in a way that cannot be tracked directly back to you) before it is 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 emphasize that some of the authorized 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 working 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 authorized Sponsor representatives (including the contract research organization 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 layman’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.

**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 Association of the British Pharmaceutical Industry (ABPI) Guidelines on Compensation, which guidelines adequately cover the compensation aspects relating to clinical trials. A copy of these Guidelines is available from the study doctor on request.

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, the National Health Research Ethics Council, the Food and Drug Administration of the United states of America, 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 carrying out 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  **Witness:** | Signature | Date |
| 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 16 years or older and of sound mind and not involved with the 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)**

1. 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)***

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

# PATIENT INFORMATION AND ASSENT DOCUMENT

*(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.

#### (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.

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  **Parent(s): Mother:** | Signature | Date |
| Name  **Father:** | Signature | Date |
| Name  **Legal Guardian**: | Signature | Date |
| Name  **Study Doctor:** | Signature | Date |
| Name  **Witness:** | Signature | Date |
| 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

|  |  |  |
| --- | --- | --- |
| **NAME OF MEMBER** | **FIELD OF INTEREST** | **DESIGNATIONS FOR REC** |
| Prof J R Snyman  MBChB, M Pharm Med, MD | Pharmacologist | Chairperson  Research Ethics Expert  Experience in Quantitative Research Methodologies  Expert in biostatistics, White, Male |
| Dr M Groenewald  MBChB, DCH (SA), PG Dip Int Res Ethics(UCT) | General Practitioner | Vice Chair  Research Ethics Expert  Medical Professional, White, Female |
| Prof M Kakaza  MBChB, Mmed(Neuro) | Specialist Neurologist | Research Ethics Expert  Medical Professional, Black, Female |
| Mrs B Fineberg  BSc (Hons); H.D.E | Educator | Layperson, White, Female |
| Dr N Naidoo  BSc, BMedSc, MBBCh, MPH, MMed (Clinical Pathology) | Clinical Pathologist | Medical Professional, Indian, Male |
| Ms N Madolo  BHSc Biomedical Science | Quantitative Research | Quantitative Research, Black, Female |
| Mr M le Roux  B.Th, M.Div | Medicolegal Advisor | Legal Representative, White, Male |
| Mr R Masemola  BCom(Law), LLB, Cert. in Corp Govern | Legal Advisor | Legal Representative, Medico Legal Advisor, Black, Male |
| T Coetzee  PG Dip (health Res Ethics); M Phil (Applied Ethics) | Research Ethics Project Manager | Research Ethics Expert, White, Female |

# ANNEXURE 6: FEE STRUCTURE FOR PROTOCOLS 2023

Please request an invoice accordingly.

(Excluding VAT) – Rates to be updated annually each July

|  |  |
| --- | --- |
| **APPLICATION:** | **RATE:** |
| New Protocol  (Full Review – Committee Meetings) | R19 112 |
| Rapid Review (10 Working Days)  Subject to approval | Additional 30% |
| Expedited Review – (3 Working Days)   1. New Protocol (minimal risk) 2. Amendment (minimal risk)   Subject to approval | 1. R12 960 2. 10 800 |
| Major Amendment - (Ethical Changes) e.g., Protocol or PID, Changes in patient recruitment  (Full Review – Committee Meetings) | R9 554 |
| Minor Amendment – Sponsor Name Changes, Addresses, Administrative not involving ethical concerns  (10 Working Days) | R4 658 |
| Annual Review  (5 Working Days) | R4 658 |
| Additional Sites – after initial application.  (5 Working Days) | R1 551 per site |
| Student/Doctor Unsponsored Study/Surveys  (Full Review – Committee Meetings) | R4 299 |

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

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**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 organizations, must be approved SAMAREC. In assessing such advertisements, SAMAREC will give consideration to 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. Non-specific and generic information regarding payment details or reimbursement to potential research participants may appear in the advertisement or notice.
7. The Guiding Principles enunciated in paragraphs 8, 9, 10, 11, 12, 14, and16, 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**

**TEL: (012) 000-0000 OR TEL: 086 000 0000**

*The health research protocol was approved by South African Medical Association Research Ethics Committee on dd/mm/yy, SANCTR registration number XX dd/mm/yy.*

# 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 carrying out 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.

1. *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.

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

Printed name of Principal Investigator Date Principal Investigator’s Signature

# DECLARATION BY SUB- AND CO-INVESTIGATORS AND OTHER STUDY

Name:

Title of Trial:

Protocol:

Site:

Designation:

1. I will carry out 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 carrying out 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.

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

Printed Name Date Signature

# ANNEXURE 9: 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 10: 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,**

* 1. the Provider remains custodian of the Materials;
  2. the Provider hereby transfers the Materials to the Recipient, and the Recipient accepts the Materials subject to the terms and conditions below; and
  3. 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;
  4. the recipient shall use the Materials to conduct non-commercial research in relation to the research project;
  5. the Parties agree to conduct themselves hereunder in compliance with the SAMAREC Standard Operating Procedures on research on human biological materials; and
  6. 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. 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; |
| **“Clinical Research Organization”** | Shall mean a company or organization 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 2016 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 evaluating the ethics of research protocols developed for clinical trials to be conducted in the private healthcare sector; |
| **“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 organization 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. |

1. **OBLIGATIONS OF THE PROVIDER**
   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**.

* 1. 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 Material.
  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.

1. **ACKNOWLEDGMENTS BY AND OBLIGATIONS OF THE RECIPIENT**
   1. The Recipient acknowledges that the Materials have been obtained and/or developed by the Provider.
   2. The Recipient acknowledges that the Materials are of health research value.
   3. The Recipient may only carry out research according to the protocol approved by SAMAREC.
   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 Material to be transferred to the Recipient.
   5. The Recipient acknowledges that the Materials may contain sensitive and confidential information, which information the Recipient undertakes to protect and keep confidential.
   6. Other than those parties stipulated in **Annexure A**, the Provider may not transfer or otherwise provide the Material 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.
   7. Should the Materials become identifiable for any reason whatsoever, the Recipient must inform the Provider and SAMAREC without delay.
   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.
2. **USE AND PURPOSE OF MATERIAL**
   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.
   2. The Recipient agrees that the Material will be stored at, including any Biobank, the following address:
   3. The Recipient shall not, use the Materials for any purpose other than that permitted in terms of this Agreement.
3. **BENEFIT SHARING**

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

1. **TERM AND TERMINATION**

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

1. **TERMINATION OF PROJECT**
   1. In the event that the Project terminates, for any reason whatsoever, the Recipient will provide the Provider and SAMAREC with a Termination Report.
   2. Termination of the Project will occur under one or more of the following circumstances:
      1. the Project reaches completion;
      2. the Project cannot be carried out by the Recipient for any reason whatsoever, including but not limited to the following:
         1. the Donor(s) withdraw consent for use as contemplated hereunder, and in such that the numbers render continuation of the Project impracticable or impossible;
         2. the Recipient entity dissolves, winds-up or ceases to continue operating;
         3. SAMAREC withdraws approval for the Project in its entirety;
         4. either Party terminates the Agreement on reasonable notice; or
         5. a force majeure makes continuance of the Project impracticable or impossible.
   3. On termination, the Recipient will immediately discontinue using the Material for any purpose whatsoever and destroy the Material.
   4. Destruction, return to the Provider or transfer of Materials will be undertaken, or any other arrangements made, with the express approval of SAMAREC.
2. **INFORMED CONSENT**
   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, insofar as the Secondary Uses have been approved by SAMAREC.
   2. 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.
   3. The Donor(s) must be informed and accept that on termination of this Agreement, the Material will be returned to the Provider or destroyed, or any other arrangements made, as determined by the Provider under clause 7.
   4. The Donor(s) must be made aware that all Materials and associated data are de- identified.
   5. In the event that the Recipient wishes to conduct studies or use the Material 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.
3. **DISPUTE RESOLUTION – NEGOTIATION, MEDIATION AND ARBITRATION**
   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.
   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.
   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.
   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”).
   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.
   6. The periods for negotiation or mediation may be shortened or lengthened by written agreement between the parties.
   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.

* 1. 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.
  2. The references to AFSA shall include its successor or body nominated in writing by it in its stead.
  3. 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.

1. **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 in so far as they are applicable.

1. **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).

1. **PUBLICATIONS AND PUBLICITY**
   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 (2013), 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 [(h](http://www.icmje.org/icmje-)t[tp://www.icmje.org/icmje-](http://www.icmje.org/icmje-) recommendations.pdf) as amended from time to time.
   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.
   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 Material, unless otherwise requested by the Provider.
   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.
   5. Notwithstanding the above, and where relevant, publications must be subjected to the applicable protocol and relevant third party agreements.
2. **LIMITED LIABILITY**
   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.
   2. In no event shall either party be liable to the other or any third party in contract, delict or 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.
   3. The Provider will not be liable to the Recipient for any claims or damages arising from the Recipient’s use of the Material.
   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.
3. **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.

1. **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.

1. **VARIATIONS**

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

1. **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.

1. **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.

1. **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.

1. **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 2016.

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 2016.

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 Material 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 Organization 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 organization) 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**

**ACKNOWLEDGEMENTS**

This MTA is an adaptation of the University of the Witwatersrand MTA template Version 3 dated 02 Dec 2016