THE SOUTH AFRICAN MEDICAL ASSOCIATION NPC
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ANNEXURE 2:

SAMAREC NON CLINICAL APPLICATION FORM, V3

Protocol Number		
Protocol Title		
Type of Study: Eg, General Research, Case Study, Ethics Waiver..		
Invoicing Details		
VAT Number		
Contact Person		
Contact Number		
Email Address		
Postal Address		
SUBMISSION DETAILS		
New Study	☐	
Major Amendment	☐	Protocol or Informed Consent Document – Ethical Changes
Minor Amendment	☐	Administrative Changes, e.g., Address
Annual Renewal	☐	
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 ☐ Medium ☐ Low ☐
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 study going to be conducted in the Private Sector?	☐	☐
2. Covering letter	☐	☐
3. Research Summary	☐	☐
4. Research proposal	☐	☐
5. Participant Information and Informed Consent Document (PID) This document must be submitted in MS-Word format.	☐	☐
6. Data collection tools (questionnaires and/or interview guides	☐	☐
7. Details and breakdown of financial arrangements with researchers if any	☐	☐
8. Information pertaining to recruitment e.g., advertisements, bulletins and information placed on	☐	☐

the Internet.		
9. Curricula Vitae of all study personnel	☐	☐
10. Declarations of all study personnel	☐	☐
11. Do you wish to make a presentation?	☐	☐
12. Have you submitted all the requested documentation electronically?	☐	☐
13. Is the study number clearly visible on all the documentation?	☐	☐
14. Have you included details of the financial arrangements with investigators and confirmed that patients will be reimbursed for expenses incurred?	☐	☐
15. Will patients/participants be expected to pay for anything? If so, elaborate on costs	☐	☐
16. Placebo Justification,– where applicable the placebo justification must be included in the cover letter.	☐	☐
17. Are there any potential additional risks or discomfort in respect of patients or participants? If yes, please elaborate in your Covering Letter.	☐	☐
18. Are all relevant details (names of Investigators, Declarations of Trialists, etc.) filled in?	☐	☐
19. 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, Research Ethics Training Evidence and / or Dispensing Licence	☐	☐
20. Does the study clearly stipulate that the investigator may independently publish his or her results?	☐	☐
21. Is the Study High Risk?	☐	☐
22. Have you included a Data Management Plan for the study?	☐	☐
Section B: 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 (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 guidelines of the ABPI/POPIA?	☐	☐
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/Study number/Participant Information and Informed Consent Document, SAMAREC Version XX dated XXX"	☐	☐
5. Does the Informed Consent paragraph provide names of the patients/particpants, 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 template?	☐	☐
8. When you refer to the PID, 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/Investigator should undertake the consent process and therefore sign the consent section.	☐	☐
11.	Is the Informed Consent Process done in a confidential setting?	☐	☐

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

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 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 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 market place, regardless of whether the participant is employed. See the latest SAHPRA TIE Reimbursement Guidelines of trial participants in South Africa. Ethical consideration for Research Ethics Committees. Researchers must submit planned payment schedules and amounts together with a justification to the REC when making application for ethics review and must be included in the Informed Consent Documents. The proposal 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 reimbursements offered 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 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 inducements should be clearly explained and justified to SAMAREC.

Noted and Accepted by Applicant:

_____

Print Name

_____

Signature

_____

Date