**THE SOUTH AFRICAN MEDICAL ASSOCIATION NPC**
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# ANNEXURE 2:

# SAMAREC APPLICATION FORM, V5

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|---|---|---|
| **Protocol Number** | | |
| **Protocol Title** | | |
| **Study Phase eg. Phase 1** | | |
| **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) ☐<br>Medium (less than serious) ☐<br>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? (In Excel Format to show calculations) | ☐ | ☐ |

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| 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?<br>• Name and Practice address<br>• Qualifications and tertiary institutions<br>• Clinical trials experience: Details of previous and current trials, dates, and whether completed or ongoing<br>• Conferences and/or Congresses attended – if applicable<br>• Proof of personal indemnity insurance cover, i.e., MPS or other valid insurance membership number<br>• Health Professions Council of SA (HPCSA) registration number<br>• Date and signature<br>• Good Clinical Practice Training (GCP)<br>• Dispensing Licence<br>• 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?<br>• Please ensure no gaps in the document e.g., signature pages, paragraphs, headings etc.<br>• 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. | ☐ | ☐ |

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|---|---|---|---|
| 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