SITE STAFF SOP, NOV 2023, V1

Research Ethics Committee

Final Version	Reason for Amendment	Effective Date
1	Developed and published for implementation	November 2023
	Administrative changes	March 2024

1. OBJECTIVE

To ensure that all documentation relating to site staff is properly indexed and organized, with the protocol number clearly visible, and to establish a standardized procedure for submitting additional site staff with the required documents.

2. SCOPE

This Standard Operating Procedure (SOP) applies to all staff involved in trial related procedures and the submission of additional site staff at SAMAREC.

3. RESPONSBILITIES

3.1 All staff involved in touching patients are responsible for submitting all documents related to clinical trials.

3.2 Ensure that the protocol number is clearly visible on all sections of each document.

3.3 Organize relevant attachments for each study staff member, including but not limited to CV, Declaration, HPCSA/SANCA Registration, Malpractice Insurance, GCP Certificate, Dispensing License,

3.4 Maintain filing systems based on the protocol number, not the name of the drug/study title involved.

3.5 Submission of Additional Site Staff: Applications responsible for submitting additional site staff must adhere to the following guidelines:

3.5.1 Prepare a covering letter and application form that includes the following details:

3.5.2 Protocol number.

3.5.3 Name of the additional site staff member including site name and address

3.5.4 Position or role of the additional site staff.

3.5.5 Attach all relevant documentation for the additional site staff, including but not limited to:

3.5.6 CV

3.5.7 Declaration

3.5.8 HPCSA/SANCA/SAPC Registration

3.5.9 Malpractice Insurance

3.5.10 GCP Certificate

3.5.11 Dispensing License

4. PROCEDURE

4.1 When submitting documents related to a clinical trial, review them for completeness and accuracy.

4.2 Ensure that the protocol number is clearly visible on each section of the document.

4.3 Organize relevant attachments for each study staff member, creating a separate folder or section for each individual.

4.4 Maintain a filing system based on the protocol number. In the computer system, use a standardized digital naming convention.

5. APPROVALS/CONTINUING REVIEW

5.1 Once approval is obtained, ensure that the approved documents are properly filed and maintained within the document management system.

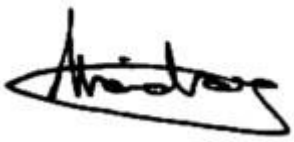
5.2 Resignations of site staff should be reported to SAMAREC including the resignation dates and evidence of work portfolio being maintained in the interim periods.

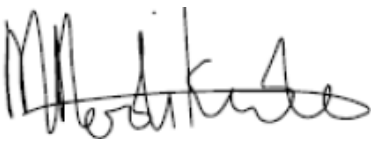
5.3 Any changes or revisions to site staff should be documented and reported to SAMAREC.

5.4 Ensure all site staff are informed of changes.

Noncompliance with this SOP may result in delays and errors in clinical trial related documentation.

Please ensure all relevant and updated SAMAREC SOPs, SA GCP and DOH Guidelines are adhered to.





Dr N Naidoo
SAMAREC Chairperson
10 Oct 2024

Dr M Nodikida
SAMA CEO
10 Oct 2024