



**SOUTH AFRICAN
MEDICAL ASSOCIATION**
UNITING DOCTORS FOR THE HEALTH OF THE NATION

**ACTIVE AUDITING
FORM, OCTOBER
2023, v2**

**RESEARCH ETHICS
COMMITTEE**



GENERAL INFORMATION:

Protocol Title:	
Protocol Number:	
Principal Investigators:	
Date of Audit:	
Address of Site:	
Name of Auditor:	

PROTOCOL:

Comments:

Is the correct version of the protocol approved by REC used	
The protocol included all inclusion and exclusion criteria	
Deviations and violations were recorded and justified	
Amendments were approved by REC	
Availability of investigators to confirm conduct of trial according to protocol and GCP	

INFORMED CONSENT:

Comments:

Site file was available	
Patients were able to consent in a private location	
Correct versions of Informed Consent Documents were signed	
Contact details of Principal Investigator were given to participants	

GENERAL:

Randomization	
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Patients Enrolled	
Patients Withdrawn	
Patients Completing Study	
Number of Serious Adverse Events	
Number of Protocol Deviations, and were site staff retrained? Corrective action?	

REMARKS:
