ANNUAL PROGRESS REPORT/RENEWAL

Human Research Ethics Committee (HREC)
OHRP Number: IORG0006278 FWA
Registration Number: IRB00007553 SA
NHREC Registration Number: REC-270606-013

SANBS
Registration No. 2000/026390/08

This report must be submitted by the principal investigator (PI) to the HREC secretariat, who will forward it to the HREC chairperson, on an annual basis until the research project is completed. It is a requirement that all PIs ensure that an annual progress report is provided for all approved research.
Principal Investigator to complete the following:

Principal Investigator Information

Principal Investigator	
Email address	
Contact Number	
Protocol Title	
HREC Ref No	
Last approval date	
Are there any sub-studies linked to this protocol	
If yes, provide reference numbers and clearance certificates for all sub-studies N.B: A separate progress/renewal form must be submitted for each study	

Protocol Status

Research-related activities are ongoing	
Research-related activities are complete, long-term follow-up only	
Research-related activities are complete, data analysis only	
The main study is complete but sub-study research-related activities are on-going	
Study is closed If closed, indicate the study closure date	
Indicate whether a report on the study was submitted to the HREC and the submission date	

Progress of Study

Study Enrolment

How many participants are enrolled in the study?	

How many refused consent? Indicate the reasons for refusal of consent.	
How many withdrew from the study? Indicate the reasons for withdrawal.	
How many were Lost to Follow Up? Indicate steps taken to trace participants.	
How many Premature Treatment discontinuations? (where applicable) Indicate reasons and follow-up of these participants.	
How many Premature Study discontinuations? Indicate reasons and follow-up of these participants.	

Amendments

How many amendments have there been since the original approval?	
How many amendments have been approved since the last review? Indicate the Dates _____	
Are new protocol changes/amendments being requested as part of this continuing review?	

Adverse Events

Please provide/attach a narrative summary of serious adverse events and/ or unanticipated problems since the last progress report. Please indicate changes made to the protocol and informed consent document(s) as a result (if not already reported to the HREC). Please comment on whether causality to any study procedure or intervention could be established.

Have participants received appropriate treatment/ follow-up/ referral when indicated (e.g. in the case of abnormal or incidental clinical findings, distress or anxiety)?		
Yes ☐	**No** ☐	**Not applicable** ☐
If yes, please describe		

Has there been any agency, institutional, or other inquiry into non-compliance in this study, or any finding of non-compliance concerning a member of the research team		
Yes ☐	**No** ☐	**Not applicable** ☐
If yes, please explain.		

List of Documentation for Approval

Signature

Signature of PI:	Date: