LIFE HEALTHCARE HEALTH RESEARCH ETHICS COMMITTEE

STUDY CLOSEOUT/DISCONTINUATION FORM

NOTE FOR RESEARCHERS
In accordance with the Life Healthcare Health Research Ethics Committee (HREC) TORs and SOPs which are accessible via https://www.lifehealthcare.co.za/careers/education-and-training/research-and-human-research-ethics-committee/ researchers must notify the HREC when a study has been completed or discontinued. This report formally closes the study with the HREC, and no further participant recruitment or interaction may occur after the approval of this closeout report.

1. GENERAL STUDY APPLICATION	
1.1. Researcher Details	
1.2. Mobile Number	
1.3. Email	
1.4. Study Title	
1.5. HREC Ref Number	
1.6. Date of Life Healthcare Original Approval	
1.7. Expiry Date of Current HREC Ethics Approval (including approval of amendments)	
1.8. For Postgraduate Research: Expiry Date of University Ethics Approval **For Clinical Studies:** Date of Expiry from Pharma Ethics, SAHPRA or related REC for clinical study	
1.9. List of approved Life Healthcare Facilities	

2. STUDY STATUS AND OUTCOME		
2.1. Reason for submission	Study **completed** (final closeout)	
	Date of Completion:	
	Study **discontinued** (termination by researcher, sponsor or ethics committee or regulator)	
	Date of Completion:	
2.2. Date of completion or discontinuation		
2.3. Recruitment has **not yet** commenced		
2.4. Data collection **discontinued**		
2.5. Data collection related activities are complete; **no further engagement with participants** is required		

3. REASON(S) FOR DISCONTINUATION (If reason for item 2.1. is discontinuation, please complete)

3.1. Terminated due to adverse event(s)	
3.2. Insufficient funding	
3.3. Slow data accrual/Insufficient participant accrual	
3.4. Research did not commence	
3.5. Researcher left affiliated sites/cancelled studies	
3.6. Other, please specify.	

4. ETHICAL AND SAFETY

4.1. Has there been any deviations, amendments or violations since the study approval or last report?	Yes No
If yes, provide details including any actions taken and attach relevant documentation (e.g., corrective action plans).	
4.2. Has any unanticipated problems involving risk to participants or others occurred?	Yes No
If yes, provide details including a description of the event and actions taken to mitigate harm.	
4.3. Have any Adverse Events (AEs) or Serious Adverse Events (SAEs) occurred that are related to the research procedure?	Yes No
If yes, provide a summary of the events, their assessment to the study, and actions taken. Attach any relevant AE/SAE reporting forms already submitted.	
4.4. Was there any identified risks observed which need to be addressed?	Yes No
If yes, provide details of identified risk and actions taken to mitigate harm.	

5. POST CLOSURE ACTIVITIES

5.1. Final report has been submitted to overseeing committee (eg. sponsor, SAHPRA, institutional REC)	Yes No
If Yes, Provide details of committee where final report submitted.	

5.2. Describe the manner in which research findings have been disseminated to participants, communities, and/or stakeholders	
5.3. Is data currently stored securely as per the approved protocol?	Yes No
If No, provide reason and corrective measures to be undertaken.	
5.4. Provide date of data destruction. Date:	
5.5. Provide the method of data destruction	
5.6. If study has been complete, has a copy of study been submitted to Life Healthcare Research Office?	Yes No
If No, provide details.	

6. REQUIRED DOCUMENTATION FOR STUDY PROGRESS REPORTING

6.1. Final Study Report/Lay Summary of Results (if available)	
6.2. The last Life Healthcare HREC Study Progress Form	
6.3. Sponsor's Closeout Letter (for sponsored studies)	

7. DECLARATION BY RESEARCHER

I the undersigned researcher confirm that:

- The information provided in this Study Closeout/Discontinuation Form and all accompanying documents is accurate and complete
- All ethical obligations concerning the conduct of this study, including participant follow-up and data management, have been met.
- I have retained all study records for the required period as per the approved protocol and institutional/national requirements.

Signature of Researcher: _____ Date: _____