STUDY PROGRESS 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/ The HREC is mandated to monitor research projects. This Study Progress Monitoring is a mandatory document to be completed by the researcher as a means of updating to the HREC on the status and ethical conduct of an approved research study. **Failure to comply with annual reporting requirements may result in the suspension or termination of the study**

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. CURRENT STUDY STATUS

Recruitment and enrollment commenced and is currently ongoing		Data Analysis and report writing ongoing	
Recruitment and Enrollment completed Date of Completion:		Study Completed Date of Completion:	
Data collection commenced and is currently ongoing		Study discontinued Date of discontinuation:	
Data collection completed Date of Completion:			
Other (please specify)			

3. SUMMARY OF PARTICIPATION	
Minimum and maximum number of participants approved for study	
Total number of participants recruited to date	
Total number of participants currently active on the study	
Number of participants outstanding for study	
Number of participants withdrawn from study	
Reason for withdrawal (if applicable)	
Number of Questionnaires/Interviews completed	
Total number of Questionnaires/Interviews required as per protocol	

4. ETHICAL CONDUCT OF RESEARCH		
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. Amendments/Extensions		
Has there been any amendments or extensions made since the originally approval?	Yes	
	No	
If Yes, Provide date of approval for amendment and or extension		

6. DATA MANAGEMENT AND STORAGE		
6.1. Is data currently stored securely as per the approved protocol?	Yes	
	No	
If No, provide reason and corrective measures to be undertaken.		
6.2. If the study is complete or nearing completion, provide date of data destruction. Date:		
6.3. What is the method of data destruction?		
6.4. If study has been complete, has a copy of study been submitted to Life Healthcare Research Office?	Yes	
	No	
If No, provide details.		

7. REQUIRED DOCUMENTATION FOR STUDY PROGRESS REPORTING	
Life Healthcare HREC Ethics Approval	
Ethics approval from university or Pharma Ethics, SAHPRA etc. for clinical study	
Amendment approval (if applicable)	
Extension of study approval (if applicable)	
Adverse Event or Serious Adverse Event Report Form	

8. DECLARATION BY RESEARCHER

I the undersigned researcher confirm that:

- The information provided in this Study Progress Form and all accompanying documents is accurate and complete
- I will report any further changes, adverse events, or unanticipated problems to the Life Healthcare Health Research Ethics Committee as per the TOR and SOP

Signature of Researcher: _____ Date: _____