

AMENDMENT OF STUDY APPLICATION 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/> ethical oversight is required for any amendments or deviations from the originally approved study protocol. Researchers are required to use this form to apply for approval of proposed amendments to an already ethically approved study.

**No aspect of the proposed amendment(s) is to be implemented until written approval has been granted by the Life Healthcare HREC.**

**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. Name of Life Healthcare Facility originally approved	

**2. NATURE OF AMENDMENT**

(Tick all applicable)

Change in Study Title	Change in Participant Recruitment Process
Change in Principal Investigator	Change in Informed Consent Process
Addition/Removal/Change of Co-Investigator(s) / Study Personnel	Change in Data Collection Process or Methods
Addition/Removal/Change in Study Site(s)	Change in Data Management Process
Change in Research Methodology	Change in Risk Profile of Participants
Change in Sample Size or Sampling Method	Extension of Data Collection Period
Other (Please Specify)	

**3. IMPACT OF AMENDMENT ON PARTICIPANTS (IF APPLICABLE)**

3.1. Will the amendment change the risks or benefits for participants? Explain

3.1. Will the amendment require re-consenting of current participants? If yes, outline the re-consenting process.

**4. IMPACT OF AMENDMENT ON SCIENTIFIC VALIDITY**

4.1. How does the amendments affect the research aim, objectives/hypothesis, or overall design of the study?

**5. DESCRIPTION OF AMENDMENT**  
(Describe the proposed change and the reason for the amendment)

**6. REQUIRED DOCUMENTATION FOR AMENDMENT REQUEST**

Revised Study Protocol detailing proposed changes from original protocol	
Ethics Approval from Institution for amendment of study	
Postgraduate Studies - Letter from Institution/Supervisor indicating approval of amendment of study	
Revised Recruitment Material/Informed Consent or Data Collection Method	
Other supporting documents	

**7. DECLARATION BY RESEARCHER**

I the undersigned researcher confirm that:

- The information provided in this Amendment of Study Application Form and all accompanying documents is accurate and complete
- I understand that no aspect of the proposed amendment(s) may be implemented before receiving written approval from the Life Healthcare Health Research Ethics Committee
- 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: \_\_\_\_\_