

**Postgraduate Studies, Research Development, Integrity & Ethics
Sefako Makgatho University Research Ethics Committee (SMUREC)**

AMENDMENT NOTICE

07 April 2022

Prof Hyla Kluyts
Department of Anaesthesiology
MEDUNSA
0204

Dear Prof Kluyts ,

MEETING: 03 /2022
SMUREC Ethics Reference Number: SMUREC/M/184/2020: IR

The Amendment request received was reviewed by members of Sefako Makgatho University Research Ethics Committee on **07 April 2022**.

Title: The South African COVID-19 Surgical Outcomes Study
Principal Investigators: Prof H Kluyts
Prof B Biccard
Department: Anaesthesiology
School: Medicine
Type of Study: Independent Research

The following amendments were requested:

Additional Staff Add Dr C Steyl as investigator
Methodology Remove validation of cost prediction model from protocol- Changes/ deletions made in relevant sections – WHO dataset, Introduction, Secondary Objectives, Participants (hospitals), Dataset & Variables
Describe Well-Architected Review as contributing to data governance and data security. Additions to paragraph 3.7 Data Security, Management and Ownership, p17: Silicon Overdrive assisted in a Well Architected Review of the system, and recommendations to improve data governance and data security were made and implemented.
Ethical considerations Describe access to data for telephonic patient follow up. The PSHR database is stored on MongoDB Cloud Services. Access to the database is through secure login by authorized personnel using Metabase. The personnel with authorized access are the PI, Prof Hyla Kluyts, and the Safe Surgery SA Research and Development Assistant, Ms H Duvenage. Apart from data export for analysis, data will be accessed to obtain information for telephonic follow-up of patients, and to monitor recruitment and participation.

Documents received for review: The South African COVID-19 Surgical Outcomes Study Version no 9 Dated January 2022

Motivation:

a) Access to hospital cost data denied by participating hospital group b) Process for data access not available/defined with original SMUREC submission c) Well Architected Review is a service provided by Silicon Overdrive, unknown at the time of original submission.

SMUREC **NOTED** and **APPROVED** the above mentioned amendments for the study.

The new Clearance Certificate to be issued separately.

Sincerely

PROF C BAKER

CHAIRPERSON

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