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**Approval Notice**

**New Application**

20/04/2020

**Project ID :**14994

**HREC Reference No:** N20/04/008\_COVID-19

**Project Title:** COVID-19: sequencing the virus from South African patients

Dear Prof Susan Engelbrecht

The **New Application** received on 17/04/2020 was reviewed and **approved** by members of **Health Research Ethics Committee** via **expedited** review procedures on 20/04/2020.

Please note the following information about your approved research protocol:

**Protocol Approval Date: 20 April 2020**

**Protocol Expiry Date: 19 April 2021**

Please remember to use your Project ID 14994 and Ethics Reference Number N20/04/008\_COVID-19 on any documents or correspondence with the HREC concerning your research protocol.

Please note that the HREC has the prerogative and authority to ask further questions, seek additional information, require further modifications, or monitor the conduct of your research and the consent process.

**After Ethical Review**

Translation of the informed consent document(s) to the language(s) applicable to your study participants should now be submitted to the HREC.

Please note you can submit your progress report through the online ethics application process, available at: Links Application Form Direct Link and the application should be submitted to the HREC before the year has expired. Please see [Forms and Instructions](#) on our HREC website ([www.sun.ac.za/healthresearchethics](http://www.sun.ac.za/healthresearchethics)) for guidance on how to submit a progress report.

The HREC will then consider the continuation of the project for a further year (if necessary). Annually a number of projects may be selected randomly for an external audit.

**Provincial and City of Cape Town Approval**

Please note that for research at a primary or secondary healthcare facility, permission must still be obtained from the relevant authorities (Western Cape Department of Health and/or City Health) to conduct the research as stated in the protocol. Please consult the Western Cape Government website for access to the online Health Research Approval Process, see: <https://www.westerncape.gov.za/general-publication/health-research-approval-process>. Research that will be conducted at any tertiary academic institution requires approval from the relevant hospital manager. Ethics approval is required BEFORE approval can be obtained from these health authorities.

We wish you the best as you conduct your research.

For standard HREC forms and instructions, please visit: [Forms and Instructions](#) on our HREC website <https://applyethics.sun.ac.za/ProjectView/Index/14994>

If you have any questions or need further assistance, please contact the HREC office at 021 938 9677.

Yours sincerely,

Mrs. Melody Shana

Coordinator

HREC1

*National Health Research Ethics Council (NHREC) Registration Number:*

*REC-130408-012 (HREC1)•REC-230208-010 (HREC2)*

*The Health Research Ethics Committee (HREC) complies with the SA National Health Act No. 61 of 2003 as it pertains to health research. The HREC abides by the ethical norms and principles for research, established by the [World Medical Association \(2013\). Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects](#); the South African [Department of Health \(2006\). Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa \(2nd edition\)](#); as well as the Department of Health (2015). [Ethics in Health Research: Principles, Processes and Structures \(2nd edition\)](#).*

*The Health Research Ethics Committee reviews research involving human subjects conducted or supported by the Department of Health and Human Services, or other federal departments or agencies that apply the Federal Policy for the Protection of Human Subjects to such research (United States Code of Federal Regulations Title 45 Part 46); and/or clinical investigations regulated by the Food and Drug Administration (FDA) of the Department of Health and Human Services.*