



REFERENCE NO: HPDME 13/18/1

4th February 2022

Health Research and Development Division

Notification of IRB Review: **New application**

Dr Sikhulile Moyo
Botswana Private Bag BO 320
Gaborone
Botswana

Dear Dr Sikhulile Moyo

Protocol Title: **GENOMIC CHARACTERISATION OF SARS COV-2
INFECTIONS IN BOTSWANA V1.0 DATED DECEMBER 16
2021 HRDC # 00945**

HRDC Review Type:	Full Board/HRDC
HRDC Review Date:	25 th November 2021
HRDC Approval Date:	25 th November 2021
HRDC Effective Date:	04 th February 2022
HRDC Expiration Date:	24 th November 2022
Risk Determination:	Minimal risk

Thank you for submitting new application for the above referenced protocol. The permission is granted to conduct the study.

This permit does not however give you authority to collect data from the selected sites without prior approval from the management. Consent from the identified individuals should be obtained at all times.

The research should be conducted as outlined in the approved proposal. Any changes to the approved proposal must be submitted to the Health Research and Development Division in the Ministry of Health for consideration and approval.

Furthermore, you are requested to submit at least one hardcopy and an electronic copy of the report to the Health Research, Ministry of Health and Wellness within 3 months of completion of the study. Approval is for academic fulfillment only. Copies should also be submitted to all other relevant authorities.

Vision: *A Healthy Nation by 2036.*

Values: *Botho, Equity, Timeliness, Customer Focus, Teamwork, Accountability*



Continuing Review

In order to continue work on this study (including data analysis) beyond the expiry date, submit a Continuing Review Form for Approval at least three (3) months prior to the protocol's expiration date. The Continuing Review Form can be obtained from the Health Research Division Office (HRDD), Office No. 7A.7 or Ministry of Health website: www.moh.gov.bw or can be requested via e-mail from Mr. Kgomoitso Motlhanka, e-mail address: kgmmotlhanka@gov.bw As a courtesy, the HRDD will send you a reminder email about eight (8) weeks before the lapse date, but failure to receive it does not affect your responsibility to submit a timely Continuing Report form

Amendments

During the approval period, if you propose any change to the protocol such as its funding source, recruiting materials, or consent documents, you must seek HRDC approval before implementing it. Please summarize the proposed change and the rationale for it in the amendment form available from the Health Research Division Office (HRDD), Office No. 7A 7 or Ministry of Health website: www.moh.gov.bw or can be requested via e-mail from Mr. Kgomoitso Motlhanka, e-mail address: kgmotlhanka@gov.bw . In addition submit three copies of an updated version of your original protocol application showing all proposed changes in bold or "track changes".

Reporting

Other events which must be reported promptly in writing to the HRDC include:

- Suspension or termination of the protocol by you or the grantor
- Unexpected problems involving risk to subjects or others
- Adverse events, including unanticipated or anticipated but severe physical harm to subjects.

Attachments;

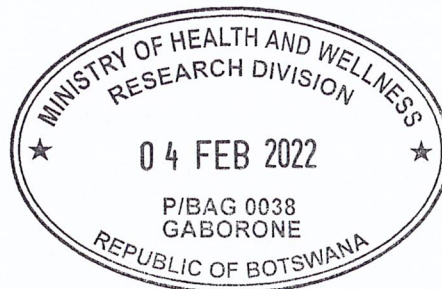
1. HRDC New application form dated 16 December, 2021(Clean and Tracked versions)
2. Study proposal version 1.0 dated 16 December 2021(Clean and Tracked versions)
3. Study budget and justification
4. CVs for Investigators

If you have any questions please do not hesitate to contact Mr Kgomoitso Motlhanka at kgmotlhanka@gov.bw at 3632751. Thank you for your cooperation and your commitment to the protection of human subjects in research.

Yours faithfully



Dr Patrick Masokwane
for/PERMANENT SECRETARY



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