



**HARVARD**

Human Research Protection Program

Harvard T.H. Chan School of Public Health  
Office of Regulatory Affairs and Research Compliance  
90 Smith Street, 3rd Floor  
Boston, MA 02120  
Federalwide Assurance FWA00002642

### **Notification of Initial Study Approval**

March 7, 2022

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**Protocol Title:** Genomic Characterisation of SARS CoV-2 Infections in Botswana  
**Principal Investigator:** Sikhulile Moyo  
**Protocol #:** IRB21-1661  
**Funding Source:** NIH/FIC- 3D43TW009610-09S1 (Active); NIH/NIAID-5K24AI131924-04 (Active);  
**Review Date:** 2/15/2022  
**STUDY Effective Date:** 2/15/2022  
**IRB Review Type:** Expedited  
**IRB Review Action:** Approved

The Institutional Review Board (IRB) of the Harvard T.H. Chan School of Public Health approved this Initial Study. This approval does not expire and you will not be required to submit an annual renewal application. However, you are responsible for submitting the following to the IRB, as applicable. Any change or update to the research must be submitted in ESTR via a Modification. Once the study is eligible for closure, a closure request must be submitted in ESTR via the Close Study activity. All reports of new information must be submitted in ESTR via the Report New Information activity. If you are unsure what to submit, contact the Harvard T.H. Chan School of Public Health IRB office for further assistance.

The documents that were finalized for this submission may be accessed through the IRB electronic submission management system at the following link: [IRB21-1661](#)

This approval includes review of all study documents and initial IRB application materials. The IRB-approved documents can be viewed on the Documents Tab of the ESTR Workspace (linked above). For instructions on how to navigate the ESTR Smartform and ESTR Workspace, visit the ESTR Support Site – Accessing a Submission (<https://estrsupport.fss.harvard.edu/accessing-submission>).

The IRB made the following determinations:

- An alteration and/or waiver of the requirement to obtain consent is appropriate as set forth at 45 CFR 46.116(f);
- Risk Determination: No greater than minimal risk

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University Area IRB <http://cuhs.harvard.edu>  
Harvard Longwood Campus IRB <http://www.hsph.harvard.edu/orarc>



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- Research Information Security Level (based on Harvard Research Data Security Policy): Sensitive

#### Questions?

If you have any questions, leave a comment on the ESTR Workspace. For instructions on how to enter a comment in the system and notify the Review Specialist/IRB Coordinator, visit the ESTR Support Site – Communicating with Staff (<https://estrsupport.fss.harvard.edu/communicating-with-staff>).