Mass General Brigham IRB
Mass General Brigham
399 Revolution Drive, Suite 710
Somerville, MA 02145
Tel: 857-282-1900
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Cede Review Request: APPROVED

Protocol #: 2022P000421

Date:	March 07, 2022
To:	Lockman, Shahin, MD BWH Mass General Brigham > BWH > Medicine > Infectious Disease
From:	Mass General Brigham IRB 399 Revolution Drive, Suite 710 Somerville, MA 02145
Title of Protocol:	Genomic Characterisation of SARS-COV-2 infections in Botswana
Relying Institution:	BWH
Reviewing IRB:	Harvard T.H. Chan School of Public Health IRB (ORARC)

You may begin once you receive documentation of approval from Harvard T.H. Chan School of Public Health.

STEP 1	**Determine Eligibility for External IRB Submission** The Mass General Brigham IRB has determined this protocol is ELIGIBLE FOR RELIANCE and may be submitted to the External IRB for review and approval.	**COMPLETE**	✓
STEP 2	**PI/Study Team Completes Cede Protocol** 1. Complete application form sections in Insight (refer to Cede Review Guide) 2. Attach documents (Protocol & Consent Form) 3. Resubmit in Insight	**COMPLETE**	✓
STEP 3	**Mass General Brigham IRB Conducts Administrative Review** 1. Departmental Review 2. Verify training of study staff 3. Complete eCOI, as applicable 4. Complete ancillary reviews (**N/A**) 5. Verify Reliance Agreement [**HSPH via SMART IRB Master Reliance Agreement – SMART ID 6664**]	**COMPLETE**	✓
STEP 4	**PI/Study Team Submit any amendments/other events that require local review, including:** 1. Change in PI/Study Staff. 2. Changes in funding.	**PENDING**	

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	3. Changes in conflicts of interest. 4. Changes for which there is a specific institutional policy/state law requirement. 5. Changes to the Investigator Drug Brochure [IB]. 6. Significant changes to the detailed protocol, such as changes in drug dispensation, dosing or the targeted population. 7. Changes to plans for research radiation exposure. 8. Other changes that require additional MGB ancillary review, including Radiation Safety, Biomedical Engineering, Research Information Security Office, nursing or OII. 9. Local events that may require additional review by MGB, including local unanticipated problems, reviewing IRB determinations that the MGB study team engaged in serious or continuing non-compliance, privacy breaches affecting MGB participants, or complaints from local participants.		

NOTE: THE CLINICAL TRIAL AGREEMENT BETWEEN THE SPONSOR AND THE INSTITUTION MUST BE EXECUTED BEFORE THE RESEARCH MAY BEGIN.

Questions related to this project may be directed to IRB@partners.org

cc:

Shahin Lockman, MD, Principal Investigator, Infectious Disease, Medicine