

NATIONAL HEALTH RESEARCH AUTHORITY

OFFICE OF THE DIRECTOR AND CHIEF EXECUTIVE OFFICER

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Date: 04th August, 2021

To all Researchers, heads of research institutions and research establishments

C.C:

Permanent Secretary Technical Services, Ministry of Health NHRA Council Chairperson NHREB Chairperson Director General, ZNPHI Chairpersons of all Research Ethics Committees

Dear Sir/Madam

Re: Lifting of temporal suspension of COVID-19 Risky Research Activities

Reference is made to the above captioned subject matter and our circular letter dated 18 June 2021 and 1st July 2021. As you are all aware, the COVID-19 epidemiological situation has improved since we last communicated to you over a month ago. We however wish to urge all our researchers not to drop the guard with regard to strengthened measures to protect both the researchers and research participants against COVID-19.

Considering the need to continue to adduce evidence towards our effective response to not only COVID-19 but to all other public health threats, and in the light of the reduced numbers of cases and deaths from COVID-19, we have decided to conditionally lift the temporal suspension of all research activities that involve direct interaction or contact with research participants with effect from today, August 4, 2021. Research activities have been authorized to continue on condition that strengthened infection control measures that have been discussed with Principal Investigators of various studies that engaged NHRA during the suspension period are enforced. Systems to enforce and monitor adherence to the strengthened measures must be put in place.

Strengthened COVID-19 Infection Control Measures

At a minimum, the following strengthened measures should be implemented:

1.0 Study specific COVID-19 risk identification, analysis, and mitigation

Principal Investigators should submit to NHRA a short description of risks of exposure to COVID-19 associated with specific studies they are undertaking or intend to undertake as well as specific measures put in place to mitigate those risks. They should also clearly describe systems or

mechanisms they have put in place to enforce and monitor compliance to those measures. For those studies where Principal Investigators have already submitted this; they do not need to resubmit.

2.0 Strengthened risk mitigation measures

- 2.1 For all COVID 19 studies that involve direct exposure with patients or SARS COV-2 positive clients or clients whose status is unknown but requires direct contact such as physical examination or collection specimens, staff collecting data or conducting research procedures should at the minimum be provided with Filtering Facepiece Respirators (FFP).
- 2.2 Where the study is being undertaken under conditions of low virus abundance (virus-limited) environment such as outdoors or tent with both a free flow of air on both sides, surgical masks may be used where budget limitations cannot allow FFP respirators. The research team should preferably double mask in this case.
- 2.3 Where the study is being undertaken under conditions of high virus abundance (virus-rich) environment such as exist in hospital COVID-19 isolation centres, NIOSH or other approved FFP respirators FFP3 or N99 are recommended with a full COVID-19 protective gear. Where FFP3 or N99 is not available, FFP2 or Surgical N95 respirator can be used.
- 2.4 With regard to guideline 2.3 above, the PI should ensure that the research team is well oriented on proper donning and doffing procedures as well as other general infection control measures.
- 2.5 For all studies, the social distancing rule shall be at least 2metres.
- 2.6 No staff member should be exposed to a virus-rich environment for over 4hours per day.

3.0 Monthly reports of Covid-19 Infections

Principal Investigators will be expected to submit to NHRA a monthly report of new COVID-19 infections occurring in the workplace/study site to help NHRA evaluate or assess risk. This will require that **all research staff in direct contact with research participants** should have a monthly COVID-19 test. We will be sending a monthly reporting form in due course for your guidance. The reports should be submitted by the fifth of day of each month, the first report will be for the month of August, 2021 to be submitted by 5th September, 2021.

Should you have any questions regarding the implementation of this guideline or should you need further guidance, please contact Prof. Victor Chalwe on 0979883237 or you may contact me directly on 0974770293.

I wish to thank you most sincerely for your cooperation and stay safe. Yours sincerely,

Prof. Godfrey Biemba

Director/CEO

National Health Research Authority