UNIVERSITY OF KWAZULU-NATAL
INYUVESI YAKWAZULU-NATALI

June 28th 2021 BREC Amended level 4 Lockdown Guidance.

See https://www.gov.za/documents/disaster-management-act-regulations-alert-level-4-during-coronavirus-covid-19-lockdown-1

1. All BREC approved researchers and applicants must be familiar with prevailing SA Department of Health DoH COVID-19 Infection Prevention and Control Guidelines.

2. All current BREC-approved studies involving contact with human participants are required to conduct a new COVID-19 risk assessment for participants and researchers, especially but not limited to, health care settings, and ensure that they comply with or exceed current national requirements.

3. All proposed new studies involving involvement with human participants or other personnel must conduct and include in the BREC application a risk assessment for participants and researchers, especially in health care settings, and review their risk mitigation measures, and ensure that they comply with or exceed current national requirements.

4. All previously approved HIV and TB Clinical trials are permitted to continue provided that the full protections detailed in Annexure 1 of this document, plus any further such protections that may be announced in future, be applied to protect participants, study staff and other parties.

5. All other previously approved phase 1, 2 and 3 clinical trials are permitted to continue provided that the full protections detailed in Annexure 1 of this document, plus any further such protections that may be announced in future, be applied to protect participants, study staff and other parties.

6. All previously approved COVID-19 clinical trials are permitted to continue provided that the full protections detailed in Annexure 1 of this document, plus any further such protections that may be announced in future, be applied to protect participants, study staff and other parties.

7. All previously approved observational (i.e. non-interventional) studies are allowed to continue provided that that all prevailing guidelines including Annexure 1 of this document, and emergent COVID-19 protections and social distancing guidelines are rigorously applied by the researcher to protect participants, researchers and other parties. Renewed gatekeeper permissions may be required if relevant.

8. All previously approved phase 1 clinical trials (other than HIV and TB trials) be assessed by the PI and BREC for risk/benefit on a case by case basis including the full protections detailed in Annexure 1 of this document, plus any further such protections that may be announced in future, be applied to protect participants, study staff and other parties.

9. Researchers must be sensitive to COVID-related and other pressures at research sites and should delay studies if the site is clearly stressed/under pressure and appropriate further informal or formal consultations with gatekeepers must be engaged in to determine timing of the proposed study.

10. All new submissions of COVID-19 clinical trials and COVID-19 observational studies will be flagged for rapid full or expedited review and be allowed to proceed as soon as all ethics, gatekeeper and regulatory requirements have been satisfied and provided that the full protections detailed in Annexure 1 of this document, plus any further such protections that may be announced in future, be applied to protect participants, study staff and other parties. PIs of planned multi-site COVID-19 applications should be advised to consider seeking reciprocity of ethics review from the primary national PI's REC of record.

11. All adverse events in any BREC-approved study, including COVID-19 infections of research participants, research staff or related parties must be reported to BREC within 7 days or less of occurrence on the standard BREC SAE report form available at: http://research.ukzn.ac.za/Libraries/Notices2011/BREC_Serious_Adverse_Event_Form_2010_sflb.sflb.ashx and emailed to BREC@UKZN.ac.za

12. This guidance will be revised from time to time as National Lockdown Regulations and other relevant factors may change.

13. Where any researcher/PI is in doubt they must consult with BREC BREC@ukzn.ac.za before proceeding.

Prof D R Wassenaar

Chair: UKZN BREC

28th June 2021

BREC COVID-19 LEVEL 3 GUIDELINE ANNEXURE 1

Addendum: Mitigation of risk

A: Mitigating Risk of transmission to participants and patients:

Clinical trial and research sites must be able to observe reasonable levels of physical distancing. This can be achieved through the following actions:

Standard infection control measures such as adequate ventilation, regular disinfection, regular cleaning.
Appropriate face mask covering **nose and mouth** for participants and patients.
Education of participants and study communities about COVID-19.
Triaging for Acute Respiratory Symptoms at the entrance and prior to scheduled visits and where facilities and equipment are compatible, providing COVID19 testing on site. Advising testing or referral and isolation for symptomatic participants.
Conducting activities in well ventilated, outdoor spaces wherever possible (TB research sites have already established well-ventilated areas).
Limiting the number of people in research spaces and limiting the number of participant visits per day.
Spacing participant visits through appointments and door control.
Ensuring that adequate handwashing/sanitisers are in place.
Conducting remote (i.e. non-face-to-face) activities virtually where possible.
Restricting patient contact to a few research staff as possible.
Carefully considering patient flow to reduce time in the clinic and improve infection control measures. Limiting participants' use of public transport.
Ensuring adequate infection control in vehicles where participants are transported.
Any additional national risk-prevention standards as introduced from time to time.

B: Mitigating Risk of transmission to research staff:

Ensuring adequate and appropriate personal protective equipment for clinic staff including adequate protective respirators, eye/face screens, overalls/aprons and gloves. Ensure adequate staff training on COVID-19.
Ensure staff with co-morbidities are not front line.
Rotating staff to have time off from the front line.
Ensuring that the best possible infection control measures are adopted.
Checking staff well-being daily, including symptoms, temperatures and offering testing when needed.
Limiting staff use of public transport.
Ensuring adequate infection control in vehicles where staff are transported.
Providing additional measures for elderly staff with additional health issues.

Any additional national risk prevention standards as introduced from time to time.

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