

URGENT RESEARCH OFFICE NOTICE

10th Nov 2020

UKZN BIOMEDICAL RESEARCH ETHICS COMMITTEE (BREC) REVISION TO RESEARCH CONSTRAINTS AND SAFEGUARDS DURING LEVEL 1 LOCKDOWN.

BREC has replaced the lockdown level 2 guidance applicable to approved BREC studies with the following; effective from 11th November 2020:

- A. Resumption of non-interventional/observational studies will still be considered by BREC on a case-by-case basis subject to i) a satisfactory risk/benefit ratio, ii) renewed agreement from the local site manager(s) that they can accommodate the resumption of the research, iii) that interview/focus group research adopts use of online/telephonic media as far as possible or, if face-to-face/in person, strict social distancing, mask wearing and handwashing must be implemented, iv) that the Principal Investigator (PI) complies with national and UKZN COVID-19 safety guidelines.
- B. All interventional studies may resume subject to i) renewed agreement from the local site manager(s) that they can accommodate the resumption of the research and that ii) the PI complies with national and UKZN COVID-19 safety guidelines.
- C. In both cases PIs must be sensitive to obvious signs of stress or distraction at study sites and delay their procedures considerably as required.
- D. Where a PI is in doubt, please consult with the BREC chair.
- E. PIs are reminded:
 - i. All amendments must receive prior BREC approval
 - ii. All studies must be recertified/renewed annually.

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Founding Campuses:  Edgewood  Howard College  Medical School  Pietermaritzburg  Westville