

## URGENT COVID-19 NOTICE TO ALL RESEARCHERS WORKING UNDER CURRENT UKZN BREC ETHICS APPROVALS

### COVID-19: UKZN BIOMEDICAL RESEARCH ETHICS COMMITTEE (BREC) RECOMMENDATIONS FOR BREC- APPROVED CLINICAL TRIALS, STUDIES AND RESEARCH SITES INVOLVING HUMANS

We are anticipating community COVID-19 spread in South Africa. Therefore, all research activities where people are brought together for research purposes, where research participants and research staff and students and/or other parties are placed at risk by the nature of data collection, or where specimen collection poses transmission risk, must undergo immediate risk assessment to determine risk of COVID-19 transmission. BREC's duty is to ensure the protection of all UKZN research participants, staff and students through reducing the risk of COVID-19 transmission.

**In line with current government recommendations to practice social distancing, we must minimise the risk of transmission at research sites and in all BREC-approved studies involving human participants.**

Over the next week, **each current BREC-approved or provisionally approved** research study or study site must develop a plan to minimise exposure to COVID-19 risk for all parties involved in the study, including but not limited to research participants, researchers and student researchers. In some cases de-escalation or suspension of all research activities may be necessary because limiting infections and protecting participants and research staff and students should be the priority.

Where relevant, these plans must be discussed, urgently and in advance, with relevant stakeholders, including community representatives (e.g. CABs) where such representatives have been engaged with to date, to retain and maximise trust, transparency and stakeholder engagement with the study in question.

BREC recommendations are as follows:

1. Limiting infections and protecting research participants and research staff and student researchers and proximal role players should be the priority.
2. All non-therapeutic or non-interventional research involving contact with human participants should be suspended, with the exception of social science studies involving telephonic or other online/remote methods of data collection. Where feasible, researchers may, with the consent of their participants, switch from face-to-face to remote (e.g. online, telephonic) data collection. If this switch is implemented, the researcher must record the participant's consent and ensure that the participant's privacy is protected if sensitive information is elicited that might be overheard.
3. All exceptional reasons to continue 'research as usual' should be discussed with BREC.

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4. For therapeutic research and clinical research trials:
  - a. All therapeutic research and clinical research trials should be placed on hold and research activities should be suspended where possible, unless all research visits coincide with routine clinical visits for necessary clinical care independent of study visits and suitable protections are in place for study staff.
  - b. Whenever feasible, telephonic visits or follow-ups should be substituted.
  - c. Principal investigators and study sites should implement measures to ensure that there is no interruption of required medication/essential treatment or monitoring of adverse events.
  - d. Only critical study visits, where benefits significantly outweigh the potential harm of COVID-19 infection, should continue uninterrupted but with full risk assessment to minimise COVID-19 exposure to all role players. Study visits for critical medication or monitoring purposes should continue in consultation with BREC.
  - e. New enrolments to studies should be suspended. Potential exceptions to this recommendation should be discussed with BREC.
5. Evidence-based recommendations and resources regarding hand hygiene, cough etiquette and social distancing should be implemented immediately at all study sites.
6. Researchers and study sites should develop a 'COVID-19' template register in case retrospective contact tracing becomes necessary.
7. Routine recording of COVID-19 status may be implemented without additional BREC review and approval.
8. Every effort must be made to inform research participants timeously of those changes that impact on them.
9. Implementation of these recommendations may be done without submission of a BREC amendment request. However, all such changes must be reported to BREC as soon as possible for review and noting.
10. Amending protocols to include COVID-19 testing and participant feedback should be urgently considered and sent to BREC for rapid review using the standard BREC amendment form but flagged in a cover email/letter as a rapid review request.
11. Should any research staff, students or participants develop symptoms suggestive of COVID-19, they should be referred through local clinical pathways or should be advised to call the National Coronavirus Hotline (0800 029 999). Alternatively they can contact the UKZN COVID-19 Emergency task team at [covid19@ukzn.ac.za](mailto:covid19@ukzn.ac.za) for advice on where to access testing.

It must be noted that as the COVID-19 pandemic unfolds these guidelines may change to comply with current government, international, UKZN recommendations and/or emergent international best practices.

**All precautions to prevent transmission and reduce risk must be urgently implemented.**

BREC will continue to function administratively to support our many research participants and the research community for as long as permitted, including the online processing and review of routine correspondence and new applications.

Work is currently underway regarding steps to be taken to facilitate rapid review of COVID-19 related research protocols, in consultation with several REC chairs at SA universities, SAHPRA, international research ethics guidance and in compliance with DoH (2015) research ethics guidelines, particularly section 3.4.1.

Your support and cooperation at this critical time are essential and much appreciated.

Yours sincerely,



Prof V Rambiritch (Chair: BREC)



Prof D R Wassenaar (Deputy Chair: BREC)

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