UNIVERSITY OF SOUTH AFRICA COVID-19 GUIDELINES FOR ETHICS REVIEW COMMITTEES (ERCs)

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A responsible approach to human participant, community engaged, animal, environmental, molecular and cell research is required in the context of COVID-19. Unisa supports the continuation of research activities, where possible, guided by principles and activities supported by the Policy on Research Ethics and as stated in the **Covid-19 statement from UNISA on 8 April 2020.**

The following guidelines are applicable to Unisa Ethics Review Committees (ERCs) based on national guidelines and governmental directives, however, it is important to note that these guidelines will change in accordance with the roll-out of the different stages of the Government's Covid-19 Risk Adjustment Strategy:

1. **New research applications**:

   1.1 ERCs will continue to accept and review research ethics applications but will clearly indicate where the ERC does NOT wish this study to commence with immediate effect in accordance with the lockdown regulations.
   1.2 Low risk Covid-19 studies could undergo rapid expedited review, while medium and high-risk studies could undergo rapid full review.
   1.3 ERCs should participate in developing rapid review processes in line with the Unisa policy on research ethics, the Unisa standard operating procedure (SOP) on research ethics risk assessment and the Department of Health guidelines on health research ethics (2015).
   1.4 The general statement on Covid-19, dated 8 April 2020, needs to be included as an addendum to all ethics approval certificates issued until further notice.

2. **Approved/ongoing research studies**:

   2.1 No research involving face-to-face contact or research studies involving settings where it is difficult to institute physical distancing or practice protective measures may continue without formal notification and approval by the ERC that granted the approval in consultation with one of Unisa's registered Health ERCs/RECs.
   2.2 Where feasible, researchers may, with the consent of the participants, move from face-to-face to remote data collection and follow-up visits. This could be in the form of online data collection (telephonic, e-mail or other platforms considered only when safety and confidence can be ensured). A progress and amendment report

(Form 4) needs to be submitted to the relevant ERC for expedited review of changes to the study proposal prior to data collection.

2.3 Amendments to the study proposal needs to be inserted in the information letters and informed consent forms and should be e-mailed to the participants or designated authorities as arranged by the researcher. This will be applicable for online data collection and interviews by telephone or e-mail.

2.4 If the consent cannot be obtained in writing due to an imposed travel ban, a temporary site closure (e.g. for health or safety reasons), or other extenuating circumstances, the verbal consent must be fully documented and witnessed. Both verbal and written informed consent must be obtained unless there are good reasons for not doing so. Verbal consent should be obtained in the presence of an independent witness who should verify this in writing or submit evidence of this in the form of an audio-visual recording.

2.5 Every effort must be made to inform research participants timeously of those changes that impact on them.

2.6 Unisa supports the use of Microsoft Teams for recruitment and data collection activities.

2.7 The use of online tools such as Zoom, WhatsApp and Skype create privacy and confidentiality concerns and is not supported by Unisa.

2.8 Where or when it is unavoidable to reduce, suspend or postpone research activities, the onus is on the principal researcher to notify the ERC and to provide a rationale why the research needs to continue.

2.9 The ERC must notify the Unisa Research Ethics Review Committee (URERC@unisa.ac.za) of all ongoing studies that may pose a risk of harm relating to the Covid-19 pandemic within 48 hours.

2.10 ERCs must be mindful that the frequency of reporting and monitoring of ongoing research studies could increase relating to the risk level of the study.

2.11 Delays in data gathering may influence the validity of approval certificates. ERCs should inform researchers that they must apply for an extension of the approval period if necessary. No data may be gathered without a legitimate research ethics approval certificate.

3. Approved research that may continue without ERC notification

Research conducted by Unisa researchers that does not engage participants face-to-face and thus limits or does not pose the risk of COVID-19 infection may continue without ERC notification.

3.1 Research studies that collect data online or consists of the review of records are considered of low risk in current circumstances and may continue.

3.2 Data science research and other forms of research that does not require face-to-face interaction may continue.

3.3 Ecological (plant and animal), behavioural ecology, eco-physiological and agricultural studies where appropriate safety precautions can be taken and legitimate access to the facilities negotiated may continue if it complies with the lockdown and essential service requirements.

4. **Laboratory-based research**

4.1 Laboratory-based research where appropriate safety precautions can be taken and legitimate access to the facilities negotiated may continue if it complies with the lockdown and essential service requirements.
4.2 The URERC (URERC@unisa.ac.za) must be informed of all laboratory research relating to COVID-19.
4.3 The researchers remain responsible to ensure safety and protective measures, and to continue to minimise risk.
4.4 ERCs and researchers must abide by college specific guidelines relevant to their disciplines.
4.5 ERCs and researchers are also referred to international guidelines on Covid-19 research in laboratories: https://www.cdc.gov/coronavirus/2019-ncov/lab/biosafety-faqs.html

5. **General**

5.1 National instituted protective measures such as hand hygiene, cough etiquette, and physical distancing should be implemented, and monitored at sites/laboratories where these studies will continue.
5.2 Researchers should develop a 'COVID-19' template register in case retrospective contact tracing becomes necessary (names and contact details of all present on site to be registered daily from everyone going in and out) when it is unavoidable to reduce, suspend or postpone research activities.
5.3 Should any research staff, students or participants develop signs or symptoms suggestive of COVID-19, please call the National Coronavirus Hotline (0800 029 999).
5.4 The unique dynamics of social/physical distancing and lockdown regulations, more than ever, create a need for psycho-social support for researchers, participants and ERCs chairpersons and members.
5.5 Unisa is part of the current national discourse on creating support systems for ERCs in collaboration with several Research Ethics Committee chairs at SA universities, SAHPRA, the MRC and others. The research ethics community at Unisa will be updated on new developments to consider in conducting and reviewing research.

Acknowledgement:

Covid-19: HSRC research ethics committee (rec) recommendations for rec-approved research studies involving humans**,** Prof Theresa Rossouw (Chairperson: REC), Dr Mokhantso Makoae (Deputy chairperson: REC), Prof Ann Strode (Deputy chairperson: REC).

Research ethics support in Covid-19 Pandemic (RESCOP): Proposed rapid review process for South African RECs. Meeting 24 March 2020.

Stellenbosch University (SU) Faculty of Medicine and Health Sciences (FMHS) Researchers' Position Statement on Research Involving Human Participants (Clinical Research), 6 April 2020.