UNIVERSITY OF SOUTH AFRICA UPDATED COVID-19/NATIONAL DISASTER GUIDELINES FOR ETHICS REVIEW COMMITTEES (ERCs): TERMINATION OF THE DISASTER MANAGEMENT ACT 57 0F 2002 ON 21 JUNE 2022

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Following the termination of the national state of disaster, a responsible approach to human participant, community engaged, animal, environmental, molecular and cell research is required in the context of living with COVID-19. Unisa supports the continuation of research activities, where possible, guided by principles and conditions supported by the Policy on Research Ethics and the National Health Research Ethics Council (NHREC) guidelines on major incidents and research, including public health emergencies (2022).

It is important to note that these guidelines could change within the context of the Disaster Management Act 57 of 2002 relevant to any national disaster, but in particular to COVID-19. RECs and researchers will use the guidelines set out in the previous Covid-19 Unisa Guidelines documents depending on national legislation and regulations:

1. **New research applications**:

1.1 ERCs will continue to accept and review research ethics applications in line with the Unisa Policy on Research Ethics

1.2 Low risk Covid-19 studies could undergo rapid expedited review, while medium and high-risk studies could undergo rapid full review due to the need to conduct research on COVID-19

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 termination of the national state of disaster, need to be interpreted responsibility, with the knowledge and insight gained during the pandemic, and under guidance of the NHREC guidelines on major incidents and research, including public health emergencies.

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

2.1 Where feasible, researchers may, with the consent of the participants, move from online data collection (telephonic, e-mail or other platforms) to face-to-face data collection and follow-up visits considered when the safety of the researcher(s) and

participants can be ensured. Form 4 (Progress and Amendment) 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 communicated to the participants in the information letters and informed consent forms prior to data collection. Due care must be taken to ensure the safety of all persons involved in research.

2.4 If the consent cannot be obtained in writing due to legitimate reasons (health of safety reasons, newly instituted restrictions) 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 (consult the Unisa SOP on Informed Consent, 2020 for additional guidance on electronic consent).

2.5 Every effort must be made to inform research participants timeously of any changes in research protocols or studies that might impact them.

2.6 Remote and telephonic interaction with research participants could be employed taking special care that confidentiality and privacy should remain respected and ensured.

2.7 Where or when it is unavoidable to reduce, suspend or postpone research Activities during national disasters, the onus is on the principal researcher to notify the ERC and to provide a rationale why the research needs to continue.

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

2.9 Delays in data gathering during national disasters 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 a health or safety risk 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.

3.4 Research studies where the ERC has approved face to face data collection may continue without any changes.

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 safety regulations.
4.2 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 if applicable: 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, masks and physical distancing should be considered at sites/laboratories where studies will continue that may pose a health and safety risk.
5.2 Should any research staff, students or participants develop signs or symptoms suggestive of COVID-19, please call the National Coronavirus Hotline (0800 029 999).
5.3 Researcher(s) and ERC's are responsible for the safeguarding of Unisa, researchers and research participants safety and well-being at all times (Please refer to the Policy on Research Ethics).

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.

NHREC. 2022. Final Guideline in a pandemic Guideline 3.4.1: Major incidents and research, including public health emergencies.