

2021 HEALTH RESEARCH ETHICS COMMUNIQUÉ 2: RESEARCH GUIDANCE IN THE TIME OF THE ADJUSTED LEVEL 3 LOCKDOWN

Target group	All researchers/ investigators who are actively embarking on, engaged in research or required to do so (including undergraduate, postgraduate, postdoctoral students), supervisors/ promotor and research support staff
Purpose	To provide guidance on the continuation of health and medical research in the context of the adjusted lockdown level 4
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Document active	2021/07/29 until further notice and with agreement from the Vice-Rector Research, SU and the Vice-Dean, Faculty of Medicine and Health Sciences (FMHS), SU
Authors	Chairs, Health Research Ethics Committees (HREC); Undergraduate Research Ethics Committee (UREC), Head of the Health Research Ethics Office (HREO)

1. BACKGROUND

- 1.1. The President has announced a move to an adjusted lockdown level 3 as from Monday 26 July 2021.
- 1.2. The highly transmissible Delta variant of the virus has been identified as driving the third wave of infections.
- 1.3. The HREC therefore is of the view that researchers need to reflect on their research activities and how to proceed with the necessary caution and vigilance in terms of protecting participants and communities from unnecessary risk and safeguarding themselves against the transmission of COVID-19.
- 1.4. The purpose of this Communiqué is to provide guidance to support research activities in a manner that, very importantly, does not place participants at unnecessary risk of infection or consequently become a potential driver for escalating transmission and infections consequently placing strain on the health care services and health care workers.
- 1.5. ***It is recommended that all research activities requiring in-person contact with research participants be carefully executed and monitored, taking cognisance of the level 3 lockdown requirements and in-the-time of COVID-19 guidance as previously published by HREC. HREC advocates for an “ethics of responsibility” in protecting research participants.***

2. GUIDELINES FOR GOING FORWARD DURING ADJUSTED LEVEL 3

2.1. Previously Approved Research

- 2.1.1 For studies that have been previously granted ethics approval, HREC requests researchers to continue to reflect on approved research activities and, where possible, to continue “safer” alternatives for participants (such as online and virtual means or tele-medicine alternatives) that can be implemented to replace in-person follow up.
- 2.1.2 Where such virtual or online mechanisms have not been approved by HREC as part of the original protocol, an urgent amendment can be sought.

2.2. Newly approved research

- 2.2.1. For in-person studies that have been granted recent ethics approval and are still to commence, HREC recommends that consideration is given to delaying implementation, where feasible.
- 2.2.2. Where non-essential research can be conducted via virtual or online platforms and has been previously approved for such virtual platforms, the virtual activities can be re-activated.
- 2.2.3. Where approved protocols do not have a virtual alternative approved, researchers can seek an urgent amendment.

3. NEW HREC SUBMISSIONS

Going forward, all new HREC submissions need to, where feasible, include an alternate data collection strategy that aligns with the HREC’s in time of COVID-19 guidance and can be adjusted according to national lockdown regulations.

4. REVIEW OF HREC SUBMISSIONS

HREC may exercise its right to prioritise the review of certain new protocols, amendments, and progress reports in-the-time-of-Covid due to an unprecedented pressure on the HREC system and reviewers. Researchers are welcome to email the Health Research Office (ethics@sun.ac.za) to request and provide a rationale if there is a need to consider the prioritisation of a study.

5. CONCLUSION

- 5.1. This guidance will be revised in alignment with National Lockdown Regulations and relevant information regarding the local context – please visit the HREC webpage regularly for updated information.
- 5.2. The onus is on the researcher to contact the Health Research Ethics Office if uncertain or concerned about how, or if at all, to proceed. Where any researcher/PI is in doubt they must consult with HREC before proceeding. Please contact the following persons:

HREO/HREC

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