HEALTH RESEARCH ETHICS COMMUNIQUE 2 - RESEARCH GUIDANCE IN THE TIME OF OF THE COVID-19 PANDEMIC: LEVEL 1 AND LOWER

Target group

All researchers/ investigators who are actively embarking on, engaged in research or required to do so (including undergraduate and postgraduate students and postdoctoral fellows), supervisors/ promotors and research support staff

Purpose

To provide guidance on the continuation or commencement of health and medical research in the context of lockdown level 1 and lower in the Western Cape

Publication date: 2020/10/05

Document active: 2020/10/05 and until further notice and with agreement from the Vice-Rector Research, SU and the Vice-Dean, Research and Internationalization, Faculty of Medicine and Health Sciences (FMHS), SU

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1. BACKGROUND

1.1. The SA Government declared a move to lockdown level 1 and has promulgated guiding regulations with effect from 21 September 2020 https://www.gov.za/sites/default/files/gcis_document/202009/43727gon1011.pdf

1.2. Whilst infection rates in the Western Cape and other provinces appear to have flattened and or declined, it must be acknowledged that the pandemic remains unpredictable and thus researchers need to be mindful of such localized changes and to respond to such circumstances in a responsible and ethical manner.

1.3. The HREC therefore believes that researchers need to remain vigilant in the face of COVID-19, irrespective of the pandemic levels, inclusive of protecting participants and communities from risk and safeguarding themselves against the transmission of COVID-19.

1.4. The statements outlined in the HREC position statement dated 2020-03-20 and the HREC Communique 1 dated 2020-07-12 remain relevant and need to be considered together with this communique (HREC Position Statement.pdf).

1.5. HREC may revert to the above (1.4) if and when a negative trend in infection levels and/or change in lockdown levels is promulgated – either locally or nationally.

2. GUIDELINES FOR RESEARCH GOING FORWARD

2.1. HREC acknowledges the challenges faced by supervisors and postgraduate students needing to meet educational outcomes (for degree purposes) as well as researchers needing to meet deadlines set by sponsors. The importance of supporting the continuation and/or initiation of essential health and medical research studies to the benefit of communities, groups and individuals is acknowledged.

2.2. Aligned to the SA Governmental regulations related to level 1 (see hyperlink in 1.1) as well as the relevant Directions by the Ministers and in line with SU guidance related to remote working, researchers are advised to adopt or continue to utilize virtual or online methodologies as the preferred method of engagement, where feasible.

2.3 All face-to-face research studies will still be considered medium to high risk, depending on study design, methodology and data collection methods.

2.4 HREC wishes to point out the responsibility for managing and mitigating the risks to the multiple stakeholders involved in conducting face-to face or in-person research in the current circumstances:

2.4.1 Risks to research participants

- Becoming infected by a researcher or fellow research participant that might be asymptomatic/symptomatic during a research-related visit.
- Potential exposure to risk during travel to or from these sites for the purpose of participating in the research.
- Being infected due to handling objects contaminated by the virus at a study site.
- Potential for being more severely affected by COVID-19 if over the age of 60 and/or having a comorbidity or an illness causing an immunocompromised health status.
- Spreading the virus from the research site into the home or community.
- Being fined or arrested for not adhering to appropriate lockdown alert level restrictions e.g. not wearing masks, travelling without appropriate permits, etc. Please contact pennyvdb@sun.ac.za re enquiries around permits.

2.4.2 Risks to researchers

- Researcher/postgraduate student becoming infected by handling objects contaminated by the virus.
- More severely affected by COVID-19 if over the age of 60 and/or having a comorbidity or an illness causing an immuno-compromised health status.
- Researcher/postgraduate student becoming infected by entering/ conducting research in an area with a high incidence and/or probability of COVID-19 infections.
- Infecting co-researchers due to the aforementioned actions.
- Infecting own family members due to the aforementioned actions.
- Being fined or arrested for not adhering to appropriate lockdown alert level restrictions e.g. not wearing masks, travelling without appropriate permits, etc.

2.4.3 Reputational risks to researchers and/or the University

- Participants must be informed of the protocols put in place during their interactions with the researcher. Participants must receive a copy of these protocols for their reference before the research/data collection takes place.

2.5 Research at institutions and companies: The researcher must fully comply with the regulations, directions or guidelines when interacting with institutions or organizations, as various bodies, companies, schools and institutions may have their own Occupational Health and Safety regulations, directions, standards and guidelines related to COVID-19.

2.6 HREC supports a careful consideration of the safety of researchers and participants within the context of face-to-face research as follows:

2.6.1 Research activities in the time of the pandemic need to proceed in a considered manner with careful moral sensitivity to participant voluntariness and willingness, and engagement with the community[1].

[1] Some useful guidance: https://www.nuffieldbioethics.org/publications/research-in-global-health-emergencies/read-the-short-report; https://apps.who.int/iris/handle/10665/250580

2.6.2 When researchers request face-to-face clinical trials/ intervention studies to resume or to start for the first time, a clear case for being *essential research* in line with health priorities as well as the parameters set down by the prevailing lockdown conditions needs to be made. This request needs to unpack the critical need for the research to continue or to start, taking into account the legitimate ethical concerns that health care workers and other valuable resources such as PPE are, in the time of COVID-19, vulnerable and stretched and are required where it matters most.

2.6.3 Current and new research studies related to vulnerable communities, groups, and individuals, such as the aged and persons with underlying disease/co-morbidities or who are immuno-compromised need to be considered as high risk. Online or virtual data collection methods remain the preferred, and HREC will only consider a well-argued scientific and ethical rationale as well as well-described safety measures that will be in place to conduct such a study. Such a study will serve at a full HREC meeting.

2.7 *HREC will consider all face-to-face studies or amendments thereof by applying the following principles:*

2.7.1 The research participants and team members need to be protected from the risk of being exposed to COVID-19. All in-person research will be treated as medium to high risk and thus, requires a Risk Mitigation Plan describing clear pragmatic measures to protect participants and staff (both health care and research) to be included with submissions for ethics approval. Kindly refer to point 4 below.

2.7.2 SU research units to also comply with current university requirements for workplace preparation (Please consult the return to work protocol for further information) and institute the processes for approval of workplace readiness through SU's Institutional Committee for Business Continuity (ICBC), Workstream on Campus Operations.

2.7.3 The COVID-19 related implications of the studies that continue or start will be carefully monitored and reported on through standard HREC processes.

2.7.4 Where the same pool of potential participants is targeted for different studies (e.g. inpatients in ICU), a clear outline of collaboration and data sharing amongst researchers is preferred and researchers to provide evidence that such has been explored with fellow researchers and/or relevant gate keeper. This is important to avoid placing further stress on participants, the community, health care workers, or the health care environment.

2.7.5 The researcher or research teams are cognizant of bottlenecks that may occur at healthcare facilities with the move to Risk Alert level 1 and that studies may not place an increased burden on facilities and/or participants and/or health workers.

3 GUIDANCE FOR STUDY TYPES

3.1. CLINICAL TRIALS[2] AND OTHER FACE-TO-FACE/IN-PERSON INTERVENTION STUDIES

[2] Clinical trials are one form of an intervention study. An exhaustive list of intervention study possibilities is not possible, but examples only are agents, treatments, approaches, equipment, applications, programmes or policies.

3.1.1. All previously approved and new HIV and TB clinical trials and other essential face-to-face research studies to be allowed to resume provided that points 2.6.2 above and 4 below is clearly described in the amendment seeking resumption of study.

3.1.2. Previously approved phase 2 and 3 clinical trials and essential research intervention studies to be allowed to resume provided that point 4 as outlined below is clearly described in the amendment.

3.1.3. Previously approved COVID-19 clinical trials and essential research intervention studies to be allowed to continue accepting that provisions in point 4 are in place/were included and that such studies will be continuously monitored in line with current and future local, provincial, and national guidelines.

3.1.4. Previously approved phase 1 clinical trials (other than HIV and TB trials and other essential research studies) to be assessed by the PI and HREC for risk/benefit - inclusive of the points raised in point 4 below.

3.1.5. Previously approved face-to-face essential research intervention studies to be allowed to resume provided that points outlined in section 4 below are adhered to in the amendment.

3.1.6. Where face-to-face interviews or focus groups are the preferred methodology, researchers need to ensure that the requisite social distancing and infection mitigation protocols are in place such as adequately sized venues or holding groups in private outdoor spaces.

3.1.7. All new and as yet unapproved clinical trials and intervention studies (other than for COVID-19) to be reviewed on a case-by-case basis as part of the standard review process, including that all prevailing and emergent COVID-19 protection and risk mitigation guidelines are clearly outlined by the researcher to protect participants, researchers, and other parties – refer to point 4 below.

3.2. COVID-19 STUDIES

3.2.1. All new submissions of COVID-19 studies will continue to be considered for rapid review and be allowed to proceed as soon as all ethical, gatekeeper, and regulatory requirements have been satisfied, inclusive of any further protections that may be announced in future - refer to point 3 of HREC Position Statement (2020/3/20).

3.3. OBSERVATIONAL STUDIES

3.3.1. All previously approved observational (i.e. non-interventional or "non-therapeutic") studies that involve NO direct human contact with participants will be allowed to proceed - refer to point 5 of HREC Position Statement (2020/03/20).

3.3.2. All previously approved observational (or non-interventional) studies that involve direct human contact with participants to be assessed by the PI and HREC on a case-by-case basis, requiring that all prevailing and emergent COVID-19 protections, health and social distancing guidelines are rigorously applied by the researcher to protect participants, researchers, and other parties. Renewed gatekeeper permissions may be required if relevant.

3.3.3. All new and, as yet, unapproved observational studies (other than for COVID-19) be reviewed as a part of the standard review process. Such studies to also include all prevailing and emergent COVID-19 protection and social distancing guidelines

as to be rigorously applied by the researcher to protect participants, researchers, and other parties. Gatekeeper permission may be required, if relevant.

4 WHAT IS REQUIRED OF RESEARCHERS?

If your study has been previously approved for in-person/face to face research, and you/your research team wish/es to resume the study, you are required to:

4.1 Submit an amendment in which there is clear justification for the in-person activities associated with the study.

4.2 A clear risk-benefit analysis should be included in the amendment requesting resumption or commencement of research.

4.3 Evidence that the continuation or start of such a study is supported by the Western Cape Government and/or the health service in which it takes place is to be submitted after ethics clearance and before the initiation of the study. Such gatekeeper permission is considered as critical in the context of the Western Cape[3].

4.4 In the case of sponsored studies, PIs need to submit written confirmation from the sponsor that they support the study opening/reopening.

4.5 Upload a copy of your Risk Mitigation Plan that outlines the necessary steps for precautions and measures in place to prevent spread of COVID-19 for example, daily screening of research staff and participants, availability of PPE, cleaning of study premises and equipment, plan for isolating symptomatic staff or participants etc. This is to include workplace plan and walk through risk assessment as required by law before staff may return to work, protective equipment, mask etiquette, hand hygiene, cough etiquette, social distancing, plan for contact tracing, how researchers and participants who become COVID-19 positive will be managed, and so forth.

4.6 The "in the time of COVID-19" register – refer to 3.6 of HREC Position Statement (2020/03/20).

4.7 Budget to enable implementation of Risk Mitigation Plan (including costs of PPE, sanitizers, deep cleaning etc.).

4.8 In the case of approved studies to be undertaken in other countries the researcher needs to motivate face-to-face research with due consideration of the specific country's lockdown regulations and the most recent COVID-19 statistics for the research site/locality. Please take note of the latest SU statement on travel, should the research require traveling / field work.

5 CONCLUSION

5.1 The HREC will continue to maintain a dual system until further notice.:

i. Rapidly reviews COVID-19 studies and amendments to previously approved studies wishing to continue/start in the time of COVD-19.

[3] The role of gatekeepers (such as provincial hospitals, clinics, schools and other educational facilities, and non-governmental facilities) in advising researchers regarding the resumption, limiting or suspension remains invaluable as they possess information relevant to the specific context. Their guidance should be respected as access to a research site is not for the HREC to decide.

ii. Reviews non face-to-face/online and carefully planned face-to-face new studies to support researchers and to counteract a backlog from developing.

5.2 Principal Investigators (PIs) of multi-site COVID-19 applications may be advised to consider seeking reciprocity of ethics review from the primary national PI's REC of record.

5.3 The onus remains 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 either:

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Dr B Pretorius blanchep@sun.ac.za

HREC Chairs
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This document wishes to acknowledge the following documents and/or inputs:

1. Greeff, M. 2020. IMPLICATIONS OF ALERT LEVELS FOR RESEARCHERS AND POSTGRADUATE STUDENTS DURING THE COVID-19 PANDEMIC (VERSION 2). North-West University.
2. Nottingham University Hospitals. June 2020. RESEARCH RESTART.