POSITION STATEMENT OF THE HEALTH RESEARCH ETHICS COMMITTEES OF SU ON ETHICAL RESEARCH CONDUCT IN THE TIME OF THE COVID-19 OUTBREAK

Target group	All researchers/ investigators who are actively embarking on, engaged in research or required to do so (including undergraduate, postgraduate, postdoctoral students), supervisors/ promotors and research support staff
Publication date	2020/03/20
Document active	2020/03/20 till 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. A state of national disaster has been declared in South Africa following an increase in confirmed cases of COVID-19. President Cyril Ramaphosa has instated a strategy of social distancing among South African to reduce the transmission of the virus.

1.2. Stellenbosch University released a statement on 16 March 2020 with decisions on how the usual business of the university will operate. The Minister of Higher Education and Prof Wim De Villiers confirmed that research activities will continue, where possible.

1.3. The HREC therefore asks researchers and postgraduate students to remain calm but vigilant in the face of COVID-19, inclusive of protecting participants and communities and safeguarding themselves against the transmission of COVID-19.

1.4. The HREC of the Faculty of Medicine and Health Sciences, SU therefore wishes to affirm the following statements as outlined.

2. GUIDING PRINCIPLES

2.1. Of critical importance is the ability to protect the participant, the community, and the researcher(s) and research support staff from any harm while promoting health, preventing disease and/or discomfort, providing treatment and holistic and compassionate care.

2.2. The need to have a cautious but positive approach is important – the implementation of clear pragmatic measures to protect participants and staff should have first priority whilst not neglecting our ethical duty to provide care.

2.3. The mitigation of the risk - benefit ratio of a research study is non-negotiable, but more so in research taking place at the interface of research and clinical care provision, research that require face-to-face contact, and the collection of data in public spaces.

2.4. In the face of such risk, direct or face-to-face research interactions need to be reduced, postponed or suspended. Adjusted timelines may need to be negotiated with relevant stakeholders.

2.5. Where or when it is unavoidable to reduce, suspend or postpone research activities, protective measures such as hand hygiene, cough etiquette, and social distancing should be designed, implemented, and monitored at study sites.

2.6. The respect for the participant's rights should always be carefully considered, for example the right to decline participation or right to withdraw or collectively exploring alternative ways of participation.

2.7. The consideration of vulnerable groups such as the children, prisoners, pregnant women, intellectually impaired persons, or economically or educationally disadvantaged persons is of paramount importance. Current and new research findings related to vulnerable communities, groups, and individuals such as the aged and persons with underlying disease or immuno-compromised need to be continuously considered.

2.8. 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.

2.9. Research for degree purposes: SU and the relevant HREC will negotiate processes to mitigate the possible negative fallout to student progress (both new research and research that is in progress).

2.10. The COVID-19 outbreak and its ramifications are difficult to measure or predict, but the suggested time frame for this position statement to be enacted is not less than four weeks from date of publication.

2.11. Staff, researchers and supervisors are requested to carefully monitor any further news, directives and guidance on this matter - please visit the Health Research Ethics website regularly.

3. RESEARCH RELATED TO THE HEALTH CARE EMERGENCY ITSELF

Research that relates to the national disaster itself is considered to be emergency research and adheres to the ethical research principles and practices of such research.

3.1. Careful consideration of and, where indicated, preferential consideration for research that relates to the global and national emergency and COVID-19 will be enacted by HREC.

3.2. HREC accepts that the full palette of research foci and methodologies (for example biomedical, clinical, intervention, epidemiological, health systems, human interactional, socio-psychological) will come into play in emergency research during and after the COVID-19 outbreak.

3.3. Community engagement, informed consent, and other ethical considerations need to be carefully formulated, negotiated, applied and monitored.

3.4. The Health Research Ethics Office will be available for guidance/consultation, and also provide meaningful international and where possible local literature, on emergency research ethics.

3.5. The health research ethics review of such proposed studies may often require full committee review, but the Committee will endeavour to expedite/hasten such a review process if deemed necessary.

3.6. Researchers who conduct such studies need to develop an '*in the time of COVID-19*' template register in case retrospective contact becomes necessary. This register will contain personal, identifiable information which must be handled, stored and secured with due diligence and strict adherence to privacy laws.

3.7. This submission to also include the template for the "*in the time of COVID-19*" register.

4. ONGOING RESEARCH STUDIES THAT MAY CONTINUE WITH HREC NOTIFICATION AND APPROVAL

HREC accepts that a number of research studies need to continue due to the value of such for participants, continued treatment, the meeting of pre-determined data points, and so forth. However, these studies are considered to have an inherent risk in the COVID-19 outbreak context.

4.1. The studies that may come into play are for example clinical trials, intervention studies, non-therapeutic longitudinal studies, retrospective studies, and community-based studies (for example at clinics, public centres, and participant dwellings).

4.2. If a researcher is not able to pause such a study, and wishes to continue, an amendment must be submitted to HREC outlining the intent and stipulating the precautions that will be in place and adhered to, as well as the monitoring of such application of precautions. Examples are minimizing participant encounters, waiting time and duration interaction, providing hand sanitizers or soap and water, protective clothing, active social distancing and so forth.

4.3. This submission should also include the template for the "*in the time of COVID-19*" register (see #3.6 above). This register will contain personal, identifiable information which must be handled, stored, and secured with due diligence and strict adherence to privacy laws.

4.4. Administrative systems to be put in place to prioritize participant communication and data collection queries

4.5. Such an amendment will be considered by HREC on a rolling basis, and where necessary, referred to the full committee for deliberation and decision-making.

5. ONGOING RESEARCH STUDIES THAT MAY CONTINUE WITHOUT HREC NOTIFICATION

The HREC accepts that a number of studies conducted at the FMHS are not engaging participants face-to-face and thus limits or does not pose the risk of COVID-19 infection. Guidelines for such studies are as follows:

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

5.2. Further, data science research, some forms of educational research (innovative teaching and learning strategies that does not require face-to-face interaction), and laboratory-based research (except research related to COVID-19) may continue.

5.3. The onus remains on the researcher/s to ensure safety and protective measures at all times, and to continue to minimise risk.

5.4. If uncertain, please contact the Health Research Ethics Office for guidance.

6. NEW RESEARCH STUDIES

In the interest of participants and researchers, the general consensus is that new face-to-face or studies with an inherent risk to participants and/or researchers should not be embarked upon for the duration of this moratorium.

6.1. HREC wishes to state that although this sounds like a blanket statement, we would be willing to consider well-motivated submissions as exceptions only.
6.2. The researcher needs to provide an accompanying letter with a detailed rationale for why this study needs to enacted in this time.
6.3. The HREC will continue to accept and review submissions according to own capacity, but will clearly indicate where the HREC does NOT wish this study to commence with immediate effect but only at a time as published on the HREC website, provided the researcher/s has outlined the necessary precautions that will be put in place.

7. ACTIVE CONTRACTUAL AGREEMENTS RELATING TO RESEARCH FUNDING AND EMPLOYMENT OF RESEARCH STAFF

7.1. Researchers who are dependent on internal, and more so external, sources of funding and sponsorship should consider the potential risks that COVID-19 and social distancing strategies will have on project milestones and audit reporting deadlines. Where possible, researchers should engage with the funder/sponsor regarding these timeframes.
7.2. Researchers who have concerns regarding their legal or contractual agreements with research assistants and fieldworkers may need to consult with SU Legal Services or the Research Legal Advisor on what clauses are in place or apply during circumstances that prevent normal research processes from taking place and that would prevent them from complying with such agreements and contracts.

8. THE WAY FORWARD – KEY DIRECTIONS

HREC needs to put measures in place to manage research reviews and amendments during this time. It has already looked at emergency meeting arrangements and related matters and will continue to seek meaningful ways to support health care researchers.

Regarding the suspension or continuation of research studies, the following provides a summary:

8.1. Researchers to focus on follow-up research activities rather than recruitment of new participants.
8.2. Researchers who choose to suspend their research must notify the HREC so that research approval periods can be suspended until reactivation is advised by the researcher.
8.3. Research that involves face-to-face interaction will NOT be just allowed to commence or to continue. Researchers who deem it necessary to continue (not to suspend) interactive/face-to-face research activities, need to submit an amendment to the relevant

HREC to confirm that research activities will proceed and what measures will be put in place to limit potential transmission and exposure. The researcher is also referred to the '*in the time of COVID-19*' template register mentioned above.

8.4. Researchers who decide to amend their research activities (for example only continuing with certain aspects of the study or collect data in a different way) must submit an amendment to HREC as soon as possible.

9. Important contact details

- The National Institute for Communicable Diseases (NICD) hotline: 0800 029 999 (number operational Monday to Friday from 08:00 until 16:00).
- Campus Health Services: Stellenbosch Campus 021 808 3496/3494; Tygerberg Campus 021 938 9590
- Campus Health Services after hours emergency number: 076 431 0305
- Health Research Ethics Office 021 938 9677

This document acknowledges the use of the following documents

Blockman, M. 2020. COVID-19: Faculty of Health Sciences Human Research Ethics Committee Recommendations for research studies and research sites involving humans. UCT Circular to staff, 17th March 2020.

Hansen, L. 2020. Draft memorandum: REC statement on research activities during the COVID-19 Outbreak. SU REC: SBER, 17th of March 2020.

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