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HEALTH RESEARCH ETHICS COMMUNIQUE 1: RESEARCH GUIDANCE 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 and postgraduate students and postdoctoral fellows), supervisors/ promotors and research support staff

Purpose

To provide guidance on the continuation of health and medical research in the context of lockdown level 3 in the Western Cape

Publication date 2020/06/12

Document active 2020/06/12 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

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 SA Government declared a move to lockdown level 3. There is a mention of hotspots but guiding regulations and preferred practices are not yet clear.

1.2. The Western Cape, and particularly the Cape Town Metro, Tygerberg Hospital and surrounds currently have the highest number of confirmed COVID-19 cases and the highest death rate. Testing is well managed, but currently is impacted by a lack of necessary equipment to do or expand such.

1.3. The health care services are under tremendous strain, and according to media reports, a high number of health care workers have become infected. The availability of sufficient PPE seems to be a constant and serious concern.

1.4. 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.

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

1.6. However, it is important to reflect on the importance and necessity of essential research and ways to directly and indirectly support participants, researchers and very importantly, the health care services and health care workers under strain.

2. GUIDELINES FOR GOING FORWARD

2.1. HREC recognizes the potential and real harm that the discontinuation of essential research studies may hold in the wider health care context and for researchers needing to meet educational outcomes, for example for degree purposes.

2.2. The letter from the Deputy Director-General (DDG) of the Department of Health dated 13/05/2020 supports the continuation of critical research related to HIV and TB – see Annexure A. This communique from the DDG needs to be reflected on in the wider context of health care to include the full range of essential studies.

2.3. HREC thus supports a careful consideration of the safety of researchers and participants within the context of a severely stressed community, health care environment and health care workforce as follows:

2.3.1. 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 concern 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.

2.3.2. Current and new research findings related to vulnerable communities, groups, and individuals such as the aged and persons with underlying disease or who are immuno-compromised need to be considered.

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

2.4.1. The research participants and team members not to be placed at risk of being exposed to COVID-19. An implementation plan describing clear pragmatic measures to protect participants and staff (both health care and research) to be included. This is to include protective equipment, hand hygiene, cough etiquette, social distancing and so forth.

2.4.2. SU research units to also comply with current university requirements for workplace preparation and institute the processes for approval of workplace readiness through SU's Institutional Committee for Business Continuity (ICBC). This process may run parallel to HREC review and approval.

2.4.3. The "in the time of COVID-19" register is a requirement for documentation, follow-up and tracing – refer to 3.6 of HREC Position Statement (2019/03/20).

2.4.4. 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 ethical clearance and before the initiation of the study. Such gatekeeper permission is considered as critical in the context of the Western Cape[1].

2.4.5. A budget to cover the cost of appropriate PPE is submitted that will enable researchers and participants to access such equipment. Additionally, such equipment cannot be the responsibility and to the cost of the health care provider.

2.4.6. An outline is provided of how researchers and participants who become COVID-19 positive will be managed if becoming COVID-19 positive.

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

2.4.8. A clear outline of collaboration and data sharing amongst researchers is provided. This is important to not further stress participants, the community, health care workers, the health care environment.

2.4.9. The researcher or research teams are cognizant of bottlenecks that may occur at healthcare facilities with the move to level 3 lockdown and that studies may not place an increased burden on facilities that are engaged in fighting the COVID-19 pandemic.

[1] Critical gatekeepers (such as provincial hospitals and clinics) may wish to limit or suspend research activities in their facilities/ units for risk-related and resource constraint reasons. This is not for the HREC to decide.

3 GUIDANCE FOR STUDY TYPES

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

3.1.1. All previously approved *HIV and TB clinical trials* to be allowed to resume provided that points 2.3 to 2.4 are outlined in the amendment.

3.1.2. Previously approved *phase 2 and 3 clinical trials* to be allowed to resume provided that points 2.3 to 2.4 are adhered to in the amendment.

3.1.3. Previously approved *COVID-19 clinical trials* to be allowed to continue accepting that 2.3 to 2.4 is in place/ was 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) to be assessed by the PI and HREC for risk/benefit - inclusive of the points raised in 2.3 to 2.4.

3.1.5. Previously approved face-to-face intervention studies to be allowed to resume provided that points 2.3 to 2.4 are adhered to in the amendment.

3.1.6. 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 social distancing guidelines are clearly outlined by the researcher to protect participants, researchers, and other parties – refer to 2.3 to 2.4 above.

3.2. COVID-19 STUDIES

3.2.1. All new submissions of COVID-19 clinical trials, intervention and observational 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 such protections that may be announced in future - refer to point 3 of HREC Position Statement (2019/03/20).

3.2.2. 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.

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 (2019/03/20).

3.3.2. All previously approved observational (or non-interventional) studies that involve direct human contact with participants be assessed by the PI and HREC on a case-by-case basis, requiring that all prevailing and emergent COVID-19 protections 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. CONCLUSION

4.1. Currently, HREC maintains a dual system that will continue until further notice. HREC:

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

i. Rapidly reviews COVID-19 studies and amendments to current studies wishing to continue/ start in the time of COVD-19.
ii. Reviews non face-to-face/ online studies and new studies to support researchers and to counteract the development of a backlog.

4.2. The above system however places significant strain on HREC reviewers. We invite previous HREC members and/or academic staff with an expressed willingness to be part of HREC work to make contact with Prof. B Pretorius (email below) as a matter of urgency.

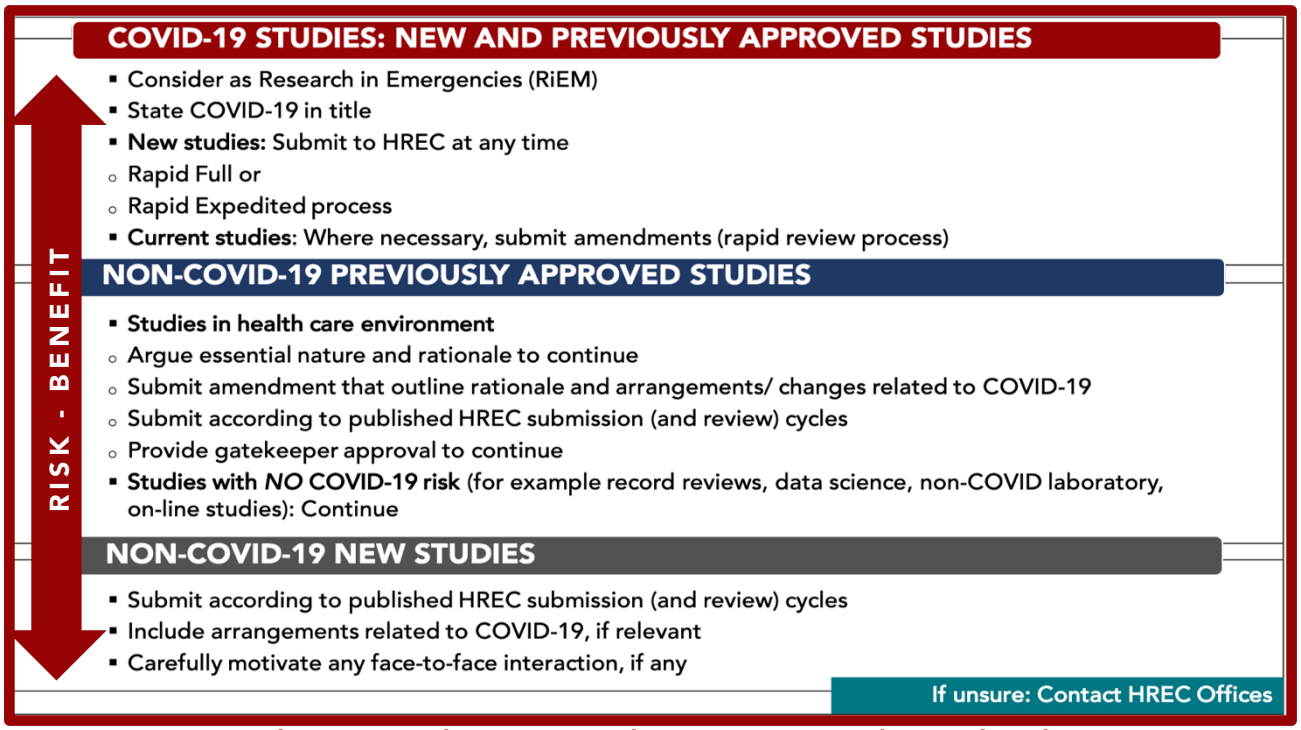
4.3. This guidance will be revised from time-to-time as National Lockdown Regulations and other relevant factors may change – please visit the HREC webpage for updated information.

4.4. 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 either:

Head, HREO:
Prof. B Pretorius blanchep@sun.ac.za
HREO Technical support
Elvira Rohland elr@sun.ac.za
Ashleen Fortuin afortuin@sun.ac.za
HREC Chairs
HREC 1: Dr P Fernandez pf3@sun.ac.za
HREC 2: Prof AS van der Merwe asvdmerwe@sun.ac.za
UREC: Prof R Blaauw rb@sun.ac.za

4.5. This document kindly acknowledges the following draft documents and/or inputs

i. Prof. D Wassenaar (UKZN BREC),2020/05/28 "Proposed UKZN BREC revision to research constraints anticipating change to Level 3 lockdown (draft)".
ii. Prof. A Dhai (UKZN, Steve Biko Centre for Bioethics) - e-mail communication to author 31/05/2020.



Summary diagram – to be interpreted in conjunction with 2. and 3. above.

ANNEXURE A: HIV and TB research: Letter from the Deputy Director-General (DDG), Department of Health

13/05/2020

health

Department:
Health
REPUBLIC OF SOUTH AFRICA

Private Bag X828, PRETORIA, 0001. 27th Floor, Room 2710, Civitas, Cnr Thabo Sehume & Struben Street, PRETORIA, 0001
Tel: +27 (0) 12 395 8000, Fax: +27 (0) 12 395 8422

Enquiries : Dr Y Pillay
Telephone : 012-395-8078

Professor Linda-Gail Bekker
The Desmond Tutu HIV Centre
University of Cape Town
CAPE TOWN
8000

Dear Prof Bekker

RE: HIV AND TUBERCULOSIS CLINICAL RESEARCH REMAINS A CRITICAL PRIORITY IN SOUTH AFRICA IN THE ERA OF THE COVID-19 PANDEMIC: A POSITION STATEMENT

Thank you for the position statement and letter recently forwarded by yourself on behalf of researchers in South Africa to the National Minister and Department of Health regarding HIV and tuberculosis research in South Africa dated April 2020.

We have reviewed this and agree that provided sufficient infection control measures are in place, and in collaboration and consultation with appropriate ethical review boards, clinical and programmatic research of HIV and TB treatment and prevention modalities should be considered essential healthcare interventions and should be allowed to continue urgently.

This should be carefully monitored and reviewed regularly by the institutions that are mandated to provide ethical review for these activities.

Yours sincerely

DR. YOGAN PILLAY
DEPUTY DIRECTOR-GENERAL: COMMUNICABLE AND NON-COMMUNICABLE DISEASES
DATE: 13/5/2020

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