

UNIVERSITY OF CAPE TOWN (UCT) FACULTY OF HEALTH SCIENCES (FHS): SUMMARY OF APPROACH TO RESEARCH IN TIME OF COVID-19 OUTBREAK

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Introduction

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The 2019-20 coronavirus outbreak was recognised as a pandemic on 11 March 2020. To reduce transmission, South Africa declared a national lockdown that commenced at midnight on 26 March 2020, which restricts interaction – people are instructed to stay at home other than for specified essential activities.

The below outlines the UCT FHS approach to research in the context of the COVID-19 outbreak, and in the context of lockdown (or potentially partial lockdown) periods. The approach is subject to change as the national and international situation evolves.

Research in general

For more detailed information, see:

- '[Research and postgraduate work during lockdown](#)', UCT Deputy Vice-Chancellor for Research and Internationalisation, 1 April 2020
- '[COVID-19 update: research activities](#)', UCT Deputy Vice-Chancellor for Research and Internationalisation, 18 March 2020
- '[Update on COVID-19 for research community](#)', FHS Deputy Dean for Research, 17 March 2020

Summary points:

- In line with the national lockdown to stop the spread of COVID-19, the University has put on hold all research being done on campus or at other field sites or facilities (*i.e.* outside of one's home) except where deemed essential (see below).
- Researchers, including research staff, postgraduate students and postdoctoral fellows should continue with their research remotely where possible.
 - Postgraduate researchers could work on research reviews and papers, analyse data, and write up parts of their theses. Supervisors should work closely with their postgraduates using remote tools to provide support.

- Similarly, postdoctoral fellows could work on reviews, papers and data analysis, as well as applying for grants and assisting postgraduates they co-supervise.
- Research groups should ensure, where possible, that those involved in projects have access to information they need to carry out work remotely (e.g., literature, computational resources and files, existing datasets).
- Disruption to essential facilities and services in the FHS may have a direct impact on patients' diagnoses and care, animal welfare, health and safety, and certain laboratory-based scientific and clinical research (see below). These facilities and services require appropriate staffing to allow for continuity of activity, with specific arrangements defined by the leadership of these facilities/ services.
 - They include: Biosafety Level 2 and Biosafety Level 3 Labs; Management of -80°C freezers and cryofacilities; Liquid nitrogen services; Management of biohazardous waste; Testing and fuelling of generators; Maintenance of CO₂ supply; Radioactive facilities; Research animal facilities; Reagents requiring specialised storage facilities; Facilities/ services supporting long-term and critical studies; Mortuary
- Certain laboratory-based scientific and clinical research may be assessed as 'essential' and as needing to take place on campus or other facilities (such as clinics), *i.e.* outside of one's home:
 - Essential research should align with the need for benefit to outweigh risk, as assessed through appropriate regulatory processes and in alignment with the prevailing national & international context (e.g., lockdown regulations). Further details as relevant to the nature of the research are provided below.
 - During assessment, serious practical implications of the research must be considered (for impact on the research itself and potentially on the health service), such as sustained availability of personal protective equipment (PPE), access to supplies, and potential limitations on research support services.

Research involving human participants

For more detailed information, see:

- ['Update on COVID-19 for research community'](#), FHS Deputy Dean for Research, 17 March 2020
- ['COVID-19: Faculty of Health Sciences Human Research Ethics Committee recommendations for research studies and research sites involving humans'](#), Chairperson FHS Human Research Ethics Committee, 17 March 2020

Summary points:

- All research activities where people are brought together for research purposes, where research participants and research staff and students are placed at risk by virtue of the nature of data collection, or where specimen collection poses transmission risk, should be urgently reviewed to determine the risk for COVID-19 transmission.
- Existing clinical and population-based research studies should proceed if the benefit to study participants outweighs the risks of participation, and particularly the risk of contracting the SARS-CoV-2 virus through participation.
- The risks and benefits associated with research participation should be reassessed regularly by Principal Investigators (PIs) as these are likely to change over time as the COVID-19 epidemic evolves. PIs should liaise with the Faculty's Human Research Ethics Committee (HREC) about participant risks and benefits.
- Each research study or study site should therefore de-escalate or suspend research activities.
- All non-therapeutic research involving human participants should be stopped. Exceptional reasons for research to continue can be discussed with the HREC.
- For therapeutic research and clinical research trials:

- Where possible, studies should be placed on hold and research activities suspended.
- Where possible, telephonic or video-conferenced visits or follow-up should occur.
- PIs and study sites should implement measures to ensure there is no interruption of required medication or monitoring of adverse events.
- Only critical study visits where benefits significantly outweigh the potential harm of COVID-19 infection should take place going forward. Study visits for critical medication or monitoring purposes should continue in consultation with the HREC.
- New enrolments to studies should be suspended. Potential exceptions to this recommendation can be discussed with the HREC.
- For studies that continue to have participant contact, efforts should be made to reduce transmission risk for both participants and research staff.
 - Study team-participant interaction should be restricted only to essential staff.
 - Recommendations regarding hand hygiene, cough etiquette and social distancing should be implemented immediately at study sites.
 - Studies must develop an SOP outlining their procedures for reducing transmission risk.
- Researchers and study sites should develop a ‘in the time of COVID-19’ template register in case retrospective contact tracing becomes necessary.
- Should any research staff, students or participants develop signs or symptoms suggestive of COVID-19, they should call the National Coronavirus Hotline (0800 029 999), the Provincial Hotline (021 928 4102), or WhatsApp ‘Hi’ to 060 012 3456.

Research involving animals

For more detailed information, see:

- [‘Faculty of Health Sciences Animal Ethics Committee in response to COVID-19 and subsequent lockdown period’](#), Chairperson FHS Animal Research Ethics Committee, 26 March 2020

Summary points:

- Researchers and students involved in animal research should work with the FHS Animal Research Ethics Committee (AREC) and Core Research Animal Facility (RAF) to suspend non-essential animal research or ensure essential animal research is able to continue appropriately.
- Researchers should:
 - Give serious consideration to terminate active studies (this was by close of business on 26 March), to enable samples and data from the studies to be salvaged before the lockdown period;
 - Reduce animal numbers as far as possible by only breeding the minimal number of animals that are required in order to keep the various genetic strains of animals alive;
 - Keep the AREC updated by submission of amendments.
- Given potential suspension or delays of animal research, the AREC will consider extensions favourably.

Research involving laboratories

For more detailed information, see:

- [‘Update on COVID-19 for research community’](#), FHS Deputy Dean for Research, 17 March 2020

Summary points:

- Heads of physical laboratories and research facilities should take steps to ensure continuity of critical functions, and to enable staff to perform essential tasks while practising physical distancing and social solidarity.

- Departments, groups and facilities should:
 - Identify procedures and processes that require regular attention from staff (e.g., cell culture maintenance, animal studies).
 - Ensure emergency contact information for critical staff is available.
 - Coordinate with colleagues who have similar research activities to identify ways to ensure coverage of critical activities.
 - Prioritise the most critical research activities, and those that can only be carried out in specific facilities, consulting with relevant staff and students.
 - Recognise lack of availability of a full research support staff complement on site, consider the possible impact of this on research activities, and ensure these activities are left in a safe state daily.
 - Perform experiments in a way that minimises accumulation of biological, chemical or physical hazards given potentially prolonged absence of support staff. Further, experiments should take into account the possibility of failure of air supply, cooling, power, water supply, vacuum or other connection etc.
 - Maintain physically hazardous equipment (cryogenic, heated, pressurised, under vacuum, etc.) in a safe state.

COVID-19-specific research

For more detailed information, see:

- [‘Research and postgraduate work during lockdown’](#), UCT Deputy Vice-Chancellor for Research and Internationalisation, 1 April 2020
- [‘Biosafety Guidelines for Research on Covid-19 and Sars-Cov-2’](#), FHS Faculty Biosafety Committee, 5 April 2020

Summary points:

- Research on COVID-19 and its aetiologic agent, SARS-CoV-2, is deemed ‘essential’ at UCT. However, COVID-19-focused studies should align with the need for benefit to outweigh risk, as assessed through appropriate regulatory processes and in alignment with the prevailing national & international context (e.g., lockdown regulations).
- The FHS HREC, AREC and Faculty Biosafety Committee (FBC) will assess studies through their normal processes (following online submissions), and in the context of lockdown or partial lockdown, and will conduct rapid reviews where appropriate and possible.
 - To assist these committees in their assessment, researchers should also describe why their proposed research is important during the outbreak period and any mitigating steps they will take to reduce risks to the study or introduced by the study.
 - This could include information on, where applicable: benefit of research on the current COVID-19 outbreak with clear timeline of proposed work, reason for the work to be done at UCT, how the research will address minimisation of COVID-19 transmission, potential impact of the research on clinical service delivery and care, resource implications (including availability of PPE and screening/testing for COVID-19), access to supplies, limitations in research support services, overlap/ harmonisation with other COVID-19 research initiatives, and whether they anticipate needing any additional support from UCT during lockdown or partial lockdown.
- Human research ethics approval and informed consent are required in disaster/ pandemic research involving human participants, samples or data (refer to [South African Good Clinical Practice guidelines 2nd edition](#), Department of Health, 2006).
 - The HREC has arranged a rapid review process, while making sure that participant safety is not compromised. PIs are encouraged to discuss their proposed ideas with the HREC before formal submission.

- Information on HREC approved studies will be coordinated to support issues of safety, risk, equity and access to data and biological specimens.
- The Health & Safety (H&S) and Biosafety risks of COVID-19 research are significant and carry important practical considerations for research design, and subsequent laboratory management and maintenance.
 - To ensure best practice the FHS has, through consultation and shared reference material, developed guidelines for working with infectious materials from COVID-19 patients, which can be viewed in the FHS [Biosafety Guidelines for Research on Covid-19 and Sars-Cov-2](#).
 - Detailed SOPs must be prepared for handling all SARS-CoV2-infected material and must be submitted for formal H&S risk assessment. To expedite review, applications for FBC approval should be submitted simultaneously for H&S and FBC approval. Thereafter, FBC-reviewed proposals will be submitted automatically to UCT's Institutional Biosafety Committee (IBC) for assessment.
 - No work should be initiated without IBC approval.
 - The PPE requirements of SARS-CoV-2/ COVID-19 work must be carefully considered. BSL-2 and BSL-3 laboratories carry limited stocks of PPE. This, coupled with the prevailing uncertainty about the future availability of replacement stocks, means the long-term sustainability of any research work might be precarious. For this reason:
 - The risk/ benefit analysis of any proposal should include an assessment of the impact of PPE-intensive research activities on the local availability of these items;
 - All FBC applications will be required to include a clear statement regarding the ability to maintain adequate PPE for the work proposed.

Funding

Ongoing funding

- UCT's Research Contracts & Innovation Office (RC&I) is compiling information on major funders' approaches to the research they fund in the time of COVID-19. This information can be found in the document '[Covid-19 Impact on Research Activities: Funders Responses and Requirements](#)'.
- Universities South Africa (USAf) is engaging with national funding bodies at a sectoral level regarding project deadlines and research funding.

New proposals

- Research proposals (and, where applicable, research contracts) will continue to be reviewed prior to submission through the FHS standard internal approval process.
- COVID-19-specific research funding calls are being released by a range of funders, as well as opportunities to supplement current grants with COVID-19 work. These will be reviewed through UCT's standard internal approval systems; however, at internal approval stage in the FHS, researchers will be alerted to the potential for resource risks (such as availability of PPE) and asked to acknowledge that they have considered these, and that they understand that were the study to be funded they might have to adequately address these concerns with the relevant committee (HREC, AREC, Biosafety) for the study to be approved. The detailed assessment of these risks will be conducted at committee review, however highlighting any risks at proposal approval stage is expected to help raise awareness.

External regulatory aspects

Provincial Health Research Committee: approval for research on the health service platform

- Standard applications through the National Health Research Database will not be processed during the lockdown period.

- For researchers intending to do COVID-19-specific research in community settings or on the district platform, this can be expedited by emailing all documentation (post ethics approval) to Virginia Zweigenthal (virginia.zweigenthal@uct.ac.za) and Melvin Moodley (Melvin.Moodley@westerncape.gov.za), who will facilitate approval.
- For proposed research at Groote Schuur Hospital, Tygerberg Hospital and Red Cross War Memorial Children's Hospital, researchers should approach these facilities regarding proposed submissions through their usual route.

South African Health Products Regulatory Authority (SAHPRA)

- During the national lockdown, SAHPRA will work remotely with a limited number of employees (see www.sahpra.org.za/be-prepared-for-covid-19/).
- If UCT researchers experience challenges in negotiating SAHPRA approval for their studies, they can contact the Chair of the FHS HREC, Mark Blockman (marc.blockman@uct.ac.za), for assistance.

Department of Environment, Forestry and Fisheries (DEFF)

- DEFF are operational during the national lockdown, but may only deal with cases motivated as urgent.
- All applications or communications to DEFF and the South African Veterinary Council (SAVC) should go through UCT's Office of Research Integrity (ORI) and not directly with these Departments.

Insurance

- For COVID-19 specific research, were these studies to need UCT no-fault insurance cover (they may be covered separately by sponsor's insurance) then researchers would be expected to follow the usual route in declaring them via UCT to the brokers, who will engage the underwriters/insurers to determine cover.

Research administration

- FHS research administration offices are operational and have contingency plans in place to maintain continuity of services wherever possible while personnel are working remotely. The Faculty Research Office, Faculty Research Ethics Office and Faculty Research Finance services will continue to work with UCT's central research administration offices to support ongoing operations.
- UCT Libraries are physically closed, but are open for virtual support for research (see www.lib.uct.ac.za/lib/virtual-support).