



Faculty of Health Sciences: Ethics Office for Research, Training and Support
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COMMUNIQUE: NO 5

RESEARCH DURING THE DIFFERENT LOCKDOWN ALERT LEVELS

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Dear Researchers, staff and students

We hope that this mail finds you and your families safe and healthy. This is the **fifth** in a series of communiques that have been sent to you by the Faculty of Health Sciences Ethics Office (see attached the previous four communiques for your convenience i.e. FoHS_Ethics Office_COVID 19_Communique 1-4). The COVID-19 pandemic and the government's response to it by declaring a **state of emergency** and following an **Alert Level** lockdown approach, has had a huge impact on how we may conduct research. We have seen this in the amendment requests that we have received since the lockdown was implemented.

We have also noted a great deal of confusion amongst researchers about whether they can proceed with their research or not. As we realize that the COVID-19 pandemic will still be with us for a considerable amount of time, we would like to provide greater clarity on this issue, and as such we are sharing the attached document, entitled "**Final Alert Levels and Research**" as setup by Prof Minrie Greeff (Emeritus Professor) regarding the realities of what research *can and cannot* be undertaken, during the different lockdown restriction alert levels. It should be noted that the type of research that can be undertaken during each restriction alert level, is guided by the type of activities that are allowed under that specific restriction alert level. These recommendations (which have also been distributed nationally amongst other ethics committees and researchers) are provided in order to reduce the impact of the risks as indicated under section 2 in the attached document.

As it currently stands, research that requires **physical human participant interaction** in close proximity e.g. *face-to-face qualitative or quantitative interviews, focus groups, human sample collection, etc.* (except clinical research as part of patient care or treatment and vaccine trial research or laboratory work linked to COVID-19 research), *cannot be undertaken* until, at least **Level 2**, and then only in an extremely limited capacity, as per Lockdown restrictions and special permission or guidelines by the university. This also pertains to research being undertaken in **homes, communities, restricted government facilities, schools and facilities for the aged, as well as bringing participants to the university**. Research that can be undertaken via **email, telephone or an online platform** can, however, proceed as well as **electronic surveys**. Furthermore, please note the conditions indicated for **laboratory work** under the various alert levels and the accompanying restrictions. *Numerous*

precautionary measures will have to be implemented (as indicated under *sections 3 and 4* in the attached document), before you will be allowed to proceed with your research.

Important note: It is the responsibility of each researcher to be aware of the alert level we find ourselves in as a country and to adhere to all regulations and guidelines of the specified alert level. Should an alert level revert back to a higher alert level, the researcher should adjust to the indicated implications discussed in the attached table.

Based on the aforementioned implications, we understand that you may want to make certain *proactive changes* to your research studies, which will be urgent and will require a *quick response from the Scientific Committees and the Ethics Committees*. To ensure this process runs smoothly and a quick response is possible, we would again like to bring the **existing process for the amendment of approved research studies (2.2.4_SOP_Ethics_1.4)**, as well as additional processes to follow to ensure an expedited process under your attention and also offer our support to those researchers wanting to undertake such processes, in order to ensure the continuation of your research during this time or immediate continuation as soon as the Lockdown level allows it.

When wanting to amend an approved research study impacted by the COVID-19 pandemic, the existing SOP (2.2.4_SOP_Ethics_1.4) for this process still remains in place. The process to be followed is clearly discussed under **Section 8.4** of this SOP entitled, “*Application for an amendment to an approved study*”. The process as described in this SOP is handled via the **expedited process**. This SOP is freely available on our website at the following URL i.e. <http://healthsciences.nwu.ac.za/healthethics/sops> but is also attached to this notification for your convenience.

The process that should be followed, is as indicated below:

- a. Ensure all your amendments are indicated in yellow highlight in the amended documents.
- b. Submit your request to either Ethics-HRECAApply@nwu.ac.za or Ethics-AnimCare@nwu.ac.za, with a cover letter with a specific subject title indicating, “Amendment request (COVID-19): NWU-XXXXX-XX-XX”. The letter should include the title of the approved study, the names of the researchers involved, the nature of the amendment/s being made (indicating what changes have been made as well as where they have been made), which documents have been attached and any further explanation to clarify the amendment request being submitted.
- c. Name the emails, to which you attach the documents that you send, with a specific subject line indicating that it is an amendment request e.g. “Amendment request (COVID-19): NWU-XXXXX-XX-XX”. This e-mail should indicate the nature of the amendment.

Any 1) amendments, 2) request for extensions or 3) any other kind of modification to the proposal or other associated documentation must be submitted for review by the appropriate NHREC-registered ethics committee within the Faculty of Health Sciences, and must be approved, prior to these changes being implemented. This means that we cannot approve amendments retrospectively i.e. after they have been implemented in the study.

Additional actions required by you for proactive amendments:

If you are planning to amend your research study, during this time, please contact the Head of the Ethics Office, Prof Wayne Towers at [072 149 2960](tel:0721492960) or wayne.towers@nwu.ac.za and the Chairperson, Prof Petra Bester at [082 298 3567](tel:0822983567) or petra.bester@nwu.ac.za (for research involving human participants) or Prof Tiaan Brink at [082 920 9698](tel:0829209698) or tiaan.brink@nwu.ac.za (for research involving animals), at least before you **plan to submit the application for review**, so that we can timeously appoint appropriate reviewers and proactively manage the process of the review of your amendment.

Please inform us at your earliest convenience should you have any queries. We wish you all great strength and peace in the weeks and months to come.

Issued by: The Head of the Ethics Office, Chairpersons of NWU-HREC and NWU-AnimCareREC and research ethics advisor