



Faculty of Health Sciences: Ethics Office for Research, Training and Support
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COMMUNIQUE: NO 7

COVID-19 RESEARCH RISK ASSESSMENT AND MANAGEMENT

2 July 2020

Dear Researchers, staff and students

We hope that this mail finds you and your families safe and healthy. The Ethics Office presents the following communique in response to recent discussions that have been had during the most recent NWU-HREC and NWU-AnimCareREC meetings. During these discussions it was determined that most applications that are reviewed at present by these research ethics committees (RECs), do not make provision for the **risk** inherent in a research study due to the **COVID-19 pandemic**, and how this risk will be **mitigated**, even though COVID-19 will be with us for the next two to three years. Researchers thus place *themselves*, their *participants* and the *university* at great risk if they do not have a clear indication of how they plan to mitigate these risks inherent within their research. As such, the following document, entitled “**COVID-19 research risk assessment and management approach**” was set up by Prof Minrie Greeff to assist researchers in assessing and managing risks associated with COVID-19 when doing research. This document provides an excellent guide to:

- a. Researchers and postgraduate students that are in the *planning phase* of their research study and are preparing it for submission to one of the RECs.
- b. Researchers and postgraduate students that have *submitted an application* to one of the RECs and are currently in the process of handling *rebuttals*, pertaining to the feedback from the REC.
- c. Researchers and postgraduate students that have *obtained approval* for their studies but are amending the methodology of their studies, giving them the opportunity to continue during the COVID-19 pandemic.
- d. Researchers and postgraduate student that have *obtained approval* of their studies but have to *amend their risk mitigation strategy* to include the risks related to COVID-19, before they can resume their research.
- e. Researchers and postgraduate students whose studies were *put on hold* due to the alert level and now have to *obtain permission to resume* their research and *amend their studies* to include COVID-19 related aspects.

When wanting to amend the COVID-19 research risk assessment and management of an approved research study to accommodate the risks associated with 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://health-sciences.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-HRECAppl@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 amendments for review**, so that we can timeously appoint appropriate reviewers and proactively manage the process of the review of your amendment.

Important note: Amending the COVID-19 research risk assessment and management of a project does not automatically mean that a researcher can proceed with a research study. The researcher first has to obtain permission for their research study to proceed from the appropriate REC (**as indicated in Communiqué 6**), before they can continue with data collection. See also the *template* attached to Communiqué 6.

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.

Note: Please read this communiqué in congruence with the document "**COVID-19 research risk assessment and management approach**" (Prof Minrie Greeff, 29 June 2020).

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