



Faculty of Health Sciences: Ethics Office for Research, Training and Support
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COMMUNIQUE: NO 4

PROACTIVE ACTIONS SHOULD AMENDMENTS TO APPROVED RESEARCH STUDIES BE REQUIRED DUE TO THE COVID 19 PANDEMIC

04 May 2020

Dear Colleagues and Post-graduate students

We hope that this email finds you and your loved ones safe and healthy during these uncertain and challenging times.

The Faculty of Health Sciences and the Health Sciences Ethics Office for Research, Training and Support, understand the major impact/possible impact that the COVID-19 pandemic and subsequent lockdown has had on the research being undertaken within the Faculty and the University at large. We also understand the major knock-on effects that this will have on postgraduate students being able to complete their degrees, as well as our research outputs within the Faculty. We understand that in order to mitigate these risks there needs to be pro-active changes made to approved research studies, to allow for research studies to be able to continue during the COVID-19 pandemic or to immediately resume as soon as a lock down level allows it. These proactive changes may include (but are not limited to):

1. Changing the recruitment strategy e.g. from an in-person process to a telephonic process
2. Changing the approved methodology to use data collection methods that ensure physical distancing
3. The implementation of risk-mitigating strategies to prevent infection risk and not entering communities for data collection
4. Changes in time schedules etc.

We understand that such proactive changes 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 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 lock down 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://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:

1. Ensure all your amendments are indicated in yellow highlight in the amended documents.
2. 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.
3. 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 or wayne.towers@nwu.ac.za and the Chairperson, Prof Petra Bester at 082 298 3567 or petra.bester@nwu.ac.za (for research involving human participants) or Prof Tiaan Brink at 082 920 9698 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