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COMMUNIQUE: NO 3

COVID-19 AND MAJOR INCIDENT RESEARCH

4 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 importance of specific research focussed on COVID - 19 or aspects related to the disease. We know that research and innovation are key aspects to overcoming this disease. We also realize that research about these aspect will be urgent and require a quick response from the Scientific Committees and the Ethics Committees. To ensure this process runs smoothly, we would like to bring the existing processes for research of such nature under your attention and offer our support to those researchers wanting to undertake research on the COVID-19 pandemic or related aspects.

With regard to undertaking research on COVID-19 and its impact during this time, we have two very clear SOPs for this process. 1) the expedited review process SOP (2.2.4_SOP_Ethics_1.7) describing the process that is to be followed when submitting major incident research, and the handling of the application in an expedited fashion and 2) the reciprocal review process SOP (2.2.4_SOP_NWU-HREC_2.2) indicating the process that is to be followed when a research study has obtained ethics approval from another NHREC-registered Research Ethics Committee, but the study itself is to be undertaken within the NWU context or in collaboration with another university.

The processes described in both of these SOPs are handled via the expedited process. It should, however, be noted that although these requests are handled by an expedited process, this does not mean that any ethical standards can be circumvented, and as such a full application, with all the usual documentation, is required to ensure participant protection. These SOP's are freely available on our website at the following URL i.e. http://health-sciences.nwu.ac.za/healthethics/sops but are also attached to this notification for your convenience.

Please note: If you are planning to undertake this type of research, 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 application.

If you are planning to undertake this type of research, it is important to ensure that you pay special attention to the following ethical aspects:

1. Please ensure that all risks pertaining to infection risk are included in the risk/benefit ratio analysis, as well as the mitigating strategies that will be undertaken to reduce this risk
2. The process of obtaining informed consent is still a critical aspect of any research study and must be sufficiently addressed, even when undertaking research during a disaster.
3. Researchers should be aware of the different types of informed consent that can be implemented in emergent situations, such as delayed consent or proxy consent, especially when working with participants that are mentally incapacitated e.g. in a coma or seriously ill, at the time of data collection. Section 3.2.4.4 of DoH2015 describes the minimum conditions for research involving adults who are incapacitated as follows: "Research involving incapacitated adults should be approved only if:

    a. The research, including observational research, is not contrary to the best interest of the individual;
    b. The research, including observational research, places the incapacitated adult at no more than minimal risk (i.e. the 'everyday risk standard' which means the risk is commensurate with 'daily life or routine medical, dental or psychological examinations and in social or education settings activities' – referred to as 'negligible risk' in some guidelines); or
    c. The research involves greater than minimal risk but provides the prospect of direct benefit for the incapacitated adult. The degree of risk must be justified by the potential benefit; or
    d. The research, including observational research, involves greater than minimal risk, with no prospect of direct benefit to the incapacitated adult, but has a high probability of providing generalizable knowledge; i.e. the risk should be justified by the risk-knowledge ratio;
    e. Greater than minimal risk must represent no more than a minor increase over minimal risk;
    f. The legally appropriate person (treatment proxies as stipulated in NHA s 7 or s 27(1)(a) of the Mental Health Care Act 17 of 2002) gives permission for the person to participate; and
    g. Where appropriate, the person will assent to participation. Note that the incapacitated person's refusal or resistance to participate, as indicated by words or behaviour, takes precedence over permission by a proxy.
    h. The National Health Act specifies the sequence of legally appropriate treatment proxies as spouse or partner; parent; grandparent; adult child; brother or sister. The Mental Health Care Act provides, in no particular sequence, that legally appropriate proxies are spouse; next of kin; partner; associate (defined as 'a person with a substantial or material interest in the well-being of a mental health care user or a person who is in substantial contact with the user'); and parent or guardian. "

4. Researchers should make it clear in the documentation to the participants, exactly what will happen with their data and their samples, once it has been collected and researchers must adhere to what permission is being given by the participants.
5. Samples collected are seen as highly infectious and very clear processes should be described about sample management and destruction.

6. Samples cannot be sent out of the country without the submission of the gazetted material transfer agreement (MTA) that must be signed by the chairperson of the NWU-HREC before an export permit will be provided by the Department of Health. Similarly, any samples and/or data that is to be sent out of the country must have prior permission from the participants that the samples and/or data may be sent out of the country. At a time like this, researchers should be vigilant about collecting and sending samples from Africa, without prior intensive consultation with a team made up of the chairperson of the REC, selected members of the REC and knowledgeable consultants.

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