RESEARCH ETHICS GUIDELINES IN THE LIGHT OF THE COVID-19 LOCKDOWN REGULATION

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COLLEAGUES

This communication is addressed to all supervisors, promoters, researchers, FRIC chairs and all engaged in research related activities

The COVID-19 lockdown situation and its regulations are in place nationwide and internationally, in some form or another. At VUT this has created a vastly changed landscape, as we are all experiencing. One of the areas that this has impacted on is the conducting of research, and therefore, with it, the changing demands on the ethics of that research.

In attempting to deal with the current circumstances, the following guidelines are to be followed. ***It must be emphasised that these guidelines rely BOTH on the integrity of the researcher towards the science of their project, as well as the integrity of the researcher and research team towards the ethics of research. With this undertaking in place, all FRECs and the CREC undertake to accommodate the changing landscape to the best of their abilities and within the confines of research ethical practice and principles.*** Although VUT has separated the functions of science and ethics, for the sake of avoiding conflicts of interest, these are difficult times that require extra ordinary measures and a collaborative approach.

In our view there are two scenarios that need attention. The first scenario deals with research projects that *have already received ethical approval*. The second deals with research projects that *are in the process of seeking ethical approval*. In both cases the integrity of the research projects AND the ethics concerns are at play, and we urge researchers to think this way.

A NOTE ON TERMINOLOGY: Throughout what follows we shall be referring to ***"a research project".*** This term refers to ALL research, whether it is a Masters, a Doctorate, research for Non-Degree Purposes, internal research data gathering, and even Advanced or Post-Graduate Diploma research related projects, where data that is not literature based is being gathered. It also refers to applications that are submitted from outside of VUT.

<u>SCENARIO ONE</u>: Ethics approval has been granted.

In this scenario, a research project has already been submitted for scrutiny by a research ethics committee and has been granted final approval. Such an approval would have been generated under 'normal' research data gathering circumstances. At present the situation where the data is to be gathered, has changed, because of the lockdown. The COVID-19 Lockdown regulations are now in place and must be followed.

This implies that the conditions for which the research ethics was approved have also changed. Thus, for all intents and purposes, the approval cannot hold. Rescinding the ethics approval will serve no benefit.

However, the key principle is to determine the following: ***if the research project is to be adapted to work 'within the lines of' the limitations imposed by the COVID-19 regulations, the biggest impact will be on the methodologies used to gather the data.*** This is the core concern. If the methodologies change, the science of the project changes (and this is the domain of the FRICs – they approved the science of the project). If the methodologies and the science change, we potentially have a different set of concerns for the ethics committees to consider (and this is the domain of the FRECs – they approved the research *on the basis of the FRIC approval*). Does this imply a complete resubmission/application, taking the new circumstances into consideration? And what then happens if the situation on the ground returns to normal before the data is gathered?

We do not want the entire DRIC to FRIC to FREC process to be re-done. It is at this point that the integrity of the researcher and researcher team (including the FRICs) come into play, as well as the necessity to communicate changes to the research.[1] We propose the following:

1. The Principle Investigator (PI) must determine whether the change in methodology is so radical that it changes the direction of the project (we recommend a consultative process, which might be with a sub-committee of the FRIC, as it is at this point that the integrity of the process is at its most vulnerable);
2. The changes from the original methodology to the new methodology are placed in a table form;
3. A copy of the original ethics approval letter, the table, and a letter applying for a "variation of research ethics consideration" which explains the reason for the application are submitted to the relevant FREC;
4. The FREC scrutinizes the proposed changes and, if satisfied, issues a "variation of research ethics approval" to the applicant (and the others who would normally get a copy of the approval letter, as per the policy);

In this way there is a clear paper trail/trajectory for the FREC from what was applied for originally, what was approved, what variation was applied for, and what variation was ethically approved.

<u>SCENARIO TWO</u>: An application for research approval is being generated.

(This matter needs much discussion by the FRICs, as a major decision has to be made by them, as will become evident).

There are two ways that this process can play out:

- Because there is no clarity as to when (or whether) the COVID-19 lockdown regulations might be lifted during the course of the research, a decision is made to prepare the project *as if the regulations are NOT lifted.* Thus, if they are lifted, the project still stands as it has originally been planned. This might have a bearing on the type of data being gathered, the robustness of the methodology and data, and therefore the possible impact of the research. This is a science decision. However, if this approach is followed, then, inevitably, the

[1] There are two threats at play. (1) It may be that changing the methodology invalidates the research – the science problem. (2) If the methodology changes, and the ethics does not, VUT's insurance only covers what was *originally* approved by the Ethics committees. So, in the case of a Serious Adverse Event (SAE) the research team may not be covered. Hence the importance of communication

research ethics committees scrutinize and grant approval for the applied for project. (If changes are made later, as indicated in Scenario One, above, then that process would then follow through the "variation of research ethics application"). In this approach, however, there is no time delay in the research, and therefore, as soon as the approval letter is received, the data gathering may commence.

- The second possible decision is where the PI and the research team (and perhaps with the input from the FRIC) decide that the application will be made *as if the COVID-19 regulations have been lifted and everything has returned to normal* (or pre COVID-19 status). The research ethics application follows the normal course. HOWEVER, the major change is that approval letter from the FREC/CREC will state categorically the areas where data *cannot* be gathered under the current COVID-19 conditions (In this way it protects itself and the university). In this case, the applicant has two options: Option one indicates (as with Scenario one, an application for "variation of research ethics" and follows that process. Option two is to wait until the COVID-19 regulations are lifted, apply to the relevant FREC to have the ethics approval letter reworked to remove the COVID-19 restrictions in the original letter, and then proceed with the original project. (This application can be processed in a very short time).

CONCLUSION

We end this set of guidelines by suggesting some of the places where the COVID-19 regulations might have an impact on the research project and where particular, accepted, research methods might be at play. This list is by no means exhaustive, and additions rely on the integrity of the researcher and ethics teams as they work through their understanding of the implications of the lockdown and the COVID-16 regulations.

1. Face to face interviews
2. Census gathering by research assistants
3. Questionnaire completion through verbal question and answer
4. Focus groups
5. In situ interventions
6. Site specific research
7. Laboratory SOPs that require lab assistants
8. In situ observations
9. Participant observation
10. Team construction projects
11. Prototype development that relies on external expertise (e.g. use of the 3D printing lab)
12. Videography data gathering
13. Collaborative research projects
14. Community engagement projects
15. Education

We trust that these guidelines are of use to you, and we invite engagement to refine, develop or change the guidelines so as the maintain the integrity of the research and the ethics process, but at the same time acknowledging time constraints

(Developed by Prof Allan Munro and Prof Thiri Padayachee)