

GUIDELINES FOR RESEARCH ETHICS APPLICATIONS FOR NON-DEGREE PURPOSE RESEARCH

PURPOSE OF THIS DOCUMENT: To facilitate research approval for non-degree research projects.

PREAMBLE

The Policy on Research Ethics indicates that all research undertaken at VUT needs to undergo research ethics scrutiny before the research may proceed. Traditionally this may have only been rigorously applied to Masters and Doctoral research, but the Policy now includes research undertaken for Non-degree Purposes (NDP) as well. This is a new development and is predictably in line with research funding from sources such as the NRF and the DHET subsidy system.

The purpose of this document is to assist all researchers, who are doing NDP research, to understand the procedure to be followed in making application for research approval. It explains what is expected by the Research Ethics Committees, and how the application process will develop.

FRIC INVOLVEMENT:

The Policy on Research Ethics states that all research, including NDP research, needs to have the 'science' of the project scrutinised and approved. This task is undertaken, in respect of Master's and Doctoral studies, primarily by the FRIC or the DRIC. The role of the Higher Degrees Committee [HDC] and the Research and Innovation Committee [SRIC] will not be discussed at this stage. Unless otherwise decided upon by the University, the FRIC or the relevant DRIC will now need to take on this extra role, namely of approving the science of the proposed NDP research project for research which falls within the domain of a particular FRIC or DRIC. It is acknowledged that this task might not be included in the current 'Terms of Reference' of the FRIC or DRIC. Presently, the high-powered research members of each FRIC or DRIC are ideally placed to scrutinise the science of the research taking place in their Faculty. Should there be applications where the ambit of the research does not fall within a particular faculty, then those applications will be forwarded directly to the CREC for consideration and approval. This may include NDP research carried out by non-academic departments at the university.

NDP research applications are not the same as the full proposals that are expected from Masters and Doctoral students, where the development of the proposal is central to Post-Graduate training. It would thus make sense to find a system that:

(1) Has the *integrity* of the research at heart,

(2) Provides *sufficient information* to an FRIC or DRIC to make an informed decision as to the viability of the proposed project,

(3) *Does not consume the vast amounts of time* that go into preparing a Masters or Doctoral proposal, and

(4) Makes provision for the documentation prepared for the FRIC or DRIC also being used to *guide the Research Ethics Committee* as it deliberates the ethics of the project.

The target, therefore, is to determine an appropriate system that will assist the FRIC or DRIC, as well as the FREC or CREC, to make decisions that take the particular NDP situation into account. What follows is a proposed system, for consideration by both the FRIC and/or DRIC and the FREC/CREC.

Proposed FRIC/DRIC guidelines

The following guidelines are proposed for discussion (the key question being whether what follows would adequately enable an FRIC/DRIC/FREC to make an informed decision to approve an application or not):

1. The submitted NDP project proposal document should be seen as part of an extended abstract. This is, perhaps, useful as it would already provide a large part of the abstract for the article, publication or presentation. The final abstract would also contain the results and findings.
2. The cover page of the document should contain the name, contact details and departmental affiliation of the PI or Principle Investigator, the names, contact details and departmental affiliations of co-researchers, details of any collaborative agreements in place and, if applicable, the source of funding for the research project.
3. The document should address the location and relevance of the research. This can possibly be seen as the 'equivalent' of the Background and Motivation/Rationale for the study with just sufficient references to justify the assertions made.
4. The document should confirm the purpose of the study. The purpose could be regarded as equivalent to an Aim, or research question, which could identify the objectives.
5. The document should, as far as is possible, also outline the envisaged outcomes of the research and any projected benefit.
6. The key area, however, would be the science of the project and, generally, this will be captured in the Method and Design section. From a science

perspective, the FRIC/DRIC would possibly scrutinise this aspect to whether the purpose of the project is attainable (with all that this concept entails) and able to deliver the dependable results that are expected. From the ethics point of view, the FREC would use this section to see how the research might engage with humans, animals or the environment, and how the researcher plans to manage this. The key is for the document to contain enough relevant information (not necessarily justified by the literature) so that the experienced members of the FRIC/DRIC can follow the protocol that the applicant has committed to.

7. The accepted Method and Design requires implementation. All major deviations would need deviation approval. This would require that the changes to be made, should be submitted for ethical approval.
8. The potential prospect for prototyping, commercialisation, IP or other related exploitations of the research, could also be addressed.
9. The FRIC/DRIC may furthermore ask for certain instruments to be used, such as questionnaires and the like.

If these proposed guidelines are acceptable, then some submission documents might be very short, and some longer, depending on the nature of the research to be undertaken. Whatever the case, the guidelines will provide a clear plan of action.

Once the FRIC/DRIC has approved the application, the approval is documented in a letter from the Chair, and is captured in the FRIC/DRIC minutes which may serve, as is currently the case with Masters and Doctorates from some FRICs/DRICs, as the equivalent of the approval letter.

THE FREC REQUIREMENTS

Once the FRIC/DRIC has signed off on the project, the following documents need to be submitted to the FREC for consideration, as an application for ethical clearance:

1. The document submitted to the FRIC/DRIC for approval,
2. The FRIC/DRIC approval document (letter or extract from the minutes), and
3. The relevant, and signed, Research Ethics Application form, together with any annexures that are pertinent (SOPs, Information leaflets and Informed Consent, instruments, gatekeeper letters and so on, where relevant).

It should be noted that annexures, where relevant, have to be developed anyway, so this is not an added burden.

Generally the aforementioned applications can progress to waiver, expedited review, full review, or escalation to the CREC.

It is hoped that these guidelines will assist researchers in preparing their applications. Any suggestions you may have for refinements of the system are welcome. Please forward any suggestions or proposals you may have, in this regard, to the compilers of this document:

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