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ETHICS ELECTIVE PROPOSAL
Guidance and instructions

The Centre for Medical Ethics & Law is able to accommodate a limited number of researchers and elective students. We typically receive more applications than we can accommodate.

In order for the Centre to assess your application, please email a description of the project to the Centre administrator, detailing your study using the guide below, and what you wish to accomplish. Include a synopsis of your CV, of no more than 2 pages. Centre administrator: kelseyf@sun.ac.za

The project description should include an overview of the hypothesis, the methods that will be employed, and the expected outcomes and analytic methods that will be used.

Please use the guide below to prepare your application.

Research Guide

Outline of proposal: Summary

The project summary should be no more than 300 words and at the most a page long (font size 12, single spacing). Provided preferably on a separate page, it should *summarise* all the central elements of the protocol, for example the rationale, objectives, methods, populations, time frame, and expected outcomes.

Rationale & background information

Specify the reasons for conducting the research in light of current knowledge. Include a statement of the need/problem that is the basis of the project, the cause of this problem and its possible solutions. Answer the question of why and what: why the research needs to be done and what will be its relevance. This should be followed by a list of the most relevant publications on the subject.

Protocol
Study Design

This part of the application follows your summary. The design of the study should include information on the type of study envisaged, the research population or the sampling frame and the expected duration of the different components of the elective.

The methodology section should include detailed information on the interventions to be made, procedures to be used, observations to be made, etc. Interventions could also be in the realm of qualitative research, for example providing training or information to groups of individuals.

Examples of procedures could be: doing a questionnaire survey, carrying out a focus group discussion as part of research or writing up a case report with ethical analysis for publication.

In the case of a randomized controlled trial, additional information on the process of randomization and blinding, description of stopping rules for individuals, for part of the study

or entire study, the procedures and conditions for breaking the codes etc. should also be described.

A graphic outline of the study design and procedures using a flow diagram would be useful. This should include the timing of the stages.

Safety Considerations

The safety of research participants is foremost. Safety aspects of the research should always be kept in mind. It is useful to remember that even administering a research questionnaire can have adverse effects on individuals.

Follow-Up

The research protocol must give a clear indication of what follow up will be provided to the research participants, if applicable, and for how long.

Expected Outcomes of the Study

The protocol should indicate how the study will contribute to advancement of knowledge, how the results will be utilized, not only in publications but also how they might affect health care, health systems, or health policies.

Duration of the Project

The protocol should specify the time that each phase of the project is likely to take, along with a detailed timeline for each activity to be undertaken.

Problems Anticipated

This section should discuss the difficulties that the investigators anticipate in successfully completing their projects within the time frame stipulated. It should also offer possible solutions to deal with these difficulties.

Ethics

The protocol should have a description of ethical considerations relating to the study. This should not be limited to providing information on how or from whom the ethics approval will be taken, but this section should document the issues that are likely to raise ethical concerns. It should also describe how the investigator(s) plan to obtain informed consent from the research participants (the informed consent process).