<**Title of Research Protocol**>



<**Name of Candidate**>

<**Name of Supervisor/s and qualifications**>

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**INSTRUCTIONS: Update the Table of Contents as the final step before submitting your protocol.**

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List of Figures

**INSTRUCTIONS: Update the List of Figures as the final step before submitting your report.**

**A list of figures follows the contents on a new page, and precedes a list of tables. The figures should be numbered according to the specific chapters in which they are found. For instance, in Chapter 1 the first figure would be Figure 1.1; second figure would be 1.2; and so on and so forth. In Chapter 2, the first figure would be Figure 2.1; the second figure would be Figure 2.2; and so on and so forth. See example below:**

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**INSTRUCTIONS: Update the List of Tables as the final step before submitting your report.**

**Tables should be numbered according to the chapters in which they are found in the same way figures are numbered. See examples below:**

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Nomenclature

**INSTRUCTIONS: Delete any acronyms that you do not use in your report. Add any additional acronyms that you use. The first time you use an acronym it should be written out in full with the acronym in parentheses afterwards. Note: Abbreviations are listed in alphabetical order**

AIDS Acquired Immunodeficiency Syndrome

HIV Human Immunodeficiency Virus

M&E Monitoring and Evaluation

TB Tuberculosis

1. INTRODUCTION / BACKGROUND

The introduction should explain, for the non-expert but intelligent reader of your document, what the background is to your proposed study. You should formulate the question being asked, or the hypothesis of the study, in the context of the prevailing scientific knowledge on the subject. Therefore in this section you should also include a brief review of the relevant literature that has led to the idea or conceptualisation of your project. Usually about **five pages** and between ten to twenty references will suffice. You need to review the literature first (read through it) and then analyse and critique the arguments presented in that literature when you write this section. Only information relevant to the study should be included as the primary purpose to this part of the protocol is to justify the study in the light of previous information. At this stage the “story” of the research should be quite clear to the assessors. The paragraphs should therefore be carefully structured and lead the reader carefully and deliberately towards the final paragraph which should contain the research question/aim. This may be expressed as: “Therefore the aim of my study is to …”. You can then add a sentence indicating your hypothesis which is a statement predicting the outcome of the study.

1. STUDY AIM AND OBJECTIVES

This section requires you to be specific about the research questions or problems to be studied, which were raised in the introduction. It is probably the single most important section of a proposal. State exactly what it is you intend to do, and what outcomes you will measure to find answers to the questions you have in mind. Your study aim should correspond with the study title. You may list the study objectives, or specify them in paragraph form, but the reader must be left in no doubt as to what your objectives are. Objectives are usually written starting with “to” and then using words such as describe, explain, compare, measure etc. For example, To describe the characteristics of ….

1. METHODS

This section should include all the information relating to your plan of action. Specifically, address the following:

i) State who/what participants are to be studied. If they will be animals, give details such as their species, body weight, sex and number. If human beings are to be studied, specify the population and state which of its characteristics are relevant to your study. In both cases specify the inclusion and exclusion criteria you will use in selecting your participants where appropriate.

ii) Explain what experimental groups the animals, participants, or members of the population will form, which participants will act as controls and whether when the study will be open, or single/double blind, cross-over or parallel in nature, or a clinical trial. For each of (i) and (ii), justify your selection of experimental subjects and sample size. Possible headings to use include: site of study, control participants (if used) – how selected, and study design. It is essential that every detail regarding your methods section is explained in your protocol. i) If using tissues or tissue samples, X-rays, patient records etc, state the choice(s) of material for your study and justify your choice(s), in terms of type of study material, size of sample, control material or tissue etc to be used. ii) What intervention(s) is (are) to be made? Describe what each intervention involves.

iii) What measurements or observations are to be made? Describe the variables to be controlled and the techniques to be used, and identify and explain which of these are established techniques, and which will require development, or require you to work somewhere other than in your institution or require someone else to perform the measurements. The level of detail in this section should be such that the reader clearly understands how these measurements are designed to enable you to elicit a conclusion from your research questions.

iv) If a pilot study will be necessary, explain what aspects of the proposal may change as a result of its outcome.

The methods section has to be particularly clear and be linked to the objectives and thus using headings to clarify these relationships would be preferable. If the project is risky, meaning that there may be no results, state if:

• The project is built on previous work

• What the alternative plan is if the first part of the project fails (particularly important if the subsequent sections depend on the success of the first section)

• The work has already started, particularly if there are preliminary results. If you are planning to run a retrospective case review you should submit your data sheet indicating exactly what data you will be taking from the files. This is best presented as tick boxes which you can use for documenting the data from the patient files. It is important to check that the data obtained from the files will be sufficient to answer all the objectives. Please make sure that you mention, particularly if you are using any retrospective analysis, what data you will be collecting yourself.

1. DATA ANALYSIS

Specify the methods to be used in the analysis of the data of each section of the work, the statistical tests that will be used and whether expert statistical help will be necessary. If it will, state whose help will be needed. The data analysis required to fulfil each objective should be specified. It is not enough to give every possible test and mention that you will be using one of them “as applicable”. The importance here is to let the assessors know that you have thought about the data which will be produced and how you will deal with that data to answer each objective.

1. ETHICS

If the study raises ethical issues, such as research on sensitive participants or research on children, explain how you will deal with these issues. State whether clearance has already been obtained from the relevant ethics committee, or when you envisage making a submission to the committee. An ethics application form is required for all studies unless there are no human participants involved and then there is an ethics waiver such as would be obtained for cell lines. Different ethics forms need to be completed for animal and human studies.

1. TIMING

State when the study will commence, and its expected duration.It is better in this section to fill in a Gant chart indicating the time expected to be taken on the various component parts of the project. It is preferable that the time indicated should be appropriate in order to complete the degree in the recommended time.

1. FUNDING

Start with providing a predicted budget for your project. Include all expenses including assay kits, photocopying and transport. This is best done as a table. Explain how the project will be funded. There may be a need to specify the sources of funding for specific aspects of the project, or to pre-empt a question as to where funding would come from, possibly for particularly expensive equipment, agents or tests. If a drug company is donating agents to be used, please disclose this information. It is essential at the protocol submission stage that funding is available or there should be evidence of proposed funding especially if the project (s) is expensive. If funding is available a letter to that effect should be attached from the person holding the funds to confirm that funding is available for this particular project.

1. PROBLEMS

If there are any issues, which you consider may compromise your progress with the project, such as availability of study material or patients, or problems of a technical nature, please raise these issues, so that the Faculty Committee can attempt to help you.

REFERENCES

You should list the references in an accepted referencing format - Vancouver (numbering) referencing style should be maintained throughout the document. All references in the reference list must be cited in the text and vice versa. In text use (Companion et al. (2004)) and in reference list use a style like:

1. Companion F, Friend P and R Buddy. Ways to travel. 2004 J Sociology 142: 534-8.

If you obtain journal articles through the web you only have to give the URL if there are no page numbers allocated to the article. If there are page numbers it implies that the article is in printed form somewhere and only the journal reference is required.

APPENDICES

Appendix A: E.g. Research Questionnaire

Appendix B: E.g. Wits Ethics clearance

Appendix C: E.g. Hospital CEO clearance