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Disclaimer

This template has been developed as part of the *Clinical Research Protocol Writing (CRPW)* short course, offered by Stellenbosch University, South Africa. It contains all information necessary for protocol approval in most contexts. However, researchers are advised to consult with their own institutions and environments regarding the requirements, format, and structure as well as the content therein. The examples and suggestions in this guideline always need to be qualified by the researchers' own considerations and context.

MS Word formatting

Note that this template has been created using the "Styles" feature in Microsoft Word, which allows for the automatic generation of a table of contents. On this website you can learn how to use heading styles and update the table of contents in this document.

<<Researchers should delete this cover page when drafting their protocols>>

Title title title title title title title title title title title title title title title title title title title title

Research protocol

In partial fulfilment of the degree

<<insert degree title here (if applicable) >>

<<insert your department or affiliation here (if applicable)>>

<<insert your faculty here (if applicable)>>

<<insert your university here (if applicable)>>

Primary investigator

Title and full name <<your name>>

Department of <<insert>>, <<your university or institution>>

Supervisor

Title and full name

Department of <<insert>>, <<your university or institution>>

Co-supervisor

Title and full name

Institutional affiliation

<<Insert final date of final version here>>

Table of Contents

1. Definitions

<<Add definitions for 3-5 key terms or concepts if necessary.>>

2. Introduction

<<Include a brief overview of your research story and purpose here. Most researchers write the introduction last i.e. once the other sections of the protocol are complete.>>

3. Literature review

<<Provide an in-depth narrative review. This should be structured as a series of paragraphs that provide context for your study and develop an evidence-based argument for why your research is needed and important.>>

3.1. Subheading 1

3.2. Subheading 2

4. Problem statement and rationale

<< This can be a separate section or appear as the last paragraph of your literature review. The rationale summarises the overall story told in the literature review. It also highlights the gap that exists and motivates for why a study is needed to address this gap. Basically, this section aims to answer, “so what?” and “who cares?”>>

5. Research question

<< This is your overall aim phrased as a question so don’t forget to add a question mark!>>

6. Hypothesis

<<You will provide a hypothesis for any study involving inferential statistics (usually comparative and relationship-type studies). If you are doing a purely descriptive study, you

can state: “No hypothesis as this is a descriptive study and no inferential statistics will be employed”.>>

7. Aims and objectives

<<Aim = the overall goal you want to achieve. Objectives = a list of tasks or smaller steps that allow you to achieve your overall aim. You can present your objectives as a numbered or bulleted list.>>

8. Methodology

8.1. Study design

<<Name and describe your study design, if applicable.>>

8.2. Study setting/site

<<Where will the research take place? This section is important for readers to understand the context of your study and how it might be different from other settings.>>

8.3. Study population

8.3.1. Sample characteristics

<<What are the characteristics of the people who are eligible for your study? Motivate for why you have chosen these participants with these characteristics.>>

8.3.2. Inclusion criteria

<<What characteristics will you use as inclusion criteria?>>

8.3.3. Exclusion criteria

<<What characteristics will you use as exclusion criteria? Motivate for your choices.>>

8.3.4. Sample size calculation

<<What is the size of the population from which you will draw your sample? How big will your sample be and why? Have you calculated a sample size or done a power calculation? What software did you use and what information did you use for your calculation?>>

8.3.5. Sampling and recruitment strategy

<<Describe the sampling strategy (such as convenience, stratified random, etc.) and recruitment process i.e. when, where, how and by whom?>>

8.4. Data collection

8.4.1. Procedure

<< Describe your data collection process in a logical sequence of events. What methods will you use to generate data? Justify your choice. Where will you collect data and under what conditions? Who will collect the data? If not yourself, why are they most suitable? Do they have expertise in quantitative research methods? Do they require any training? >>

8.4.2. Measures

<<What measures or instruments will you use to collect data? If using a questionnaire or another tool or measure: Is this new or has it been used previously? Do you have permission to use it (if applicable)? Has it been validated in your context? What types of questions does it include? How will a questionnaire (or any other measure) be scored and how will you interpret those scores?>>

8.5. Data management plan

<<Where will data be captured and stored? Will data be backed up anywhere? Who will have access to it? How will you address confidentiality and anonymity of the data? How long will you keep the data?>>

8.6. Storage of biological specimens

<<Will any biological specimens be taken? Where will these samples be stored and who will have access to them? Will these samples be used for any other research? If you won't be collecting any biological specimens, you can delete this section.>>

8.7. Data analysis plan

<<What descriptive (summary) statistics you will use? What inferential statistical tests you will use to address your hypothesis (if any)? What software you will use? The level of statistical significance? Who will conduct these analyses? You are encouraged to provide 'dummy' tables and figures.>>

9. Ethics and regulatory compliance

9.1. Approval by regulatory authorities

<<You will need to state that ethics approval will be obtained from your institutional ethics review board or committee. Study approval will also be gained from other necessary bodies from your institution (such as Institutional Research and Planning at Stellenbosch University) if staff and students or alumni are among your participants, hospital management or Department of Health (DOH) for accessing health care facilities or patients. Also mention that your study will be conducted in accordance with the Declaration of Helsinki and the DOH Guidelines for South African Good Clinical Practice.>>

9.2. Informed consent

<<Describe the process you'll follow to obtain informed consent from your participants. If minors will be recruited, please describe process of obtaining assent. If you're doing a retrospective chart or record review, you will need to request a waiver of informed consent. You will need to write a letter to your institutional ethics review board or committee requesting this.>>

9.3. Risks and benefits to participants

<<Describe all possible risks and benefits to participants. Also indicate how you will compensate participants for their time and effort and any inconvenience.>>

9.4. Social value

<<What difference will this research make and to whom? Similar to your rationale section above: “so what?” and “who cares?".>>

10.Study limitations and assumptions

<<State any limitations, such as poor generalisability. Or any assumptions, such as “we assume all patient folders contain accurate and consistent information”.>>

11.Conflict of interest

<<Usually none to declare. But if you’re being funded by a pharmaceutical company or have any other affiliations that might be seen to bias the research, please state this.>>

12.Study timeline

<<Example of a simplified Gantt chart below. Update and adapt for your own purposes. Always good to factor in extra time i.e. if you think data collection will take 2 months, make it 3. Life happens!>>

List of tasks	Jan-Feb 2022	Mar-Apr 2022	May-Jun 2022	Jul-Aug 2022	Sep-Oct 2022	Nov-Dec 2022	Jan-Feb 2023	Mar-Apr 2023	May-Jun 2023	Jul-Aug 2023	Sep-Oct 2023	Nov-Dec 2023
Literature review	X	X										
Prepare protocol		X										
Submit to ethics			X	X								
Data collection					X	X	X					
Data analysis								X	X			
Drafting of dissertation									X	X	X	
Submit for examination												X

13.Study budget

<< Institutional ethics review boards or committees and any other approval bodies will want to see that you have thought through the financial aspects of your project. If funds are required, you must state who will cover the costs or to which funder(s) you have applied or will apply.>>

14.Dissemination of results

<<How will you share your findings and with whom? Your immediate environment? Hospital management? Departmental or conference presentations? Journal articles? The participants or community? Also include which Equator Network reporting guideline you will use for the write-up.>>

15.References

<<Use Mendeley or other software to assist with referencing. Manual referencing is a pain!>>

16.Appendices

<< Informed consent leaflet, any other permissions, and data collection sheets or other data collection tools. These should typically be included for divisional/departmental protocol approval, but check what the requirements are for institutional ethics review board or committee approval.>>