

Faculty of Health Sciences

Guidelines on Writing a Research Protocol

A well-written protocol will facilitate the process of obtaining institutional and ethical approval for your research and increase your chances of obtaining funding for your project.

The format given in these guidelines is designed for quantitative, epidemiological and clinical research in the health sciences. However, the format is applicable to most areas of inquiry.

The guidelines include the following:

Content	Page
<i>Title Page</i> Please write all the necessary detail on the title page.	2
<i>Executive Summary</i> An executive summary might be required by the Ethics Committee.	3
<i>Table of Content</i> Find out from your supervisor if a table of content is needed. A protocol is a short document and a table of content might not be necessary.	4
This section of the guidelines also shows you the headings and sub-headings to use and the information that needs to be found in sections and sub-sections of your protocol.	
<i>Guidelines for Writing the Title</i>	7
<i>Example of a Gannt Chart</i>	8
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University of Pretoria
Faculty of Health Sciences
(Write the name of your university school or department here.)

Title of the Research Project

for the degree (name the degree - if applicable)

Author (full name & surname)

Student number (if applicable)

Contact details:

Address:

Tel:

Fax:

Cell:

Email:

Supervisor: (Title, initials, surname)

Co-supervisor: (if applicable)

Date:

Executive Summary

The instructions given here are based on guidelines from the Ethics Committee. Remember that you are giving a summary of what readers will find in your protocol and that you are not providing an introduction or background material to your research.

Write your summary in paragraph form and make sure that it covers the questions set out below in the sequence in which they are asked. The questions themselves should not appear in your summary.

- Why is the project necessary?
- What do you aim to do?
- What methods will you use for carrying out the project?
- What will be the project outputs?
- What is the projected impact of the project?

An approximate word count: 500 words

¹Table of Content

The numbered headings and sub-headings that you find in this table of content should be used in your protocol. Don't use the instructions set out on these pages. Use the instructions to guide you on what to include in the various sections of your protocol.

1. Background, Literature Review and Research Problem

- Give some background to your topic. (Be brief.)
- On the basis of a review of the relevant and up-to-date literature state what is known about the topic.
- State what is not known about the topic.
- Mention any weaknesses (in the method used, for example) in the literature reviewed.
- Mention any gaps in the literature.
- State what research problem you have derived from a combination of the background to the topic and the literature.
- Briefly justify the research you intend to carry out on the basis of what you have already written in this section

3. Hypothesis, Aim(s) and Objectives

Hypothesis (for analytical studies only)

A hypothesis is a provisional and possible explanation for a problem. Make sure that your hypothesis is clearly defined.

Study aims

In one sentence state clearly what the goal of your research is.

Study objectives

Before you write your objectives remember that you can produce quality results only if the thoughts that have gone into establishing your objectives are of good quality.

Your objectives need to:

- State exactly what is to be achieved
- Be short but complete
- Be specific, attainable, measurable and realistic

4. Methods

¹ Protocol headings adapted from: Joubert G, Ehrlich R, editors. Epidemiology - a research manual for South Africa. 2nd ed. Cape Town: Oxford University Press Southern Africa; 2008.

4.1 Study design

4.2 Study setting

4.3 Study population and sampling

4.3.1 Study population (inclusion and exclusion criteria)

4.3.2 Sampling method

4.3.3 Sampling size

4.4 Measurements

- Describe your measurement instrument (such as a clinical examination or a questionnaire)
- Describe how you will carry out measurements
- State your variables, grouped according to exposure and outcome variables (if relevant)
- Give a detailed description of “case status” or exposure status (if applicable)
- Refer to the validity and reliability of the measurement instrument (if applicable)
- State how you will ensure quality control

Methods and techniques that are not standard or supported by the literature must be clearly explained. Make use of diagrammatic representation in your methods section.

4.5 Pilot Study

State how you will pilot your research if it needs to be piloted.

5. Data Management and Analysis

State what statistical methods you will use, provide a statistician’s report, and explain how your data will be stored.

5. Ethical and Legal Considerations

You need to mention:

- Approval of your research by the relevant departments
- Consent of participants
- Privacy of information and confidentiality
- Potential harms and benefits brought about by your research

- Any conflict of interest

6. Logistics, Time Schedule and Action Plan

It is important for you to set out the names and roles of the members of the project team. Their signatures should be given as well.

For your project-management timetable use an action plan or Gantt Chart in which you write the exact dates on which specific actions will occur. (See Page 8 for an example of a Gantt Chart and Page 9 for an example of an action plan.) State the responsibilities of the contributors or authors who form your project team.

For your action plan:

- State a specific objective
- Decide how you will know when you have met the specific objective
- Express this in a statement of standards
- List the programme steps necessary to accomplish the specific objective
- Schedule the beginning and completion of each step
- Establish controls necessary to assure achievement of the objective

7. Budget/Resources

State what the budget for your research is and motivate your budget.

8. Reporting of Results

State how the results will be reported and who will be given access to them.

9. References

The Vancouver system of referencing is used by the Faculty of Health Sciences except in the School of Health Care Sciences, which uses a version of the Harvard system. For qualitative research carried out in schools other than the School of Healthcare Sciences it might be appropriate to use the Harvard system.

The reference numbers (for the Vancouver system) you use in the body of your protocol must all appear in your reference list. Each item in your list must be correct and complete. Use Refworks or another suitable software package to help you.

A complete guide to referencing can be found on the Faculty of Health Sciences website.

10. Appendices

You need to append:

- Data-collection tool (for example an information leaflet for participants, an informed consent form, your questionnaire)
- Letters of approval
- Ethics consent forms

Please note that the numbering of the pages of your data-collection tool should not make it appear as though the tool is a continuation of your protocol. These pages should be numbered “1 of 5”, “2 of 5” etc.

Guidelines for Writing the Title

The title should be short, concise, practical, worthwhile, and represent a contribution to science.

Here is an example of a good title to a protocol:

“Smokeless tobacco use, exposure to cigarette advertisements and smoking intention among non-smoking youths in Ghana during 2006”

In her protocol the author focuses on the association between smokeless tobacco use, exposure to cigarette advertisements and smoking intention among non-smoking youths. The words “the association between”, however, have not been included in the title. Similarly words such as “A comparison of ...” and “An approach to ...” do not need to be included.

Here is another example of a good title:

“The non-initiation of anti-tuberculosis therapy in smear-positive pulmonary tuberculosis in eThekweni district of KwaZulu-Natal, 2007”

In this protocol the author compares the non-initiation of anti-tuberculosis therapy with non-initiation in KwaZulu-Natal generally. She also discusses possible explanations for the high rate of non-initiation in eThekweni. Notice that the words “comparison with” or “explanations for” do not appear in the title.

Example of a Gantt Chart:

GANTT CHART

[illegible]

Example of an action plan:

ACTION PLAN

ACTIONS	RESPONSIBLE	TIME	BUDGET	ACTION SPECIFICATION	
Literature study					
Statistics					
Ethical aspects					
Funding					
Experimental Procedures					
*Technique Development					
*Specimen collection & determination					
Data file					
Statistical analysis					
Publication preparation					
Congress presentation					