**A1**

**EXAMPLE OF A PROTOCOL TEMPLATE**

University of Pretoria

Faculty of Health Sciences

School of Medicine

Title

(must be short and concise and reflect your primary aim;

Use Title Case)

Degree: (for example, MMed Surgery)

Author:

Student no:

Contact details:

Address:

Tel:

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Cell:

E-mail:

Supervisor: (name)

E-mail address:

Co-supervisor: (name if relevant, otherwise delete)

22 June 2011

**EXECUTIVE SUMMARY**

The must answer the following questions (but don’t include the actual questions in the summary, and please note: no references in the executive summary):

* Why is this project necessary?
* What are you going to do?
* How are you going to do the project?
* What are the project outputs?
* What is the impact of the project?

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**1. Defining the research problem**

This gives a brief overview of the research problem (maximum 2-3 paragraphs). For example: TB in the age group 3-6 years is increasing disproportionately to other age groups. Various risk factors have been identified but the role of day-care centres has not been investigated.

**2. Literature overview and motivation**

Content will be determined according to your protocol, but should include the following (don’t use as subheadings):

* Historical background
* Why is this subject important?
* What is known from previous studies?
* Critically appraise and show limitations of previous studies, if any
* What factors (and why) led to the research project?
* Justification/relevance/impact of your study (based on the above aspects: for example, importance of subject, gaps in knowledge, request from the institution, what the anticipated impact of the research may be etc)

**3. Aim and objectives**

 For example:

 Aim: To investigate risk factors for TB in children aged 3-6 years in Limpopo Province

 Objectives:

1. To determine the relationship between birth weight and development of TB at the age of 3-6 yrs
2. To determine the relationship between day care, type of care giver and TB …
3. To determine the relationship between socio-demographic factors and TB …

 Alternatively, in the case of an analytical/experimental study, use the following:

Hypothesis: Our hypothesis is that the type of day-care centre is associated with risk of TB in children between 3-6 years old.

**4. Methods**

**4.1 Study design**

 For example: Observational, cross-sectional

**4.2 Setting**

 For example: Tertiary care dermatology clinic

**4.3 Patient/research object selection**

Sampling strategy and sampling frame, if relevant, or patient selection/recruitment, including inclusion and exclusion criteria, randomisation and blinding procedures, if relevant.

**4.4 Measurements**

Here you mention what you are going to measure (the variables), how you are going to measure these (including definitions, if relevant) and what steps you are going to take to avoid measurement error (random and systematic error).

**4.5 Data analysis**

 Here you often need statistical advice.

For example: Descriptive statistics will be used to describe the sample, and paired T-tests will be used to compare the blood pressure before and after exercise. A P value of < 0.05 will be regarded as statistically significant.

**4.6 Sample size**

Here you most definitely need statistical advice from a qualified statistician or other trained / experienced person. RESCOM is in the process of compiling a list of recognised statisticians and other suitable colleagues who may be consulted for advice. Details will follow.

For example: To detect a clinically significant difference of 5mm Hg between pre- and post-exercise with an alpha value of 0.05 and a power of 90%, 33 subjects are required. Statisticians are required to state which tests will be used in the study on their attached letter of clearance. This information must also be noted in this section of the protocol.

**5. Ethical considerations**

What are the ethical issues of importance in your study and how will they be addressed? Are you obtaining informed consent (specify detail)? To which committee(s) are you applying for approval?

**6. Budget**

|  |  |  |
| --- | --- | --- |
| Item description | Cost |  |
|  |  |  |
|  |  |  |
| Total project cost |  |  |

**7. Timelines and project management**

Here you could include a Gantt chart and details as to how the project will be managed.

**8. Contributors and authorship (Reporting)**

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Department | Contribution | Author or acknowledgement |
|  |  |  |  |
|  |  |  |  |

 Note: In general, statisticians are not automatically given authorship unless they have played a significant role in the project design and development. If so, their authorship will have been mutually agreed upon during the planning stages, and this will be reflected in the table above.

**9. References**

Only use the Vancouver style: see

<http://0-www.lib.monash.edu.au.innopac.up.acza/tutorials/citing/vancouver.html>. Include a maximum of three website references.

**10. Appendices**

This should include your questionnaire/informed consent, letters of approval etc.

*Reference:*

*Aldous C, Rheeder P and Esterhuizen T. 2011. Writing your first clinical research protocol 1st ed Cape Town: Juta and Company Ltd. South Africa.*