Guideline for Writing a Protocol

General introduction

Writing a research proposal is the first step in conducting any research. Whether you intend to submit the proposal to an ethical committee, a research body or a funding organisation, it is vital that the proposal reflects your knowledge of how research should be conducted and your commitment to its principles.

The content of the research protocol should be agreed in all its details by all supervisors and co-workers. It should not be changed in principle while a study is in progress unless unexpected and severe complications occur; in this event the protocol should then be rewritten from the start if the original research question is still relevant.

It is advisable to perform a pilot study, involving a few procedures or patients, before writing the protocol to find out from the start whether the work is feasible or not and to identify problem areas which are to be avoided in the future.

Here are some brief guidelines to writing your research proposal explaining how each section of the proposal can be satisfactorily completed.

Paper used

Type the protocol on A4 (212 mm by 297 mm; Thickness: 80 g/m2) white bond paper with margins of at least 2.5 cm.

Format

All protocols must be submitted in Times New Roman Regular font size 12 point. Use double-spacing throughout, except partly in the title page and in the supervisors' page. Start a new page for each of the main sections. Only one side of the sheet must be typed. Do not divide words at end of lines. All pages should be consecutively numbered, beginning with the title page. Type the page number followed by the total number of pages in the upper right corner.

Copies

Submit the original signed protocol with the required number of photocopies. Always keep a number of photocopies for your supervisors and for your own use.

Signatures

All supervisors and co-workers must sign every page of the protocol. These signatures should be put on the original protocol before producing the photocopies.

Sections

All protocols should contain the following sections:

Title page

Supervisors' page

Background

Aim

Methods

Analysis of results

References

Appendices

Title page

Every part of the title page should be written in both Arabic and English (Appendix I). The title page should include the title of the proposed thesis, the scientific degree for which the thesis is prepared, the official name of the candidate in full followed by his or her degrees, the current post held by the candidate, the department, faculty, and university to which the protocol will be submitted, and the year in which the protocol was approved (Appendix I).

Title details

The title of the research proposal (protocol) should convey the main purpose (research question) of the research. The title is usually the first part of the protocol to be read and therefore should convey maximum information in fewer words (not more than 12-15 words) than any other part of the protocol. In other words, it should indicate the area of research, introduce the research question and specify the research method to be used. Titles should not include any kind of abbreviations.

Supervisors' page

Every part of the supervisors' page should be written in both Arabic and English (Appendix II). The full names of the supervisors and their academic degree should be written in descending order of involvement. Ideally, the role of each supervisor should be stated.

The number of supervisors can range from two to four per thesis (master's or doctor's degree). At least one of the supervisors should be an assistant professor or professor; i.e.: lecturers are not allowed to supervise alone.

Background

All protocols include a section in which the scientific background or rationale to the research topic is presented. A good background should cover the following issues:

The importance of the topic

The background often begins with a statement of the importance of the research topic based on, for example, the number of people who suffer from the disease being studied or the cost that it presents to the health authorities.

A brief review of current research

The background then should introduce the specific area to be studied including a brief review of related research especially the important and recent ones. It is essential to do a literature search (e.g. Medline, Embase) to be sure you have covered the literature adequately.

The need for further research

At this point you need to present the case for the need for further (your) research by highlighting the problems and gaps in present knowledge.

The broad long-term benefits of the proposed research

The background often concludes with the broad long-term benefits of the proposed research.

Aim(s) of the study

This section is where you should state the hypotheses that your study will test or the research questions it will address. The aims of your study should be briefly stated. Seldom number more than three. Do not include aims for which your study cannot provide results. Beware of too many aims in one study as this leads to imprecise thinking and poorly defined results. The aim(s) of the study should be precise, clear, and carefully stated.

Methods

This is the longest section of the protocol as it presents the study design in detail It is advisable to divide this section into several subheadings to guide the reader to where key information lies. The methods section should:

Specify the study design

The study design should be given in some detail. Some of the more common designs are: clinical trials, surveys (cross sectional surveys), case-control studies, cohort studies, qualitative studies, economic evaluation.

Define the study subjects

The study subjects must be described in detail. When dealing with patients you should include the following information as well as any other points relevant to your particular study:

- The criteria for including subjects in the investigation (age range, gender, special characteristics related to the condition you are investigating).presence of other disease, too old or too young).
- The diagnostic criteria (if relevant).

- The recruitment methods. (from clinic lists, from referral doctors case-notes,from computerised patient lists, electoral role, routinely collected personal records such as birth and death registers etc.).

On the other hand when dealing with animals their source and strain should be mentioned.

Describe how the data will be collected

The data to be collected should be specified, indicating how it will be measured. The following are important aspects of data collection:

1. Questionnaires

If a questionnaire or interview is to be used a list of the items to be covered should be given. It is necessary to have the completed pro forma ready, piloted, clearly designed and attached to the protocol as an Appendix

2. Physical measurements

If physical measurements are to be made (e.g. peak flow, muscle strength, or blood pressure) the type of equipment which will be used should be described and the manufacturer's name given.

3. Biochemical measures

If biochemical measures are to be made (e.g. serum cholesterol, urinary sodium) the analytical techniques which will be used should be described and referenced. The reference should give the methodological details so they need not be repeated except in outline in the protocol. If there is no reference, a full description will be required.

Outline the study interventions

It is vital to describe the study procedures or interventions in enough detail that others can repeat them:

- When using drugs you have to mention both their scientific and brand name followed by the manufacturing company, city and country. The exact drug regimen should be clearly stated covering the dosage, schedule and route of administration.
- When using apparatuses its name should be mentioned followed by the manufacturer, city and country.
- When describing procedures a full description should be presented in such detail that others can perform them in the same manner. Procedures that can be referenced can be shortly described.

Studies that involve following patients over time should mention how follow-up will be organised. For randomised controlled trials, the method of randomisation must be described.

End points

It is important and crucial that every researcher has a clear idea about the end points of his/her study. End points are events which are used to indicate the end of the study relevant to the research subjects. Furthermore, they are used in the statistics to calculate sample size and determine statistical results of the research work. Such end points are usually referred to as primary end points, others, can only be considered as secondary (intermediate) end points.

Describe sample size calculation

Formal sample size calculations are required for all research studies. These indicate how many study subjects are needed so that, if the research ideas are correct, it is very likely that a statistically significant result will be obtained. If the study is too small a real effect may be overlooked. If it is too large, resources will be wasted. It is advisable to consult a statistician for defining the sample size.

Ethical aspects

When research will entail work done on human subjects, indicate whether the procedures to be followed are in accord with the Declaration of Helsinki (www.wma.net/e/policy/b3.htm). Do not start a study until approval from the local ethical committee is received. Furthermore, when experimenting with animals mention what guide lines are to be used and if they comply with the National Research Council's guide for the care and use of laboratory animals (www.nap.edu/readingroom/books/labrats/).

Analysis of results

State how you will analyze the results obtained in order to fulfill your aim. State the comparisons, correlations and exact statistical methods that will be used.

Potential

In this section please explain the likely impact of the study findings on health care delivery. Explain what the results will do for patient care, or how will they improve it, or save money. Clarify how the implications are not limited to the narrow confines of the research, but will be carried across to the wider areas of health care.

References

There are many reference styles in the literature. However, the commonest style used in medical publishing is the Vancouver Style. Regardless of the style any reference system is composed of two parts; citation of the reference in the text and the reference list at the end of the text. It is your responsibility to verify the references against the original documents.

General rules

Number references consecutively in the order in which they are first mentioned in the text. Identify references in text, tables, and legends by arabic numerals (in parenthesis).

Each author's surname should be followed by the initials of all his/her names and the initials should not be spaced. There is no punctuation between surname and initials. Separate successive authors by comas. End the succession by a full-stop. Do not use 'and' before the last author.

When a reference includes six or less authors, list them all. However, if a reference contains seven or more authors, list only the first six and add 'et al'.

When referring to information from manuscripts accepted but not yet published, mention the journal followed by 'in press'. Information from manuscripts submitted but not yet accepted should be cited in the text as 'unpublished observations' (in parenthesis).

For the last page number remove the first digits when repeated from the first page number eg 636-42 instead of 636-642

It is your responsibility and not the editor's/reader's to verify the references against the original documents.

For more and up-to-date information on referencing please consult the ICMJE Uniform Requirements for Manuscripts Submitted to Medical Journals on the following web site: www.nlm.nih.gov/bsd/uniform_requirements.html

العنوان باللغة العربية

Title in English Language (in Times New Roman, Bold, Font Size 14)

Protocol of a thesis submitted to the	خطة بحث مقدمة إلى
Medical Research Institute	معهد البحوث الطبية
University of Alexandria	جامعة الإسكندرية
in partial fulfillment of the	إيفاء جزئيا لشروط
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