Guidelines for writing a research project synopsis or protocol

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"Success is often the result of taking a mis – step in the right direction."

Al Bernstein

A protocol or a synopsis of a research project is a document submitted to an authority or an institution for the purpose of

1. Ethical clearance
2. Formal registration to universities for the award of a degree or doctorate
3. Peer review
4. Financial assistance from organizations like ICMR, DST, NACO, DGHS, and MHRD

Synopsis is the gist of your planned project submitted for approval from competent authorities. It gives a panoramic view of your research for quick analysis by the reviewers.

Thus, a protocol or a synopsis forms an integral part of a research project or a thesis. Many universities have made it mandatory for the postgraduate degree student to prepare a thesis as a part of their postgraduate training. A good knowledge about how a protocol or a synopsis is written is imperative to all people involved in medical research.

Literally, protocol (Greek word, protokollon – first page) means a format procedure for carrying out a scientific research. Synopsis (Greek word, sun – together, opsis – seeing) means brief summary of something. Frequently, both the terms are used as synonyms but the term 'synopsis' is used more often.

A synopsis should be constructed in a manner that facilitates the reviewer to understand the research project at a glance. It should be brief but precise. A synopsis can be structured in the following manner:

1. Title
2. Statement of the problem and hypothesis
3. Aims and objectives
4. Review of literature
5. Research methodology
6. References
7. Official requirements

Title

The title of the research project should be brief but informative; sensationalization of the title is best avoided. It should neither be too short nor too long. Any name of the institution, the number of cases to be studied should not be included. The hypothesis to be studied can be included.

Examples:

a. "Study of ectopic pregnancy"
   This was a title chosen for university registration. The title is too short. It does not state the problem or the hypothesis and is least informative. More meaningful title shall be, "Study of ectopic pregnancy in relation to morbidity, mortality, and intervention in a referral hospital".
b. "A novel sustained release matrix based on biodegradable poly (esteramides) and, impregnated with bacteriophages and an antibiotic shows promise in management of infected venous stasis ulcer and other poorly healing wounds", (Int. J Dermat vol 8 2002). The title is long and ill conceived. It gives a confusing picture about the study problem. Such long titles are best avoided. Certain amount of sensationalization is also present by using term 'novel'. More meaningful title shall be, "Response of venous stasis ulcers and

How to cite this article: Betkerur J. Guidelines for writing a research project synopsis or protocol. Indian J Dermatol Venereol Leprol 2008;74:687-90.

Received: May, 2008. **Accepted:** June, 2008. **Source of Support:** see Acknowledgment. **Conflict of Interest:** None Declared.

other poorly healing wounds to a biodegradable matrix impregnated with bacteriophages and an antibiotic". The other details about the new method can be mentioned while stating the problem.

c. "Fine needle aspiration, as a diagnostic tool for papulonodular skin lesions". This is an acceptable, informative, and precise title. It states the hypothesis correctly.

Statement of the problem or hypothesis

The problem being studied should be mentioned in precise and clear terms. Understanding the problem aids the researcher in constructing the research proposal. It also allows the person to formulate the hypothesis. The problem under study should be relevant to the present. A brief account of its utility at the local or national level has to be discussed. The present status of the problem and the necessity for taking up the study needs to be mentioned.

Hypothesis is mentioned as a tentative prediction or explanation of the relationship between two or more variables. Hypothesis should not be a haphazard guess but should reflect the knowledge, imagination, and experience of the investigator. Hypothesis can be formulated by understanding the problem, reviewing the literature on it, and considering other factors. A researcher can state the problem and the hypothesis in about 200 words covering all the aspects described above.

Aims and objectives

All research projects should have objectives and aims and every effort should be made to achieve them. The objectives and aims should be only a few (2–3). They must pertain to the study problem. Usages of terms like "first study", "the only study", etc. should be avoided.

Review of literature

Review of literature is a very important part of a research project. It achieves the following:

a. Familiarizes the reader to the problem under study.
b. It describes the work done by others either at local or international level on it or similar subject.
c. It helps the researcher to understand the difficulties faced by others and the corrective steps taken or modifications made by them. The researcher can anticipate similar or additional problems during the study and review of literature helps him in anticipating them.
d. Research methodology of the researcher can be structured and modified after reviewing the literature.
e. The review assists in identifying various variables in the research project and conceptualizes their relationship.
f. Review of literature in a synopsis helps the reviewer in assessing the knowledge of the researcher. The reviewer can assess the work put in by the researcher and also assists in assessing the feasibility of the study.

The review of literature in a synopsis need not be exhaustive. The relevant information should be covered in about 300 words quoting 8–10 authentic, easily retrievable references. Literature can be reviewed by using various scientific-information-gathering methods. These are journals, national or international; bulletins of organizations like WHO, CDC, and ICMR; books; computer-assisted searches like Medline and Medlar; and personal communications with other researchers. Internet provides a vast avenue for information gathering. Care must be taken to retrieve only relevant information. In this era of information technology review of literature is literally "just a click away".

Research methodology

In a synopsis the research methodology adopted should be mentioned in about 150–200 words. The research methodology forms the core of the research project. The

Proforma for registration of subjects for dissertation/thesis

1	Name of the candidate and address	
2	Name of the institution	
3	Course of study and subject	
4	Date of admission to course	
5	Title of the topic	
6	Brief resume of the intended work:	
	6.1 Need for the study	
	6.2 Review of literature	
	6.3 Objectives of the study	
7	Material and methods	
	7.1 Source of data	
	7.2 Method of collection of data (including sampling procedure, if any)	
	7.3 Does the study require any investigations or interventions to be conducted on patients or other humans or animal? If so, please describe briefly.	
	7.4 Has ethical clearance been obtained from your institution in case of 7.3	
8	List of references (about 4-6)	
9	Signature of candidate	
10	Remarks of the guide	
11	Name and designation of (in block letters)	
	11.1 Guide	Signature
	11.2 Co-guide (if any)	Signature
	11.3 Head of department	Signature
12	12.1 Remarks of the chairman and principal	Signature

methodology should cover the following aspects:

a. Study design
b. Study settings
c. Sampling
d. Variables
e. Controls
f. Study methods – examinations or investigations
g. Data collection
h. Data analysis
i. Ethical clearance

Study design

The methodology starts with selection of study design. A single study design or a combination can be selected e.g.:

Descriptive designs

Cross-sectional study or survey
Epidemiological description of disease occurrence
Community diagnosis
Study of natural history of a disease

Observational analytical designs

Prospective study
Retrospective study
Follow-up study

Experimental designs

Animal studies
Therapeutic clinical trials – drugs
Prophylactic clinical trials- vaccines
Field trials

Operational designs

Study settings

A mention about the research setting should be made. This includes information about the institution, facilities available, time of study, and population of study.

Sampling

Sampling is selecting a sample of appropriate size for the study. The sample size depends on the study design. The study population can be population of cases, population of people, or population of recipients of certain treatment.

There are many methods for sampling like simple random, systemic and stratified sampling, cluster sampling, etc. Care should be taken to ensure that the sample size is adequate to produce meaningful results. The sample size should be adequate to apply all relevant tests of statistical significance. The samples should be representative of the population and should be reliable. This minimizes sampling errors.

Variables

Variables are the factors that can change. These changes can affect the outcome of a research project. Thus, it is important to identify the variables at the planning stage. They should be quantified with a measurable unit. Knowledge of the various variables in a research project will assist in refining the objectives. Usually, objectives of a research will be to see the effect of independent variables on dependent variables. There are four types of variables.

Independent variables

These are the variables that can be manipulated by the researcher and the effects of that are observed on the other variables. For example, predisposing factors, risk factors and cause.

Dependent variables

The changes occur as a result of independent variables. For example, disease and outcome.

Intervening variables

These may influence the effect of independent variables on the dependent variables. For example, while studying the response of HIV-AIDS to HAART the outcome may be influenced by the presence of antitubercular drugs.

Background variables

These are changes that are relevant in the groups or population under study. These need to be included in the study. For example, age, sex, and ethnic origin.

Controls

Control groups increase the validity of the research project. They usually consist of units of same population but differ in some respects. Controls are not necessary for all research projects. As far as possible they should be used in all analytical studies, drug trials, and intervention programs.

Study methods

Here the researcher will have to describe the method of data collection, which may be in the form of:

1. Questionnaire
2. Interviews
3. Medical examination
4. Laboratory investigations
5. Screening procedures

A sample of the proforma should be prepared and attached.

The possible cost involved and any financial assistance received must be mentioned.

Data collection

A brief note on how data are collected should be included. The information should be about:

1. The organizational setup
2. Training to data collecting team
3. Logistic support
4. Plans for collaboration with other organization should be included

Data analysis

Data analysis is an important part of a research project. A good analysis leads to good results. The plans for data analysis should be mentioned under the following heads Statistical methods, Computer program used, and Data sorting method. A general statement "appropriate statistical methods will be used." must be avoided.

Ethical clearance

Wherever necessary, ethical committee clearance from the institute should be obtained. The certificate must be attached. Ethical clearance is required in all human and animal studies.

References

All references quoted in review of literature and anywhere else in the synopsis should be listed here. There are two styles for writing references, Vancouver style and Harvard style. Vancouver style is easy to follow as it depends on the numbers as quoted in text.

Official requirements

A synopsis is incomplete if it does not contain the following information:

1. Name of the researcher and designation
2. Name and designation of the guide
3. Name and designation of head of department\institution
4. Name of the institution
5. Signatures of all with official seal

Synopsis writing is an important step in a research project. A good synopsis will give maximum information in minimum words. A well-conceived synopsis will go a long way in convincing the reviewer about the ability of the researcher to conduct the project. In cases of need for financial assistance, the request will be considered favorably. Thus, all research workers should make efforts to prepare a well-structured synopsis.

ACKNOWLEDGMENTS

The author is thankful to M/s Jaypee Brothers Medical Publishers for their permission to reproduce this article from the "Handbook on Health Professional Education" published by them.

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