

**NBE GUIDELINES
FOR PREPRATION & SUBMISSION
OF THESIS PROTOCOL**

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1. INTRODUCTION

Research is defined as a systematic methodological scientific approach for basic facts in order to find solutions based on these facts. Research investigations may be carried out in one of two ways: interventional studies (experiments) or non-interventional surveys of naturally occurring phenomenon (descriptive and analytical studies).

It is assumed that the protocol for a research proposal is a study plan, designed to describe the objectives, background, methodology, organization, the participants, interventional procedures and assessment tools of the trial. One may begin to write a clinical protocol after many discussions among numerous individuals. Hence, we can say that the protocol is a self-contained document or the 'operating manual' to refer to while conducting the research related activities.

The style used in writing research protocols depends on the skills and personality of the candidate writing the protocol. He should refer to the Contents of a Thesis Protocol in the (NBE Guidelines) before the writing phase commences. The minimal writing requirements are that the language should be clear, concise, precise and consistent without excessive adjectives or adverbs and long sentences. There should not be any redundancy in the presentation.

After the development of the first draft of the protocol he should read and rewrite as often as necessary before the copies are submitted to other individuals for review. In reviewing one's own draft, it is helpful to question whether (1) each section is placed in the appropriate order, (2) each paragraph within a section is placed in the appropriate order to carry ideas and statements forward smoothly and without gaps or sudden changes in direction or logic and (3) each sentence is having definite meaning and is required for inclusion in the protocol. Introductory phrases at the start of sentences that do not add meaning to the sentence should be deleted. Check for colloquialisms or clichés and replace them with more appropriate terms. Finally, read each sentence by itself, for its connotations as well as denotations, before deciding whether it conveys the intended meaning and should remain in the protocol.

Scientific writing is often made confusing when different terms are used but they have the same or approximately the same definition. Thus a concept such as adverse reactions should be written using the same single term throughout the protocol and not sometimes as adverse experiences, adverse events, medicine reactions, adverse medicine reactions, side effects or untoward effects, unless different definitions are intended. Other examples of when a single word or term should be used throughout the protocol (unless differences are intended and are defined) include (1) medicine or drug, (2) volunteers, patients or subjects (3) clinical study or clinical trial (4) disease, condition or problem (5) case report form or data collection form.

The most obvious technique for improving the quality of the protocol as already stated is reviewing of the protocol as critically as possible by the student. Another established method for improving the quality of the protocol lies with the Thesis Guide and Co – Guide. It is their responsibility to proof read the protocol in terms of both the content and format. Finally the protocols have to be approved by the research committee of the hospital attached and the Ethics Committee.

The development or preparation of the Thesis Protocol by the candidate will help him in understanding the ongoing research activities in his area of interest. Further it helps in creating practical exposure to research and hence it bridges the connectivity between clinical practice and biomedical research. Such research exposure will be helpful in improving problem solving capacity, updating with ongoing research and implementing these findings in clinical practice.

2(a) TITLE PAGE

The general information should be provided on the Title Page as:

i) A good title should be short, accurate, informative, and concise; it should avoid abbreviations. It should also reflect the details of the study undertaken e.g., whether a prospective or a retrospective study / whether a cross-sectional or a randomized trial / whether an equivalence or superiority or inferiority trial etc.? [Titles like: A study on prevalence on asthma in North India (hospital based) should not be encouraged]

ii) The name and title of the investigator who is responsible for conducting the research.

iii) The address and telephone numbers of the site

2(b) PROJECT SUMMARY

The summary should give a clear idea to the reader regarding the central question that the research is intended to answer and also its justification. It should specify the hypothesis (if applicable) and the research objectives. In addition, the summary should briefly describe the methods and procedures laid out in the methodology. The anticipated outcome of the study must also be mentioned.

2(c) INTRODUCTION AND BACKGROUND

This is critical in any protocol. It familiarizes the readers with the background of the issue at hand. It is crucial that this is handled well. It must reflect why the issue is topical and its current importance in the vast sea of research being done globally.

2(d) REVIEW OF LITERATURE

This is another crucial area in a protocol. The review must be precise and concise. Unrelated articles in a review only serve to make the thesis bulky. This is against the trend nowadays. Most universities specify the number of pages the thesis is restricted to. An excellent review of literature brings out the lacunae in literature and helps in generating a research question for the candidate to work on.

2(e) LACUNAE IN LITERATURE

This is the most critical aspect to be tackled while selecting a topic. This reflects the candidate's diligence in reviewing the topic at hand. Only after the topic is reviewed well does the candidate or researcher find out the areas in the selected topic which need answers or are inadequately researched.

2(f) RESEARCH QUESTION

This is vital to any research proposal. Unless a valid question has been formulated by the candidate which seeks a cogent answer the whole exercise may become redundant. ONLY VALID QUESTIONS NEED TO BE RESEARCHED FOR SEEKING THE RIGHT ANSWERS.

2(g) AIMS AND OBJECTIVES

The 'Aims' refers to what would be achieved by this study or how this study would address a bigger question / issue. The 'Objectives' of the research stem from the research question formulated and should at least include participants, intervention, evaluation, design. There should be ideally a primary objective which is the main focus of the research proposal. The secondary objectives are the other aspects in the research proposal which need answers. These may include the adverse effects or the adverse events.

2(h) MATERIAL AND METHODS: This section should include the following:

- (i) Study area: The patient recruitment area (out-patient and / or in-patient of a department in the hospital) must be listed out.
- (ii) Study population: The target population to be enrolled in the study must be defined and then patients are selected from the target population as per the listed out inclusion and exclusion criteria.
- (iii) Sample size: The number of subjects to be recruited into the study must be listed out.
- (iv) Study design: The designs are experimental, descriptive or analytical. A typical experimental design must include whether it is an open label / single blind / double blind study, whether it is an active or placebo controlled and whether it is an cross-over or parallel design (e.g., double blind, placebo controlled, parallel design).

A description of the measures taken to minimize / avoid bias including randomization and blinding, maintenance of randomization codes and procedures for breaking codes must also be listed out.

- (v) Study intervention if any should be listed out in detail.
- (vi) **Study duration:** A description regarding duration of subject participation including follow-up if any and description of discontinuation criteria must be listed out.

- (vii) **Method of measurement of outcome of interest:** The outcome variable (primary and secondary) and its measurements must be defined clearly by avoiding all possible biases. The visits at which these measurements are to be assessed and recorded must be listed out.
- (viii) **Data Collection Methods:** All the definitions of the variables and the quality control issues regarding them must be mentioned.
- (ix) **Data Collection Forms:** All the data pertaining to the research (including the medical history, medication history and physical examination) must be entered onto to the data collection forms directly or transcribed from laboratory or other forms.

2(i) STATISTICAL METHODS

This is also a critical aspect of research. The section on statistics should include the following parts, namely, statistical hypothesis and sample size determination, definition of analysis set, analysis of demographic data and baseline characteristics, analysis of efficacy and safety parameters. The statistics should also define the analysis sets clearly from which conclusions of the study are to be derived. It is important that the candidate decides on a sample size using the statistical formulae. Even if a sample size of convenience is used ultimately (due to time constraints in thesis) this should be reflected in the work.

2(j) ETHICAL CONSIDERATION

It must be noted that the clearance of the research proposal by the Ethics Committee is compulsory for all the studies including the ones without interventions.

2(k) REFERENCES:

Relevant references must be listed out in Vancouver style. The habit of listing cross references without even reading them must be discouraged; sometimes foreign language cross references is quoted. This is wrong. It must be seen that the references are topical and current. The thesis with majority references being very old shows that the candidate has not reviewed the topic well.

2(l) ANNEXURES

The Patient Information Sheet and the Informed Consent Form in English and Vernacular Languages, Questionnaires, Measurement tools, Data Collection Forms, etc. should be enclosed in the Annexure

3. ETHICS COMMITTEE

3(a) It is mandatory to have ethics committee approval before initiation of the research work.

3(b) The researcher should submit an appropriate application to the ethics committee in a prescribed format of the ethics committee concerned. The following documents should be submitted for review:

(i) **Research Protocol:** The research protocol prepared having all the contents required for a Thesis Protocol as per the NBE Guidelines.

(ii) Patient Information Sheet (PIS) in English and / or vernacular languages.

(iii) The protocol must be accompanied by the PIS addressed to the subject that he is being asked to take part in a research study. The information provided to him should be in simple language which he can read and understand so that he can decide to take part in the study or refuse to take part in the study after discussing with his family doctor or his family members. The PIS must include information on the following and a copy of this must be given to the subject:

1. What is the background to and purpose of the study?
2. Do I have to take part?
3. What will happen to me if I take part?
4. What do I have to do?
5. What are the possible side effects, risks and discomforts of taking part?
6. What are the possible benefits of taking part?
7. What if new information becomes available?
8. What are the costs of taking part?
9. How will my personal data be used?
10. Will there be provision for free treatment for research related injury?
11. Will compensation be paid to the subjects if disability or death results from such injury?
12. Whom should I contact if I need more information or help?

(iv) Informed Consent Form (ICF) in English and / or vernacular languages:

The subjects informed consent should be taken on the form that he or his legally acceptable representative can read and understand. The format of the ICF must be as follows:

INFORMED CONSENT FORM

Subject identification number for this trial _____

Title of the Project: _____

Name of the Principal Investigator _____ Tel. No. _____

I have received the information sheet on the above study and have read and / or understood the written information.

I have been given the chance to discuss the study and ask questions.

I consent to take part in the study and I am aware that my participation is voluntary.

I understand that I may withdraw at any time without this affecting my future care.

I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible persons (ethics committee members / regulatory authorities). I give access to these individuals to have access to my records.

I understand I will receive a copy of the patient information sheet and the informed consent form.

Signature / Thumb Impression of subject

Date of signature

Printed name of the subject in capitals

Signature / Thumb Impression of legally
accepted representative

Date of signature

<<The legally acceptable representative signature should be added if the subject is a minor or is unable to sign for themselves. The relationship between the subject and the legally acceptable representative should be stated. The impartial witness

signature should be added if the subject / legally acceptable representative is unable to read or write and consent should be obtained in his presence.>>

Printed name of legally acceptable representative in capitals

Relationship of legally accepted representative to subject in capitals

Signature of the person conducting the
informed consent discussion

Date of Signature

Printed name of the person conducting the
Informed consent discussion in capitals

Signature of impartial witness

Date of signature

Printed name of the impartial witness in capitals

- (v) Researcher's Current CV
- (vi) Any Amendment(s) to the Protocol / PIS / ICF: The amendment (s) made to the protocol / PIS / ICF can be incorporated in the research plan only after getting the ethics committee approval.

4. PROTOCOL SIZE:

The thesis protocol should be restricted to about 12-15 pages. The suggested format should include:

4(a)	Title and details	1 page
4(b)	Synopsis	1/2 - 1 page
4(c)	Introduction and Background	1-2 pages
4(d)	Review of literature and lacunae	2-3 pages
4(e)	Research question and Aims and Objectives	1 page
4(f)	Material and Methods	2-3 pages
4(g)	References	2-3 pages
4(h)	Data Collection Forms, PIS, ICF & mandatory certificates	4-6 pages