Writing Thesis Protocol

Dr. Dheeraj Shah, Reader, Department of Pediatrics

Dr Anil Arora, Professor of Orthopedics

The first step towards acquiring a post graduate thesis is the writing of a thesis protocol and the presentation of the same to the research/thesis committee for a critical appraisal. The protocol needs to be corrected according to the suggestions given by the committee. Finally, it needs to be approved by the University. The thesis protocol is then considered an official document and the thesis work needs to conform to the same.

General Guidelines

Following are the general guidelines of University of Delhi, for starting your work on protocol (and thesis)

1. The feasibility of conducting the study within available resources (especially financial) and time frame shall be considered.
2. In case of interventional studies involving animal or human subjects, the projects and concerned department should fulfill the ethical and other requirements necessary for human/ animal experiment, and necessary approval should be obtained as required under rules and regulations in force.
3. The project design should satisfy the statistical requirements in respect of sample size, and proposed analysis of data (*wise to discuss your study with statistician before finalizing*).

4. It must be ensured that the same thesis topics are not repeated year after year. The thesis-protocol must accompany a disclosure/ explanation if a similar study has been undertaken already under University of Delhi during last five years.

The recommended format of Thesis-Protocol is as follows:

Title Page	Page- 1
Certificate from Institution	Page-2
Introduction/ background including lacunae in existing knowledge	Page-3
Brief review of literature	Page-4-6
Objectives of research project	Page-7
Patients/ Subjects/ Materials and Methods including plan of statistical evaluation	Page-8-10
Index of references (Vancouver system of references)	Page-11-12
Appendix, if any (Consent Form, Data Sheet etc.)	

Other technicalities:

- Four copies to be submitted
- Pages: Generally should not exceed 12 (can add appendix)
- Font size:12
- A4 size paper
- Line spacing: Double space
- Margins: At least 2.5 cm on both sides
- Pattern: Justified

Structure of the Protocol

New PG students should look into the departmental library for PG theses and protocols submitted in the previous years. They can study the form which is standardized. The protocol needs to be written in a systematic manner. A well-written protocol makes the job easy for the evaluation committee. Avoid spelling and grammatical errors and write the references in a uniform style. The structure of a thesis protocol usually consists of the following elements:

A. Title page

This page carries:

- Title of thesis (Write in title case or capital letters)
- Name of the University
- Degree (with discipline) for which the thesis is being submitted
- Years of the batch under the name of candidate
- Name and Signature of Candidate
- Name and Signature(s) of Supervisor and Co-supervisor(s)

It is very important to avoid any spelling mistakes in this page as it may lead to the problems matching with final thesis report at the time of submission. An example of the cover page is given at the end of this chapter:

B. Introduction Section

Function

- To establish the context of the work being reported. This is accomplished by discussing the relevant available literature (with citations) and summarizing our current understanding of the problem you are investigating;

- State the purpose of the work in the form of the hypothesis, question, or problem you investigated; and,
- Briefly explain your rationale and approach and, whenever possible, the possible outcomes your study can reveal.

The Introduction must answer the questions

- What am I studying?
- Why is it an important question?
- What do we know about it before I do this study?
- How will this study advance our knowledge?

Style

Use the active voice as much as possible. Some use of first person is okay, but do not overdo it.

Structure

The structure of the introduction can be thought of as an inverted triangle - the broadest part at the top representing the most general information and focusing down to the **specific problem** you will study. Organize the information to present the more general aspects of the topic early in the introduction, then narrow toward the more specific topical information that provides context, finally arriving at your statement of purpose and rationale.

- Begin your Introduction by clearly identifying the subject area of interest. Do this by using key words from your Title in the first few sentences of the Introduction to get it focused directly on topic at the appropriate level. This ensures that you get to the primary subject matter quickly without losing focus, or discussing information that is too general.
- Establish the context by providing a brief and balanced review of the pertinent published literature that is available on the subject. The key is to summarize (for the reader) what we know

about the specific problem till now. This is accomplished with a general review of the primary research literature (with citations) but should not include lengthy explanations that you will probably discuss in greater detail later in the discussion. Lead the reader to your statement of purpose/hypothesis by focusing your literature review from the more general context (the big picture-i.e. importance of infant feeding practices to their overall growth and development) to the more specific topic of interest to you (e.g., effect of consistency of foods on total caloric intake)

- What literature should you look for? Latest Review articles or systematic reviews on the related topic are particularly useful because they summarize all the research done on a narrow subject area over a brief period of time (a year to a few years in most cases).
- Provide a clear statement of the lacunae in the current status of knowledge.
- Then state briefly how you will approach the problem. Do not discuss here the actual techniques or protocols used in your study (this will be done in the Materials and Methods).
- Be sure to clearly state the purpose and /or hypothesis that you will investigate. It is most usual to place the statement of purpose or hypothesis near the end of the introduction, often as the topic sentence of the final paragraph. For example: 'This study will investigate the effect of varying consistencies of complementary feeding on total caloric intake in breastfed infants' 'The purpose of this study is to determine the effect of enzyme concentration on the reaction rate of .....'

The hypothesis is the explanation you are proposing for certain observations. It is a tentative answer to the question you have posed above. It should be accompanied by a prediction of results expected under certain conditions if the hypothesis is correct. It is not necessary to use the words "hypothesis" or "null hypothesis", since these are usually implicit if you clearly state your Research Hypothesis.

Writing thesis protocol: Dr Dheeraj Shah, Prof Anil Arora

C. Aim and objectives Section

Aim is a broader term- this is what the study intends to fulfill.

The study fulfills its aim by achieving certain ***objectives***.

Example:

Aim: "To evaluate the effect of zinc supplementation during pregnancy on birth weight of newborns"

Objectives: the above aim will be achieved by

- Comparing the birth weights of live born babies in the zinc supplemented and placebo groups
- Comparing the proportion of small-for-gestational age babies born to mothers in zinc supplemented or placebo groups

Aims and objective should be clearly defined and specific.

D. Review of Literature Section (Discussed in detail elsewhere)

What is the current knowledge about the subject of study? In what ways the problem has been approached by others and what are the results? Are the reported studies contradictory? What are the lacunae in the existing knowledge?

E. Material and Methods section

When (……..to ……..) and *where* the study will be carried out.

- *Type of study*- Prospective/Retrospective. Descriptive or analytical. If analytical, whether observational (cohort, case-control or cross-sectional) or interventional (RCT, cross-over)
- *Subjects*
- Target population (Define Subjects of your study)
- How will be the subjects chosen- age group, sex- Why being specific?

- Any control group
- Sample size- basis of this number
- Place where subjects will be recruited from
- Inclusion criteria- Define ages, criteria for defining disease condition / normalcy
- Exclusion criteria- Subjects who otherwise are eligible for inclusion but would be excluded because of possibility of introducing bias.
- *Method of Randomization* - How Randomized? How allocation concealment or/and blinding is done?
- *Intervention/Procedure*
- Detail if using a new method or else quote standard reference if anybody else has already described the method you are going to use.
- Make sure to describe any modifications you have made of a standard or published method.
- Quantitative aspects- masses, volumes, incubation times, concentrations, machine specifications (include manufacturer's name and address e.g Genzyme, Adelaide Australia)
- Frequency and duration of intervention.
- Procedures and *schedules* of examination / investigations / treatment, and observation of outcome measures.
- Dosage, formulations, schedules, duration of drug treatments, if any
- *Withdrawal criteria*
- Rules for withdrawal must be pre-defined, no bias
- Define procedures to handle protocol violators and dropouts, withdrawals, therapy failures
- *Outcome measures (like union of fracture, hemoglobin, birth weight etc.)*

Mention who will make the assessments and using what tools. Methods of observation and quantification, should be measurable, specific, sensitive, reproducible. Ensure quality control of assessments.

Primary Outcome Measures

- On which sample size is based
- On which study hypothesis is based
- Main thrust of interest

Secondary Outcome Measures

- Other outcomes of possible interest

- Statistical analysis
  - Use of pre-defined statistical methods
  - Level of significance or the level of confidence

Style

The style in this section should read as if you were verbally describing the conduct of the experiment and if anybody wants to repeat your study, he or she can actually do it Remember to use the future tense throughout - the work being reported is **to be** done,

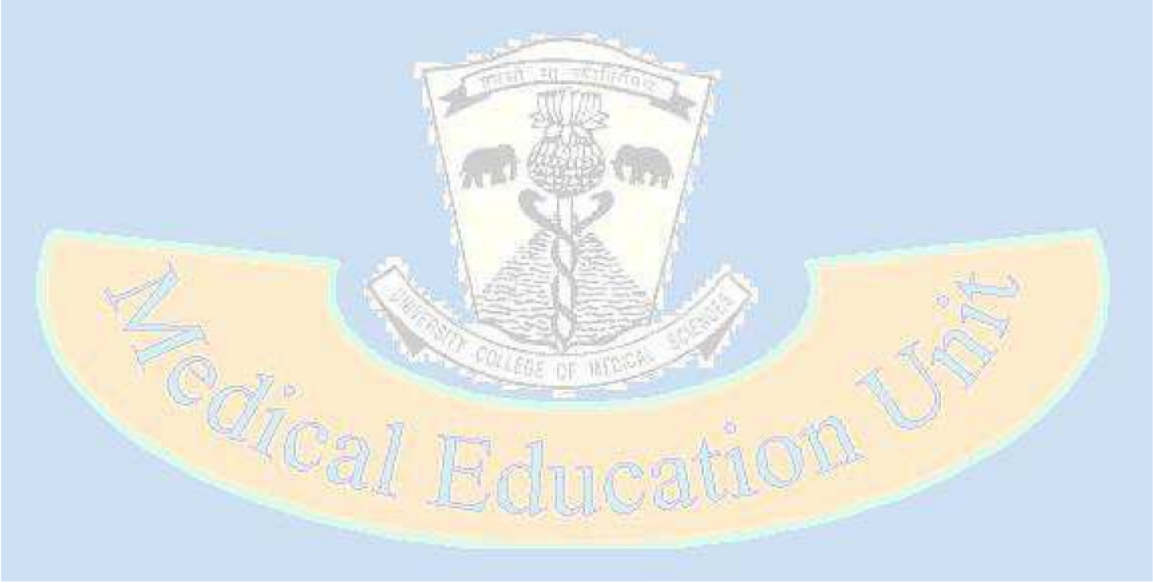
F. References Section (Discussed in detail elsewhere)

G. Case Record Form (Clinical Data Sheet)

- The data sheet will have
  - Information about the subject
  - Information about the procedure carried out
  - Outcome measure(s) at predefined interval

- Your observations and comments about that very particular case

- Must capture required, relevant, accurate and analyzable data.
- The case record form will vary, according to the study.
- *The CR number or identification number of the patients should be printed as the first item on the case record form if study is hospital based.*



Sample case record form (Example)

CASE RECORD FORM

CR No.: Case No.:

Name:

Age/Sex:

Date of admission:

History:

General Physical Examination:

Local Examination:

Investigations

(a) Hb

(b) Urine-Routine/Microscopic examination

X-ray:

- X-ray of involved thigh with hip and knee (A/P and Lateral view)

Type of fracture:

1. Transverse 2. Segmental 3. Oblique 4. Spiral 5. Comminuted (Winquist Type 1/2)

Randomization no:

Operative procedure:

- Reduction and stabilization with TENS
- Reduction and stabilization with Rush nail

Duration of surgery:

Postoperative follow up:

Day 1 :

- Post operative radiological evaluation Comment
- Limb length measurement

3 Weeks :	
• Pain/Tenderness at fracture site	yes/no
• Radiological evaluation	comment
• Limb length measurement	
3 Months :	
• Radiological evaluation	comment
• Hip and knee range of motion	
• Limb length measurement	
• pain and tenderness at nail entry site	yes/no
6 Months :	
• Radiological evaluation	comment
• Hip and knee range of motion	
• Limb length measurement	
• pain and tenderness at nail entry site	yes/no
Observations/Comments:	

Informed consent

Before requesting an individual's consent to participate in research, the investigator must provide the individual with the following **information in the language he/she is able to understand.**

- Title of the research project
- The identity of the research teams with address and phone number of contact person/s
- The aims and methods of the research
- The expected duration of the subject's participation

- The benefits that might reasonably be expected as an outcome of research to the subject or to others
- Any alternative procedures or courses of treatment that might be as advantageous to the subject as the procedure or treatment to which he/she is being subjected
- Any foreseeable risk or discomfort to the subject resulting from participation in the study
- The extent to which confidentiality of records could be maintained
- Responsibility of investigators
- Whether free treatment for research related injury by the investigator/institution will be provided
- Whether any compensation/reimbursement/insurance cover for participation or risk involved
- Freedom of the individual to participate and to withdraw from research any time without penalty or loss of benefits which the subject would otherwise be entitled to
- Publication, if any, arising out of this research.

Sample informed consent form

I _____ r/o _____ age _____ give my free and voluntary consent to be included in the above mentioned clinical study. I have been explained to my full satisfaction the nature and purpose of treatment and possible complications by one of the treating doctors, Dr._____. During the course of the study, I also give my voluntary consent to undergo any blood or radiological investigation and any other relevant investigation and clinical photography required for the study. I will abide by the prescribed medication regimen and other instructions. I will present myself / patient at the designated time and place in the hospital during study follow-up. During the course of the study I will immediately inform about any adverse events related to my treatment. I will give my cooperation to the concerned treatment doctor and the hospital staff. I give my consent for publication of the results of the study. I will not seek any reward or compensation for the study. I have been explained that I can withdraw from the study at any time of my own will without any adverse effect on my treatment.

I also give my voluntary consent to be enrolled in either treatment group (drug or placebo *as the case may be*) depending upon the randomized allocation.

Signature/Thumb impression **Date and time**

Patient's Name

( ) _____ _____

Or

Parent's / Guardian's name

( ) _____ _____

Name of witness

( ) _____ _____

Name of doctor

(Dr.) _____ _____

Sample Title Page

Protocol of Thesis to be submitted to the _(Name of University)___

towards the partial fulfillment of the requirement for the

Degree of _____MD/MS (Discipline)_____

(Batch __Year-Year_____)

Title of Thesis

Name of student:_____

Signature_____

Name of Supervisor:_____
(along with designation and affiliated department)

Signature:_____

Name of Co-Supervisor(s):_____
(along with designation and affiliated department)

Signature:_____

Name of Department and Institution