
GUIDELINES FOR WRITING A MD (Paediatric) THESIS RESEARCH PROTOCOL FOR THE DEPARTMENT OF CHILD HEALTH, INSTITUTE OF MEDICINE, MAHARAJGUNJ CAMPUS.

(Also applicable for other MD thesis).

The success of any thesis depends greatly on this stage which generally takes several weeks. The aim of these guidelines is to provide postgraduate students at the Department of Child Health, with a general outline on how to write a MD thesis protocol. The list of recommendations given below will greatly facilitate MD students to start the MD thesis work smoothly. This article supplements the article, How to Write a MD Thesis, written by Prof Pushpa R Sharma (available in the PDF format at the HealthNet: health resources of Nepal:Thesis). It may be useful to prepare a standard document format with the following headings then fill in the different sections as new protocols are written.

1. SYNOPSIS (1 page)

Rationale and objectives: less than 8 lines. Materials, methods and principle evaluation criteria: less than 8 lines. Expected results and possible implications: less than 8 lines.

2. RATIONALE

- 2.1. Presentation of the problem.
- 2.2. Data in the literature (with references).
- 2.3. Reasons for conducting the work in light of current knowledge and local situation.

3. OBJECTIVES

- 3.1. Main objective.
- 3.2. Hypothesis or hypotheses to be tested +++ (needed to calculate sample size)
- 3.3. Secondary objective(s) (optional)

4. EXPERIMENTAL DESIGN

- 4.1. Volunteers (healthy subjects and/or patients), number of subjects, source of recruitment.
- 4.2. Inclusion criteria
- 4.3. Non-inclusion criteria:
 - 4.3.1. Concerning past history, concomitant diseases.

- 4.3.2. Concerning the study subjects.
- 4.4. Experimental protocol
 - 4.4.1. Type of trial (controlled or uncontrolled; open or blind; cross-sectional or longitudinal).
 - 4.4.2. Study design (optional)
 - 4.4.2.1. Treatment(s) (formulation, dosage, times per day, duration).
 - 4.4.2.2. Reference treatment or placebo.
 - 4.4.2.3. Randomization method.
 - 4.4.3. Study procedures (clinical and biological procedures with the time schedule): what is done, who does it, when.

5. NUMBER OF SUBJECTS INCLUDED

The sample size, or the number of subjects included, depends on the *alpha* and *beta* risks accepted, on the degree of difference between the principal evaluation criterion to be demonstrated between the groups, and on the variance of this criterion in the control group. These figures should be established consulting a statistician. (Dr. Mahesh Maskey or Mr Chitra Kumar Gurung in the Department of Community Medicine could be contacted).

6. ANALYSIS METHODS AND PARAMETERS MEASURED

- 6.1. Strategy for statistical analysis (which parameter should be compared and correlated with which other parameter).
- 6.2. Statistical tests used for each analysis and the rationale for the analysis.
- 6.3. Place where data analysis is performed and software used.

7. MATERIALS AND METHODS

- 7.1. Subject compliance to treatment (assessment method) (as applicable).
- 7.2. Observation diary. +++ (who keeps the diary; who comments).
- 7.3. Drug use (if applicable).
- 7.4. Written informed consent (to be obtained).
- 7.5. Study monitor (optional).
- 7.6. Quality assurance (who monitors quality and with what methods).

8. STUDY DURATION

(indicate the planned duration of the entire study and the planned duration of participation for each included subject).

9. STUDY CENTER

(indicate whether the place is authorized for the thesis works).

10. STUDY BUDGET

11. FINANCIAL SOURCES Indicate that financial support is ensured.

12. BIBLIOGRAPHIC REFERENCES