PT. B. D. SHARMA UNIVERSITY OF HEALTH SCIENCES, ROHTAK

E-mail
Speed Post

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To

Directors/Principals
of all constituted/affiliated
Medical & Dental institutions,
of UHS, Rohtak

Sub. Format of Thesis Protocol for Post Graduates.

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The 'Format for Thesis Protocol' for Post Graduates approved by the University authorities is enclosed herewith for implementation please.

23/7/2018

Encl: As above

Superintendent (Acad.)
For Dean Academic Affairs

STRUCTURE OF THE PROTOCOL

The submitted protocols should consist of the following sections in sequence:

- Title page: Signed by candidate
- Certificate from supervisor and co-supervisor(s)
- Ethical justification
- Declaration form by Postgraduate/candidate
- Introduction
- Review of literature
- Aim and Objectives
- Materials & Methods
- Statistical Analysis
- Consent Form
- Patient Information Sheet (PIS)
- References
- Annexures
- Proforma

Every section should start on a separate page.

FORMAT FOR THESIS PROTOCOL
(Ideally not to exceed 15-20 pages)

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(1. Senior Professor, dept of Pediatrics, 2. Senior Professor, dept of Psychiatry, 3. Professor, dept of Anaesthesia, 4. Senior Professor, dept of Medicine, Pt B.D. Sharma, UHS, Rohtak)

Ideally thesis protocol should be presented in a departmental faculty meeting and later institutional board and ethical meeting for constructive inputs, modified and submitted well in time as per university protocol/guidelines. It should then be approved by the Institutional Ethical Committee.

A. Cover page Title (See annexure)

B. **Title should be;**

- Informative (declarative, descriptive, indicative, neutral or interrogative), sharp, & concise
- Preferably one sentence (nominal, compound or full sentence)
- Succinct
- Relevant
- Avoid abbreviations and question mark
- Not more than 12-16 words and 150 characters
- Use key words in the beginning
- SPICED (Setting, Population, intervention, Condition, End-point, Design)
- Research question + research design + population + geographic area of study (what, how, with whom, where).

C. Introduction/Background (1-2 pages)

a. Describe briefly the problem under consideration (disease/ condition), current status and its significance.

b. Discuss about 'What is known?' and 'What are the gaps or lacunae?'

c. Write about the research question, rationale, hypothesis and its importance. How would answering this research question modify the current state of knowledge?

d. Conclude this section by stating what the proposed plan is to answer the question.

e. Definition(s), if any.

D. Review of Literature:

a. Summarize the background knowledge about the magnitude of the problem under consideration.
b. Discuss the relevant pathophysiology/issues under consideration (Do not include textbook material- very obvious facts).
c. Review available studies on the subject/intervention related to research question (not more than 10 years old references).
d. Approach by other researchers.
e. Analyse the findings and do not copy/paste the abstract.
f. Identify relevant gaps and lacunae in the knowledge
g. This will facilitate writing a para on 'Rationale for the study. Try to answer Why?
h. List literature in chronological orders
i. Presentation of review of literature should be in Vancouver Style and names of authors should be avoided in text and the reference number should be super-scribed at the end of each sentence preceded by full stop.
j. It is good to provide a summary table of the relevant studies.

Authors Journal Year	Objective	Design	Characteristics of the participants Sample size	Methods	Outcome measures	Results	Strengths	Limitations

E. Research Question

a. Preferably as question format and not a statement
b. Clear, focused, and precise
c. Use PICOT(S) to frame the question (Population, Intervention, Control, Outcome, Time frame, Study design)
d. S.M.A.R.T.- Specific, Measurable, Achievable, Relevant, Time format.

F. Aim and Objectives

a. 'Aim' refers to what would be achieved by this study or how this study would address a bigger question or issue.

b. 'Objective' refer to 'what you would actually do in this study.

   I. Primary objective refers to your main research question (primary outcome) and is the basis for the sample size. Only one or two objectives should be framed.

   II. Secondary objective refers to additional questions which is usually used for 'generation of hypotheses'.

c. Should be SMARTPICO and ethically viable

d. It will be good to provide a table in the following format.

Objectives	Outcomes	Method of measurement of Outcome

G. **Flow diagram of study** including time frame should be displayed

H. Details of Methodology

a. Study design and setting

   I. Descriptive (case series, case-control, cohort) or Prospective or Retrospective or Observational

   II. Analytical

   III. Interventional (random, non-random)

b. Study period

c. Study subjects: Inclusion and exclusion criteria with definitions

d. Sample size: For different types of study different formula will be used. http://clincalc.com/stats/samplesize.aspx https://www.cmrp-journal.com/article/S2352-0817(14)00040-3/pdf

   I. Basis of sample size: Based on primary outcome or assumptions. May be prevalence, odds ratio, risk, benefit.

   II. How many subjects?

   III. Correct for estimated drop outs if any during study

For further reading on sample size calculation
http://www.ijpm.info/text.asp?2013/35/2/121/116232
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4017493/
https://www.sciencedirect.com/science/article/pii/S2352081714000403

e. Method of recruitment
f. Randomization, if applicable
    Sequence generation
    Allocation concealment
g. Blinding/ masking
h. Intervention if any- discuss in detail
i. Record the co-interventions/ confounders
j. Follow up of the study participants, if applicable. If there are multiple measurements, it is good to provide a table with the measurements and the time. Below is an example:

Assessment	Week 0	Weeks 4,8, 16, 20	Week 12	Week 24
Clinical evaluation	√	√	√	√
Anthropometry	√		√	√
Haemoglobin	√		√	√

k. Method of measurement of Outcome of interest- Outcome variable (Primary and secondary) clearly defined; measurements to be defined clearly; avoiding all possible biases
l. Study questionnaire and formats: Prepare to include all the required information in a systematic manner (placed in annexure)
m. Data collection methods
    i. Define all variables
    ii. Quality control issues
n. Data management and statistical analysis
    i. Describe procedure to enter data
    ii. Software to be used for data entry and statistical analysis
    iii. Handling of missing data
    iv. Prepare dummy tables for data analysis

I. **Ethical consideration-** Compulsory for all studies, even the one without intervention, even for questionnaires.

J. **References: Use Vancouver style** and follow ICMJE guidelines. For further reading available at
http://www.nlm.nih.gov/bsd/uniform_requirements.html
http://www.nlm.nih.gov/citingmedicine
https://www.imperial.ac.uk/admin-services/library/learning-support/reference-management/vancouver-style/citing/
https://guides.lib.monash.edu/citing-referencing/vancouver

K. **Annexures:** Questionnaires/ Measurement tools, etc and these should be numbered with clear mention of the same in the text also.

L. **Patient/ parent information sheet and Consent form**: Both in English and local languages.

GENERAL GUIDELINES

- Font Type: Times New Roman, Calibri, Arial, Tahoma, Verdana, San-serif
- Font size: Text 12 point, sub-heading 14 point, heading 16 points, and Table body: 10 point
- Spacing: 1.5 for body of thesis or 1.0 for references
- Margins: Left 3cm, right 2.5cm, top and bottom 3.0cm
- Page number: Right upper border 1.3cm below and 2.5cm medial to page
- Paragraph spacing: 9-12 point (97.5 to 100% of font size)
- Paper: $8^{1/2}$ X 11 inches (A4) Print on both sides of page for the body of thesis.
- Page Numbering: Title page should be numbered as "i" and continue in alternate Roman numerals till introduction. From Introduction onwards numbering is done with Arabic numerals.
- To submit six monthly report.
- The system of references should be in accordance with the Vancouver Style and with the American National Standard for Bibliographic References. **Limit the number of references in the thesis plan to 20.**
- Do not use bold and underline together.
- All pages of the plan are to be signed by the candidate with date.
- Keep in mind you will require a master chart compiling your data for thesis

Annexures

Title Page

NAME OF YOUR INSTITUTE

Protocol of Thesis to be submitted towards partial fulfilment of the requirement for the Degree of: MD/MS/M.Ch/DM/Other (Subject..)Examination

1.	Name of the Candidate	:	
2.	Father's Name	:	
3.	Address of candidate	:	
4.	Name of University from which graduated	:	
5.	Year and month of passing MBBS Examination	:	
6.	Date of joining M.D. course	:	
7.	Proposed subject of thesis	:	
8.	Facilities for work on the subject	:	All facilities exist at Pt. B.D. Sharma, PGIMS, Rohtak /(Your college)
9.	Detailed scheme according to which candidate proposes to work	:	Plan attached
10.	Name and address of Supervisor	:	
11	Name and address of Co-supervisor	:	

Signature of Candidate

CERTIFICATE OF SUPERVISOR

I/We certify that all facilities for the study on the subject of thesis entitled "xxxxxx" exist in PGIMS, Rohtak/(Your college) and these shall be provided to candidate (..Name..) in pursuance of his/her plan of thesis. I/We shall guide the candidate in his/her work and shall ensure that the data being included in the thesis are genuine and that the work is being done by the candidate himself/herself.

(Signature of Supervisor)
Name and Designation

(Signature of Co-supervisor)
Name and Designation

ETHICAL JUSTIFICATION

The proposed study entitled "----------"

Informed written consent will be taken from all the subjects. No drugs/drugs will be administered during the study. No invasive/invasive procedures will be done on the subjects. All the procedures including the drugs used in the study do not carry any harmful effect on the patients. Thus the present study is well within the ethical norms and is ethically justified.

Signature of Candidate

Name and Signature of

SUPERVISOR

Name and Signature of

CO-SUPERVISOR

Name and Signature of HOD

with full details

Declaration by the Postgraduate Student

I hereby declare that:

1. The study will be done as per Institutional protocol and guidelines.
2. Study shall be initiated only after clearance from institutional ethical committee.
3. Written, Informed consent of the patients/control (volunteers) will be obtained.
4. In case of children and mentally handicapped both patients/control (volunteers) written informed consent of the parents/care givers will be obtained.
5. The probable risks involved in the study will be explained in full to the subjects/parents/care givers in their own language.
6. I will terminate the study at any stage, if I have probable cause to believe, in the exercise of the good faith, skill and careful judgement required for me that continuation of the study/experiment is likely to result in injury/disability/death to the subject.
7. Disclosure:

i. Financial/ funding	(None)	(Yes)
ii. Conflict of intrest	(None)	(Yes)
iii. Association	(None)	(Yes)

if any of these is yes please disclose in full

Date: _____

(Signature of PG Student)

Department

Signature of Supervisor

Department

PATIENT INFORMATION SHEET (PIS)
(it is must to have PIS in patients language also. E.g. Hindi)

The protocol must be accompanied by the Patient Information Sheet addressed to patient. The Informed Consent Form to be used in the study should be signed by two witnesses. While formulating the patient information sheet, investigator must provide the subjects with the following information in simple language, which can be understood by subject.

- Aim and methods of the project or research work
- Expected duration of the participation of the subjects
- Any benefits to be expected from the research
- Any risk to the subject associated with the work
- Maintenance of confidentiality of data and record
- Provision of free management for research related damage
- Compensation of subjects for disability or death resulting from such damage
- Freedom of subject to participate in the study/project and to withdraw from research at any time without any reason and no harm will be done
- Explaining intervention/detail/risk of procedure
- Telephone number and address of the candidate and one of the investigators must be mentioned
- Patient should be informed that the data obtained in the study and photograph, if taken, will be published in the journal. The identity of the subject and confidentiality of the data will be ensured

INFORMED CONSENT FORM
[In English and Hindi (local language)]

Protocol / Study number: _____
Patient identification number for Thesis: _____
Title of project: _____
Name of Investigator: _____ Mobile No. _____
The contents of the information sheet dated ..... (Version)..... that was provided have been read carefully by me / explained in detail to me, in a language that I comprehend, and I have fully understood the contents. I confirm that I have had the opportunity to ask questions. The nature and purpose of the study and its potential risks / benefits and expected duration of the study, and other relevant details of the study have been explained to me in detail. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal right being affected.
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 individuals from ..... or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records, to present in meetings & conferences, and publication if desired.
I agree to take part in the above study.

---------- Date:
(Signature / Left Thumb Impression) Place:

Name of the Participant: _____
Son / Daughter/wife: _____
Complete postal address: _____

This is to certify that the above consent has been obtained in my presence.

Signature of Investigator Date: Place:

Witness – 1

Signature
Name of supervisor and co-supervisor with designation

Witness – 2

Signature

CASE RECORD FORM

The patient's "Case Record Form" should be annexed in the end of the protocol. It may have following sections.

- Identification: Like serial number, randomization number, name, age, sex, address, tel. no. etc.
- Clinical Profile
- Data entry