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

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Ideally This should be presented in a Faculty meeting , for constructive inputs modified and submitted well in time to Academic Section

Suggestions: Preparation of thesis protocol is a teaching-learning exercise for PG students. The thesis protocol may be presented first in the department where all Residents and faculty are present. They all can ask questions which should be answered by the candidate and supported by the Supervisor. The protocol after incorporating the changes should be presented in the PG committee/Faculty meeting. It should then be approved by the Ethical committee.

A. Cover page as per institution policy with Title

B. **Title**

1. Informative
2. Preferably one sentence
3. Succinct
4. Relevant
5. Avoid abbreviations

C. Introduction/Background (1-2 pages)

a. Describe the problem under consideration (disease/ condition) briefly.

b. Discuss about 'What is known?' and 'What are the gaps?': Should clearly summarize the 'Review of Literature'.

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

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

D. Research Question

a. Preferably as question format and not a statement

b. Clear, focused, and precise

c. S.M.A.R.T.- Specific, Measurable, Achievable, Relevant, Time format

E. Review of Literature: Following sections are suggested.

a. Summarize the knowledge about the magnitude of the problem under consideration (disease/ condition).

b. Discuss the relevant pathophysiology/ pathology (do not include textbook material- very obvious facts)

c. Review available studies on the subject/ intervention related to research question. **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

d. Write a summary of the review- 'What is already known about the subject?' preferably in bulleted points. Classify as level of Evidence * study designs

e. Identify relevant gaps and lacunae in the knowledge
f. This should facilitate writing a para on 'Rationale for the study' Try to answer Why ? .

F. <u>Aims and Objectives</u>

a. 'Aims' refer to what would be achieved by this study or how this study would address a bigger question/ issue.
b. 'Objectives' refer to 'what you would actually do in this study. Should be should have PICO (participants, intervention, control and outcomes).
c. Primary objective refers to your main research question(primary outcome _) and is the basis for the sample size.
d. Secondary objective refers to additional questions which are usually for 'generation of hypotheses'.
e. It will be good to provide a table in the following format

Suggestion: It is advisable to have specific one or two objectives in the study. The PG has to study, do clinical work up and emergency duties. Study should be such that can be completed in the stipulated time with ease.

Objectives	Outcomes	Method of measurement of outcome

G. <u>Flow diagram of study including time frame</u>

H. <u>Detailed Methodology</u>

a. Study design and setting
  i. Descriptive] Prospective or Retrospective
  ii. Analytical]
  iii. Interventional]
  iv. Observational
b. Study period
c. Study subjects: Inclusion and exclusion criteria with definitions
d. Sample size:
  i. Basis of sample size: the assumptions for the calculation should be stated clearly based on primary outcome or valid assumptions made. Like for each risk factor at least ? 8 subjects
  ii. How many subjects?
  iii. Correct for estimated drop outs if any during study
e. Method of recruitment
f. Randomization, if applicable
  i. Sequence generation
  ii. Allocation concealment
g. Blinding/ masking
h. Intervention if any- discuss in detail
i. Record the co-interventions/ confounders

j. Follow up of the study participant, 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	√		√	√
Hemoglobin	√		√	√

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.** Missing data handling
- **iv.** Prepare dummy tables for data analysis

I. <u>Ethical consideration</u>- Compulsory for all studies, even the ones without intervention, even for questionnaires.

J. <u>Competing interest if any-</u> disclose source of funding, association etc.

K. <u>References:</u> Use Vancouver style and be numbered as appear in the text.

L. **<u>Annexures:</u>** questionnaires/ measurement tools, etc.

M. <u>Patient/ parent information sheet and Consent form:</u> Both in English and local languages.

PATIENT INFORMATION SHEET (PIS)

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 them.

i) Aims and methods of the research
ii) Expected duration of the subject participation
iii) The benefits to be expected from the research to the subject or to others
iv) Any risk to the subject associated with the study
v) Maintenance of confidentiality of records
vi) Provision of free treatment for research related injury
vii) Compensation of subjects for disability or death resulting from such injury
viii) Freedom of individual to participate and to withdraw from research at any time without penalty or loss of benefits to which the subject would otherwise be entitled.
ix) Amount of blood sample to be taken should be mentioned in PIS in ml
x) Costs and source of investigations, disposables, implants and drugs / contrast media must be mentioned in the PIS.
xi) Telephone number/contact number of the candidate and one of the investigator must be mentioned in the PIS.
xii) **Suggestion:** 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.

CASE RECORD FORM

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

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

MASTER CHART

Entire data should be attached with the thesis at the end in the form of annexure. It should be mentioned in the thesis protocol.

PATIENT INFORMED CONSENT FORM

Patient identification number for this trial: _____

Title of project:_____

_____

Name of Principal Investigator: _____Tel.No(s)._____

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. I give permission for these individuals to have access to my records.

I agree to take part in the above study.

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

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

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

Signatures of the Principal Investigator Date:
Place:

1) Witness – 1

Signatures

Name:

Address:

2) Witness – 2

Signatures

Name:

Address:

NB Three copies should be made, for (1) patient, (2) researcher, (2) Institution