FORMAT FOR THESIS PROTOCOL

The thesis protocol should be arranged as:

- 1. Introduction
- 2. Review of literature
- 3. Aims and Objectives
- 4. Material & Methods
- 5. Statistical Analysis
- 6. Ethical Consideration
- 7. Consent
- 8. Information to patients
- 9. References
- 10. Annexures
- 11. Proforma.

Each thesis should preferably have a guide and co-guide from the same department and where ever required, co-guide(s) from other department can be included. Maximum number of co-guides should not generally exceed 3. The Professor & Head of the department should normally get two PG/Fellowship candidates as supervisor per year because the Head of the department is always one of the Internal Examiner for MD/MS/Fellowship examination as per MCI norms and the thesis of a PG/Fellowship student is an essential part of the total examination process. The remaining PG/Fellowship students in a department should be allotted on rotation amongst all other eligible PG/Fellowship teachers who have been recognized as such by the RPIHEF.

- **A Cover page** as per institution policy (Sample enclosed).
- **B Title:** Title should be informative and relevant. It should preferably one sentence/phrase typed in sentence case. Abbreviations should not be used.
- C Introduction/Background (1-2 pages) and it should include: i) Describe the problem under consideration (disease/condition) briefly, ii) Discuss about "What is known? and "What are the gaps?" summarise the review of literature briefly, iii) Write about the research question and its importance. How would answering this research question modify the current state of knowledge?, iv) Conclude this section by stating how the proposal plans to answer the question which should be focused, measurable, achievable and relevant, clear and precise. (However, all these points need to be put in a para form without any bullets/subheadings)
- **D** Review of Literature should (Not more than 5 pages), i) Summarize the knowledge about the magnitude of the problem under consideration (disease/condition), ii) Discuss the relevant pathophysiology/pathology (do not include textbook material very obvious facts), iii) Review available studies on the subject/intervention related to research question. It is good to provide a summary table of the relevant studies where ever required, iv) Write a summary of the review-

"What is already known about the subject?, v) Identify relevant gaps in knowledge,

vi) This should facilitate writing a para on "Rationale for the study" which should be concluding part of the review of literature.

- NOTE: i) The available literature should be listed in chronological order and write in your own words rather than reproducing the para from the sources.
 - ii) 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.
- **E** Aims and Objectives:
 - 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 would you actually do in this study.
- **F** Material and Methods: The number of cases should be such that the candidate is able to collect data within 6-12 months and the entire work is finished within 2 years after registration. It is advisable to either carry out pilot study or look into the hospital attendance for relevant material.

The methodology should mention: i) **Study design and setting:** Descriptive, analytical or interventional, ii) Sample size which is adequate, iii) **Duration of study** including collecting of data, analysis, writing and final submission, iv) **Method of recruitment**, **Inclusion and Exclusion Criteria** vi) **Sampling technique**, vi) **Type of Intervention**, if any, vii) **Method of follow up** and tools used for assessment, viii) Procedure for recording/controlling confounding variable, if any. Standardization of method and reference to methodology should be given wherever necessary.

- **G** Statistical analysis: Mention procedure for data entry, statistical methods/software for statistical analysis, methods for handing missing data etc.
- **H** Ethical consideration and informed consent: When reporting experiments on human subjects, it should be indicated whether the procedures followed were in accord with the ethical standards on human experimentation (as per the guidelines laid down by the Central Ethical Committee of the ICMR). When reporting experiments on animals, procedures adopted for the care and use of laboratory animals need to be mentioned (Sample enclosed).
- **I Time frame for submitting the Plan:** It is advisable that the candidate should submit the plan of thesis within 6 months after registration.
- **J Reference:** Use Vancouver style and include reference which the candidate has accessed & read. Number of references should be limited to 15-20.

Bibliography

i. Journal: The titles of the journals should be abbreviated according to the style used by the Index Medicus. The list of journals indexed, published annually, in the January issue in the index medicus may be consulted.

In citing reference to research papers published in scientific journals, list all authors, but if the number exceeds six, list six followed by "et al" **Example:** Gupta GS, Kinsky RG. Effect of immunization with sperm specific lactate dehydrogenase with and without muramyl dipeptide as adjuvant. Indian J Med Res 1991; 100: 98-105

ii) Website: e.g. Hemlata (2006) People "Democracy Weekly Organization of Communist Party of India. Marxist, Vol XXX, No.17 April 23rd 2006, Accessed from <u>http://www.CSRindia.org/depad-current-project.html</u>. Last Accessed on 30th April, 2011.

iii) Books and other monographs:

- \Box <u>Personal author(s)</u>: Colson JH, Armour WJ, Sports injuries and their treatment. 2nd rev. ed. London S Paul:1986.
- ☐ Editor (s) or compiler(s) as author(s): Matyavati GV, Raina MK, Sharma M, editors, Medicinal plants of India. Vol. I New Delhi: Indian Council Medical Research; 1976.
- Organization as author and publisher: Virginia Law Foundation. The medical and legal implications of AIDS. Charlottesville : The Foundation; 1987
- □ <u>Chapter in a book</u>: Weinsterin L, Swartz MN, Pathogenic properties of invading micro-organisms. In: Sodeman WA, editors. Pathologic physiology: mechanisms of disease. Philadelphia : Sunders; 1974p. 457-72.

iv) Conference proceedings

Vivian VL, editor, child abuse and neglect: a medical community response Proceedings of the First AMA National Conference in Child Abuse and Neglect; 1984 Mar 30-31; Chicago, Chicago: American Medical Association: 1985.

v) Conference paper

Harley NII. Comparing radon daughter dosimetric and risk models. In Gammange RB, Kaye SV, editors. Indoor air and human health. Proceedings of the Seventh Life Sciences Symposium; 1984 OCT 29-31 : Knoxville (TN) Chelsea (MI0 : Lewis; 1985p. 69-78.

vi) Scientific or technical report

Akutsu T. Total heart replacement device. Bethesda (MD): National Institute Health, National Heart and Lung Institute; 1974 Apr. Report No. : NIH-NHLI-2185-1.

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vii) Dissertation:

Thesis (doctorate): Satyanarayana K. Some biochemical studies on the tenotomized gastrocnemius muscles of frog. Rana hexadactyla (Lesson), Ph.D

thesis. Tirupati Sri Venkateswra University: 1976.

vii) Patent

Harred JF, Knight AR, McIntyre JS; Inventors: Dow Chemical company, assignee. Epoxidation process. US patent 3.654.317.1972 Apr 4.

viii) Unpublished material:

 \Box In press

Lillywhite HB, Donald JA. Pulmonary blood flow regulation in an aquatic snake science. In press.

□ Unpublished data/personal communications:

Unpublished data and personal communications should be indicated in the text itself and not numbered.

(i) (Swami KS, unpublished work); (ii) Swami KS, personal communication); (iii) (National Institute of Nutrition, unpublished data).

All references given must be original and complete. References "cited by" and "quoted by" from other publications should be avoided.

- **K** Annexures: questionnaires/measurement tools etc.
- L Patient information sheet and consent form: Both in English and local languages.

The text of the thesis protocol should be typed in 12-size Times New Roman font on both sides of the paper. Paragraphs should have 1.5 spacing. Each section should start from a new page. Pages should be numbered starting from first page of introduction. Page number should be inserted centrally aligned at bottom of the page.

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 (no scientific terms), also **local language conversion: e.g. Hindi**, 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 form the research to the subject or to others.
- iv. Any risk to the subject associated with 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. If at any time they feel to withdraw form the study they can do so. No questioning will be done form the participant in this context.
- xii. Address and phone number of the student must be given in the patient information sheet.
- xiii. It should be accompanied with Standard Consent form: With place for signatures of patient or parents (in case of enrolled subject being minor), witness and the researcher.

PATIENT INFORMED CONSENT FORM

Patient identification number for this trial:

Title of projects: _____

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	2) Witness -2
Signatures	Signatures
Name:	Name:
Address:	Address:

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

APPLICATION FOR THE APPROVAL OF THE SUBJECT OF THESIS FOR M.D./M.S. /Fellowship (Subject Name) EXAMINATION. RAMNATH PRASAD INSTITUTE OF HIGHER EDUCATION FOUNDATION

 Name of the student Father"s Name i) Name of the department in which registered 	 Dr. xxxxx Mr. xxxx Department of xxxx, e.g. Government Medical College and
	Hospital, Sector-32, Chandigarh.
ii) Date from which registered	: xxxxx
4. Degree for which plan of thesis is submitted	: M.D./M.S. /Fellowship (Subject Name)
5. Year and month of passing MBBS examination	: xxxxxx
6. Name of the university from which passed	: xxxxxxx
7. Proposed subject of thesis	: xxxxxx
8. Facility available for proposed work	: All facilities available at Government eg Medical College and Hospital.
9. Details of the cost likely to be incurred on animals, laboratory equipments etc required for thesis project.	: Nil



RAMNATH PRASAD INSTITUTE OF HIGHER EDUCATION FOUNDATION EAST CHAMPARAN

Your Thesis Title Here

YOUR NAME HERE, MD/PhD

Submitted to RPIHE Foundation in Fulfillment of the requirements for the

Fellowship in (Branch Name) (Size- 22) (Batch-20.....-20....)

Supervisor Name

Co-Supervisor Name

NAME, DESIGNATION AND ADDRESS OF SUPERVISORS

1. Supervisor	: Dr. xxxxxx Designation
	RPIHE Foundation

2. Co-Supervisor(s) If yes : Dr. xxxxx Designation RPIHE Foundation

PLACE:

(SIGNATURE OF CANDIDATE)

DATE:

CERTIFICATE

I/We certify that facilities for working on the thesis entitled "xxxxx" do exist in the department/RPIHE Foundation under my/our charge and these shall be provided to candidate for his/her research work 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.

(Signature of Supervisor) Name and Designation (Signature of Co-supervisor) Name and Designation

(Signature of Co-supervisor) Name and Designation