ALL INDIA INSTITUTE OF MEDICAL SCIENCES RAJKOT

Guidelines for submission of thesis protocol for MD/MS/MDS examination

Name	Designation	Function	Signature
Dr. Patnana Arun Kumar	Addl. Asst. Dean (Research)	Preparation	
Prof. Dr. (Col) Ashwini Agarwal	Vice Dean (Research)	Review	
Prof. Dr. (Col) CDS Katoch	Executive Director & CEO	Approval	

REVISION SUMMARY			
Revision No.	**Issue No.**	**Issue Date**	**Revision History**
0	1.0	27/02/2024	NA

Preparing a thesis during post-graduation is a significant milestone in a student's academic and professional journey. Thesis preparation and writing require in-depth research knowledge and critical analysis capability to contribute new insights or perspectives to the existing body of knowledge. Post-graduate students should follow the guidelines for preparing and submitting the thesis protocol as a partial fulfilment of their academic degree.

The thesis protocol should include Title, Introduction/Background, Review of literature, Aims and Objectives, Hypothesis, Material and Methods, Statistical analysis, Ethical considerations, Additional documents (Questionnaires/Proforma/Case record forms) if applicable, References and Timelines associated with the research proposal. Guidelines for the above are as follows:

Title:

i. The title should be informative and relevant.
ii. It should preferably be one sentence/phrase typed in sentence case.
iii. Should include the type of the study (randomized/observational/cohort/case-control study)
iv. Abbreviations should not be used.

Introduction/Background *(Not more than 1-2 pages and a maximum of 500 words) and it should*

i. Describe the problem under consideration (disease/condition) briefly,
ii. Discuss what is known. and what are the gaps?
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 relevant, clear and precise.

Review of Literature *(Not more than 5 pages and 1500 words)*

i. Summarize the knowledge about the magnitude of the problem under consideration
ii. Discuss the relevant pathophysiology/pathology
iii. Review available studies on the subject/intervention related to the research question. It is good to provide a summary table of the relevant studies wherever 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 the Rationale for the study which should be the concluding part of the review of the literature

Note:

i. The available literature should be listed in chronological order and written in your own words rather than reproducing the para from the sources.
ii. Presentation of the review of literature should be in Vancouver Style names of authors should be avoided in the text and the reference number should be super-scribed at the end of each sentence preceded by a full stop.

Aims and Objectives:

i. Aims refer to what would be achieved by this study or how this study would address a bigger question/issue.
ii. Objectives refer to what would you do in this study.
iii. The protocol should have only one primary and one or more secondary objectives relative to the research question/aim of the study.
iv. Objectives prepared should be SMART (Specific, Measurable, Achievable, Relevant and Time-bound)

Hypothesis: Null hypothesis of the research question should be mentioned.

Materials and Methods:

The number of cases should be such that the candidate can collect data within 6-12 months and the entire work is finished within 2 years after registration. It is advisable to either carry out a pilot study or look into the hospital attendance for relevant material.

The methodology should mention:

i. **Study design:** Randomized/Clinical/Observational/Prospective
ii. **Setting or place of the study:** Departments involved / patient recruitment area
iii. **Population/participants, Method of recruitment, Inclusion and Exclusion criteria**
iv. **Sample size** calculation as required
v. **Duration of study** including collecting of data, analysis, writing and final submission,
vi. **Sampling technique**,
vii. **Type of Intervention**, details of (Instruments / Questionnaire, Frequency and duration of intervention/follow-up of subjects (if relevant), Procedures and schedules, Dosage, formulations, schedules, duration of drug treatments/surgical technique, suture (if relevant), Withdrawal reason(s), Stopping rules, Adverse response / side effect procedures and conditions for breaking the codes if any.

viii. Outcomes (primary/secondary) of the study
ix. Permission to use copyrighted questionnaire/proforma should be included
x. Approval from concerning governing bodies (DCGI/DGFT) related to the research
xi. Method of follow-up and tools used for assessment,
xii. Procedure for recording/controlling confounding variables, if any. Standardization of method and reference to methodology should be given wherever necessary.

Statistical analysis:

i. Mention procedure for data entry, statistical methods/software for statistical analysis, methods for handling missing data etc.
ii. Justification for the sample size chosen (Max100 words);
iii. The signature of the Epidemiologist/CFM specialist/ statistician Consultant with a stamp is mandatory.

Ethical considerations:

i. 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).
ii. When reporting experiments on animals, procedures adopted for the care and use of laboratory animals need to be mentioned.

Additional documents (if any):

i. Questionnaires / Proforma / Case record forms / Any other additional documents should be submitted.
ii. Participant Information sheet (PIS) and Informed Consent Form (ICF) in the prescribed format (as available on the Institutional website) should be submitted in Gujarati, Hindi and English languages.
iii. Assent form/waiver of consent form should be submitted as per the requirement and applicability of the research protocol.

References:

i. References should be in order of their appearance in the text (not alphabetically) and follow PubMed Central guidelines along with Vancouver Style.
ii. References should follow the standards summarized in the NLM's Sample References webpage (https://www.nlm.nih.gov/bsd/uniform_requirements.html) and detailed in the NLM's Citing Medicine, 2nd edition (https://www.ncbi.nlm.nih.gov/books/NBK7256/).
iii. Place the number of references at the end of the sentence as the superscript to which the reference is related. Use commas to separate multiple reference numbers.
iv. Number of references should be limited to 15-20.

Timelines:

i. The candidate should submit the plan of thesis within 4 months after registration.
ii. The important milestones of the thesis with concerned duration/timelines should be submitted along with the protocol.

General instructions:

i. Select fonts type Times New Roman and size of 12 points for text.
ii. The size of the titles should be 14 and Bold, and the size of the subtitles should be 12 and Bold. Bolds and Italics should not be used in the text. Furthermore, the coloured text should not be used. Use the same type of print size throughout the document.
iii. Paragraphs should have 1.5 spacing.
iv. The left-hand margin must be 1.5". Other margins should be 1.0".
v. The protocol should be submitted and printed on both sides of the paper.
vi. Each section should start from a new page.
vii. Pages should be numbered starting from the first page of the introduction.
viii. The page number should be inserted centrally aligned at the bottom of the page.
ix. Thesis protocol should be supplemented with all necessary and applicable Annexures.

LIST OF ANNEXURES

अखिल भारतीय आयुर्विज्ञान संस्थान राजकोट, गुजरात 360006 All
India Institute of Medical Sciences, Rajkot, Gujarat 360006
Institute of National Importance under PMSSY, MoHFW
Government of India www.aiimsrajkot.edu.in

Annexure - 1

[TYPE THESIS TITLE HERE]

Font: Times New Roman; 20; Bold; Center, spacing: 1.5,

Submission of Thesis Protocol in partial fulfilment of the requirements for the degree of
[Font: Times New Roman; 12; Center]
Name of degree MD/MS/MDS
In

Department of

[Font: Times New Roman; 18; Center]

By
Name of Candidate
[Font: Times New Roman; 14; Center]

Under
[Name of the Guide]
[Font: Times New Roman; 16; Center]

ALL INDIA INSTITUTE OF MEDICAL SCIENCES, RAJKOT

(Font: Times New Roman; 18; Bold; Center)

[Month and Year of protocol submission]
Font: Times New Roman; 18; Center

Annexure - 2

CONTENTS PAGE

Annexure - 3

APPLICATION FOR THE APPROVAL OF THESIS PROTOCOL

Name of the student	
Degree for which thesis protocol is submitted	MD/MS/MDS
Department	
Batch of admission in the course	January/July - Year
Proposed title of thesis protocol	
Duration of the proposed work	
Facility available for proposed work	

(Applicant signature with date)
Applicant's name:
Department:
All India Institute of Medical Sciences,
Rajkot, Gujarat.

Signature of the Guide with date and stamp

Signatures of Co-Guides with date and stamp

Signature of Head of the Department with date and stamp

Annexure - 4

CERTIFICATE

I/We certify that facilities for working on the thesis entitled "…….
……." do exist in the department, hospital, and laboratory under my/our charge and these shall be provided to the 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 the Guide with date and stamp

Signatures of Co-Guides with date and stamp

Signature of Head of the Department with date and stamp

Annexure - 5

UNDERTAKING FORM

I/We inform you that the work related to the thesis entitled "……. ……." has not started and that the work will be done as per Good clinical practice guidelines.

I/We also inform you that the scales/questionnaire/scores to be used are not copyrighted or permission to use them has to be obtained before the start of the study.

(Applicant signature with date)
Applicant's name:
Department:
All India Institute of Medical Sciences,
Rajkot, Gujarat.

Signature of the Guide with date and stamp

Signatures of Co-Guides with date and stamp

Signature of Head of the Department with date and stamp

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Institute of National Importance under PMSSY, MoHFW
Government of India www.aiimsrajkot.edu.in

Annexure - 6

TITLE PAGE FORMAT FOR RESEARCH CELL

1. Title of the project:

   ……

   ……

2. Post-graduate student details

   Name :

   Period :

3. Guide details

   Name :

   Designation :

   Department :

For use of the office of the Research Cell only:

Temporary thesis protocol code	
Thesis protocol Receiving date	
Date of issuing acknowledgement for the thesis protocol	
Date of thesis protocol evaluation by Research Cell (RC)	
RC suggestions for the project proposal (if any)	
Date of receiving the revision(s) after RC evaluation	
Date of Research Review Board (RRB) presentation	
RRB suggestions for the project proposal (if any)	

Date of revision received after RRB presentation	
The date of the thesis protocol forwarded to the Institutional Ethics Committee (IEC) for evaluation	
IEC presentation date	
IEC suggestions for the project proposal (if any)	
Date of receiving the revision after the IEC presentation	
Date of issuing the Permanent thesis protocol (if approved by the IEC)	
Date of issuing the thesis protocol approval	
Date of receiving six monthly progress report(s)	1. 2. If applicable: 3. 4.
Date of receiving the thesis protocol completion report	
Date of RRB presentation of the thesis protocol	
Date of thesis protocol completion report forwarded to IEC for evaluation	
Date of issuing the thesis protocol closure letter	

Comments if any:

Annexure - 7

PARTICIPANT INFORMATION SHEET

Title of the thesis protocol:

Name of the PG student:

Name of Guide:

1. You are invited to take part in this research study. The information in this document is meant to help you decide whether or not to take part. Please feel free to ask if you have any queries or concerns.
2. What is your expected duration of participation?
3. What procedures will be followed during this study?
4. What are the risks and discomforts to you?
5. What benefits are expected from this research?
6. What are the alternatives available to you?
7. Are the data/records of the participants kept confidential?
8. What will be the treatment schedule(s)?
9. What compensation and/or treatment(s) are available to the Participant in the event of a trial-related injury?
10. Whom to contact for trial-related queries and what are the rights of the Participant in the event of any injury?
11. Are the participants paid to take part in this study?
12. What are your responsibilities during participation in the study?
13. Statement that participation is voluntary, that the Participant can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the Participant is otherwise entitled.
14. Participant or Participant's representative will be notified promptly if significant new findings develop during the course of the research which may affect the Participant's willingness to continue participation will be provided.
15. Statement of foreseeable circumstances under which the Participant's participation maybe terminated by the Investigator without the Participant's consent.
16. Additional costs to the Participant that may result from participation in the study.
17. The consequences of a Participant's decision to withdraw from the research and procedures for orderly termination of participation by the Participant.
18. A statement that the particular treatment or procedure may involve risks to the Participant (or to the embryo or fetus, if the Participant is or may become pregnant), which are currently unforeseeable
19. Approximate number of Participants enrolled in the study:
20. Any other pertinent information

For further information/questions, you can contact:
PG Student Name: …… Name of the Guide: ……..

You are also free to contact: The Head of Department of……, AIIMS Rajkot.
In case of conflicts, you can contact the Institutional Ethics Committee at the following address:
The Institutional Ethics Committee, AIIMS Rajkot

Annexure - 8

INFORMED CONSENT FORM

Title of the thesis protocol:

Subject's Initials: …… Subject's Name: ……...

Date of Birth/Age: DD/MM/YYYY, …… Years

Address of the Subject: …….

Qualification: ……..

Occupation: Student or Self-Employed or Service or Housewife or Others (Please click as appropriate)

Annual Income of the subject: ……. INR

Name and address of the nominees and his relation to the subject: ……..

(for compensation in case of trial-related death)

i. I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions.
ii. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
iii. I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted about it, even if I withdraw from the trial.
iv. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.
v. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purposes.
vi. I agree to take part in the above study.

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative/Legal guardian :

Signatory's Name: ……..

Signature of the Investigator: ……. Date: DD/MM/YYYY

Study Investigator's Name: ……

Signature of the Witness: …… Date: DD/MM/YYYY

Name of the Witness: ……

Copy of the Patient Information Sheet and duly filled Informed Consent Form shall be handed over to the subject and his or her attendant.

Annexure - 9

CHECKLIST:

1. Application for the approval of thesis protocol
2. Certificate by the Guide and Co-Guides
3. Undertaking page
4. Title page for the Research Cell
5. Copy of the detailed protocol (Introduction/Background, Review of literature, Aims and Objectives, Hypothesis, Material and Methods, and Ethical considerations)
6. Participant Information Sheet (PIS) in Gujarati, Hindi and English
7. Informed Consent form (ICF) in Gujarati, Hindi and English
8. Questionnaire/Case record form if any
9. References in Vancouver style
10. One hard copy of the thesis protocol along with all other applicable forms/documents submitted to the Office of the Research Cell.
11. Soft copy of the thesis protocol along with all other applicable forms/documents submitted to the Research Cell through email (researchcellaiimsrajkot@gmail.com).

Note:

i. All applicable forms/documents should be submitted in the prescribed format as available on the Institutional website.

ii. Institutional guidelines should be strictly followed (wherever applicable) for conducting the thesis of post-graduate students.