



## University School of Medical & Paramedical Health Sciences Guru Gobind Singh Indraprastha University, New Delhi

### Regulations for Thesis Protocol and Thesis in Postgraduate Medical Courses

(Effective 28 January 2019)

#### 1.0 Requirement for Writing a Thesis

##### 1.1 M.D. and M.S. courses

Each postgraduate student pursuing MD or MS course must complete a thesis on an approved research project under the guidance of a recognised supervisor in compliance with the guidelines of the university.

The scholar must write a thesis protocol, obtain the necessary approval, and once that is granted, conduct the research project observing the highest standards of intellectual honesty and probity. During the course of research project, the student must keep a systematic record of the obtained data. During the course of thesis, his/her progress will be duly monitored by the parent institution.

Once the research work is complete, the student shall analyse the results and write a thesis in keeping with the standard guidelines.

##### 1.2 Postgraduate Diploma Courses

There is no thesis for the postgraduate diploma courses.

##### 1.3 D.M. and M.Ch. courses

1.31 In super-speciality D.M. and M.Ch. courses, conducting a thesis project is optional provided the requirements detailed in Clause 1.32 are fulfilled.

1.32 If a particular institute takes a decision to opt out of thesis in the curriculum, each student enrolled with the institute must publish at least two research papers or at least two review articles on the subjects specified by the supervisor. These articles must either be published or accepted for publication in an indexed journal. The candidate must fulfil this condition before being considered eligible to appear in the final examinations.

1.33 Whenever an institute decides to exercise the choice of letting the candidates do research papers/review articles instead of thesis, the decision must be communicated to the Dean, USM & PMHS, before the closing of the thesis protocol submission date.

1.34 If a candidate fails to fulfil the conditions stipulated in 1.31 or 1.32, the Head of Institution must **not** recommend the candidate to appear in the final university examinations.

#### 2.0 Compliance

2.1 The university shall notify each year a detailed timetable for the submission of thesis protocol and thesis work for the specialty (M.D., M.S.) and super specialty (D.M., M.Ch.) courses. Each candidate and each affiliate institution must comply with the notified timetable.

2.2 The thesis must be submitted to the university at least six months before the commencement of the final university examinations. A candidate shall be allowed to appear for the final university examination only after the acceptance of the thesis by the examiners.

2.3 In pursuance of clause 13.9 of the Medical Council of India's Postgraduate Medical Education Regulations, it is mandatory upon each postgraduate student pursuing a postgraduate degree course in any of the broad specialities or super specialities to make at least one poster presentation, to read one paper at a national/state conference and to present one research paper which should be published/accepted for publication/sent for publication during the period of student's postgraduate studies so as to make him eligible to appear at the postgraduate degree examination.

2.4 The PG cell/Head of each affiliate Institution will ensure that each postgraduate student has complied with clause 2.3 before recommending him/her to appear in the final university examinations.

### **3.0 Supervisor and Co-supervisors: Eligibility, Allocation, and FAQs**

#### **3.1 Supervisor**

3.11 A faculty member who stands recognized as a postgraduate teacher and meets the prescribed guidelines of the university shall qualify to be a supervisor. Those not possessing a teaching designation of the university will not be eligible to supervise a postgraduate.

3.12 The number of students that a supervisor may be allotted must comply with the prescribed MCI norms. This number varies between different subjects: basic sciences, broad specialties and super specialties.

3.13 The allotment of postgraduate students to supervisors within the department shall be carried out by the respective Heads. The process of allocation of students to supervisors must be carried out by a draw of lots.

Should the number of postgraduates in a department be fewer than the number of recognised supervisors, the allotment shall be carried out through a rotation process, where there is an equal opportunity for each faculty.

3.14 Should any Head of Department fail to observe the university guidelines, the Head of that Institution may exercise his/her discretion and allot the postgraduate students afresh among the recognised supervisors.

3.15 The terminology to be used in the thesis protocol/ thesis for the postgraduate teacher shall be supervisor and co-supervisor. Other terminologies like guide, chief guide, co-investigator, principal investigator shall not be permitted.

3.16 Each research project can have only one supervisor.

#### **3.2 Co-supervisors**

3.20 A faculty member recognized as a postgraduate teacher and who meets the prescribed guidelines of the university shall qualify to be a co-supervisor. Those not possessing a teaching designation of the university will not be eligible to co-supervise a postgraduate.

3.21 While finalizing a thesis protocol, each supervisor will ensure that the proposal does not list too many co-supervisors. Up to a maximum of five co-supervisors may be included, provided each co-supervisor is likely to contribute substantively to the thesis project.

3.22 If the nature of research requires that a co-supervisor be included from the same department, this may be permitted, provided the project is such that it requires a co-supervisor from the same department.

3.23 No faculty member shall be permitted to co-supervise more than five thesis projects in any particular year.

3.24 It shall be the duty of Head of Institution to permit only those faculty members as co-supervisors who fulfil the university eligibility criteria and are likely to contribute substantively to the research project.

3.25 Should any controversy or conflict arise regarding the nature of research and whether the project requires specific co-supervisor/s, the matter shall be referred to the Chair, Board of Studies, USM & PMHS, GGSIP University, whose decision in the matter shall be final.

3.26 In case a research project requires assistance of a department which is a non-teaching unit or does not possess a recognised supervisor/co-supervisor, the thesis proposal may list the department as a co-investigative department. However, no officer of the co-investigative department should be listed as a co-supervisor either in the thesis plan or thesis.

3.27 In case a research project requires the inclusion of a co-supervisor from outside the institution, and if such a faculty is a recognised teacher with a UGC recognised university, the Chair, Board of Studies, USM & PMHS, GGSIP University, may grant one-time permission to such a faculty for a specific thesis project based on the requirement of the project.

The candidate and supervisor, however, must make a request to this effect through their Head of Institution to Chair, Board of Studies, USM & PMHS, GGSIP University, at least two weeks prior to the date for submission of thesis protocol.

3.28 In case a research project requires the inclusion of a co-supervisor from outside the institution, and if such a faculty is not a recognised teacher with any UGC recognised university, the Chair, Board of Studies, USM & PMHS, GGSIP University, may grant one-time permission to such a faculty for a specific thesis project based on due consideration of the faculty's qualification, designation, experience and requirement of the project.

The candidate and supervisor, however, must make a request to this effect through their Head of Institution to Chair, Board of Studies, USM & PMHS, GGSIP University, at least two weeks prior to the date for submission of thesis protocol.

### **3.3 If a supervisor leaves an institution before the completion of thesis**

In case a supervisor leaves an institution — on transfer or for any other reason — before the final submission of a thesis, a supervisor fulfilling the university eligibility criteria and working in the parent department may be appointed as supervisor for the completion of the thesis. If no such supervisor is available, candidate's co-supervisor may help complete the project. In either case, the name of the original supervisor must be omitted from the work. This change in supervisor, however, would require a formal request from the Head of Department, duly forwarded by the Head of Institution, to Chair, Board of Studies, USM & PMHS, GGSIP University, for grant of approval.

### **3.4 If a co-supervisor leaves an institution before the completion of thesis**

In case a co-supervisor leaves an institution before the final submission of a thesis, the thesis may be submitted without his/her name and signature, provided that the supervisor remains in place.

### 3.5 Rule regarding superannuating teachers

If a teacher is superannuating before the last date of submission of thesis (as per the calendar of USM & PMHS) for that batch, s/he cannot be a supervisor. The Head of Institution has to ensure that this guideline must strictly be adhered to.

### 3.6 Change in supervisor

No change in supervisor is permitted once the protocol has been approved by the USM & PMHS committee except in the circumstances as stipulated in clause 3.3 above.

## 4.0 Writing a Thesis Protocol

4.1 Each postgraduate student in consultation with his/her supervisor must choose a specific research topic, draw a comprehensive study design, and write a study proposal in the form of a thesis protocol.

4.2 While selecting a subject for research, the following points must be taken care of:

4.2.1 The proposed study should be feasible in the existing time frame and existing institutional resources, and that the requisite machinery and equipment, and other essential prerequisites for the proposed study should be available in the institution.

4.2.2 The sample size should be calculated on the basis of pertinent statistical formula, and it must satisfy the requirements of study design and the proposed statistical analysis.

4.2.3 The thesis protocol should not be a repetition of a similar study undertaken in the previous five years in the university.

4.2.4 The study should not be based on a retrospective collection and analyses of data from case summaries/records available in the institution.

4.2.5 The participants enrolled in the thesis project should not have to bear any financial costs on account of any investigations, devices, implants or drugs which form a part of the study.

4.2.6 The study should not require you or your supervisor to partake of any obligation or any favour from a pharmaceutical company, device manufacturer or medical supplier.

4.2.7 The study should **not** be based on a “drug trial”.

This clause stands even though the Drug Controller General of India’s guidelines under G.S.R. 313(E) notified on 16th March, 2016, sub-rules 4 and 5 state that:

*Sub-rule 4. No permission for conduct of clinical trial intended for academic purposes in respect of approved drug formulation shall be required for any new indication or new route of administration or new dose or new dosage form where, (a) the trial is approved by the Ethics Committee; and (b) subject to the provisions of sub-rule 5, the data generated is not intended for submission to licensing authority.*

*Sub-rule 5. The Ethics Committee shall however inform the licensing authority about the cases approved by it and also about cases where there could be an overlap between the clinical trial for academic and regulatory purposes and where the said authority does not convey its comments to the Ethics Committee within a period of thirty days from the date*

*of receipt of communication from the Ethics Committee, it shall be presumed that no permission from the licensing authority is required.”*

Clause 4.2.7 has been incorporated to safeguard the interest of the postgraduates. A serious adverse reaction can lead to abandonment of the study. Further, the issues of compensation, insurance and other statutory obligations must be met if a drug trial is conducted, which a postgraduate cannot be expected to meet.

4.3 The thesis protocol must be presented, discussed, and finalized within the department before it is put up before the Institutional Review Board (IRB) and Institutional Ethics committee (IEC).

4.4 The IRB-IEC should scrutinize each thesis protocol and accord their formal approval; following which the same must be approved by the Head of Institution.

4.5 The submission of a thesis is obligatory before a candidate is permitted to take the final postgraduate examination both under MCI and university rules. Writing of the thesis protocol is the first basic step towards meeting this goal. Any candidate, who fails to submit the thesis protocol by the notified date, shall therefore be liable to disciplinary action, except if she is on maternity leave. The supervisor must proactively try and prevent such an eventuality and inform the Head of Institution well in time, so that remedial action can be instituted.

4.6 If a candidate fails to submit the thesis protocol by the notified date, the Principal/ Dean/ Head of the Institution may initiate disciplinary action and stop the salary of the candidate or cancel his/her registration from the postgraduate course. Such action is specified under Ordinance 16 of GGSIP University.

4.7 Where a decision to cancel a candidate's registration is taken, the affiliate institution shall convey the decision to Dean, USM & PMHS, GGSIP University and the Officer In charge, Admissions, GGSIP University, so that the candidate's name is struck off from the university's rolls.

## **5.0 Format of Thesis Protocol**

While writing a thesis protocol, each candidate must abide by the following format:

### **5.1 Font selection for body text**

The text of thesis protocol should be printed in Times New Roman/Arial/Calibri or similar font, 12 point font size, on both sides of A4 size paper in double space, with at least 2.5 cm margin and justification on both sides.

### **5.2 Font selection for cover and preliminary pages**

The cover page and preliminary pages may be printed in a font size and type of the candidate and supervisor's preference.

### **5.3 Cover page and binding**

5.3.1 The cover page must carry the Name of the Course; Batch Year; Thesis Title; Name of the Candidate; Name and Logo of the University; and the Name of the Department and College.

5.3.2 The thesis protocol must be bound; spiral binding being the simplest.

### **5.4 The First Preliminary page**

The title page must carry the Name, batch and signatures of the candidate; Name and qualification of the supervisor with his/her GGSIP University designation and his/her signatures; Name and qualification of the co-supervisor(s) with his/her GGSIP University designation and his/her signatures; Name and qualification of the Head of Department with his/her GGSIP University designation and his/her signatures; and Name, qualification and signatures of the Principal/Dean and Head of Institution.

Use a font size and format the text effectively to limit this data to no more than one or two pages.

5.4.1 Supervisor and Co-supervisor may, if they so desire, also append the teaching designation given to them by the Ministry of Health & Family Welfare, or their parent department, but this must be clearly stated. Such teaching designations cannot be a basis for a claim to be a supervisor/co-supervisor.

### **5.5 Certificates**

The following certificates must be attached as a part of the preliminary pages. Else, the thesis protocol will summarily be rejected.

5.5.1 An undertaking from the candidate that the thesis protocol does not violate the copyright act in any way, is free of plagiarism and that the “questionnaires” or “scores” being used are “copyright free” or that the necessary permission for their usage has been obtained from the copyright holders.

5.5.2 A certificate issued by the supervisor and co-supervisor(s) certifying that the thesis work of the candidate in the department shall be undertaken under their direct guidance.

5.5.3 A certificate from the candidate, supervisor, and the Head of Department carrying the following declarations:

- That the proposed study is feasible in the existing time frame and existing institutional resources, and that the requisite machinery and equipment, and other essential prerequisites for the proposed study are available in the institution.
- That the sample size has been calculated on the basis of the pertinent statistical formula, and satisfies the requirements of the study design and the proposed statistical analysis.
- That the thesis protocol is not a repetition of a similar study undertaken in the previous five years in the GGSIP University.
- That the study is not based on a retrospective collection and analyses of data from case summaries/ records available in the institution.
- That a participant enrolled in the thesis project shall be provided with the facility of all investigations, drugs, and devices being employed as a part of the study free of cost.
- That the study does not require the postgraduate student or supervisor to partake of any obligation or any favour from a pharmaceutical company, device manufacturer or medical supplier.
- That the study does not employ any “off-label drug trial”.

5.5.4 Certificate of the Institutional Review Board/Thesis Protocol Review Committee

5.5.5 Certificate of the Institutional Ethics Committee

### **5.6 Table of Contents**

List the contents and number the pages in sequence.

## 5.7 Introduction

A brief background that why the study is being proposed should be presented in a maximum of 2 pages.

## 5.8 Brief Review of Literature

Present the current state of the knowledge in a lucid comprehensive manner over a maximum of 5 pages. Do not simply tabulate the previous studies.

## 5.9 Lacunae in Existing Knowledge

## 5.10 Research Question and Hypothesis

5.11 **Aim(s) and Objective(s):** Primary and/or Secondary Objective, if any.

## 5.12 Material and Methods:

5.12.1 Venue of Study

5.12.2 Type of Study

5.12.3 Duration

5.12.4 Sample Size Calculation

5.12.5 Definitions used for Study Purpose

5.12.6 Inclusion and Exclusion Criteria

5.12.7 Detailed Study Flow Chart/Diagram

5.12.8 State details of the participant evaluation procedures/tests/surgical procedures/gold standard being employed etc.

5.12.9 Outcome Measures

5.13 **Statistical Methods.** Explain how you would employ them to analyse the obtained results.

5.14 **References.** Begin with “Introduction” and number each reference in sequence in order of their appearance in Vancouver style. Use recent references (avoid archaic citations except while writing history).

5.14.1 Cite references in numerals in superscript as they appear in the text.

5.14.2 Do not offer more than 10-15 references.

5.14.3 Do not use the term “bibliography”

## 5.15 Appendix

5.15.1 *Questionnaire*

5.15.2 *Study Pro forma.* If you are using any scores, questionnaires or pro forma which are copyrighted, submit the permission for their usage; or a declaration with due reference if they are available free of cost for academic usage.

5.15.3 *Patient Information Sheet.* This must be bilingual both in English and in Hindi. State the purpose of study, how the participant stands to benefit out of the study, procedures and tests that will be done, how will they be done, what would be their potential side effects or risks, if any, etc. State your name and contact number and your supervisor’s name and contact number. You must state clearly if any ethical issues exist.

5.15.4 *Informed Consent Form.* This must be bilingual both in English and in Hindi. It must carry the name and contact number of the participant with his/her signature, and the name and contact number of a witness with his/her signature.

5.15.5 *Candidate's Check List*. The 2-page check list will allow you to test out if your thesis protocol meets the basic requisites. Fill it up, and place it at the end of the thesis protocol, numbering the page.

## **6.0 Submission of thesis protocol**

6.1 Each institution must collect all thesis protocols and submit **only one copy** of each thesis protocol, in bound form, to the USM & PMHS, GGSIP University by the notified date. Certificates listed under clause 5.5 must also be bound to each thesis protocol. Do not send them in a bunch separately.

6.2 Each institution must also e-mail a comprehensive subject-wise list of candidates, their supervisors, co-supervisors, title of thesis, and a column for review to [dean.usmpmhs@ipu.ac.in](mailto:dean.usmpmhs@ipu.ac.in) without fail. Submissions without the soft copy shall not be accepted.

## **7.0 Monitoring of the thesis project**

7.1 The progress of the thesis project must be assessed at the end of 6 months and 12 months from the commencement of project.

7.2 This monitoring shall be carried out in the respective departments in consultation with the IRB/Institute Protocol/ Research Committee and the assessment report must be submitted to Dean/Principal/Head of Institution for onward transmission to the Dean, USM & PMHS.

7.3 If the IRB/Institute Protocol/ Research Committee find that a candidate's progress is less than satisfactory, the Dean/Principal/Head of Institution may initiate suitable disciplinary action against the defaulting candidate.

## **8.0 Format of the Thesis**

### **8.1 Cover**

The cover of the thesis should carry the name of the course; batch year; thesis title; name of the candidate; name and logo of the university; and the name of the department and college.

*Font selection for cover and preliminary pages:* The cover page and preliminary pages may be printed in a font type and size of the candidate and supervisor's preference.

### **8.2 Spine of the thesis**

The spine of the thesis should carry the name of the course, name of the candidate and title of the thesis, and the year of submission.

### **8.3 Title page of the thesis**

The title page must carry: Name of the Course; Batch Year; Thesis Title; Name of the Candidate; Name and Logo of the University; and the Name of the Department and College.

### **8.4 Preliminary pages**

8.4.1 **The First Page:** It should carry the name, batch and signatures of the candidate; name and qualification of the supervisor with the GGSIP University designation and his/her signatures; Name and qualification of the co-supervisor(s) with the GGSIP University designation and his/her signatures; Name and qualification of the Head of Department with

the GGSIP University designation and his/her signatures; and Name, qualification and signatures of the Principal/Dean and Head of Institution.

Use a font size and format the text in a manner that this data takes no more than one or two pages.

8.4.2 **Table of Contents:** List the contents and number the pages in sequence.

8.4.3 **Undertaking by the Candidate:** The candidate must submit a undertaking that the thesis does not violate the copyright act in any way, is free of plagiarism and that the “questionnaires” or “scores” being used are “copyright free” or that the necessary permission has been obtained from the copyright holders. No figures/tables/illustrations, which are copyrighted whether by a journal or form a part of a book, can be published without the written permission of the copyright holders.

8.4.4 The undertaking must be supplemented with a report from any of the commonly used plagiarism software indicating that the submitted thesis has less than 20% similarity. This report must be duly signed by the postgraduate student.

8.4.5 **Certificate from the Supervisor, Co-supervisor(s) and Head of Department:** The thesis should carry a certificate issued by the supervisor, co-supervisor and HoD certifying that the candidate has undertaken the thesis work in the department under the direct guidance of the supervisor and co-supervisor(s). Further, that the investigations, drugs and devices used in the study were provided free of cost to the participants and no ‘Off-label drugs and devices’ were used for the study.

8.4.6 **Certificate of the Institute Protocol/ Research Committee and Ethical Committee:** The thesis must submit carry a certificate of the Institute Protocol/ Research Committee and Institute Ethical Committee certifying the work.

8.4.7 **Acknowledgements**

8.4.8 **Glossary of abbreviations**

8.5 **Main body of the thesis:**

**Font selection for body text:** The text of thesis protocol should be printed in Times New Roman/ Arial/ Calibri or similar font, 12 point font size, on both sides of A4 size paper in double space, with at least 2.5 cm margin and justification on both sides.

**Sequence:**

8.5.1 *Introduction*

8.5.2 *Review of Literature*

8.5.3 *Lacunae in Existing Knowledge*

8.5.4 *Research Question*

8.5.5 *Hypothesis (do not publish null hypothesis)*

8.5.6 *Aims and Objectives*

8.5.7 *Material and Methods*

8.5.8 *Results*

8.5.9 **Discussion:** Discuss the salient findings of the work, highlight any new understanding, theorem or concepts that might have come to light, and briefly consider the strengths, limitations and weaknesses of the study. Do not limit discussion to a comparative presentation of the study findings to findings of other similar studies.

8.5.10 *Summary and Conclusion*

8.5.11 *References*: Begin with the “Introduction” section and number each reference in the order of their appearance sequentially in Vancouver style. Use numeral superscript to allude to each reference. Do not use the term bibliography.

#### 8.6 *Appendices*

8.6.1 Append the Questionnaire

8.6.2 Append the Study Pro forma

8.6.3 Append the Classifications/Scores employed in the study

8.6.4 Append permission(s) to use/reproduce copyrighted material

8.6.5 Append the Master Chart

8.6.6 Append a copy of the University approved protocol

### **9.0 Submission of Thesis**

9.1 Submit **four hard copies** of the thesis to the Office of Controller of Examinations, GGSIP University, Dwarka Campus, Delhi, by the notified date.

9.2 In case a student fails to submit the thesis by the specified date, s/he will be debarred from taking the final university examination and will be permitted to appear in the supplementary examination or in the next examination following the submission of thesis and its acceptance (vide Ordinance 16 of the GGSIP University and MCI regulations).

### **9.0 Evaluation of Thesis**

The thesis shall be examined by a minimum of three examiners; one internal and two external examiners, who shall not be the examiners for Theory and Clinical examination. A candidate shall be allowed to appear for the Theory and Practical/Clinical examination only after the acceptance of the thesis by the examiners {clause 14.4(a)}.

*These guidelines were drawn in pursuance of Board of Studies, USM & PMHS, recommendations {16 November 2018} and were approved by the School Research Committee, USM & PMHS, on 28 January 2019. They are applicable with immediate effect and supersede all pre-existing guidelines issued in this regard. Should the Medical Council of India bring any significant changes in these regulations, the same shall be incorporated.*

## Declaration and Certificates to be attached with thesis protocol

### Declaration

(5.5.1)

I wish to undertake a thesis project entitled “(title of the project)”, to fulfil the essential requirement for the award of degree of {name of the course e.g., Doctor of Medicine (Radio-diagnosis)} from the Guru Gobind Singh Indraprastha University, New Delhi.

I hereby declare that the thesis protocol does not violate the copyright act in any way, is free of plagiarism, and that the “questionnaires” or “scores” being used are copyright-free or that the necessary permission has been obtained from the copyright holders. The work does not include any diagrams, figures, tables, and flowcharts which are copied from a journal or book or infringe copyright.

Signatures of the candidate  
(Name of the candidate)

## Certificate

(5.5.2)

This is to certify that the work entitled, “*(title of the project)*”, shall be carried out under our guidance and supervision by .....*(name of the candidate)* in the Department of .....*(name of the department and institution)*, New Delhi.

Signature of Supervisor

Name of Supervisor

*(Name of the supervisor)*

*(University Designation, e.g., Professor)*

*(Department of .....)*

Signature of Co-Supervisor

Name of Co-Supervisor

*(Name of the co-supervisor)*

*(University Designation, e.g., Professor)*

*(Department of .....)*

Signature of Co-Supervisor

Name of Co-Supervisor

*(Name of the co-supervisor)*

*(University Designation, e.g., Professor)*

*(Department of .....)*

Signature of Co-Supervisor

Name of Co-Supervisor

*(Name of the co-supervisor)*

*(University Designation, e.g., Professor)*

*(Department of .....)*

Signature of Co-Supervisor

Name of Co-Supervisor

*(Name of the co-supervisor)*

*(University Designation, e.g., Professor)*

*(Department of .....)*

Certificate  
(5.5.3)

This is to certify that the work entitled, “*(title of the project)*”, shall be carried out in the Department of ..... (*name of the department and institution*), New Delhi.

It is certified that the study is feasible in the given time frame and that the institution has the machinery and equipment and other essential prerequisites for conducting the study; and that the study sample size has been calculated on the basis of reliable statistical formula, and that it satisfies the requirements of study design and the proposed statistical analysis.

It is certified that the thesis plan is not a repetition of a similar study undertaken in the previous five years in the university, and that the study is not based on a retrospective collection or analyses of data from old patient case records, and that it does not employ any “off-label drug trial”.

We undertake that the participants enrolled in the thesis project will not have to bear any financial burden on account of the investigations, devices, implants or drugs employed as a part of the study, and that the study does not require us to partake of any obligation or any favour from a pharmaceutical company, device manufacturer or medical supplier.

Signature of the candidate

Name of the candidate *(Name of the candidate)*

Signature of Supervisor

Name of Supervisor *(Name of the supervisor)*  
*(University Designation, e.g., Professor)*  
*(Department of .....)*

Signature of Co-Supervisor

Name of Co-Supervisor *(Name of the co-supervisor)*  
*(University Designation, e.g., Professor)*  
*(Department of .....)*

Signature of Co-Supervisor

Name of Co-Supervisor *(Name of the co-supervisor)*  
*(University Designation, e.g., Professor)*  
*(Department of .....)*

Signature of Head of Department

Name of Head of Department *(Name of the Head of Department)*  
*(University Designation, e.g., Professor)*  
*(Department of .....)*

Institutional Review Board Certificate  
(5.5.4)

The Institutional Review Board/Thesis Protocol Review Committee of ..... (name of the institution)..... has reviewed and discussed the research proposal entitled “.....” on .....(date).....

The Institutional Review Board duly reviewed the thesis protocol in line with the formally ratified 2019 regulations of the USM & PMHS, Guru Gobind Singh Indraprastha University, and found the Introduction; Review of Literature; Lacunae in existing knowledge; Research question and Hypothesis; Aims and Objectives; Material and Methods; Statistical methods; References; and Appendices to be suitably drawn and based on sound scientific and ethical foundation.

The Institutional Review Board confirms that the supervisor and co-supervisors of the study meet the formally ratified 2019 regulations of the USM & PMHS, Guru Gobind Singh Indraprastha University, and that neither the supervisor nor co-supervisors are a part of thesis projects more than that permitted to them.

The Institutional Review Board/Thesis Protocol Review Committee meeting was chaired by .....(name of chairperson)....., and the following members of the committee were present during the meeting:

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.

The Institutional Review Board/Thesis Protocol Review Committee approved the study to be conducted in the present form at .....(name of the institution).....

Signed by the Chair,  
Institutional Review Board/Thesis  
Protocol Review Committee

Signed by the Dean/Head of Institution,  
Name of the Dean/Head of Institution

(Institutions and candidates may use this template to fill all details and include this certificate in the bound protocol)

## Institutional Ethics Committee Certificate

(5.5.5)

(Institutions may circulate the template decided upon by their respective IEC for the candidate to fill all details and include the certificate in the bound thesis protocol)

### Declaration and Certificates to be attached with the thesis

#### Declaration

(8.4.3 & 8.4.4)

The submitted thesis “(title of the thesis)” does not violate the copyright act in any way, is free of plagiarism, and that the “questionnaires” or “scores” being used are copyright-free (or that the necessary permission has been obtained from the copyright holders). The thesis does not carry any figures/ tables/ illustrations, which are copyrighted, be it with a journal or a book.

The submitted thesis “(title of the thesis)” has been evaluated on the plagiarism check software platform “(name of the plagiarism check software platform)” and the report (copy enclosed) reads that the submitted thesis has less than .....per cent similarity.

Signatures of the candidate  
(Name of the candidate)

Certificate  
(8.4.5)

This is to certify that the work entitled, “*(title of the project)*”, was carried out in the Department of ..... *(name of the department and institution)*, New Delhi, under our direct guidance and supervision.

It is certified that the investigations, drugs and devices used in the study were provided free of cost to the participants and that no ‘off-label drugs and devices’ were used for the study.

Signature of the candidate

Name of the candidate *(Name of the candidate)*

Signature of Supervisor

Name of Supervisor *(Name of the supervisor)*  
*(University Designation, e.g., Professor)*  
*(Department of .....)*

Signature of Co-Supervisor

Name of Co-Supervisor *(Name of the co-supervisor)*  
*(University Designation, e.g., Professor)*  
*(Department of .....)*

Signature of Co-Supervisor

Name of Co-Supervisor *(Name of the co-supervisor)*  
*(University Designation, e.g., Professor)*  
*(Department of .....)*

Signature of Co-Supervisor

Name of Co-Supervisor *(Name of the co-supervisor)*  
*(University Designation, e.g., Professor)*  
*(Department of .....)*

Signature of Head of Department

Name of Head of Department *(Name of the Head of Department)*  
*(University Designation, e.g., Professor)*  
*(Department of .....)*

Institutional Ethics Committee Certificate  
(8.4.6)

(Institutions may circulate the template decided upon by their respective IEC for the candidate to fill all details and include the certificate in the bound thesis protocol)



**University School of Medicine and Paramedical Health Sciences  
Guru Gobind Singh Indraprastha University, New Delhi**

Candidate's Checklist

{ to be filled and attached as a part of the thesis protocol }

Name:		Course:	Institution:
Title of the Thesis Protocol:			
S. No.	Checklist for Thesis Protocol		Place (√) or (x)
<b>Title Page of the Protocol</b>			
1.	Does the title reflect the aims and objective(s) of the proposal?		
2.	Does the title page include your name, course, batch year, college, university?		
<b>First Preliminary Page of the Protocol</b>			
3.	Does the page carry your name and signature?		
4.	Does the page carry the name, university designation and signature of your thesis supervisor?		
5.	Does the page carry the name, university designation and signature of the co-supervisor/s?		
6.	Does the page carry the name and signature of your Head of Department?		
7.	Does the page carry the name and signature of your Head of Institution?		
<b>Undertaking and Certificates</b>			
8.	Have you attached the declaration (5.5.1) that the thesis protocol does not violate the copyright act in any way, is free of plagiarism, and you've not reproduced any "questionnaires", "scores", diagrams, figures, tables, flowcharts which may infringe the copyright act?		
9.	Have you attached your supervisor's and co-supervisors certificate (5.5.2) that they would supervise and guide your work?		
10.	Have you attached certificate (5.5.3) bearing your own, your supervisor's, your co-supervisors' and Head of Department's signatures asserting the feasibility of the study; the study sample size having been calculated on the basis of reliable statistical formula and satisfying the requirements of study design and the proposed statistical analysis; the thesis plan not being a repetition of a similar work undertaken in the previous 5 years; the plan not entailing a retrospective collection or analyses of data from old patient case records; not employing any "off-label drug trial"; assertion that participants would not bear any financial burden on account of the investigations, devices, implants or drugs employed; and that the study would not require you to take any obligation from a pharmaceutical company, device manufacturer or medical supplier?		
11.	Have you attached the certificates of your Institutional Review Board (IRB)/Thesis Protocol Review Board (5.5.4) and Institutional Ethics Committee (IEC) (5.5.5) conveying their formal approval of the project in the study protocol?		
<b>Table of Content</b>			
12.	Have you drawn a table of contents and numbered all pages of the protocol in the following sequence: ➔Introduction; ➔Review of Literature; ➔Lacunae in existing knowledge; ➔Research question and Hypothesis; ➔Aims and Objectives; ➔Material and Methods; ➔Statistical methods; ➔References; ➔Appendices?		
<b>Introduction</b>			
13.	Have you provided a brief description of the existing knowledge on your research topic under "Introduction"?		
<b>Review of Literature (ROL)</b>			
14.	Have you exhaustively reviewed the current literature on the research topic and presented a comprehensive summary of the current knowledge in a lucid manner under the Review of Literature?		
<b>Research Question and Hypothesis</b>			
15.	Have you clearly stated the research question that you wish to resolve?		
16.	Does the hypothesis match the research question and is it based on a sound scientific presumption?		
<b>Aims and Objectives</b>			
17.	Have you clearly stated the Aims and Objectives of the study?		
18.	Is the Aim in accordance with the research topic?		
19.	Are the Primary Objectives clearly stated?		
20.	Are the Secondary Objectives clearly stated?		
21.	Are the Objectives aligned with the research subject?		
22.	Are the Objectives achievable in a specified time frame?		
23.	Are the Objectives achievable within the existing resources?		
<b>Materials and Methods</b>			
24.	Have you stated the place of study?		
25.	Have you stated the period of study?		
26.	Have you stated the type of study you're undertaking?		
27.	Does the stated study type match with the research design?		
28.	Is the study population defined?		
29.	Is the method of recruitment defined?		
30.	Are the inclusion criteria defined?		
31.	Are the exclusion criteria defined?		

32.	In studies where applicable, are the study groups defined?	
33.	Do you intend to employ a control group?	
34.	Is the control group suitably matched to the participants of the study?	
35.	Is the study sample size calculated on the basis of a sound reliable statistical formula?	
36.	Does the study sample size match the study design and statistical methods you propose to employ on the data?	
37.	Have you included a detailed study flow chart in the protocol?	
38.	Have you included the details of the proposed investigations and how they relate to your study?	
39.	Do you intend to carry out any interventions?	
40.	Have you included the details of the proposed interventions?	
41.	Do you have a gold standard to clinch the diagnosis?	
42.	How accurate is the gold standard?	
43.	Have you included the outcome measures?	
44.	Have you included any "clinical scores"?	
45.	If yes, are these "clinical scores" copyright free?	
46.	If copyrighted, have you taken steps to ensure you do not violate the copyright?	
<b>Statistical methods</b>		
47.	Have you stated the statistical methods you would employ to gauge the obtained data?	
48.	Have you explained how the stated statistical methods would be employed to obtain results?	
<b>References</b>		
49.	Have you numbered each reference beginning with page 1 of the introduction and till the end of the protocol in a continuous sequence in order of their appearance (as is prescribed in Vancouver style)?	
50.	Have you cited the references as they appear within the text in Arabic numerals in superscript?	
51.	Under the reference section, have you listed the details of each reference as is prescribed in Vancouver style?	
<b>Appendix</b>		
52.	Does the protocol carry any questionnaire?	
53.	Is the questionnaire validated?	
54.	Is the questionnaire copyright free?	
55.	Have you included a detailed study pro forma to capture all significant elements of the study?	
<b>Patient Information sheet (PIS)</b>		
56.	Have you included PIS in Hindi?	
57.	Have you included PIS in English?	
58.	Does the PIS state the purpose of the study?	
59.	Does it mention how it is going to benefit the participants?	
60.	Does it state the procedures and tests to be done?	
61.	Does it elaborate how the procedures and tests will be done?	
62.	Does it mention the potential side effects and/or risks?	
63.	Does it include your and your supervisor's name and contact number?	
64.	Have you clearly stated any known ethical issue(s)?	
<b>Informed Consent Form</b>		
65.	Have you included an informed consent form in Hindi?	
66.	Have you included an informed consent form in English?	
67.	Does the informed consent form bear the name, address, contact number and signature of the participant?	
68.	Does the informed consent form bear the name, address, contact number and signature of a witness?	
<b>Binding</b>		
69.	Is the thesis protocol firmly bound?	
<b>Candidate's Checklist</b>		
70.	Have you submitted the filled up Candidate's Checklist in the bound thesis protocol?	

*Signatures of the candidate with date*

*Signatures of the supervisor with date*

*Name of the supervisor*