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1. **What sections should my protocol have?**  
   A. **Abstract**  
   B. **Research Plan**  
      - Specific Aims  
      - Significance  
      - Methods  
      - Human Subjects (If Applicable)  
      - Vertebrate Animals (If Applicable)  
      - Literature Cited

2. **Do I have to include a statistical analysis plan in the methods section?**  
   Yes. If you are not sufficiently confident to write this section, then ask your mentor or committee members for guidance or seek advice from Dr. Phillips.

3. **Do I have to include my application for Institutional Review Board (Human Subjects) approval and a copy of the proposed consent form with my protocol?**  
   a) You do NOT have to submit these documents with the protocol for the May deadline. However, you MUST include in your protocol inclusion/exclusion criteria for subjects or patient records and how participants will be contacted/recruited and “where” participants will come from. You MUST also include a statement that you are completing the Institutional Review Board (IRB) application package.  
      (See Guide to the IRB Process: [http://research.unc.edu/offices/human-research-ethics/index.htm](http://research.unc.edu/offices/human-research-ethics/index.htm))  
      (See IRB Forms: [http://research.unc.edu/researchers/forms/human-subjects/](http://research.unc.edu/researchers/forms/human-subjects/))

      If you are doing a study that involves ANYTHING to do with humans (“subjects”, patients, survey, focus groups, retrospective review of records) you will have to have Institutional Review Board (IRB) approval BEFORE you begin your research. And IRB approval requires that you complete the appropriate CITI certification (If you were enrolled in Dr. Wright’s Research Design class, completion was a requirement).  
      See OHRE Required Education - [http://research.unc.edu/offices/human-research-ethics/researchers/training/index.htm](http://research.unc.edu/offices/human-research-ethics/researchers/training/index.htm)

   b) You DO have to submit these documents with the final protocol submitted to Academic Affairs in the fall.

4. **Do I have to include my application for approval of the Laboratory Animal Protocol with my protocol?**
a) You do NOT have to submit these documents with the protocol for the May deadline. However, you MUST include in your protocol the species, strains, ages, and estimated numbers of animals. You must also include a description of the care and experimental procedures. See Training and Compliance: http://research.unc.edu/offices/iacuc/training/index.htm http://research.unc.edu/offices/iacuc/compliance/index.htm

See Animal Care and Use Application Forms: http://research.unc.edu/offices/iacuc/forms/index.htm

b) You DO have to submit these documents with the final protocol submitted to Academic Affairs in the fall.

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The following policies are intended as a guide for graduate students and faculty in the School of Dentistry Advanced Education Programs for the selection of thesis committee members. The major roles of the committee members also are outlined. Policies indicated by an * are UNC Graduate School guidelines. Others are School of Dentistry guidelines.

*1. The thesis committee must consist of at least three members of the Graduate Faculty. One of the members serves as the thesis advisor.

*2. At least two committee members must be Regular members of the Graduate Faculty. The other members may be Fixed or Special members of the Graduate Faculty. The Assistant Dean for Advanced Education must be notified if the thesis advisor is a Fixed Graduate Faculty member and/or if only one member of the committee is a Regular member of the Graduate Faculty.

3. At least one member should be from outside the student’s major program or department.

4. A thesis topic, advisor, and committee members must be selected by January of the first year.

5. All committee members must have the opportunity to participate in the development of the Research Development Seminar in which the student presents an overview of the selected area, a statement of the problem, hypotheses, and potential approaches for researching the problem.

6. All committee members must approve the protocol submitted for review to the peer group study sections which are in June of the first year and must approve the final protocol before data collection begins.

7. All committee members must participate in a committee meeting during the second year in which the progress of the project is reviewed. They also must have the opportunity to review the material developed for the Dental Research in Review Day presentation in which project progress is reported in February of the third year.

*8. All committee members must have the opportunity to review a complete draft of the thesis at least two weeks prior to the oral defense.

*9. Two-thirds of the committee members must approve the final oral defense and the thesis. The vote of the thesis committee is considered by the Graduate School to be final.


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The protocol should be prepared using Georgia font (at least 12) with one-inch margins.

The first page of your protocol is the abstract (attached as the last page of this section). The abstract page must be signed by your thesis advisor and scanned as a pdf. The abstract should be written as a structured abstract and must fit in the space provided:

1. Objectives (Specific Aims)
2. Significance
3. Methods

Organize the Research Plan to answer the following questions: (A) What do you intend to do? (B) What has already been done? Why is the work important? (C) How are you going to do the work? Include Sections D and E if appropriate for the project. Include Section F as the last section of the research plan. The suggested format is as follows:

A. **Specific Aims:** State concisely and realistically what the research described in this protocol is intended to accomplish and/or what hypothesis is to be tested. DO NOT EXCEED ONE PAGE.

B. **Significance:** Briefly sketch the background to the present proposal, critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill. State concisely the importance of the research described in this application by relating the specific aims to longer-term objectives. DO NOT EXCEED TWO SINGLE SPACED PAGES.

C. **Methods:** Describe the sample. Discuss in detail the experimental design and the procedures to be used to accomplish the specific aims of the project. Include the means by which the data will be analyzed and interpreted. Describe any new methods used, and their advantages over existing methods. Describe the tentative sequence and timetable of the investigation. Discuss the potential difficulties and limitations of the proposed procedures, and alternative approaches to achieve the aim. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised. An anticipated work schedule should be provided. ALTHOUGH NO PAGE LIMITATION IS SPECIFIED FOR THIS PART OF THE APPLICATION, MAKE EVERY EFFORT TO BE SUCCINCT.

Human Subjects: If human subjects will be involved provide a description of risks and measures to minimize risks. Include risk of psychosocial harm (e.g., emotional distress, embarrassment, breach of confidentiality), economic harm as well known side effects of study medication, if applicable, and risk of pain and
physical injury. Describe what will be done to minimize these risks.

Describe procedures for follow-up, when necessary, such as when subjects are found to be in need of medical or psychological referral. If there is no direct interaction with subjects, and risk is limited to breach of confidentiality (e.g., for existing data), state this.

Students planning to use human subjects or human specimens (teeth, blood, saliva) in their research project must submit an application and consent form(s) to the Institutional Review Board http://research.unc.edu/offices/human-research-ethics/ and receive approval prior to beginning the study.

D. Vertebrate Animals: If vertebrate animals will be used in the project, state the species, strains, ages, and numbers of the animals involved. Describe the procedures for adequate care of any animals involved. Describe the procedures to avoid unnecessary discomfort, pain or injury to the animals, by making reference to surgical anesthesia, post-trauma analgesia, tranquilizing drugs, and comfortable restraining chairs.

Students planning to use laboratory animals in their research projects are advised that formal application must be made to the campus "Institutional Animal Care and Use Committee". The committee uses a detailed application form, which is available on line at http://research.unc.edu/iacuc

E. Literature Cited: Use the citation method recommended by your department.
ABSTRACT OF RESEARCH PLAN
Graduate Student Master's Thesis Development Program
School of Dentistry, Advanced Education Programs
University of North Carolina at Chapel Hill

STUDENT: PROGRAM:

TITLE OF PROJECT:

THESIS ADVISOR: ADVISOR’S SIGNATURE:

COMMITTEE MEMBERS: DATE OF SUBMISSION:

ABSTRACT OF RESEARCH PLAN:
Provide structured abstract with 1) Objective (Specific Aims) 2) Significance/Background
3) Methods. The abstract should be self-contained so that it can serve as a succinct and accurate
description of the proposed project. DO NOT EXCEED THE SPACE PROVIDED BELOW.

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The objectives of the peer study section are to provide Master’s Degree students with
- the opportunity to apply in a critical and thoughtful way the concepts learned in the research core courses
- independent feedback on the draft versions of their research protocol

**WRITING THE “PROTOCOL REVIEW”**

Each protocol will be reviewed by a primary and a secondary reviewer. The level of assignment specifies the order in which the reviewers will comment on the protocol during the study section session.

Each reviewer will independently write a critique of each of the two protocols assigned to them and bring a hard copy of the critique with them to study section.

The written review should be written without consultation with the student investigator, faculty, or other students. Include both the major good and bad points and sufficient supporting evidence to completely define each point. You can use bullet points but include enough detail to support your point, i.e. don’t write “Insufficient Details”, but explain what’s missing or needs more detail “ No exclusion criteria given” “Needs more detail about how treatments will be allocated”

The questions below are included to help you provide a critical appraisal of the following sections:

**Significance.**
- How does the background and significance illustrate the importance of the project in addressing an important problem or a critical barrier to progress?
- If the aims of the project are achieved, will scientific knowledge, technical capability, clinical practice, patient well-being, or educational practices be improved?

**Innovation.**
- Is the project original and innovative? How will the project extend or expand the knowledge base in a particular area?

**Approach.**
- Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?
- Are potential problems, alternative strategies, and benchmarks for success presented?
- If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed appropriately?
- If the project involves clinical research, are the plans for 1) recruitment 2) allocation 3) data collection 3) masking(if appropriate) 4) adverse events clearly outlined and explained?
• If the project involves a survey, are the plans for 1) identifying the sampling frame 2) confidentiality 3) response rate outlined and explained?

**Preparation of the Review**

The questions above are just reminders of what you should consider in writing your review. In the review (Student Review Template) you must give details (specify what’s good and what’s not so good) for each of the three areas re strengths/weaknesses not general statements.

The secondary reviewer should email his/her critique to the primary reviewer at least two days in advance of the study section meeting.

**Study Section Meeting**

The moderator will act as the Executive Secretary. The moderator’s role is to specify the order of review and to encourage discussion by all participants.

The student reviewers are the spokespeople for the Protocol. The person whose protocol is being reviewed will not be in your assigned group. The reviewers need to present a balanced review, no matter how good or bad the protocol may be.

During the study section, each protocol will be reviewed by the primary and secondary reviewers. Discussion will follow. All members of the group including the moderator are invited to ask questions of the reviewers about the protocol. Additional explanations or clarifications may be necessary when the reviewers have differing opinions.

Note: The primary reviewer may want to take notes during the discussion to assist in preparation of the final review.

**Sequence of Review for a Protocol**

1) The moderating faculty member will ask each reviewer to provide a preliminary Overall Impact score BEFORE the protocol is reviewed. The Overall Impact score can range from 1 = exceptional to 9 = poor. (See Scoring Guidance)

**Overall Impact.** The overall impact score (1 to 9) should reflect the reviewer’s assessment of the likelihood for the project to be successfully completed within the time frame, the significance of the project within the field, and the clarity of the methodological approach. The starting overall impact score should be a 5 (average). After careful consideration of the protocol, the score should be decreased on the basis of merit (1 to 4) or increased on the basis of deficiencies (6 to 9). See scoring guidelines.

2) The primary reviewer will provide a description of the protocol (the abstract of the protocol may be used) followed by the critique of the protocol.

3) The secondary reviewer will then present his/her critique focusing on areas/concerns/clarifications not provided by the primary reviewer.
4) After all discussion is completed, the reviewers will restate their Overall Impact score. It is expected that these scores may change based on the discussion.

5) All members of the study section will then record an Overall Impact score on the score sheet. Individual members may give an Overall Impact score that differs from the reviewers’ scores but the difference may NOT be greater than 1 point ie if the reviewers’ impact scores are a 3 and a 4, members may record a score between 2 and 5.

The secondary reviewer should email their review to the primary reviewer prior to the study section meeting. The primary reviewer has the responsibility of compiling the final review and submitting it to the Moderator for review and submission to Blair Smith. The final review prepared by the primary reviewer should be a concise compilation and summary of both reviews and the discussion during the session.

**Scoring Guidance**

<table>
<thead>
<tr>
<th>Score</th>
<th>Descriptor</th>
<th>Additional Guidance on Strengths/Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Exceptional</td>
<td>Exceptionally strong with essentially no weaknesses</td>
</tr>
<tr>
<td>2</td>
<td>Outstanding</td>
<td>Extremely strong with negligible weaknesses</td>
</tr>
<tr>
<td>3</td>
<td>Excellent</td>
<td>Very strong with only some minor weaknesses</td>
</tr>
<tr>
<td>4</td>
<td>Very Good</td>
<td>Strong but with numerous minor weaknesses</td>
</tr>
<tr>
<td>5</td>
<td>Good</td>
<td>Strong but with at least one moderate weakness</td>
</tr>
<tr>
<td>6</td>
<td>Satisfactory</td>
<td>Some strengths but also some moderate weaknesses</td>
</tr>
<tr>
<td>7</td>
<td>Fair</td>
<td>Some strengths but with at least one major weakness</td>
</tr>
<tr>
<td>8</td>
<td>Marginal</td>
<td>A few strengths and a few major weaknesses</td>
</tr>
<tr>
<td>9</td>
<td>Poor</td>
<td>Very few strengths and numerous major weaknesses</td>
</tr>
</tbody>
</table>

**Minor Weakness:** An easily addressable weakness that does not substantially lessen impact  
**Moderate Weakness:** A weakness that lessens impact  
**Major Weakness:** A weakness that severely limits impact

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The following School of Dentistry guidelines are intended to supplement UNC Graduate School’s guide on preparing a thesis. The UNC Graduate School guide deals specifically with details on formatting (i.e. font type and size; margins; spacing and indentation; etc.), references, appendices, previously published work, and copyrighting. The Thesis and Dissertation Guide is available at http://gradschool.unc.edu/academics/thesis-diss/guide.

Either of the two masters of science thesis formats described here may be selected by the student and the thesis advisor. Regardless of the format, the final document should conform to that of a thesis in which all parts are related and integrated. These two formats allow students to easily convert the thesis into manuscript(s) which can be submitted to appropriate journals for peer review and publication.**

I. The first thesis option is a combination of one publishable (or published ++) manuscript proceeded by a detailed Review of the Literature. If the publishable manuscript was submitted or published prior to graduation, the student must be the first author although not necessarily the corresponding author. The overall format of this first option thesis is in keeping with Graduate School requirements which means the thesis will begin with a title page; copyright page; abstract; optional dedication and acknowledgement(s) page; table of contents, etc. Font type and style use must be consistent throughout the thesis. The format for the first option thesis contains the following elements:

   a) An Introduction.
   b) Detailed Review of Literature, followed by the List of References for the extended literature review
   c) Manuscript sections. The manuscript should be written following instructions for authors of the target journal or publication, and will typically include a brief introduction and literature review (Introduction), concise material and methods (Materials & Methods), findings with tables and figures as needed (Results), discussion (Discussion and Conclusions), and list of references for the manuscript (References). A separate abstract for the manuscript is not permitted.
   d) The reference style may be consistent with the target journal’s instructions to authors. The reference style must be consistent throughout the thesis
   e) Appendices may be added as needed.

II. The second thesis option consists of two or more publishable (or published ++) manuscripts. For this option, if submitted prior to graduation, the student must be first author on at least one of the manuscripts although not corresponding author. The manuscripts must be publishable separately. As in the first option, the overall format of
this thesis option is in keeping with Graduate School requirements which means the thesis will begin with a title page; copyright page; abstract; optional dedication and acknowledgement(s) page; table of contents, etc. Font and style use must be consistent throughout the thesis. The format for the second thesis option contains the following elements:

a) An overall **Introduction**, illustrating the connection between the two manuscripts followed by a **List of the References** used in the introduction.

b) **Manuscript sections (manuscript #1 and manuscript #2)**. Each manuscript will typically include a brief introduction and literature review (**Introduction**), concise material and methods (**Materials & Methods**), findings with tables and figures as needed (**Results**), discussion (**Discussion and Conclusions**), and list of references for each manuscript (**References**). A separate abstract for the manuscript is not permitted.

c) The reference style must be consistent throughout the thesis even if the target journals’ instructions to authors differ.

d) Additional materials and methods may be added in the appendix as needed.

e) An overall summary for the thesis is optional.

f) **Appendices** may be added as needed.

The student must complete the work to the satisfaction of the thesis committee, successfully defend the thesis, and deliver a final copy of the thesis to the Graduate School. It is strongly recommended that a draft be taken to the Graduate School well in advance of the deadlines so that it can be reviewed for adherence to all Graduate School guidelines.

Due to the lengthy review process involved with many journals, it is not necessary for the manuscript(s) to be accepted for publication prior to completion of the degree. Whether the manuscript(s) must only be “ready to submit” to a journal or “submitted” is determined by your program/committee.

**From the Graduate School Handbook – REFERENCES**

Always begin references on a separate page either immediately following the end of each chapter or at the end of your entire document.

- If you place references after each chapter, the references for the last chapter must be placed immediately following the chapter and before the appendices.
- If you place all references at the end of the thesis or dissertation, they must appear after the appendices as the final component in the document.

++ From the Graduate School Handbook -- USING COPYRIGHTED MATERIALS
Any copyrighted materials used in your work, beyond brief excerpts, may be used only with the written permission of the copyright owner. Book and journal publishers normally hold the copyright for all materials they publish. Therefore, even if you are the sole or one of several authors of material in a published book or journal, you must obtain written permission from the copyright holder if you are including this material in your document. Remember that use of reproductions or excerpts of other media, such as music, graphic images, or computer software may also require permissions.

Your letter to the copyright holder needs to make clear that you seek written permission to preserve (on microfilm and digitally) and publish (in print and digital form) your thesis or dissertation through ProQuest and that ProQuest may sell, on demand, for scholarly purposes, single copies of your work, which includes the copyright holder's material. Your letter must also seek written permission for the document to be submitted in electronic format to UNC-Chapel Hill where it will be placed in a database and made available through the University Library to the general public at no charge via the Internet.

You are responsible for securing all necessary permissions and paying any permission fees in advance of using copyrighted materials in your work.

**Use of Your Own Previously Published Material**

Some academic programs permit you to include articles or other materials that you have previously published, that have been accepted (or submitted, in press, or under review) for publication, or that have been otherwise presented to the public within the body of your thesis or dissertation. In all such instances the following guidelines apply:

1. If the material is co-authored, your academic program must approve its inclusion in your thesis or dissertation.
2. If the material is copyrighted (if you are the sole author but the copyright is held by the publisher), you must fulfill the conditions specified in the section above on using copyrighted materials.
3. The material, if included in the body of your text, must conform to all formatting guidelines outlined in *A Guide to Thesis and Dissertations*. See the Formatting Previously Published Work section for details.
GUIDELINES ON MASTER’S THESIS DEFENSE
School of Dentistry, Advanced Education Programs
University of North Carolina at Chapel Hill

1. Notification of each thesis defense (including student’s name, topic, time, and location) must be made at least two weeks prior to the planned defense. Notice must be sent to the Graduate Dental Student Registrar, who will notify all department chairs, the student’s graduate program director, the Assistant Dean for Advanced Dental Education, the Associate Dean for Research, and the Dean.

2. The final draft must be delivered to all committee members at least two weeks prior to the defense to permit them sufficient time to review and analyze the thesis and to prepare for the thesis defense. The final draft should be in proper format and ready for submission to the Graduate School.

3. At least two-thirds of the committee must approve the final oral defense and the thesis. All committee members must attend the defense. The vote of the thesis committee is considered by the Graduate school to be final. Attendance by Skype or Zoom is acceptable.

4. The thesis advisor is responsible for advising the student on the guidelines for the defense and for proper conduct of the defense.

5. The defense is open to any students and faculty who wish to attend. After the student’s initial presentation, committee members will question the student on the thesis. Visitors are permitted to ask questions as well.

6. The initial presentation should be relatively succinct. The presentation and the open question and answer session with committee members and visitors generally should not exceed an hour in length.

7. Visitors do not observe the committee’s deliberations that follow the question and answer session.

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RESOURCES

Thesis and Dissertation Guide
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