

SCHOOL OF DENTAL MEDICINE
OFFICE OF GRADUATE STUDIES
CASE WESTERN RESERVE UNIVERSITY

INSTRUCTIONS FOR THE PREPARATION OF A THESIS PROTOCOL

PLEASE READ CAREFULLY

In order to provide assistance to graduate students, this set of instructions has been prepared as an aid to **thesis protocol** preparation. It is advisable that you follow these instructions so that the approval of your protocol is not delayed.

PURPOSE

The purpose of the thesis protocol is to provide the graduate student and their thesis committee with an outline for conducting the research project. Properly designed, the protocol should allow the student to understand the *what, why, when, and how* questions that are associated with the execution of their project. Consult your department chair on the formation of a thesis committee (see STEP 1 below). Until full agreement exists between the student, the thesis committee, and those assigned for administrative oversight, the project should not be started. One or more revisions of the protocol are to be expected. It is important that some members of the committee have expertise in the area of research being proposed so as to provide advice, direction, and supervision to the student. If expertise is lacking, or if revision fails to improve the protocol, the project should be abandoned in favor of a different project that is more likely to meet with common approval and available expertise. It is far better to have the protocol rejected than the completed thesis. Therefore, a properly developed and approved thesis protocol will help guide the student and increase the likelihood that the thesis and its defense might be accepted.

TIMING

The graduate programs at the School of Dental Medicine vary in length. Thus, the time for thesis protocol development and submission will vary. In general, the graduate student should be engaged in their program of study for a sufficient length of time to allow them to become familiar with the literature in their field and to identify areas in need of further study. Although the faculty can be helpful in identifying areas for further study, it should be one in which the student has some (special) interest. A year or more is normally needed for an approved protocol to be executed, and a thesis prepared, defended, revised, and accepted.

STEPS

1. Consult with your program director as to when and how to form a thesis committee. This is usually done at least one year prior to the anticipated time of your completion of the program. Your department chair will choose a faculty member to serve as your primary thesis advisor. This advisor will also serve as the chair of the thesis committee. The primary thesis advisor will help identify other members of the faculty (at least two) to serve as secondary advisors and as members of the thesis committee. Members of the thesis committee continue in their capacity until the student is graduated or leaves the program of study. The thesis committee will be responsible for guiding the student in the development of a thesis protocol. Once a protocol is acceptable, the thesis committee members advise the student on the conduct of the research and writing of the thesis document. Ultimately, the committee members will evaluate the student's oral defense of the thesis.

2. Once your thesis committee has been formed, it is probably a good idea to meet with the members individually or in a group to discuss the general aspects of what research project you are interested in pursuing as your thesis. Based on this meeting, you should proceed appropriately; meet again or go to step three. Consultation with a statistician should occur before the experimental design is finalized to assure that the design permits proper measurements and correct analysis of the results. Statistical design is integral to the project's successful execution.
3. Write a thesis protocol that includes all of the necessary elements (see the instructions, NECESSARY ELEMENTS). The entire protocol will be perhaps six to eight pages if all elements are used (less if some elements such as IRB approval or informed consent are not needed).
4. Meet with your committee as a group to review your protocol. Each member should hear the comments of the other members and be able to provide input. Modify or revise the protocol as needed. Develop a new protocol if necessary. Once you have revised the protocol to the satisfaction of your entire committee, if **no** IRB/Animal Experimentation committee approval is needed, ask the chair of your thesis committee to sign the **Thesis Protocol Approval Form**.
5. If IRB/Animal experimentation committee approval is necessary, ask the chair of your committee assist you in the submission of an application to the appropriate committee. Once accomplished, ask the chair of your thesis committee to sign the **Thesis Protocol Approval Form**.
6. Submit each of the following items (as a package) to the Office of Graduate Studies:
 - 1) the thesis protocol
 - 2) a timetable for your project and the preparation of your thesis
 - 3) a budget
 - 5) a signed AThesis Protocol Approval Form
 - 6) IRB/Animal Experimentation committee approval, if needed
 - 7) HIPAA compliant informed consent form, if needed.

7. After your protocol receives administrative approval, develop a detailed literature review. Once you actively engage in the execution of the project, be certain that experimental design is being followed as planned and that the data is analyzed according to the protocol. If the protocol needs to be modified, check with your committee and get their permission first. Modification of a project to the point of doing a project markedly different from the project started will require the development and approval of a new protocol before continuing.

NECESSARY ELEMENTS of A THESIS PROTOCOL

- 1) Literature Review (Brief, only a few key articles)
- 2) A statement of the Question; Objective of the Study or the Hypothesis (Clear and precise)
- 3) Experimental Design
- 4) Statistical Design
- 5) Budget
- 6) Timetable
- 7) Review and Approval by the Appropriate Human or Animal Institutional Committee (**if needed**)
- 8) Informed Consent (**if needed**)

The thesis project provides the student an opportunity to add to the body of knowledge in their field of study in a meaningful way. It also provides for a first-hand understanding of structured research, scientific method and sharing of ideas and findings.

The thesis must identify an area in need of further study. This should be based on a familiarity of the existing body of knowledge of that discipline for which a problem or question remains unanswered. Therefore, the first element is LITERATURE REVIEW. The literature review is of the key literature that helps to identify the problem (question) to be addressed by the study. It should not be an exhaustive search of the world literature. That is usually reserved for the thesis proper.

It is important to note that the references within your literature review will be cited by author (Please see the book Citing Medicine: The NLM Style Guide for Authors, Editors, and Publishers for precise directions on in-text citations as well as reference pages). A Literature Review reference page is required. This Reference page will list the

authors alphabetically as opposed to numerically.

The next element is a STATEMENT OF THE QUESTION/THESIS, OBJECTIVE OF THE STUDY, or the HYPOTHESIS that has been supported by the Literature Review. This is followed by a detailed plan, which includes the EXPERIMENTAL DESIGN to address the question (objective/hypothesis). This aspect must follow scientific method. It must be well thought out, thorough, focused, and controlled to generate results (data) that can be analyzed and might help to answer the question posed. The student must be capable of using the instruments, techniques, etc., outlined in the plan, or have available expertise. The next element is a way to analyze the data generated with application of using statistics of appropriate STATISTICAL DESIGN. Without a proper analysis of the data, the results will lack credibility and the thesis could prove to be unacceptable.

In addition to the elements above that form the main body of the protocol, a BUDGET is needed, so that the cost of conducting the study can be matched with available resources. If the resources cannot be identified, the project will have to be modified while remaining credible, or must be abandoned. This budget must be approved by the Office of Graduate Studies. A TIMETABLE for conducting the project, analyzing the data, preparing, defending, and revising the thesis must be developed. The project must fit into the maximum five-year time frame permitted to complete the program. Embarking on a project that will likely take years to complete, should be modified or abandoned. Lastly, if human or animal subjects are to be used in the study, REVIEW AND APPROVAL BY THE APPROPRIATE HUMAN OR ANIMAL INSTITUTIONAL COMMITTEE of the university must be obtained. In the case of use of human subjects, an INFORMED CONSENT must be submitted for approved for IRB approval.

Thesis Protocol Approval Form
Case Western Reserve University
School of Dental Medicine
Office of Graduate Studies

INSTRUCTIONS TO GRADUATE STUDENTS: Please complete this side of the form and present it to your thesis committee chairperson (primary advisor) who will complete the reverse side following your protocol presentation to your thesis committee. Please note that the members of your committee **MUST BE PRESENT** at the time of your thesis defense. Substitutions will not be allowed. (please print or type)

Attach a copy of the thesis protocol in its final form (see **INSTRUCTIONS FOR THE PREPARATION OF A THESIS PROTOCOL**), a budget, and (as appropriate) informed consent, IRB or animal experimentation application. Submit to the Dental School Office of Graduate Studies promptly. ***Students may not begin work on the thesis unless the protocol is approved and signed by the Thesis Committee Chairperson and the Associate Dean for Graduate Studies.*** Should the Associate Dean have questions or concerns, your thesis committee chairperson will be notified.

Your Name _____

Department _____

Committee Members (not less than three, of which two must be from your home department of study and one from outside your home department)

_____(thesis chair)

Thesis title _____

Anticipated date of graduation _____

(reverse side to be completed by thesis committee chairperson)

Thesis Protocol Approval Form

(this side to be completed by thesis committee chairperson)

INSTRUCTIONS TO THESIS COMMITTEE CHAIRPERSON: Please sign-off that the protocol for the student's thesis has been critically reviewed by the committee for the following elements and meets with the committee's approval:

- Literature review _____
- Hypothesis/objective _____
- Experimental design _____
- Statistical analysis design _____
- Reference list/literature cited _____
- Budget and time _____
- IRB/Animal experimentation approval (if applicable) _____
- Informed consent (if applicable) _____

(date of committee's protocol review)

(signature of thesis chair)

ADMINISTRATIVE REVIEW: The proper approvals have been reviewed and are acceptable to enable the student's thesis work to commence.

(Associate Dean for Graduate Studies)

(date)