

BIOS 702: Protocol Defense

Goal: The overarching goal of this course is to provide students with the opportunity to present a review of their proposed PhD research protocol and get independent feedback at an early stage of their PhD research. Students will receive critical and constructive feedback from impartial faculty members which, in some cases, may help them strengthen the overall scientific quality of their thesis proposal. This process is expected to minimize the risk of unforeseen problems being encountered closer to or even at the time of the final PhD thesis defense, thereby optimizing the successful and timely completion of the PhD by the student.

Timing: The completion of BIOS 702 in a timely manner is strongly encouraged; most students should have completed this milestone within 24 months of their enrollment in the PhD program.

Description: This course aims to provide a forum whereby the student can present their PhD research protocol and receive critical and constructive feedback from a minimum of three faculty members not otherwise involved in their PhD thesis supervision. In addition to displaying high scientific quality of their proposed research, students are expected to demonstrate their overall “project ownership”, originality, a comprehensive understanding of all research methods to be used, and integration of all the components of the proposed PhD research (e.g. all manuscripts in the case of a thesis-by-papers format) into one comprehensive advancement of knowledge in the field of biostatistics. Further details about what comprises a successful PhD dissertation can be found on the Graduate and Post Doctoral Students (GPS) webpage.

Procedures: Students will normally take this course in the year following the completion of their PhD Theory Comprehensive Examination. Students are expected, under the active tutelage of their supervisors and thesis committee members, to have developed a scientifically appropriate research question that will be addressed by rigorous research methods of the highest quality. Students need to demonstrate essential grantmanship skills in both writing and defending their protocol, including essential elements of research protocols, such as the formulation of research objectives, a description of the biostatistical methods that will be used to approach the problem, and the specific methodological advances that will be made as part of the thesis research.

The course is run over the Fall and Winter terms. It will not be offered during the summer months. The course will meet every week that a presentation is scheduled. It is expected that all students enrolled in a given academic year will attend **all** presentations by their fellow students (epidemiology and biostatistics) in both semesters, regardless of the timing of their own protocol defenses unless their absence at a specific class is approved by the course instructors. In the first week of the Fall semester, the students will meet with the course instructors to discuss the goals, expectations, and procedures. Except for this initial class, there will normally not be a class if no presentation is scheduled, although the courses instructors are available to schedule sessions for the free weeks according to the desires and requirements of the students.

The presentations will be scheduled – one per week – on a “first come” basis. Students must coordinate a suitable date with their supervisor(s) who must also attend the defense. Students are expected to submit a 1-page Abstract of their proposal at least four weeks prior to the presentation date. This allows the instructors sufficient time to identify appropriate examiner(s). There will be typically three examiners, including the two course instructors (unless a conflict of interest is present, in which case the instructor will be replaced by another faculty

member with a similar expertise) and additional ad hoc faculty member(s), selected according to the expertise required to thoroughly evaluate the proposal and complement the expertise of the course instructors. At least two weeks prior to the presentation, the students are required to submit their complete written protocol. This is limited to a maximum of 12 single spaced pages (not including the reference list). Additional non-essential material may be included in appendices but the examiners are not obliged to consider these appendices in their evaluations, so that the 12-page protocol should be a stand-alone document and should cover all the essential elements of the proposed PhD research. It is essential that, for example, in the case of a thesis-by-manuscript format, all manuscripts planned to be included in the final PhD thesis are covered (though not necessarily with the same level of detail) in the Protocol. Also, it should be emphasized that – even if the protocol may be related to a peer review grant submission, its content and format will necessarily be somewhat different from the operating grant application. Finally, it is expected that, prior to the Protocol submission, the student will receive an in-depth feedback on the content and the form of the 12-page Protocol from their supervisor(s) and – within their respective areas of expertise – from the PhD committee members, and that the submitted text of the Protocol is approved by the supervisor(s).

It is expected that the protocol defense presentation will be of high quality and equivalent to a professional presentation at a scientific conference. Students should plan no more than a 20-25 minute presentation. Strict time lines will be enforced so students should rehearse their presentation to ensure it can be completed in a timely fashion. The presentation should reflect what has been submitted in the written protocol. While – given time limitations – some omission in the oral presentation of the details of both background and methods is understandable, major deviations from the written protocol, and especially additions of new objectives or methods not discussed in the protocol are not permitted as the examiners have prepared their questions based on the written submission. To facilitate questions, it is helpful to follow standard scientific presentation etiquette that should include numbering slides so that it easy to return to specific slides for later questions. After the presentation there will be questions from the panel of examiners and audience. The question period is open ended but typically will not exceed 60 minutes. Questions are to be answered only by the presenter without any prompting or assistance from the supervisor(s), committee members or audience member. Typically, the question period involves two “rounds”, with each of the three examiners asking, in turn, a few questions in each of the two rounds. Then, the audience is invited to ask questions. Following the termination of the question period, the examiners will meet with the supervisor(s) to complete their assessment of the student’s presentation. Within two weeks of the protocol defense presentation, the instructors will provide a letter to the PhD student and supervisor(s) informing the student of their grade (Pass/Fail) as well as general and specific feedback and recommendations. Occasionally a pass may be associated with, or even conditional on, a requirement to submit some additional information. A failure will require a new written submission addressing the concerns outlined in the letter and conveyed to the supervisor(s). This may or may not require a repeat oral presentation, depending on the examiners’ judgment.

The PhD candidate must be able to present and defend the main research questions to be investigated by a) showing where the proposed PhD research fits within existing knowledge; b) showing where the proposed PhD project will extend the existing knowledge; c) showing the originality and relevance to biostatistics and, when appropriate, to other relevant aspects of modern epidemiological research; d) showing the leading and fundamental contribution of the candidate to the development of the research questions; e) answering all pertinent questions

about the research methodology including but not limited to providing description and justification for the proposed approaches, thereby clearly demonstrating their complete ownership of the protocol.

The PhD protocol defense is an occasion not only to assess the scientific quality of the project but also permits an examination of student ownership of the project, originality, methodological sophistication (consistent with the high standard and international reputation of our Department), as well as of the importance and scope of the proposed research. While it is understood that manuscript-based theses are likely to have one dominant component, we expect – according to McGill Guidelines for PhD Theses – to see a strong evidence of coherency, totality and integration of the different elements comprising the proposed thesis topic.

Grading: This course is graded in a Pass/Fail manner. A failure will require a complete revision of the written protocol and possibly an oral re-presentation (within 3-6 months).