BIOS 702: Protocol Defense

Goal: The overarching goal of this course is to provide students with the opportunity to develop research skills, and to present and defend their proposed PhD research protocol and get independent feedback at an early stage of their PhD research. Students are expected to demonstrate their overall "project ownership", originality, and a comprehensive understanding of all research methods to be used. In addition to displaying high scientific quality of their proposed research, all the components of the proposed PhD research must be integrated into one comprehensive advancement of knowledge in the field of biostatistics.

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.

Successful completion of the course includes:

1. Attendance of at least 4 workshops;
2. Attendance of at least 3 epidemiology protocols and completion of a two-page written report;
3. Attendance of all biostatistics defenses in the year of enrolment; and
4. Submission and defense of an original protocol.

Details on all components are given below.

Timing: The completion of BIOS 702 in a timely manner is strongly encouraged; students are recommended to have completed this milestone within 30 months and should have completed it within 36 months of their enrollment in the PhD program. Students wishing to delay completion of this important milestone require special permission of the Graduate Program Director.

Description: This course aims to provide a forum whereby the student can present their PhD research protocol and receive critical and constructive feedback from three faculty members, two of whom are not otherwise involved in their PhD thesis supervision. 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 Applied 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 grantsmanship and both written and oral communication skills in both preparing and defending their protocol, including essential elements of research protocols, such as the formulation of clear and concise 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. Students will also need to address specifically how performance of any newly proposed or developed biostatistical methods will be assessed. Finally, it is typical for the protocol to include and describe one or more real-life

applications in which the methods that are the core of the thesis will be expected to provide new insights (or otherwise "improved" results) over existing methods.

The course will be run as a series of workshops, which may include the following topics:

- Literature review guidelines and effective search strategies
- Grant-writing skills: "Marketing" the key ideas in a proposal
- Grant reviewing (reading the abstract, identifying points that need to be demonstrated or potential weaknesses, then going through remaining documents and checking off whether they addressed these points)
- Presentation skills
- Data sources, cleaning, and management
- Graphics and visualization
- Tools for knowledge translation (writing R packages, developing Shiny apps, etc.)
- High powered computing (using Compute Canada, paralleling code, unix scripting, requesting memory allocations, job control)
- Principles and methods of ensuring reproducibility in research (ensuring 'testing' datasets are available, validation of all steps in algorithms, version control, markdown, git, GitHub, R, RStudio, simulating data and open science principles)

Students must attend a minimum of four workshops.

Additionally, students must (i) attend **all** presentations by their fellow Biostatistics students, (ii) attend **at least three** Epidemiology protocol defenses and then write a two-page document that provides evidence that the student has reflected on the substantive or epidemiologic issues in the defenses attended and reflects on the elements of a successful protocol presentation. The written report must (i) summarize the research gap and proposed work from one of the three Epidemiology defenses based on what was presented by the student in the protocol defense, (ii) explain what are the strongest and weakest elements of the proposed research of the proposal discussed in (i), (iii) discuss the relative effectiveness of different communication strategies employed in all three Epidemiology protocols attended, and (iv) reflect on how the strategies outlined in (iii) may be relevant to the presentation of statistical content. In some cases, a student enrolled in 702 for a given academic year may defer the defense to the next academic year. In such cases, the attendance of workshops/defenses will NOT be required for the later year, although the students are welcome to attend. Students may attend workshops prior to enrolling in BIOS 702. All attendance will be recorded in their student files, and may be counted towards BIOS 702 in the year of enrollment.

In the first week of the Fall semester, the students will meet with the course instructors to discuss the goals, expectations, and procedures. The course is run over the Fall and Winter terms; protocol defenses may be scheduled at any point (subject to the availability of dates provided by the course instructor(s)) following completion of the workshops and the attendance of EPIB 702 defenses as noted above.

The protocol defense must be scheduled in coordination with their supervisor(s); the supervisor (or **one** of two co-supervisors) will be an examiner at the defense. Students are expected to submit a **one-page** Abstract of their proposal **at least four weeks** prior to the presentation date, and to identify **one** examiner who is willing and available at the proposed defense date. In the case where

the course coordinator is a (co-)supervisor, a second examiner must also be secured. Thus, two of the three examiners cannot be involved (formally or informally) in any aspect of the proposed PhD research and should not have been involved in the student's previous training (as supervisors or committee members) but can collaborate with the supervisor(s) on different projects. **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); font size should be no smaller than 10 point. 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 a 20 minute presentation (not to exceed 25 minutes). 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, followed by possible questions from the 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 decision and grade (Pass/Fail) as well as general and specific feedback and recommendations. Occasionally a pass may be 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) demonstrating the internal coherence of the proposal, so as to meet the McGill requirement that the different components (often corresponding to separate thesis manuscripts) complement each other and constitute an integral research project; e) explaining how the proposed methods will help to address analytical challenges of specific real-life application(s); f) showing the leading and fundamental contribution of the candidate to the development of the research questions; and g) 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 mastery 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. For manuscript-based theses, 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. In the case of a conditional pass, a revision of the written document is typically expected within 3-6 months. A failure will require a complete revision of the written protocol and a new oral presentation within the next 6-12 months.