Department of Biostatistics & Bioinformatics
Duke University School of Medicine

Master of Biostatistics Program
Student Handbook for Students Enrolled Effective August 2022
2022 – 2023

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Table of Contents

Introduction

Welcome to the Duke University School of Medicine Master of Biostatistics Program! We're excited to help you take your first steps into this dynamic and ever-expanding field and are here to make sure your time with us is as successful as possible. The primary purpose of this Student Handbook is to provide you with information about how our program operates and thereby assist you during your time with us at Duke. Intended as both a general orientation for new students and a more detailed reference for current students, we hope it will serve as a helpful guide as you progress through the program.

As we'd like for the Student Handbook to remain a "living document," up to date and relevant, we encourage your feedback. Continuous evaluation is important to us so please be sure to let us know if you have any questions or suggestions for improvement.

Yours,

Greg Samsa, PhD
Director of Graduate Studies
Master of Biostatistics Program

1 Program Overview

1.1 Student Expectations

In addition to the academic requirements that must be met to complete a Master of Biostatistics degree, students must also adhere to a set of student responsibilities. These responsibilities are as follows:

- To read and understand this handbook;
- To engage in ethical and scholarly conduct as described in the Duke Community Standard and the Duke University School of Medicine Honor Code of Professional Conduct;
- To meet with your assigned advisor on a regular basis (to discuss progress, electives, experiential learning opportunities, and master's project topics);
- To pay your Bursar bill in a timely manner to avoid any holds on your account that may prevent course registration;
- To register for courses at the assigned time;
- To obtain approval from your advisor to enroll in any courses outside the program before registering for those courses;
- To prepare for classes including homework and assigned readings;
- To inform the appropriate people (advisor, instructor, program coordinator) as soon as possible of any problems (personal or otherwise) that may affect academic performance;
- To complete an experiential learning opportunity (or practicum) in order to fulfill program requirements;
- To complete and pass the Qualifying Examination.
- To develop and complete a Master's Project with your mentor during your second year;
- To provide feedback about the program in the interest of continual improvement; and
- Attend and participate in class.

1.2 Program Responsibilities

Our responsibilities as a program include:

- Providing a high-quality curriculum;
- Providing instructors who are experts in their fields and committed to teaching;
- Demonstrating ethical statistical practice and training our students to engage in the same;
- Regularly reviewing student progress and providing students with graded work;
- Regularly reviewing the content of the program with the goal of continuous improvement;
- Providing experiential learning opportunities; and
- Regularly informing students about our expectations of them.

1.3 Degree Requirements

The Master of Biostatistics degree, a professional degree awarded by the Duke University School of Medicine, requires 50 credits of graded course work, a practicum experience, a qualifying examination, and a master's project for which 6 units of credit are given. Completed in the second year, the master's project serves to demonstrate the student's mastery of biostatistics. Successful completion of 44 course and lab credit hours and 6 master's project credit hours are required for all degree candidates.

1.4 Time Expectations

A full-time degree candidate is expected to complete all requirements within two calendar years of matriculation. In the event a circumstance constitutes an exception to this expectation, a plan for program completion will need to be developed with the Director of Graduate Studies.

1.5 Grades

We expect grades to be calibrated towards an objective standard of performance. Specifically, grades should reflect different levels of mastery, such that each student could be graded without any knowledge of or consideration of the performance of other students in the current class. Grades of A denote excellent performance and nearly complete mastery of the subject, grades of B denote good/adequate performance and mastery of the key topics but confusion on some points, grades of C denote substandard performance and serious gaps in the understanding of the subject matter and trigger a programmatic review, and grades of D and lower denote below substandard performance and lack of mastery of any material from the course. Any grade below a B- will trigger a review of the student's performance. (Typically, program administration will begin the review with an informal conversation with the instructor, and then enter the formal review process if indicated.)

Students whose performance is adequate or better will receive one of six grades: A+, A, A-, B+, B, and B-. Instructors are encouraged to use the top end of this scale to differentiate the performance of students whose work is particularly outstanding. Grades of C+ and below indicate substandard performance requiring programmatic review and should be assigned with this implication in mind.

Instructors are encouraged to make their grading system consistent with their course goals but otherwise have considerable flexibility in developing their grading criteria. For example, if they desire, they can set the criteria for receiving a grade of A to reflect performance that is unusually outstanding, in which case most students will receive some sort of B. If every student achieves outstanding performance the instructor can assign the entire class grades of A. If they wish, instructors can set numerical benchmarks (e.g., a total score of x is required to achieve an A) but are not required to do so.

The primary purpose of grading students is not the relative ranking of students (although it will generate a cumulative GPA for each student, which can then be ranked), but rather as a means to communicate a student's level of mastery in a particular course. In

particular, scores need not be standardized to conform to any particular statistical distribution.

Certain courses will be graded using a pass/fail scale: BIOSTAT 720, BIOSTAT 801 and BIOSTAT 802. Students who sit-in on a course do not receive a grade.

1.6 Grade Appeals

In case of a dispute about a grade, the student should first contact the instructor. If they are unable to resolve the dispute, the Director of Graduate Studies is the next person to contact. In general, the role of the Director of Graduate Studies is not to second-guess the instructor's judgment, but instead to assess whether the instructor in question has followed their grading policy and the degree to which extenuating circumstances should be taken into account.

1.7 Academic Performance Review

A student who receives any grade of C+ or below will enter the procedure for academic performance review, the primary goals of which are to identify causes of the substandard performance, develop a remediation plan, and to assess the success of that remediation plan.

If the student receives a single grade of C+ to C-, they will enter the process for academic warning. If the student receives two grades of C+ or below, or one grade of D+ or below, they will enter the process for academic probation. For this purpose, a permanent grade of I (Incomplete) is treated as an F.

Questions of academic performance will initially be considered by a Standing Committee of the faculty. The Director of Graduate Studies will serve as a non-voting member.

If a student enters the process for academic warning, a meeting of the Standing Committee will be called. The student will be invited to attend, as well as the relevant instructor. A remediation plan will be developed and signed by the student. The intention of this remediation plan is to address potential academic problems before they become more serious. The academic warning will not be included on the student's transcript.

If a student enters the process for academic probation, a meeting of the Standing Committee will be called. The student will be invited to attend, as well as the relevant instructor(s). Unless significant extenuating circumstances are deemed to be present, the student will be placed on academic probation. A remediation plan will be developed and signed by the student. The intention of this remediation plan is to set conditions by which the student can regain good academic standing. If the student does not meet the terms of the remediation plan, in the absence of significant extenuating circumstances, the next steps are suspension or dismissal. The School of Medicine Registrar will be notified of the student's academic probation, and it will be noted on the student's transcript at the completion of the semester(s) during which the status is assigned. Once the student has

been removed from probationary status, the notation on the student's transcript will be removed.

Decisions of the Standing Committee will be reviewed by the Director of Graduate Studies and then the Vice Dean for Education. Appeals of these decisions can be made to the Director of Graduate Studies, and then to the Vice Dean for Education.

1.8 Incompletes and Withdrawals

An I (Incomplete) grade indicates that some portion of the student's work is lacking for a reason acceptable to the instructor at the time grades are reported. Students will not be permitted to enroll in any course for which they have an unresolved I in a prerequisite course. A grade of I must be resolved no later than the end of the following academic semester unless the course director specifies an earlier date by which the student must make up the deficiency. In exceptional circumstances, an incomplete that is not resolved within the designated period may be extended for a specified period with the written approval of the course instructor and the director of graduate studies. If an incomplete is resolved within the approved period, the grade of I may be removed from the student's record.

Withdrawals:
In the case of a student withdrawing from a course after the drop/add period, the student will receive a grade of W, WP (withdraw passing), or WF (withdraw failing), as determined by the director of graduate studies and the course instructor.

1.9 Good Academic Standing

Maintaining good academic standing is necessary to register for courses and to take the Qualifying Examination. Good academic standing can be jeopardized by substandard grades, violation of the honor codes, and/or unprofessional behavior.

1.10 Honor Code

I. Duke Community Standard

All students are expected to adhere to the highest standards of professional behavior. The Duke Community Standard applies to all Duke students, both on and off campus. When you accepted admission to our program, you signed an oath to uphold this standard, stating that:

To uphold the Duke Community Standard:

- I will not lie, cheat, or steal in my academic endeavors;
- I will conduct myself honorably in all my endeavors; and
- I will act if the Standard is compromised.

For more detailed information on the Duke Community Standard, click here.

In addition to the Duke Community Standard, students of the Master of Biostatistics program, as students enrolled in the Duke School of Medicine, are also bound by the standards detailed in the Duke University School of Medicine Honor Code of Professional Conduct below.

II. Biostatistics and Bioinformatics Honor Code Violations

The following instances are considered honor code violations in our program:

- Observing an honor code violation and failing to report it;
- Copying another student's answers for a graded assignment when working together is allowed (for example, course homework);
- Pressuring another student to supply answers for a graded assignment when working together is allowed (for example, course homework);
- Discussing with or working with other students or faculty members on a graded assignment when working together is not allowed (for example, a take-home exam or final project that is to be completed individually);
- Copying or failing to properly reference another author's work when drafting a written report for class or for your master's project;
- Copying another student's answers on an exam or quiz during the test – with or without their knowledge;
- Discussing questions on an exam or quiz with another student during the test;
- Bringing and/or using a cheat sheet or note sheet during a closed-book, closed-note, closed-technology exam;
- Using a smart phone, smart watch, tablet, personal computer, or any other smart device during a closed-book, closed-note, closed-technology exam;
- Changing answers on a submitted assignment and/or submitted test after they have been turned in or graded as well as falsifying a date stamp on submitted assignments;
- Accepting two paid internships simultaneously without approval of the Director of Graduate Studies and the internship supervisors;
- Accepting two paid internships simultaneously and then sourcing the work out to other colleagues;
- Falsely accusing another student of an honor code violation; and
- Signing the name of anyone other than yourself on any document.

1.11 Procedure for Handling Violations of Honor Codes

All instances of potential violations of the Honor Codes, whether or not they pertain to academic performance, are handled similarly. As a first step, the Director of Graduate Studies interviews the student and others to ascertain the facts of the case. If the situation requires additional follow-up, the Director of Graduate Studies will convene the Academic Review Committee (consisting of the Director of Graduate Studies, at least four other faculty members, and the Chair as a non-voting member). The student will be invited to attend part of the meeting if desired – for example, to present additional information – but is not required to attend. The committee's recommendation will then be reviewed by a Director of Graduate Studies.

What happens next depends on the nature of the recommendation. If the recommendation is probation, suspension, or dismissal (i.e., if the recommendation affects the student's ability to attend classes and progress in the program) – the recommendation of the Director of Graduate Studies is reviewed by the Vice Dean of Medical Education as per the School of Medicine review procedures. The Vice Dean of Medical Education makes the final decision and communicates that decision to the student. Any appeals of that decision follow the policies of the School of Medicine.

On the other hand, if the decision does not involve probation, suspension, or dismissal, it will be conveyed to the student by the Academic Review Committee Chair. The student can appeal the decision to the Chair, and then to the Vice Dean of Medical Education.

1.12 Additional Ethical Responsibilities for Statisticians

Additional elements of the Duke Community Standard are specific to your role as a statistician, for example:

- Maintaining confidentiality of data; and
- Appropriately responding to inappropriate analysis requests.

Regarding these latter elements, many of the ethical issues faced by practicing statisticians are ambiguous – for example, what should be done if an investigator doesn't like the results of an analysis and demands another analysis, perhaps with some of the data points removed. This handbook is not intended to provide precise guidance about what you as a statistician should do in the above (or similar) situation. Instead, the intent is to clarify your general responsibilities. These responsibilities include the following:

- Learn about the general principles of ethical statistical practice – for example, as illustrated by the statement on that topic from the American Statistical Association;
- Attempt to follow those principles to your best ability;
- Learn about the ethical issues pertaining to scientific research in general – for example, as covered in Duke's online training program;
- When encountering an ethical dilemma (e.g., such as the above), you have an affirmative responsibility to act by informing the appropriate personnel (for example, if you encounter an ethical issue during your internship then your internship supervisor would be the natural person to inform); and
- If you are uncertain whether an action is appropriate (e.g., whether the citation of someone else's work is adequate, whether a class assignment is intended to be performed alone or in collaboration), you have an affirmative responsibility to solicit advice from the appropriate personnel (e.g., your instructor would be the natural person to ask about class assignments).

For additional information regarding ethical responsibilities for statisticians, please see The American Statistical Association's Ethical Guidelines for Statistical Practice.

2 Bill Payment and Finances

2.1 Bill Payment

Fall semester bills are typically sent out in late June and are due August 1. These dates may fluctuate slightly and are at the discretion of Duke Bursar's Office. Spring semester bills are typically sent out in early December and are due January 7. These dates may also move based on the Bursar's Office and school calendar. You will receive a bill directly from the Duke Bursar office. You can find more information on the Duke Financial Services/Bursar website. To assist students paying tuition and fees bills from abroad, Duke University has engaged Western Union Business Solutions, an option which allows you to pay your student bill in your own currency. There are no additional transaction charges from Western Union Business Solutions or Duke University, though you may be charged a transaction fee by your bank. For more information on this program click here. To initiate a wire transfer from abroad, click here.

2.2 Financial Assistance

Financial assistance for the Master of Biostatistics Program can take the form of program scholarships, paid assistantships/internships, and federal need-based financial aid packages.

Program scholarships are merit based. The funds are limited, with the available amount varying from year to year. All accepted applicants are automatically considered for these Department of Biostatistics & Bioinformatics scholarships. (No separate application for financial aid is necessary to be considered for department-awarded scholarships.)

Assistantships/internships may become available at any time. However, the number of available opportunities depends on the needs of the entities who are hiring and the fit of the student to those positions. Both paid and unpaid internships are available. Paid internships are usually awarded competitively. Both the paid and unpaid internship opportunities may meet the program requirement for an experiential learning opportunity (practicum). Information about federal need-based financial aid can be found on the Duke Financial Aid website. Students should note that federal need-based financial assistance opportunities are limited to citizens of the United States. Please note that the School of Medicine does not receive funding for work study and thus our students are ineligible for the university's work study program.

3 Registration

3.1 Registration

All students enrolled in the program and who have not been granted a leave of absence by a Director of Graduate Studies must register for courses each fall and spring until all degree requirements are completed. For your first semester, you will typically register in June or July. All first-year courses are mandatory (and similar for everyone depending on your track). You are guaranteed enrollment in B&B department courses. For all subsequent semesters, you will register during the announced registration periods in October and March. Prior to these registration periods, you will receive an e-mail from the School of Medicine Registrar with detailed instructions on how to register using your Duke Hub/ACES account.

3.2 Enrolling in Non-Program Courses at Duke

While your primary academic focus should be your program coursework, we want you to be able to take full advantage of your time with us at Duke. That said, if you would like to enroll in a non-program course here at the university, you must first obtain approval from the program by submitting the Non-Program Course Approval Form (NP-1) to the program coordinator. The administrative team will discuss your request and notify you of the decision. **NP-1 forms should be submitted at least one week in advance of course registration to allow sufficient time for processing and approval. NP-1 forms will not be accepted after the Drop/Add period ends.** The NP-1 form can be found on the Sakai Bulletin Board Site>Program Materials>MB Program Materials>Forms.

If you would like for a non-program course to confer credit towards your degree, please be sure to check the corresponding box and to indicate the number of academic credits the non-program course confers on the Non-Program Course Approval Form (NP-1). If you would like to request that a non-program course replaces a program course, please be sure to also specify which program course you would like to replace on the NP-1 form. The DGS will determine if the non-program course is appropriate to replace a program course and give final approval. To enroll in a non-program course, the student must also obtain permission from the course instructor and, if necessary, a permission code.

3.3 Enrolling in Non-Program Courses at an Interinstitutional University

If you would like to enroll in a non-program course at an interinstitutional university, you must complete an NP-1 form. Deliver the form to the Program Coordinator. The administrative team will discuss your request and notify you of the decision. NP-1 forms should be submitted at least one week in advance of course registration to allow sufficient time for processing and approval. NP-1 forms will not be accepted after the Drop/Add period ends.

Once the NP-1 form is returned to you, you must then complete the Interinstitutional Approval Form. The Interinstitutional Approval Form can be found on the School of

Medicine website. Completed forms should be submitted to the Office of the Registrar in the School of Medicine. Once you are registered for the non-program course, you will be notified by the Office of the Registrar in the School of Medicine as well as the interinstitutional university.

3.4 Sitting-In on Additional Program Electives

"Sitting-in" on an additional program elective, unlike auditing, does not involve a formal enrollment process. The student should seek verbal permission from the instructor and the program coordinator to "sit-in" during class meeting times. The student will need to work with the Program Coordinator to arrange for access to the course's Sakai site. The course will not confer degree credit and will not appear on an official transcript. Students will not be responsible for course assignments unless informed otherwise by the course instructor.

"Sitting-in" on non-program courses is not possible. This option is not offered by other departments to outside students.

4 Program Curriculum

4.1 Curriculum Timeline

Curriculum for Master of Biostatistics ***(Effective for Students Enrolled in August 2022)***
50 Total Credit Hours Required (44 credit hours of graded coursework and 6 credit hours of master's project)

Year 1
All first-year students will take the same courses unless they place out due to prior experience. No tracks are selected at this point.

First Year for ALL Students: 26 graded coursework credit hours		
FALL	SPRING	SUMMER
All courses listed are required for each student. BIOSTAT 701 (3) BIOSTAT 702 (3) BIOSTAT 703 (3) BIOSTAT 703L (NC) BIOSTAT 721 (3) BIOSTAT 801 (1) 13 credit hours	***All courses listed are required for each student.*** BIOSTAT 704 (3) or BIOSTAT 709 (3) BIOSTAT 705 (3) BIOSTAT 706 (3) BIOSTAT 722 or 821 (3) BIOSTAT 802 (1) 13 credit hours	**Qualifying Examination** Covers content from BIOSTAT 701-706, and 709 First offering is mid-June. Second offering is mid-August. **Practicum** Experiential learning opportunity with real data may be conducted at any point during summer or year two of the program.

Year 2

After consultation with the Director of Graduate Studies and/or Associate Director of Graduate Studies, all students will enroll in approved courses during fall registration. Students will officially enter a designated track after the end of drop/add in the second-year fall semester.

Tracks: Clinical and Translational, Biomedical Data Sciences, and Mathematical Statistics

Second Year: 24 credit hours - master's project (6) plus graded coursework credit hours (18)		
FALL	SPRING	SUMMER
BIOSTAT 720 (3) - Required plus 3 of the following courses* BIOSTAT 707 (3) BIOSTAT 710 (3) BIOSTAT 713 (3) BIOSTAT 719 (3) BIOSTAT 823 (3) BIOSTAT 906 (3) BIOSTAT 911 (3) BIOSTAT 914 (3) BIOSTAT 915 (3) MA 531(3) MA 590 (3) MA 731 (3)	**BIOSTAT 720 (3) -Required plus 3 of the following courses*** BIOSTAT 708 (3) BIOSTAT 709 (3) BIOSTAT 718 (3) BIOSTAT 824 (3) BIOSTAT 905 (3) MA 531 (3) MA 731 (3)	**Graduation**
Computational Biology (3): Any 500 and 600 level except 510S, 511, or 591 **Computer Science (3):** Any 500 and 600 level **Statistical Science (3):** Any 500 level except 501s Any 600 level except for 693 Any 700 level except for 701S, 790, 791. Any 800 level except for 851 Any 900 level except for 993, 994, and 995	**Computational Biology (3):** Any 500 and 600 level except 510S, 511, or 591 **Computer Science (3):** Any 500 and 600 level **Statistical Science (3):** Any 500 level except 501s Any 600 level except for 693 Any 700 level except for 701S, 790, 791. Any 800 level except for 851 Any 900 level except for 993, 994, and 995	
Total: 3 required credit hours plus 9 elective credit hours	Total: 3 required credit hours plus 9 elective credit hours	*Other courses may be requested and approved by Director/Associate Director of Graduate Studies.

Program and Track Description

In the first year, students will take all the required courses listed with an occasional exception for students with prior experience (which will be requested through the Registrar's Office).

In the second year, students may choose from a variety of courses listed. In addition, second years may request and be approved to substitute listed courses with other program and non-program courses. Director of Graduate Studies (DGS) permission is required. Each of the courses in the list may potentially be taken by students in any of the three tracks. The tracks are instead differentiated by content emphasis. The second-year curriculum is personalized and approved by the DGS. The DGS chooses the mechanism by which the appropriate emphasis of the student's proposed curriculum is assessed.

- The mathematical statistics track emphasizes preparation for doctoral study in mathematically sophisticated programs and will typically include methodologically-oriented statistical electives and demonstrated proficiency (either in coursework or by placing out) in Real Analysis.

- The biomedical data science track emphasizes computation and will typically include statistical electives and additional coursework selected from topics such as workflow best practices, software tools for large biomedical data sets, and data structures and algorithms for data-intensive applications.

- The clinical and translational science track emphasizes collaborative science and will typically include statistical electives and the application of statistical methods.

Another point of differentiation is the master's project. Approval by the DGS is the mechanism by which the appropriate match between the project topic and the track is assessed.

4.2 Course Descriptions

701. Introduction to Statistical Theory and Methods I. This course provides a formal introduction to the basic theory and methods of probability and statistics. It covers topics in probability theory with an emphasis on those needed in statistics, including probability and sample spaces, independence, conditional probability, random variables, parametric families of distributions, and sampling distributions. Core concepts are mastered through mathematical exploration and linkage with the applied concepts studied in BIOSTAT 704.Prerequisite(s): 2 semesters of calculus or its equivalent (multivariate calculus preferred). Familiarity with linear algebras is helpful. Corequisite(s): BIOSTAT 702, BIOSTAT 703 Credits: 3

702. Applied Biostatistical Methods I. This course provides an introduction to study design, descriptive statistics, and analysis of statistical models with one or two predictor variables. Topics include principles of study design, basic study designs,

descriptive statistics, sampling, contingency tables, one- and two-way analysis of variance, simple linear regression, and analysis of covariance. Both parametric and non-parametric techniques are explored. Core concepts are mastered through team-based case studies and analysis of authentic research problems encountered by program faculty and demonstrated in practicum experiences in concert with BIOSTAT 703. Computational exercises will use the R and SAS packages. Prerequisite(s): 2 semesters of calculus or its equivalent (multivariate calculus preferred). Familiarity with linear algebras is helpful. Corequisites(s): BIOSTAT 701, BIOSTAT 703, BIOSTAT 721Credits: 3

703. Introduction to the Practice of Biostatistics I. This course provides an introduction to biology at a level suitable for practicing biostatisticians and directed practice in techniques of statistical collaboration and communication. With an emphasis on the connection between biomedical content and statistical approach, this course helps unify the statistical concepts and applications learned in BIOSTAT 701 and BIOSTAT 702. In addition to didactic sessions on biomedical issues, students are introduced to different areas of biostatistical practice at Duke University Medical Center. Biomedical topics are organized around the fundamental mechanisms of disease from both evolutionary and mechanistic perspectives, illustrated using examples from infectious disease, cancer and chronic /degenerative disease. In addition, students learn how to read and interpret research and clinical trial papers. Core concepts and skills are mastered through individual reading and class discussion of selected biomedical papers, team-based case studies and practical sessions introducing the art of collaborative statistics. Corequisite(s): BIOSTAT 701, BIOSTAT 702 Credits: 3

703L. Introduction to the Practice of Biostatistics I Lab. The lab will be an extension of the course. The lab will be run like a journal club. The lab will instruct students how to dissect a research article from a statistical and scientific perspective. The lab will also give students the opportunity to present on material covered in the co-requisite course and to practice the communication skills that are a core tenant of the program. Co-requisite: BIOSTAT 703 or permission of the Director of Graduate Studies Credits: 0

704. Introduction to Statistical Theory and Methods II. This course provides formal introduction to the basic theory and methods of probability and statistics. It covers topics in statistical inference, including classical and Bayesian methods, and statistical models for discrete, continuous and categorical outcomes. Core concepts are mastered through mathematical exploration, simulations, and linkage with the applied concepts studied in BIOSTAT 705. Prerequisite(s): BIOSTAT 701 or its equivalent Corequisite(s): BIOSTAT 705, BIOSTAT 706 Credits: 3

705. Applied Biostatistical Methods II. This course provides an introduction to general linear models and the concept of experimental designs. Topics include linear regression models, analysis of variance, mixed-effects models, generalized linear models (GLM) including binary, multinomial responses and log-linear models, basic models for survival analysis and regression models for censored survival data, and

model assessment, validation and prediction. Core concepts are mastered through statistical methods application and analysis of practical research problems encountered by program faculty and demonstrated in practicum experiences in concert with BIOSTAT 706. Computational examples and exercises will use the SAS and R packages. Prerequisite(s): BIOSTAT 702 or its equivalent Corequisite(s): BIOSTAT 704, BIOSTAT 706, BIOSTAT 722 Credits: 3

706. Introduction to the Practice of Biostatistics II. This course revisits the topics covered in BIOSTAT 703 in the context of high-throughput, high-dimensional studies such as genomics and transcriptomics. The course will be based on reading of both the textbook and research papers. Students will learn the biology and technology underlying the generation of “big data”, and the computational and statistical challenges associated with the analysis of such data sets. As with BIOSTAT 703, there will be strong emphasis on the development of communication skills via written and oral presentations. Prerequisite(s): BIOSTAT 703 Corequisite(s): BIOSTAT 704, BIOSTAT 705 Credits: 3

707. Statistical Methods for Learning and Discovery. This course surveys a number of techniques for high dimensional data analysis useful for data mining, machine learning and genomic applications, among others. Topics include principal and independent component analysis, multidimensional scaling, tree-based classifiers, clustering techniques, support vector machines and networks, and techniques for model validation. Core concepts are mastered through the analysis and interpretation of several actual high dimensional genomics datasets. Prerequisite(s): BIOSTAT 701, 702, 704, 705, and 721 or 722 or their equivalents, or permission of the Director of Graduate Studies Credits: 3

708. Clinical Trial Design and Analysis. Topics include: history/background and process for clinical trial, key concepts for good statistics practice (GSP)/good clinical practice (GCP), regulatory requirement for pharmaceutical/clinical development, basic considerations for clinical trials, designs for clinical trials, classification of clinical trials, power analysis for sample size calculation, statistical analysis for efficacy evaluation, statistical analysis for safety assessment, implementation of a clinical protocol, statistical analysis plan, data safety monitoring, adaptive design methods in clinical trials (general concepts, group sequential design, dose finding design, and phase I/II or phase II/III seamless design) and controversial issues in clinical trials. Prerequisite(s): BIOSTAT 701, 702, 704, 705, and 721 or 722 or their equivalents, or permission of the Director of Graduate Studies Credits: 3

709. Observational Studies. Methods for causal inference, including confounding and selection bias in observational or quasi- experimental research designs, propensity score methodology, instrumental variables, and methods for non-compliance in randomized clinical trials. Prerequisite(s): BIOSTAT 701 and 702. Studies Credits: 3

710. Statistical Genetics and Genetic Epidemiology. Topics from current and classical methods for assessing familiarity and heritability, linkage analysis of

Mendelian and complex traits, family-based and population-based association studies, genetic heterogeneity, epistasis, and gene-environmental interactions. Computational methods and applications in current research areas. The course will include a simple overview of genetic data, terminology, and essential population genetic results. Topics will include sampling designs in human genetics, gene frequency estimation, segregation analysis, linkage analysis, tests of association, and detection of errors in genetic data. Prerequisite(s): BIOSTAT 701, 702, 704, 705, and 721 or 722 or their equivalents, or permission of the Director of Graduate Studies Credits: 3

713. Survival Analysis. Introduction to concepts and techniques used in the analysis of time to event data, including censoring, hazard rates, estimation of survival curves, regression techniques, applications to clinical trials. Interval censoring, informative censoring, competing risks, multiple events and multiple endpoints, time dependent covariates; nonparametric and semi-parametric methods. Prerequisite(s): BIOSTAT 701, 702, 704, 705, and 721 or 722 or their equivalents, or permission of the Director of Graduate Studies Credits: 3

718. Analysis of Correlated and Longitudinal Data. Topics include linear and nonlinear mixed models; generalized estimating equations; subject specific versus population average interpretation; and hierarchical model. Prerequisite(s): BIOSTAT 701, 702, 704, 705, and 721 or 722 or their equivalents, or permission of the Director of Graduate Studies Credits: 3

719. Generalized Linear Models. The class introduces the concept of exponential family of distributions and link function, and their use in generalizing the standard linear regression to accommodate various outcome types. Theoretical framework will be presented but detailed practical analyses will be performed as well, including logistic regression and Poisson regression with extensions. Majority of the course will deal with the independent observations framework. However, there will be substantial discussion of longitudinal/clustered data where correlations within clusters are expected. To deal with such data the Generalized Estimating Equations and the Generalized Linear Mixed models will be introduced. An introduction to a Bayesian analysis approach will be presented, time permitting. Prerequisite(s): BIOSTAT 701, 702, 704, 705, and 721 or 722 or their equivalents, or permission of the Director of Graduate Studies Credits: 3

720. Master's Project. Completed during a student's final year of study, the master's project is performed under the direction of a faculty mentor and is intended to demonstrate general mastery of biostatistical practice. Prerequisite(s): BIOSTAT 701 through BIOSTAT 706. Credits: 3 in Fall Semester and 3 in Spring Semester

721. Introduction to Statistical Programming I (R): This class is an introduction to programming in R, targeted at statistics majors with minimal programming knowledge, which will give them the skills to grasp how statistical software works, tweak it to suit their needs, recombine existing pieces of code, and when needed create their own programs. Students will learn the core of ideas of programming (functions, objects, data

structures, input and output, debugging, and logical design) through writing code to assist in numerical and graphical statistical analyses. Students will learn how to write maintainable code, and to test code for correctness. They will then learn how to set up stochastic simulations and how to work with and filter large data sets. Since code is also an important form of communication among scientists, students will learn how to comment and organize code to achieve reproducibility. Programming techniques and their application will be closely connected with the methods and examples presented in the co-requisite course. The primary programming package used in this course will be R. Prerequisite(s): None; familiarity with linear algebras is helpful Corequisite(s): BIOSTAT 702 Credits: 3

722. Introduction to Statistical Programming II (SAS). This class is an introduction to programming in SAS, targeted at statistics majors with minimal programming knowledge, which will give them the skills to grasp how statistical software works, tweak it to suit their needs, recombine existing pieces of code, and when needed create their own programs. Students will learn the core of ideas of programming (data step, procedures, macros, ODS, input and output, debugging, and logical design) through writing code to assist in numerical and graphical statistical analyses. Students will learn how to write maintainable code, and to test code for correctness. They will then learn how to set up stochastic simulations and how to work with and filter large data sets. Since code is also an important form of communication among scientists, students will learn how to comment and organize code to achieve reproducibility. Programming techniques and their application will be closely connected with the methods and examples presented in the co-requisite course. The primary programming package focus used in this course will be SAS. Prerequisite(s): None; familiarity with linear algebras is helpful. Corequisite(s): BIOSTAT 705 Credits: 3

732. Independent Study. Independent Study is a semester long course focused on mentored research in the practice of biostatistics. Students work with an assigned mentor. This course is only open to students by permission of the Director of Graduate Studies. Credits: 1, 2, or 3

740. Continuation. Continuation is a semester-based, noncredit bearing enrollment status used when a student is continuing scholarly activities with the same mentor. This course is only open to students by permission of the Director of Graduate Studies. Credits: 0

801. Biostatistics Career Preparation and Development I. The purpose of this course is to give the student a holistic view of career choices and development and the tools they will need to succeed as professionals in the world of work. The fall semester will focus on resume development, creating a professional presence, networking techniques, what American employers expect in the workplace, creating and maintaining a professional digital presence and learning how to conduct and succeed at informational interviews. Practicums in this semester include an informational interviewing and networking practicum with invited guests. Students participate in a professional “etiquette dinner” and a “dress for success” module as

well an employer panel. Corequisite(s): BIOSTAT 701 through 703 Credit: 1

802. Biostatistics Career Preparation and Development II. The purpose of this course is to further develop the student's job seeking ability and the practical aspects of job/internship search or interviewing for a PHD program. The goal is to learn these skills once and use them for a lifetime. Modules that will be covered include: communication skills both written and oral, interviewing with videotaped practice and review, negotiating techniques, potential career choices in the Biostatistics marketplace, and working on a team. This semester includes writing and interviewing practicum, and a panel of relevant industry speakers. Students will leave this course with the knowledge to manage their careers now and in the future. Prerequisite: BIOSTAT 801 Credit: 1

821. Software Tools for Data Science. A data scientist needs to master several different tools to obtain, process, analyze, visualize, and interpret large biomedical data sets such as electronic health records, medical images, and genomic sequences. It is also critical that the data scientist masters the best practices associated with using these tools, so that the results are robust and reproducible. The course covers foundational tools that will allow students to assemble a data science toolkit, including the Unix shell, text editors, regular expressions, relational and NoSQL databases, and the Python programming language for data munging, visualization, and machine learning. Best practices that students will learn include the Findable, Accessible, Interoperable and Reusable (FAIR) practices for data stewardship, as well as reproducible analysis with literate programming, version control and containerization. Prerequisite: Permission of the Director of Graduate Studies Credits: 3

823. Statistical Program for Big Data. This course will extend the foundation laid in software tools for data science to allow for efficient computing involving very large data sets. This course will explore the use appropriate algorithms and data structures for intensive computations, improving computational performance by use of native code compilation, use of parallel computing to accelerate intensive computations, use appropriate algorithms and data structures for massive data set, and use of distributed computing to process massive data sets. Prerequisite: BIOSTAT 821 or permission of the Director of Graduate Studies Credits: 3

824. Case Studies in Biomedical Data Science. This course will highlight how biomedical data science blends the field of biostatistics with the field of computer science through the introduction of 3 to 5 case studies. Students will be introduced to analytic programs typically encountered in biomedical data science and will implement the data science and statistical skills introduced in their previous course work. Prerequisite: BIOSTAT 707, 821, 822, and 823 or permission of the Director of Graduate Studies Credits: 3

905. Linear Models and Inference. Introduction to linear models and linear inference from the coordinate-free viewpoint. Topics: identifiability and estimability, key properties of and results for finite-dimensional vector spaces, linear transformations, self-adjoint

transformations, spectral theorem, properties and geometry of orthogonal projectors, Cochran's theorem, estimation and inference for normal models, distributional properties of quadratic forms, minimum variance linear unbiased estimation, Gauss-Markov theorem and estimation, calculus of differentials, analysis of variance and covariance. Prerequisite: Biostatistics 702, 704, 705, real analysis, and linear algebra, or consent of the instructor and Director of Graduate Studies Credits: 3

906. Statistical Inference. Introduce decision theory and optimality criteria, sufficiency, methods for point estimation, confidence interval and hypothesis testing methods and theory. Prerequisite: Biostatistics 704 or equivalent. Instructor consent required. Prerequisite: Permission of the Director of Graduate Studies Credits: 3

907. Phase II Clinical Trials. Introduction to diverse statistical design and analytical methods for randomized phase II clinical trials. Topics: Minimax, optimal, and admissible clinical trials Inference methods for phase II clinical trials; clinical trials with a survival endpoint; clinical trials with heterogeneous patient populations; and randomized phase II clinical trials. Instructor consent required. Credits: 3.

911. Modern Inferential Techniques and Theory. Stochastic processes, random walks, Markov chains, martingales, counting processes, weak convergence and basic empirical process theory and applications. Hilbert spaces for random vectors, semiparametric models, geometry of efficient score functions and efficient influence functions, construction of semiparametric efficient estimators. Applications include the restricted moment model and the proportional hazards model. The theory for M- and Z-estimators. Methods for dealing with missing data including imputation, inverse probability weighting (IPW) and the likelihood method, doubly robust IPW estimators. Prerequisite: STA 711, BIOSTAT 906, or Permission of the Director of Graduate Studies Credits: 3.

914. Graphical Models for Biological Data. Introduction to probabilistic graphical models and structured prediction, with applications in genetics and genomics. Hidden Markov Models, conditional random fields, stochastic grammars, Bayesian hierarchical models, neural networks, and approaches to integrative modeling. Algorithms for exact and approximate inference. Applications in DNA/RNA analysis, phylogenetics, sequence alignment, gene expression, allelic phasing and imputation, genome/epigenome annotation, and gene regulation. Department consent required. Credits: 3.

915. High-Dimensional Statistics and Machine Learning. The goal of this course is to provide motivated doctoral and master's students with background knowledge of high-dimensional statistics/machine learning for their research, especially in their methodology and theory development. Discussions cover theory, methodology, and applications. Selected topics in this course include the basics of high-dimensional statistics, matrix and tensor modeling, concentration inequality, nonconvex optimization, applications in genomics, and biomedical informatics. Knowledge in

probability, inference, and basic algebra are required. Department consent required. Credits: 3.

4.4 Student Advising

An important component of a student-centered program is maintaining close contact with your advisor(s). During the first year, the Director of Graduate Studies/Associate Director of Graduate Studies will be assigned as your main advisor. During the second year, your master's project advisor will oversee your master's project.

You are expected to meet with the Director of Graduate Studies at two designated times during the course of your program:

- March of Year 1: Course planning; and
- October of Year 2: Master's project and graduation planning.

In addition to the two meetings listed above, you are encouraged to meet regularly with your assigned advisor and your master's project advisor (once identified). You are also welcome to meet with the Director of Graduate Studies at any time.

4.5 Student Evaluation

Student evaluations are an integral part of helping us continuously improve the Master of Biostatistics Program. For some courses, you will receive short online surveys ("formative evaluations") approximately 25% and 50% of the way through the course. Responses will be anonymous, and the questions will be along the lines of:

- What about the course is working well?
- What about the course is not working well?
- What could be done to improve the course?

At the end of the semester, you will receive a final, more comprehensive evaluation (also anonymous). In addition to completing the formative evaluations, you should also feel free to provide suggestions to individual instructors and/or the Director of Graduate Studies.

5 Practicum

5.1 Description

All candidates for the Master of Biostatistics degree are required to complete a practicum that includes real data and is a real project. The practicum is an experiential learning opportunity which allows students to develop their (A) analytic ability; (B) biological knowledge; and (C) communication skills (what we call "the ABCs" of our program). The main goal of the practicum is to provide students with an opportunity to put the ABCs of the program into practice. The practicum is typically completed during the summer after the first year but can be completed during the second year. The practicum cannot begin until students have completed their first-year core courses (BIOSTAT 701 – 706 inclusive).

5.2 Format

The format of the practicum may vary from student to student and, generally speaking, can be anything that exposes the student to the ABCs of the program, outside of the classroom. Typically, the practicum will fall into one of two categories: a collaborative biostatistical project or an internship with one of the department's faculty members.

Students are responsible for submitting a proposal for their practicum to the Director of Graduate Studies for approval. The Director of Graduate Studies will review the proposal and may request clarification or modification of the proposal before approving. The proposal should succinctly describe the practicum and how it will lead to an experiential learning opportunity. The proposal should include a description of the opportunity, the mentor, the goals and learning objectives associated with the opportunity, and how the opportunity will allow the student to develop their ABCs.

Students must be in good academic standing with the program to begin their practicum. Students submit their practicum proposal to the DGS. To submit the PR-1 form, students should turn the completed form in to the Program Coordinator and upload their practicum proposal to their folder on the B&B Bulletin Board Sakai site. Proposals should be submitted as a PDF file. The document should use the following naming convention: PR1_Lastname_Firstname.pdf.

The PR-1 form can be found on the Sakai Bulletin Board Site>Program Materials>MB Program Materials>Forms.

5.3 Frequently Asked Questions

Q: How does the practicum relate to internships?
A: The practicum is a required part of the program, and an internship is not. However, most internships will satisfy the practicum requirement. To determine whether an internship will satisfy the practicum requirement, please discuss the details of the internship with the Director of Graduate Studies and submit the PR-1 form. The program's primary focus is the educational benefit of students participating in an experiential learning opportunity.

Although internships can satisfy this requirement, it is ultimately the student's responsibility to apply and obtain an internship. The department has established relationships with several companies/groups that offer internships and will help students identify and apply for those opportunities. When internship opportunities become available through the department, the program will make an announcement to all students asking for applications.

Q: How does the Practicum relate to the master's project?
A: The practicum and the master's project are both required components of the program. The practicum may naturally lead to a topic for the master's project, but not necessarily. Depending on the nature of the practicum, the scope of work may be substantial enough to develop a project. To determine whether the practicum will satisfy the master's project

requirement, please discuss the details of the practicum with the Director of Graduate Studies.

6 Qualifying Examination

6.1 Description

All candidates for the Master of Biostatistics degree are required to pass a written qualifying examination demonstrating their mastery of fundamental concepts acquired through completion of the first-year core courses (BIOSTAT 701 – 706 inclusive). The Master's Qualifying Examination also serves to provide students with additional information regarding their relative strengths and weaknesses in concepts fundamental to the field of biostatistics. The results of the exam should be used to inform students' selection of elective courses, suitability for experiential learning experiences, and/or preparation for doctoral studies.

6.2 Format and Structure

The Master's Qualifying Examination is a take-home examination completed in one week. The exam evaluates three competencies (probability/mathematical statistics, applied methods, and biology/communication), and each is covered approximately equally on the exam. These competencies coincide with the first-year core courses, and any material from these courses may appear on the exam. Students should be familiar with all material from these courses. Programming and writing are incorporated throughout the exam. For additional examples of the types of formulas/equations that students should be familiar with prior to the exam, please refer to past Master's Qualifying Examinations as well as past midterms and finals from the first-year core courses.

6.3 Standards and Grading

Each component of the Qualifying Examination will be graded by a member of the examining committee, which consists of departmental faculty members. On the basis of a student's cumulative and part scores, the graders will recommend the student be passed, failed, or passed with conditions. Any student whose performance is substandard (failure or passing with conditions) will be permitted one re-examination within a specified time period. Students are only required to repeat portions of the Qualifying Exam they did not pass on the first testing. If the student fails a second time, then the Qualifying Exam Committee will make a recommendation which is likely dismissal from the program. The recommendations are reviewed by the Director of Graduate Studies and the Vice Dean of Education to whom appeals can be made.

6.4 Timing

Master's students are expected to take the Master's Qualifying Examination after completing all of the core courses of the first year of study in the program. The examination typically will be offered in June following completion of the first year. Re-examinations for students whose performance is substandard will typically be scheduled for August of the same summer.

7 Master's Project

7.1 Description

All candidates for the Master of Biostatistics degree are required to complete a master's project. Typically completed in the second year, the master's project serves to demonstrate the student's mastery of core statistical concepts and the practice of biostatistics. Specifically, the project demonstrates the student's familiarity with the analytical tools of the field as applied to a specific problem, the capacity to work both independently and collaboratively as an effective member of a research team, and the ability to communicate the results of the project orally and in writing to a scientific audience. The master's project is a thesis style project. Students are required to submit a written work product and to complete an oral presentation to their examining committee.

7.2 Project Selection

While the students are ultimately responsible for identifying the advisor and topic of the master's project they plan to complete, we provide various resources to assist the students in this process. For example, internships can often lead to master's projects, as well as practicum experiences. In addition, students can meet with the Director of Graduate Studies for help or direction in formulating a project.

7.3 Types of Projects

Master's Projects may be derived from a range of investigational areas associated with clinical and translational research. These areas include, but are not limited to, clinical trials; studies of the mechanism of human disease; development of cellular and molecular markers; epidemiological and behavioral studies; and outcomes, health services, and comparative effectiveness research. All master's projects must be approved by the program (see Section 8: Project Landmarks and Forms). Students should work with their advisor to develop the details of the proposal before seeking approval from the Director of Graduate Studies.

Examples of approvable projects include, but are not limited to:

- Comprehensive data analyses, including a literature review, justification, and interpretation (e.g., the key inputs to a manuscript, although not necessarily a completed manuscript);
- A comparison of two or more analytical approaches using a simulation study, and as applied to an actual data set (this might be particularly appropriate for a doctoral bound students);
- A detailed statistical protocol (e.g., describing in detail the planned analysis of data from a randomized clinical trial, including power calculations); and
- An evaluation of the instruments used in a scientific study through a designed experiment (e.g., their validity, reproducibility, etc.).

7.4 Written Work Product

The final written work product may vary from project to project, and broadly speaking, could be anything that demonstrates the student's familiarity with the analytical tools of the field. Most typically, the work product will fall into one of three categories of documents: a manuscript, a detailed statistical report, or a descriptive research report.

Although an option, but not required, a submission-ready manuscript would take the form of a collaborative manuscript that evolves from an experiential learning opportunity during the second year of the program, and one to which the student makes a significant contribution to data analysis and interpretation and includes the student as a co-author (not necessarily the first author). The manuscript need not be accepted for publication, but should be a finished product, ready to submit to a journal. Other acceptable work product formats generally will consist of a data management and analysis plan for an IRB application or detailed statistical protocol for a manual of operations; or a descriptive research report similar to those submitted for a traditional master's thesis.

The appropriate format and length of the written work product will be determined individually in consultation with the student's examining committee, in consideration of the type of project. However, submitted work products tend to be at least 15 pages long, not including tables, figures, or references. The work product should clearly demonstrate the student's mastery of the material covered in the master's project.

7.5 Oral Exam

The final presentation should be organized like a 20-to-30-minute talk at a professional meeting. Following a period for questions from the floor, moderated by the examining committee chair, the committee will meet in closed session to discuss the student's project and presentation and to decide whether the student has met the requirement for the degree. The committee will then discuss this decision with the student. The committee will have the option of requiring modifications of the project (e.g., additional analyses, editing for clarity, expanded discussion, etc.) prior to giving its final approval. The final written work product should be distributed to the exam committee at least two weeks prior to the oral exam. ***The oral presentation should not take place until the final written work product exists and has been distributed to the examining committee***. Having the student distribute slides prior to the oral presentation is at the discretion of the examining committee. Oral presentations must be scheduled prior to April 10 for students planning to graduate in May.

7.6 Examining Committee

Three faculty or staff members shall constitute an examining committee to certify that each student has successfully completed the required master's project. The committee should include two statisticians, both of whom are on the faculty of the Department of Biostatistics and Bioinformatics at Duke University. The third member of the committee should be a Duke Faculty or staff member who has substantive knowledge in the area in which the project is conducted but does not have to be a statistical faculty member. With the approval of the Director of Graduate Studies and the two other committee members,

a faculty member from another department or institution may serve as the third member, but not as committee chair. The committee must include at least one member of the Biostatistics and Bioinformatics faculty.

7.7 Registration Requirement

The Master's Project confers a minimum of 6-degree credits through two 3-credit semesters of BIOSTAT 720. Registration for BIOSTAT 720 will occur during the second year of the program for full-time students, evenly divided between the two semesters. A grade of Z (indicative of an 'Incomplete' in independent-study-type courses) will be assigned at the end of the first semester; when a Director of Graduate Studies verifies that the examining committee recommended that the student has successfully completed the project (during the second semester of BIOSTAT 720), the Z grade will be converted to a P.

7.8 Project Landmarks and Forms

Typically, the master's project will be completed during the second year in the program (or after the completion of all first-year core courses: BIOSTAT 701 – 706, and/or 709). To assist students in making sustainable progress towards completing the project, students are required to achieve the landmarks below, which will be documented by completing the corresponding form. The landmarks and forms are outlined below, along with a timeline for completing these landmarks. Student can access the forms in the Resources Folder of the Sakai Bulletin Board Site>Program Materials>MB Program Materials>Master's Project. <u>All four forms should be turned in to the Program Coordinator as they are completed.</u>

7.8.1 MP Landmark 1: Project Proposal Approved by the Program

- *Description:* After selecting an advisor and project topic, students must submit a proposal that describes the project and the expected scope of work for approval by the Director of Graduate Studies. Students should work closely with their advisors in developing the proposal; specifically, students should work with their advisor to develop clearly defined goals, scope of work, and planned work product for the project. In addition, students should work with their advisors to identify an appropriate examining committee. Students should have their 1-2 page proposal and examining committee approved by their advisor before submitting it to the program. The Director of Graduate Studies will review the proposal and may request clarification or modification of the proposal or committee before approving.
- *Form:* To satisfy MP Landmark 1, students must submit the MP-1 form to the Program Coordinator once the Director of Graduate Studies approves and signs the form.
- *Deadline:* Students must complete MP Landmark 1 by September 7 of the second year for full-time students in good academic standing. For part-time students or for students not in good academic standing, the Director of Graduate Studies will determine the student-specific timelines for the master's project Landmarks.

7.8.2 MP Landmark 2: Project Proposal Approved by the Examining Committee

- *Description:* Once a Director of Graduate Studies has approved the project proposal and the composition of the examining committee, students should submit their proposal to all members of the committee for review and approval. Members of the committee will review the proposal and provide feedback; members may request clarification or modification of the proposal before approving. The student should work with their advisor to adequately respond to these comments and to determine whether these suggestions should be incorporated into the project proposal.
- *Form:* To satisfy MP Landmark 2, students must submit the MP-2 form to the Program Coordinator. Students should demonstrate that they have a clearly defined project proposal and an achievable scope of work, and that comments submitted by the examining committee have been considered and incorporated, if applicable, to their refined project proposal. Before submitting, students must obtain the signature of each examining committee member.
- *Deadline:* Students must be complete MP Landmark 2 by October 15 of the second year for full-time students in good academic standing.

7.8.3 MP Landmark 3: Progress Report Approved by the Examining Committee

- *Description:* Once the entire examining committee has approved the project proposal, students should begin working toward completing the project. Students should work with their advisor to determine when they have made enough progress on their project to develop a preliminary progress report. The progress report should describe the work that has been completed as well as demonstrate to the examining committee that a sufficient scope of work will be completed in the requisite timeframe. Note: It is possible that the original scope of work may not be achievable after working through the project in more detail (e.g., lab data will not be ready in time for analysis). However, the student should justify this change in plans as well as how these updated plans will meet the requirements of the master's project. The progress report should take the form of a written report that is discussed in person with the examining committee. The format of the progress report is at the discretion of the student's advisor, but the program strongly encourages an oral presentation in preparation for the oral exam. The progress report is an opportunity for the examining committee to provide feedback to the student; specifically, they should provide any suggested changes to help ensure a positive outcome during the student's oral examination.
- *Form:* To satisfy MP Landmark 3, students must submit the MP-3 form to the Program Coordinator. Students should demonstrate that they have made measurable progress towards completing their project as well as demonstrate that the proposed scope of work will be completed in the requisite timeframe. Before submitting, students must obtain the signature of each examining committee member.
- *Deadline:* Students must be complete MP Landmark 3 by January 31 of the second year for full-time students in good academic standing. For part-time students or for students not in good academic standing, a Director of Graduate

Studies will determine the student-specific timelines for the master's project Landmarks.

7.8.4 MP Landmark 4: Completion of Master's Project Approved by the Examining Committee

- *Description:* Once students have completed the approved scope of work, they should prepare a written work product (see Section 4: Written Work Product) and an oral presentation as well as schedule the oral examination (see Section 5: Oral Examination). Students should remember to schedule the exam at least two weeks prior to their desired date in order to accommodate the busy schedules of the examining committee. Once the oral examination date and time is established, students should inform the Program Coordinator who will reserve a location for the meeting. Students should distribute the written work product to the committee at least two weeks prior to the oral examination; the oral examination cannot take place until the written work product exists and has been distributed to the committee. Members of the examining committee may request clarification or modification of the written work product before approving. After reviewing the written work product and attending the oral examination, the examining committee may decide that the student has passed, conditionally passed, or failed the examination. If the committee recommends a pass, the student has successfully completed all requirements of the master's project. If the committee recommends a conditional pass, the student must satisfy the additional requirements (e.g., add detail to the written work product or improve the oral presentation and re-present) made by the committee. If the committee recommends a fail, the student will have to make substantial changes to the written work product and re-complete the oral examination. Students will get one chance at re-examination after an initial failure. Students must upload to Sakai the final copy of their thesis and slide presentation.
- *Form:* To satisfy MP Landmark 4, students must submit the MP-4 form to the Program Coordinator and upload their final written report plus slides to their file in Sakai Bulletin Board. Students must successfully complete all requirements of the master's project – a written work product and an oral examination. When the final written work product and oral examination is approved by the entire examining committee, students should obtain each committee member's signature on the MP-4 form and submit it to the Program Coordinator.
- *Deadline:* Students must be complete MP Landmark 4 by April 10 of the second year for full-time students in good academic standing. For part-time students or for students not in good academic standing, the Director of Graduate Studies will determine the student-specific timelines for the master's project landmarks. (Note: All students MUST have their oral examination scheduled prior to April 10 if they plan to graduate in May).

7.9 Delayed Completion of Master's Project

- For full-time students, their master's projects (BIOSTAT 720) must be completed by April 10 during the student's second year in order to graduate in May of that year. If the project is not completed by the deadline, the student will be assigned

a grade of Incomplete and must contact the Director of Graduate Studies with a plan to complete the project by the end of Summer Term II. If the student completes their project by the end of the Summer II term of the same year, the Incomplete will be changed to Pass and the student will graduate at the conclusion of Summer Term II. Failure to complete the project within one calendar year from the end of the Spring term in the second year, in the absence of extenuating circumstances, will result in a grade of Fail and the student will be permanently removed from the program. The student may appeal the expulsion to the Director of Graduate Studies. Students with an abbreviated schedule or for students not in good academic standing, the Director of Graduate Studies will determine the student-specific timelines for the master's project. Students may not graduate until the master's project process is completed.

7.10 Advisor Responsibilities

Each student will need a faculty member to serve as an advisor for their master's project. The primary role of the advisor is to serve as the student's mentor, with the overall responsibility for guiding the student through the process of successfully completing a project that fulfills the degree requirements. Specific advisor responsibilities are outlined below. Faculty members always have the right to seek information about the student seeking mentorship from the Director of Graduate Studies and to refuse to serve as a student's advisor based on their own criteria of evaluation.

The advisor should:

- Be able and willing to assume principal responsibility for advising the student, as well as be committed to the education and training of the student as a future member of the field of biostatistics;
- Be knowledgeable of the requirements and deadlines associated with the master's project (see Sections 1 – 9 of this chapter);
- Have adequate time available for this work and be accessible to the student. The advisor should meet one-on-one with the student on a regular basis. The advisor should provide timely feedback on the student's work to facilitate ongoing progress on the project;
- Help the student to select an examining committee;
- Provide a learning environment for the student that is intellectually stimulating and supportive;
- Consistently enforce standards of rigor and academic conduct that model the best practices in research and scholarship in the field of and practice of biostatistics for the student;
- Establish key academic milestones and communicate these to the student and appropriately evaluate the student on meeting these milestones; and
- Ensure that the student's written work product is ready for review by the examining committee and that the student is prepared to present their work at the oral examination. If not, the advisor should postpone the distribution of the written work product and re-schedule the oral examination.

7.11 Regular Committee Member Responsibilities

Each student will need an examining committee consisting of at least three faculty members for their master's project (see Section 6: Examining Committee). With the exception of the student's advisor, all voting members of the examining committee are considered regular committee members. The primary role of a regular committee member is to serve as independent reviewer of the student's work and to provide timely and thoughtful feedback to help ensure that the student successfully completes a project that fulfills the degree requirements. Specific regular committee member responsibilities are outlined below. Faculty members always have the right to seek information about the student from a Director of Graduate Studies and to refuse to serve on a student's examining committee based on their own criteria of evaluation.

The committee member should:

- Be able to and willing to assume the responsibilities associated with serving on a student's examining committee, as well as be committed to the education and training of the student as a future member of the field of biostatistics;
- Have adequate time available for this work and be accessible to the student. The committee member should be accessible to the student; at a minimum this implies availability for examining committee meetings and availability to participate in a student's oral examination;
- Provide advice to both the student and the student's advisor on the quality, suitability, and timeliness of the work being undertaken;
- Be knowledgeable of the requirements and deadlines associated with the master's project so that they can provide feedback to the student and the student's advisor on the project proposal, assuring that the plan meets not only the intellectual needs of the student, but also all program requirements;
- Take the time to review the student's written work product thoroughly to ensure that the student's work conforms to the highest standards of scholarly performance within the field biostatistics, within the expertise provided by the committee member; and
- Participate in and independently evaluate student performance in the oral examination.

8 Facilities

8.1 Building Access

During the year, Hock Plaza stays open to the public from 6:30 AM to 6:30 PM Monday through Friday. All entrances are locked after these hours, on weekends, and during holidays. You can use your DukeCard to gain access to the building after hours.

During normal business hours and after hours, your DukeCard will give you access to the tenth floor, eleventh floor (suites 1102, 1104, and 1105), third floor (main lobby), and first floor.

Hock Plaza Contact Information
Main Lobby (Security Desk) – 919.286.7668
Main Lobby Mobile – 919.628.7932

8.2 Printer

The student printers are located in room 11027 and in the 10th floor hallway. Wireless connection to this printer will be established during program orientation.

8.3 Kitchen Access/Responsibilities

The staff/student kitchens are located in room 11026 and beside the 10th floor common area. As these are communal spaces, please clean up after yourself and do not leave dirty dishes on the tables, counter, or in the sink. If storing food in the refrigerator, please be sure to label your food with name and date. Unlabeled food will be disposed of at the end of each week.

If using the department kitchen (room 11085), you may place dirty mugs into the dishwasher to be cleaned if no dishwasher lights are on. If dishwasher lights are on, please be sure to wait until the cycle is finished before opening.

8.4 Room Reservations

To request a room reservation, you may e-mail either Kendall Mincey (kendall.mincey@duke.edu) or Michelle Evans (michelle.evans@duke.edu). Please be sure to include the room number as well as the date and time you would like the room reserved. If the room is reserved for another event, we can work with you to find an alternative room, date, or time.

8.5 Mailing Address

The student mailroom is located on the 10th floor. If using the United States Postal Service (USPS), you may have mail sent to:

Your Name
Department of Biostatistics and Bioinformatics
DUMC Box 2721
Durham, NC 27710

If using FedEx, UPS, DHL, or any other courier service that will not deliver to a P.O. Box, you may have mail sent to:

Your Name
Department of Biostatistics and Bioinformatics
Hock Plaza, 10th Floor, Room 10081
2424 Erwin Road
Durham, NC 27705-3860

8.6 Technology Assistance

Technology-related issues (uploading or upgrading software required for the program, unable to connect to the network, etc.) can be addressed through Office of Academic Solutions and Information Systems (OASIS). You may email OASIS to enter a work ticket at https://intranet.dh.duke.edu/dhts/CAIO/acadsupport/SitePages/Home.aspx.

8.7 Emergency Procedures

Fire Evacuation Plan

Ground Floor, Suite G06
If the fire alarm sounds, leave the building via the back door or the stairwells and gather at the back of Hock Parking Garage on Pratt Street (across the street from the rear garage entrance). If you are in an office, close, but do not lock the door before leaving.

Second Floor, CRTP Classroom
If the fire alarm sounds, leave the building via the exit Hock Plaza loading dock.

Tenth Floor, Department Suites
If the fire alarm sounds, leave the building via the stairwells and gather in front of the BP station next to Hock Plaza (be careful not to block the BP station entrance). If you are in an office or classroom, close, but do not lock the door before leaving.

Eleventh Floor, Department Suites
If the fire alarm sounds, leave the building via the stairwells and gather in front of the BP station next to Hock Plaza (be careful not to block the BP station entrance). If you are in an office or classroom, close, but do not lock the door before leaving.

Other Emergencies
For detailed information regarding emergency communications and plans, please visit the Duke Alert website.

9 Program Administration

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