Doctor of Philosophy in Biostatistics

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Introduction

Biostatistics involves the development and application of statistical techniques to scientific research in health-related fields, including medicine, epidemiology, and public health. Students in the Ph.D. program receive state-of-the-art training in the latest statistical methodology in order to tackle the challenges associated with the study design and data analysis of modern research conducted in the health sciences. The Ph.D. program provides advanced training in biostatistical theory and methods, with the goal of enabling the student to carry out original research. In addition, students may elect to train with an emphasis on decision science or on bioinformatics.

Biostatistics involves the development and application of statistical methods in research in health-related fields, including public health, medicine, dentistry, and nursing. This program is designed to train students in biostatistics for carrying our research in biomedical fields and in statistical methods used in biomedical research.

Decision science, or formal decision analysis, is an emerging, cutting edge discipline that provides researchers with additional tools with which to develop the clinical and health-care policies and guidelines that affect public health. The decision science emphasis goes beyond traditional decision science programs by providing a mathematically rigorous, interdisciplinary approach to decision-making that is capable of adapting to the ever-changing health care environment. The decision science emphasis provides advanced training in the theory and methods of formal decision analysis, with the goal of enabling students to carry out original research. The focus of is on training a well-qualified biostatistician to work within the specialized field of decision science.

Bioinformatics requires the development and application of statistical methods for many of the areas covered by the field, including genomics, proteomics, statistical genetics, and metabolomics. Current biomedical research technologies generate high volumes of data that require extension of existing statistical methodologies and development of new methodologies in order to extract important information regarding biological processes. The emphasis on bioinformatics is designed to fulfill the expanding need for biostatisticians with advanced training in this area. Students in the bioinformatics emphasis gain a basic understanding of molecular and cellular biology, genetics, and bioinformatics and an in-depth knowledge of

statistical theory and methods. Graduates are able to carry out original statistical research in genomics, proteomics, metabolomics, and evolving areas of systems biology.

Students who complete the M.S. program in biostatistics with the Department of Bioinformatics and Biostatistics or who already possess the equivalent of an M.S. in statistics, biostatistics, decision science, or a related discipline may apply for admission to the Ph.D. program.

The Ph.D. program in biostatistics is located in the Department of Bioinformatics and Biostatistics.

Competencies

To graduate, a student must be able to demonstrate mastery of the following competencies:

Competency	***Demonstration****		
	CE	***SCP***	***Dsrt***
Read, interpret, and critically review the biostatistics content of scientific and biomedical journal articles	x		x
Analyze moderately complex research data using statistical methods involving common linear statistical models	x	x	
Analyze dichotomous, count, and time-to-event data using appropriate statistical methods, including logistic regression, log-linear models, Kaplan-Meier curves, and Cox proportional hazards models	x	x	
Assist researchers in planning research studies, proposing and evaluating statistical methods and computing power analyses		x	
Write statistical methods sections for grant proposals, clinical trial protocols, and journal articles	x		
Manage data using spreadsheet and database software	x		
Use standard statistical and graphics computer packages including SAS, R, and SPSS	x	x	x
Keep abreast of statistical methods literature to evaluate and utilize new statistical methods			x
Thoroughly understand the broad discipline of biostatistics, including its theoretic underpinnings, its history of development, current applications, and areas of active inquiry	x		x
Understand advanced biostatistical operations	x		x
Conduct independent research			x
Advance the field of biostatistics through original research			x

Students who elected to have an emphasis must demonstrate the following additional competencies, many of which represent specialization of competencies cited above:

Additional Competency by Emphasis	***Demonstration****		
	CE	***SCP***	***Dsrt***
Emphasis on Decision Science			
Read and critically evaluate decision analyses published in the literature	x		x
Provide consultation with researchers and decision makers about decision analysis methods, problems, and results		x	
Understand and apply the concepts of public health and information sciences to clinical decision making and decision analysis	x	x	
Communicate the results of decision analysis and other clinical research to decision makers, peers, and to the community through written and oral presentations and publications		x	
Thoroughly understand the broad discipline of decision science including its theoretical underpinnings, its history of development, current applications, and areas of active inquiry	x		x
Advance the field of decision science through original research			x
Emphasis on Bioinformatics			
Analyze high-throughput, biological data, such as microarrays, SNP chips, and mass spectrometer data, and understand the special statistical considerations that such data require	x	x	
Retrieve and leverage various types of biological information from online repositories	x	x	
Understand the basic biological principles that underlie our biological knowledge, and how the various forms of high-throughput data are used to address specific biological questions and expand our knowledge	x		x
Advance the field of statistics in bioinformatics through original research			x

*Key for demonstration (method): CE = Comprehensive examinations
SCP = Statistical consulting practicum
Dsrt = Dissertation

Admission

The Ph.D. program is available to students who are entering from the M.S. program or to students entering with a master's degree in biostatistics, statistics, decision science, or a related discipline.

The following are additionally required for admission:

- Graduate application (see www.graduate.louisville.edu)

- Non-refundable application fee
- At least two letters of recommendation written within past twelve months, which may be submitted with the form available at http://graduate.louisville.edu/app/grad-rec.pdf
- Submission of GRE Quantitative section score to the Graduate School (no minimum score required)
- All postsecondary transcripts (may require foreign credential evaluation if not from an accredited US institution)
- Statement of goals submitted to the department office, including the desired emphasis, if any.

Curriculum

The curriculum consists of a minimum of 37 credit-hours of coursework, including nine hours of dissertation work (PHDA-777). The student is eligible to sit for comprehensive examinations upon completion of required coursework. Upon passing the comprehensive examinations, the student enters candidacy to work on the dissertation. After the dissertation is submitted and approved, including an oral defense, the student is eligible to receive the Ph.D. degree in biostatistics.

Faculty Advisor

Upon admission to the Ph.D. program, each student is assigned to the graduate coordinator of the Ph.D. program for course advising. The graduate coordinator assumes the role of faculty advisor until the student chooses a dissertation advisor at which point this responsibility shifts to the dissertation advisor. If it becomes clear that a Ph.D. student will be working with a given faculty member prior to forming a dissertation committee, the student may request a change in course advisor by completing the form “Request to Change Academic Advisor” and having it signed by the graduate coordinator, the new academic advisor, and the department chair.

Program of Study

Upon admission to the Ph.D. program, a program of study is developed for each student by a faculty advisor and approved by the department chair. Students who did not complete the M.S. program in biostatistics with the Department of Bioinformatics and Biostatistics may be required to complete additional coursework normally offered in the M.S. program. Decisions regarding additional coursework are made by the student’s assigned faculty advisor and such courses become part of the program of study. This approach gives maximum flexibility for addressing differing student qualifications and interests.

Degree Requirements

Completion of the coursework is the prelude to sitting for the comprehensive examination. Successful completion of the comprehensive examination allows the student to enter doctoral candidacy. A doctoral candidate must then develop and successfully defend a dissertation proposal that describes an original and independent research project. Upon successful defense of the proposal, a student may then proceed to continue dissertation research. Upon successful

completion of the research, defense of the dissertation, and demonstration of the required competencies listed below, a student is awarded the Ph.D. degree.

The Ph.D. program in biostatistics is a 37 credit-hour program (minimum beyond a master's degree) including the dissertation. Additional hours may be needed for completion of the program.

Coursework

37 total credit-hours
28 credit-hours of required coursework
9 credit-hours of dissertation research

Required Coursework			
Emphasis (if any)	*Course #*	*Course Title*	*Credit-Hours*
All	PHST-710	Advanced Statistical Computing I	3
	PHST-762	Advanced Statistical Inference	3
	PHST-781	Advanced Linear Models	3
	various	Elective	3
	PHST-703	Doctoral Practicum in Consulting	1
	PHDA-777	Dissertation Research	9
	Subtotal		22
No emphasis	PHST-691	Bayesian Statistics	3
	PHST-724	Advanced Clinical Trials	3
	PHST-780	Advanced Nonparametrics	3
	PHST-782	Generalized Linear Models	3
	PHST-783	Advanced Survival Analysis	3
	Subtotal		15
Emphasis on decision science	PHDA-690	Utility Theory and Assessment	3
	PHST-691	Bayesian Statistics	3
	PHDA-701	Advanced Medical Decision Making	3
	PHDA-663	Decision Analysis	3
	PHDA-705	Statistical Methods for Cost-Effectiveness Analysis	3
	Subtotal		15

Required Coursework			
Emphasis (if any)	*Course #*	*Course Title*	*Credit-Hours*
Emphasis on bioinformatics	PHBI-751	High-Throughput Data Analysis	3
	CECS-660	Introduction to Bioinformatics	3
	BIOC-545 -OR- MBIO-667	Advanced Biochemistry I Graduate Cell Biology	3 3
	PHBI-750	Statistics for Bioinformatics	3
	PHBI-752	Statistical Genetics	3
	Subtotal		15
Degree Total			37

The student may be required to take one or more prerequisite courses for a required course if the student does not meet the prerequisites. These prerequisite courses become part of the program of study but are in addition to the number of coursework credit-hours presented above.

Electives

The student must take an elective from the following list. The student's program of study specifies the particular course to be taken.

Electives					
*Emphasis**			*Course #*	*Course Title*	*Credit-Hours*
--	*D*	*B*			
x	x		PHBI-750	Statistics for Bioinformatics	3
x	x		PHBI-751	High-Throughput Data Analysis	3
x	x	x	PHST-682	Multivariate Analysis	3
x	x	x	PHST-711	Advanced Statistical Computing II	3
x	x	x	PHST-725	Design of Experiments	3
x	x	x	PHST-785	Nonlinear Regression	3
x	x		PHBI-752	Statistical Genetics	3
x			PHDA-705	Statistical Methods for Cost-Effectiveness Analysis	3
	x		PHST-724	Advanced Clinical Trials	3
	x	x	PHST-782	Generalized Linear Models	3
		x	PHST-691	Bayesian Statistics	3
		x	PHST-780	Advanced Nonparametrics	3
		x	CECS-632	Data Mining	3

*Key for emphasis: -- = no emphasis
D = emphasis on decision science
B = emphasis on bioinformatics

The student may be required to take one or more prerequisite courses for an elective course if the student does not meet the prerequisites. These prerequisite courses become part of the program of study but are in addition to the number of coursework credit-hours presented above.

Comprehensive Examination

Upon completion of the required coursework for the Ph.D. degree, a student is eligible to sit for the doctoral comprehensive examinations. Each student must take two comprehensive exams.

- Exam 1 covers the following topics:
  - Statistical inference
  - Linear models

- Exam 2 covers the following topics, depending on the student's emphasis, if any:
  - No emphasis
    - Student choice of any two of the following:
      - Statistical computing
      - Clinical trials
      - Generalized linear models
      - Survival analysis
  - Emphasis on decision Science
    - Utility theory, assessment, and medical decision making
    - Student choice of one of the following:
      - Bayesian analysis
      - Cost-effectiveness analysis
  - Emphasis on bioinformatics
    - Statistical methods in bioinformatics (including high-throughput methods) and statistical genetics
    - Student choice of one of the following:
      - Bayesian analysis
      - Statistical computing

Dissertation

In order to complete the degree, a student must submit and successfully defend a dissertation on a topic approved by his or her major professor and the dissertation committee. Dissertation work may be started following successful completion of doctoral comprehensive examinations.

Dissertation Committee

The dissertation committee is formed by the student's proposing a major professor (or principal advisor) and four other committee members. The major professor must be a senior member of the Graduate Faculty; the other members of the committee must be members of the Graduate Faculty. One member of the dissertation committee must be external to the Department of Bioinformatics and Biostatistics. The committee is formally appointed by the dean of the Graduate School upon the recommendation of the chair of the department.

Dissertation Proposal (Pre-Dissertation Essay)

A dissertation proposal or pre-dissertation essay is submitted to the major professor and the dissertation committee. The proposal must be approved by a majority vote of the dissertation committee before the student undertakes further work on the dissertation.

The dissertation proposal is a typed document not exceeding 25 pages in length excluding topics (v) to (viii), below. The following formatting is used: Times New Roman 12-point font, margins of 1 inch on all sides and 1.5-line spacing throughout the body of the document. The Graduate School dissertation guidelines for citing references must be followed. The document is divided into the following sections and in the following sequence:

(i) Introduction and Literature Reviews – general introduction to the area of proposed research and relevant literature reviews
(ii) Specific Aims and Significance – short section describing the specific aims of the proposed research and their potential importance in the field
(iii) Preliminary Results – summary of the research findings the student already has (e.g., simulation results) towards one or more of the specific aims. This is an important component of the proposal that demonstrates the feasibility of the proposed research by the student.
(iv) Research Plan – detailed description of the research towards the specific aims to be undertaken during the rest of the doctoral study period
(v) References – complete references to all the cited literature. Journal names should not be abbreviated
(vi) Tables – including table headings
(vii) Figures – one figure per page
(viii) Appendix – copies (in PDF format) of published articles and preprints that are most relevant to the proposed research

Dissertation Preparation

The dissertation is to be prepared in format and binding according to the guidelines of the Graduate School.

Dissertation Approval

The dissertation is submitted in completed form to the dissertation committee at least thirty days before the end of the term in which the candidate expects to be graduated. A candidate is not eligible for the final oral examination until the dissertation has been accepted by the committee.

The dissertation committee schedules an oral examination of the candidate. All faculty and students of the school are invited to attend the presentation portion. The defense is scheduled at the convenience of the members of the dissertation committee. The dissertation must be approved by the full committee.

Dissertation Distribution

One unbound copy of the dissertation, signed by the dissertation committee members, must be deposited with the Graduate School before graduation. A copy of the final, signed dissertation must also be deposited with the department office.