

# **Proposal for a Ph.D. in Biostatistics at IUPUI**

**Department of Mathematical Sciences,**

**Purdue University School of Science,**

**Indiana University Purdue University Indianapolis**

**and**

**Division of Biostatistics,**

**Indiana University School of Medicine**

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INSTITUTION: Indiana University, Indianapolis (IUPUI)

SCHOOL: School of Science

DEPARTMENT: Mathematical Sciences

DEGREE PROGRAM TITLE: Biostatistics

FORM OF RECOGNITION TO BE AWARDED/DEGREE CODE: Doctor of Philosophy/Ph.D.

SUGGESTED CIP CODE: 261102

LOCATION OF PROGRAM/CAMPUS CODE: Indianapolis, IUPUI

PROJECTED DATE OF IMPLEMENTATION: August 2008

DATE PROPOSAL WAS APPROVED BY  
INSTITUTIONAL BOARD OF TRUSTEES:

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SIGNATURE OF AUTHORIZING  
INSTITUTIONAL OFFICER

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DATE

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DATE RECEIVED BY COMMISSION FOR  
HIGHER EDUCATION

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COMMISSION ACTION (DATE)

## A. ABSTRACT

This document proposes an Indiana University Ph.D. degree in Biostatistics to be offered on the campus of Indiana University-Purdue University Indianapolis (IUPUI) and administered jointly by the Department of Mathematical Sciences in the School of Science and the Division of Biostatistics in the Indiana University School of Medicine.

### Objectives

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The increasing role of the health and life sciences in Indiana naturally increases the demand for highly qualified and superiorly trained biostatisticians. Extensive biostatistics expertise is essential to support those working in the research forefront of the life sciences. The role of biostatistics in this arena can hardly be overstated; it is a fundamental scientific component of almost any of the research and development areas in the health and life sciences. The establishment of a Ph.D. program in Biostatistics on the IUPUI campus will help meet the increasing needs in our state for highly trained biostatisticians capable of working in collaborative research environments in the health and life sciences.

### Unique and Innovative Features

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The program will combine the academic strength of the Department of Mathematical Sciences, which has a very successful Master's Degree specializing in Applied Statistics, with the significant experience of health and life science collaboration of the Division of Biostatistics within the School of Medicine. This is the perfect combination of elements required to train qualified biostatisticians with the necessary mathematical skills and biomedical experience.

### Curriculum

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Students entering the program should have a Bachelor's Degree with the minimal mathematics background consisting of an undergraduate course sequence in univariate and multivariate calculus and a course in linear algebra. A minimum of 90 credit hours beyond the Bachelor's degree are required for the Doctoral degree. The 90 credit hours will consist of:

**Core Courses (36 hours):** A common core of 36 credit hours of coursework will be required of all students who begin the program after the completion of a Bachelor's degree.

**Elective Courses (12 hours):** All students must take 12 credit hours of elective statistics/biostatistics courses. At most six credit hours of the electives may be taken from 500 level courses.

**Minor Area (9 to 15 hours):** All students must complete a minor in an area related to any of health and life sciences. The minor may be obtained in areas such as pharmacology and toxicology, epidemiology, genetics, biology, physiology bioinformatics, public health and health economics, among many others and it must be approved by the student's advisor or graduate committee. The minor must contain a minimum of three graduate level courses (nine credits) in the chosen area and comply with the minor requirements of the respective department/unit.

**Dissertation (27 to 33 hours):** The remaining hours to total 90 will be guided research dissertation hours.

## **Clientele to be Served**

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The proposed program will serve semi-professional and professional statisticians working in local industries, as well as full-time graduate students in statistics who are interested in pursuing academic or industry positions in biostatistics.

## **Employment Possibilities**

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Graduates of this program are expected to enter academic positions in research and teaching universities or to conduct biostatistical research for industries in the health and life sciences.

## **B. Program Description**

The Ph.D. degree program in Biostatistics is designed for individuals with strong quantitative and analytical skills and strong interests in biological, medical and/or health related sciences. It provides rigorous training in statistical theory and methodologies that are suitable for applications in research, collaboration and consulting on a broad spectrum of health and life science problems. The program stresses the theory and concepts underlying statistical methods, the interpretation of results from experimental as well as observational studies, and the practical realities of health-related studies and their analysis. The primary goal is to prepare students for independent careers as biostatisticians in any professional health-related or biomedical environment, such as in medical research institutes, universities, government agencies and private health-industries or organizations.

## **Admission Requirements**

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Any applicant who has a suitable Bachelor's or a Master's degree from an accredited institution and shows promise for successfully completing all the degree requirements will be considered for admission to this program. In addition to satisfying general Indiana University Graduate School requirements for admission, applicants must have at least a B (3.00 GPA) average in courses taken during the last two years of their earlier degree studies, and a grade of B+ (3.50 GPA) in courses required as prerequisites for the program. The minimal mathematics background consists of an undergraduate course sequence in univariate and multivariate calculus (equivalent to MATH 163, 164 and 261 at IUPUI) and a course in linear algebra (including matrix theory). In addition, applicants should have had a calculus-based undergraduate level course in probability or statistics. Prospective applicants who do not have this background must acquire it prior to admission to the program.

Applicants are required to take the Graduate Record Examination (GRE) General Test and those whose native language is not English must also take the Test of English as a Foreign Language (TOEFL) and achieve a score of 570 (or 230 on the computer version of the test, or 79 on the internet based test). Final admission decision will be made by a faculty Admission Committee.

## **Description of Proposed Curriculum**

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A minimum of 90 credits beyond the Bachelor's degree are required for the Ph.D. degree, with at least 48 credit hours of formal coursework accumulated by the student. This formal coursework

consists of 36 credit hours of required courses and additional 12 credit hours in elective statistics/biostatistics courses of which six credit hours must be at the 600 level and above. The remaining 42 credit hours will be taken as additional coursework in a minor area (9 to 15 credits), further elective courses, independent studies, and directed Ph.D. dissertation research.

### Required Courses

Every student in the program is required to complete the following 12 courses for a total of 36 credits:

- STAT 512 Applied Regression Analysis (3 credits)
- BIOS 515 Biostatistics Practicum (3 credits)
- \*STAT 519 Introduction to Probability (3 credits)
- \*STAT 525 Intermediate Statistical Methods (3 credits)
- BIOS 527 Design and Analysis of Clinical Trials (3 credits)
- \*STAT 528 Mathematical Statistics I (3 credits)
- \*STAT 536 Introduction to Survival Analysis (3 credits)
- \*BIOS 546 Longitudinal Data Analysis (3 credits)
- STAT 619 Probability Theory (3 credits)
- BIOS 621 Statistical Computing (3 credits)
- STAT 628 Advanced Statistical Inference (3 credits)
- BIOS 636 Survival Analysis (3 credits)

\* indicates the Program's Core Courses

### The Qualifying Examination

Students must pass an initial qualifying examination, which consists of written and oral parts on the five core courses: **STAT 519, 525, 528, 536** and **BIOS 546**. This qualifying examination, which is offered twice a year, must be successfully passed within one year of completing the above five courses. Students who enter the Ph.D. program with a Master's degree and do not have to take any of the core courses will have at most one year from the date of entry to pass the qualifying examination. The preparation and the administration of the qualifying examination will be overseen by the Graduate Examination Committee. This exam may be taken at most twice and will result in one of the following three outcomes:

1. Ph.D.-level Pass: The student has demonstrated fundamental understanding of the Master's level material and the examination committee believes he/she will be successful in completing the Ph.D. program.
2. Failure at the Ph.D.-level with an option to continue for the Master's in Applied Statistics: The student has performed adequately on the Master's level material and is encouraged to apply and complete the Master's Degree Program in Applied Statistics.
3. Failure: The student has failed to demonstrate an understanding even of the basic Master's level material and thus fails the examination.

### **Ph.D. Advisor**

After passing the Qualifying Examination, the prospective Ph.D. candidate must choose a primary research advisor. The choice of the advisor may reflect the area of interest to the student and may be chosen from any of the Graduate Biostatistics Training Faculty.

### **Minor Area**

In addition to the 48 credits of the formal BIOS/STAT coursework, the prospective Ph.D. candidate must complete a minor in an area related to any of the health and life sciences disciplines. The minor may be obtained in areas such as pharmacology and toxicology, epidemiology, genetics, biology, physiology, bioinformatics, public health and health economics, among many others, and it must be approved by the student's Advisor or the graduate director of the program. The minor must contain a minimum of three graduate level courses (nine credits) in the chosen area and it must comply with the minor requirements of the respective department/unit.

### **Preliminary Examination**

The student must prepare and pass a preliminary examination, which consists of an oral presentation on an advanced research topic suggested by the student to an appointed committee of at least four faculty members, inclusive of the student's Advisor and at least one member from outside the program. This committee will serve as the research committee for the student. Prior to the actual examination, the student must provide the committee with a paper (10–15 pages) outlining the topic to be covered, clearly indicating the scope and depth of the planned research along with relevant references. In the examination, the student is expected to display an in depth understanding of the chosen subject matter. The committee may ask the student questions which normally will be directed to the subject matter of the research but may, by natural extension, also cover any other relevant topic.

### **Dissertation:**

After passing the preliminary examination, the student may begin officially working on the Ph.D. dissertation, which will be an original and publishable statistical/biostatistical research originating from and with application to well-defined life and health related problems. The research topic for the dissertation must be formally approved by the student's Committee. Typically however, the actual work on the dissertation topic and proposal begins during the preparation for the preliminary examination. The student must submit the completed written dissertation to the research Committee for reading and evaluation and subsequently he/she will have to present and defend it orally in a public forum before the Committee.

### **Sample Program**

The following sample plan of study is an illustration of courses taken by a typical full-time student.

- *First Semester*
  - STAT 512 Applied Regression Analysis (3 credits)
  - STAT 519 Introduction to Probability (3 credits)
  - STAT 521 Introduction to Statistical Computing (3 credits)
- *Second Semester*

- BIOS 515 Biostatistics Practicum (3 credits)
- STAT 525 Intermediate Statistical Methods (3 credits)
- STAT 528 Mathematical Statistics I (3 credits)
- *Third Semester*
  - STAT 536 Introduction to Survival Analysis (3 credits)
  - BIOS 621 Statistical Computing (3 credits)
  - BIOS 527 Design and Analysis of Clinical Trials (3 credits)
- *Fourth Semester*
  - BIOS 546 Longitudinal Data Analysis (3 credits)
  - STAT 619 Probability Theory (3 credits)
  - BIOS/STAT Elective (3 credits)
- *Fifth Semester*
  - STAT 628 Advanced Statistical Inference (3 credits)
  - BIOS/STAT Elective (3 credits)
  - Minor Area Elective (3 credits)
- *Sixth Semester*
  - BIOS 636 Survival Analysis (3 credits)
  - BIOS/STAT Elective (3 credits)
  - Minor Area Elective (3 credits)
- *Seventh Semester*
  - Minor Area Elective (3 credits)
  - BIOS 699 Research Ph.D. Thesis (6 credits)
- *Eighth Semester*
  - BIOS 699 Research Ph.D. Thesis (9 credits)
- *Ninth Semester*
  - BIOS 699 Research Ph.D. Thesis (9 credits)
- *Tenth Semester*
  - BIOS 699 Research Ph.D. Thesis (9 credits)

## Courses

Below are the required and elective courses in the proposed curriculum, including the number of times the currently existing courses have been offered in the past three years. Descriptions of all the courses may be found in Appendix III.

## Required Courses

Course Number	Title	C.H.	Existing Course	Times Offered in Last 3 Years
STAT 512	Applied Regression Analysis	3	Yes	3
STAT 515	Statistical Consulting Problems	3	Yes	9
BIOS 515	Biostatistical Practicum			
STAT 519	Introduction to Probability	3	Yes	3
STAT 525	Intermediate Statistical Methodology	3	Yes	0
BIOS 527	Design and Analysis of Clinical Trials	3	No	
STAT 528	Mathematical Statistics I	3	Yes	3

STAT 536	Introduction to Survival Analysis	3	Yes	3
BIOS 546	Applied Longitudinal Data Analysis	3	No	
STAT 619	Probability Theory	3	No	
BIOS 621	Statistical Computing	3	No	
STAT 628	Advanced Statistical Inference	3	No	
BIOS 636	Survival Analysis	3	No	

### Other Courses

Course Number	Title	C.H.	Existing Course	Times Offered in Last 3 Years
STAT 513	Statistical Quality Control	3	Yes	2
STAT 514	Design of Experiments	3	Yes	3
STAT 520	Time Series and Applications	3	Yes	1
STAT 521	Statistical Computing	3	Yes	2
STAT 522	Sampling and Survey Techniques	3	Yes	3
STAT 523	Categorical Data Analysis	3	Yes	3
STAT 524	Applied Multivariate Analysis	3	Yes	3
STAT 529	Bayesian Statistics and Applied Decision Theory	3	Yes	2
STAT 532	Elements of Stochastic Processes	3	Yes	2
STAT 533	Nonparametric Statistics	3	Yes	3
STAT 598 BIOS 598	Topics in Statistical Methods	1-3	Yes	9
BIOS 627	Statistics in Pharmaceutical Research	3	No	
BIOS 632	Stochastic Modeling in Biomedical and Health Sciences	3	No	
BIOS 646	Advanced Longitudinal Data Analysis	3	No	
BIOS 695	Seminar in Biostatistics	1-3	No	
BIOS 699	Research Ph.D. Thesis	1-18	No	

In addition, students in the new program will be able to take, upon approval of their academic advisor, other Ph.D. level elective courses in statistics as may be offered at Purdue University at West Lafayette or at the Bloomington Campus of Indiana University. For instance, students might consider, amongst others, elective courses such as

Course Number	Title	Cr.h.	Campus
STAT 576	Statistical Decision Theory and Bayesian Analysis	3	PUWL
STAT 598C	Statistical Methods For Bioinformatics and Computational Biology	3	PUWL
STAT 598M	Data Mining	3	PUWL
STAT S670	Exploratory Data Analysis	3	IUB
STAT S675	Statistical Learning and High-Dimensional Data Analysis	3	IUB



## **Form of Recognition**

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Students who successfully complete this program will receive an Indiana University degree of Doctor of Philosophy (Ph.D.) in Biostatistics, from the School of Science at Indiana University Purdue University Indianapolis.

## **CIP Code**

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Proposed CIP Code: 261102

## **Program Administrators and Faculty**

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### **Program Administration:**

The IUPUI Ph.D. Program in Biostatistics will be offered as an Indiana University degree and will be administrated jointly by the IUPUI Department of Mathematical Sciences, within the School of Science, and the Division of Biostatistics in the Indiana University School of Medicine. Primary administrative responsibilities reside with the Department of Mathematical Sciences, whose Chair will serve as its Principal Administrator along with the Director of Biostatistics and the respective schools' Graduate Deans as Co --Administrators.

- Benzion Boukai, Chair, Department of Mathematical Sciences, IUPUI, Professor of Statistics, Ph.D., Statistics, 1988, SUNY Binghamton—Principal Administrator
- Barry P. Katz, Director, Division of Biostatistics, IU-SOM, Professor of Medicine, Ph.D., Biostatistics, 1984, University of Michigan—Co-Administrator
- Pamela Crowell, Associate Dean for Research and Graduate Programs, SOS-IUPUI, Associate Professor of Biology, Ph.D., Biochemistry, 1988, University of Wisconsin-Madison—Co-Administrator
- Simon J. Rhodes, Associate Dean for Graduate Studies, IU-SOM, Professor of Cellular and Integrative Physiology, Ph.D., Biochemistry and Molecular Biology, 1991, Purdue University, West Lafayette—Co-Administrator

### **Committees:**

The administration of the program's academic affairs will be overseen by the program's training faculty and will be facilitated through numerous standing committees, such as: Admissions Committee, Curriculum Committee, and Qualifying Examination Committee. In all cases, the program administrators will endeavor to comprise these faculty committees with an

(approximate) equal membership from the Division of Biostatistics and the Department of Mathematical Sciences.

### **Graduate Biostatistics Training Faculty:**

- Sujuan Gao, Associate Professor of Medicine, Ph.D., Statistics, 1991, University of Southampton, UK.
- Samiran Ghosh, Assistant Professor of Statistics, Ph.D., Statistics, 2006, University of Connecticut
- Siu L. Hui, Professor of Medicine, Ph.D., Biostatistics, 1979, Yale University
- Fang Li, Assistant Professor of Statistics, Ph.D., Statistics, 2004, Michigan State University
- Lang Li, Associate Professor of Medicine, Ph.D., Biostatistics, 2001, University of Michigan
- Xiaoman Li, Assistant Professor of Medicine, Ph.D., Mathematics, 2002, University of Southern California
- Yunlong Liu, Assistant Professor of Medicine, Ph.D., Biomedical Engineering, 2004, Purdue University
- Patrick O. Monahan, Assistant Professor of Medicine, Ph.D., Measurement and Statistics, 2002, University of Iowa
- Susan M. Perkins, Associate Professor of Medicine, Ph.D., Biostatistics, 1997, University of Michigan
- Chandan K. Saha, Assistant Professor of Medicine, Ph.D., Biostatistics, 2001, University of Iowa
- Jyotirmoy Sarkar, Associate Professor of Statistics, Ph.D., Statistics, 1990, University of Michigan
- Changyu Shen, Assistant Professor of Medicine, Ph.D., Biostatistics, 2004, University of Pittsburgh
- Jason Sutherland, Assistant Professor of Medicine, Ph.D., Statistics and Actuarial Science, 2003, Simon Fraser University, Canada
- Wanzhu Tu, Assistant Professor of Medicine, Ph.D., Statistics, 1997, University of South Carolina
- Constantin Yiannoutsos, Associate Professor of Medicine, Ph.D., Statistics, 1991, University of Connecticut
- Menggang Yu, Assistant Professor of Medicine, Ph.D., Biostatistics, 2003, University of Michigan
- Honghong Zhou, Assistant Professor of Medicine, Ph.D., Biostatistics, 2006, University of Michigan

### **Needed Learning Resources**

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The proposed Ph.D. program in Biostatistics will be facilitated by the relevant teaching and learning resources already existing at IUPUI and will require no additional investments for its

implementation. The IUPUI Department of Mathematical Sciences offers a Purdue University Ph.D. program in mathematics and it has, therefore, all the necessary administrative infrastructure to support the administration of a new doctorate degree program in biostatistics. However, the academic and curricular focus of the current Ph.D. program in mathematics are not designed to provide any advanced training in biostatistics and therefore necessitates the creation of this new Ph.D. program in Biostatistics on the IUPUI campus as a joint endeavor between the two units. As was already mentioned in a previous section, the proposed program is largely built on existing resources (both curricular and the combined faculty talents and expertise), and therefore will not divert any resources away from undergraduate education on the IUPUI campus. In fact, we foresee this program and the presence of its advanced graduate students in biostatistics as likely to enhance the undergraduate education in statistics and biostatistics on our campus.

The Department has excellent facilities, in its main location at the Science Building as well as at its newly created Signature Center for Mathematical Biosciences (CMB), located at the Health Information and Translational Sciences (HITS) building, to support the learning, training and research of the graduate students in biostatistics. Similarly, the Division of Biostatistics which recently moved to the HITS building now has sufficient space to also accommodate several graduate students for their training and research activities in the Division of Biostatistics.

The Department operates a number of computing servers to support the research of its faculty and students which can be accessed from both locations. The Division of Biostatistics also has established its own library and computing system, which can be fully utilized for graduate students' training. Additionally, the excellent physical and online holdings of the IUPUI University Library and the Ruth Lilly Medical Library are sufficient to support the program.

## **C. Program Rationale**

Biostatisticians develop the mathematical and statistical models used to explain various biomedical processes; they provide quantitative support functions to clinical studies and drug development, including study design, design and management of data collection and quality control; they undertake research to develop and test novel methods for analyzing and interpreting complex data structures in emerging areas of applications and research including medicine, genomics, proteomics, environmental biology, public health services, and behavioral health research as well as in biomedical-informatics. As these areas are developed further, they will require increasingly more sophisticated biostatistical expertise in their support, and few grant applications, research articles and no drugs or medical devices can be approved, nowadays, without appropriate and frequently extensive biostatistical support.

### **Institutional Factors**

Biostatistics as a profession is already significantly present throughout IUPUI. The campus already has several units and centers with substantial research strength and expertise in statistics, biostatistics and other related areas. These include, aside from the Division of Biostatistics and the Department of Mathematical Sciences, the Regenstrief Institute, the Department of Medical

and Molecular Genetics, the INGEN funded centers for bioinformatics, genomics and proteomics, and the School of Nursing. Many of these research enterprises, including the Division of Biostatistics and the new IUPUI Signature Center for Mathematical Biosciences (CMB), are now housed in one location--the new Health Information and Translational Sciences (HITS) building of the Indiana University School of Medicine.

The Division of Biostatistics in the IU School of Medicine has 15 Ph.D. level faculty members who perform advanced research jointly with various units of the Schools of Medicine, Dentistry, and Nursing, amongst others. The faculty members of the Division also have some limited responsibilities in the education of the medical school graduate students and clinical fellows. Their activities are supported by a number of Master's-level biostatisticians. The IUPUI Department of Mathematical Sciences, which has over 30 Ph.D. level tenure track and research scientist faculty members, including 5 members working in the area of probability and statistics, offers graduate programs leading to Ph.D. and Master's degrees in pure and applied mathematics, as well as a highly successful and visible Masters degree program specializing in applied statistics with a strong affinity to biostatistics. This program, which was started in 1990 in response to a strong demand from local industries for well-trained applied statisticians, has realized a tremendous growth reflective of the even more increasing needs in Indiana. To date, over 120 applied statisticians have been trained in this program, many of whom are employed as Master's-level biostatisticians in various health and life sciences related companies and organizations in Indiana. Indeed, the availability of such a program at IUPUI has helped retain many of them in the state. Furthermore, it is worth noting that many of these graduates, who are locally bound for personal or employment and professional reasons, were initially interested in having a Ph.D. level training in statistics/biostatistics. However, in the absence of any venues for such an advanced degree program in the Indianapolis area, some of them pursued instead the Masters' degree program in applied statistics, while other prospective students have left Indiana to pursue a Ph.D. degree in biostatistics at other universities, thus contributing to the severe brain drain which troubles our state.

A campus-wide Ph.D. program in Biostatistics will help solidify the existing strength in research excellence in biostatistics and related areas. As was mentioned before, the proposed Ph.D. program in Biostatistics will be facilitated entirely by the relevant resources already existing at IUPUI and will require no additional investments for its implementation. The new degree will result in increased collaborations among the various areas the program will bring together, while at the same time providing an array of research and specialization opportunities for the students and faculty involved. The Department of Mathematical Sciences and the Division of Biostatistics are well poised for building a successful Ph.D. program in Biostatistics at IUPUI. The basic academic infrastructure already exists – a Ph.D. Program in Mathematics, Master's level program in Applied Statistics, and a critical number (20) of Ph.D. educators and research professionals in statistics and biostatistics.

## **Local and State-wide Factors**

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Outside of IUPUI, Indiana BioCrossroads was created as a partnership between leading research, academic and economic development organizations in 2002 with the specific objective of making Indiana a world-class center for health and life sciences. Already with nearly 900 existing companies, the \$13.6 billion life sciences industry of Central Indiana employs more

than 80,000 workers in medical, biomedical and biotechnology; pharmaceuticals; medical devices and instruments; hospitals and laboratories; food and nutrition; organic and agricultural chemicals; and in related research, testing and development enterprises. Indiana is home to world-class companies such as Eli Lilly & Company, Roche Diagnostics, Dow AgroSciences, Clarian Health Partners, WellPoint/Anthem, Cook Group, Guidant, Hill-Rom, Zimmer Inc. and Covance, among others as well as major public research universities, including Indiana University at Bloomington, Purdue University at West Lafayette and IUPUI with its medical center and the state's only medical school. The BioCrossroads partnership, which capitalizes on these strong foundations, seeks to attract new businesses by increasing the number of jobs, businesses, and research opportunities in the life sciences industry in Indiana. BioCrossroads is investing heavily in the state of Indiana to support the expansion and the construction of additional research facilities and centers; to forge and develop successful scientific/business collaborations; and to attract, train and retain a highly skilled life sciences workforce that would help bring national and international recognition to Indiana's health and life sciences. Inarguably, these initiatives will substantially increase the demands in Indiana for highly qualified and superiorly trained biostatisticians, since nowadays an extensive biostatistical expertise is indispensable to support the researchers working in the forefront of life and health sciences.

**Compatibility with the IUPUI Mission.** The newly adopted mission of IUPUI describes IUPUI as *“the urban research and academic health sciences campus of Indiana and Purdue universities”* with the goal of *“offering a distinctive range of bachelor's, master's, doctoral, and professional degrees.”* The proposed Ph.D. degree program in Biostatistics is highly compatible with the stated IUPUI mission and the life sciences plan of Indiana University. It is also consistent with and supportive of several of IUPUI's strategic plans, namely, to *“Facilitate the development of new graduate degree and post-baccalaureate certificate programs to meet local, national, and global needs”*; *“to encourage interdisciplinary opportunities for graduate students and post-doctoral fellows.”* ; to *“Build upon IUPUI's world-class research activities as a principal mechanism for engaging with entities in Indianapolis and Central Indiana to improve health care . . . .”* ; and to *“Connect the research and creative strengths of IUPUI with the opportunities and needs of Indianapolis and Central Indiana.”*

## **Demand and Employment Factors**

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The dire needs and employment factors affecting the area of biostatistics, nationally, are well documented in the literature. DeMets et al. (2006) discussed the growing and pressing needs for training the next generation of biostatisticians—all for adequately meeting the scientific challenges to come in the health and life sciences. A ‘White Paper’ prepared in 2002 by an Ad Hoc Committee on Biostatistics Training of the National Institute of Health (NIH), outlines the dire, and worsening, shortage of biostatisticians in the US—a grim reality of which the entire life-sciences community is acutely aware. With strict government protocols regarding even the basic aspects of data and safety monitoring of all clinical research, for instance, it is evident that a high-level of professional biostatistical support is expected in almost all instances. Cognizant of these issues, NIH has issued a Program Announcement (PAR-04-132) in support of advanced training in biostatistics with the goals of ensuring “that a workforce of biostatisticians with a deep understanding of statistical theory and new methodologies is available to assume leadership roles related to the Nation's biomedical, clinical, and behavioral research needs.” An internal report by the Task Force for Biostatistics commissioned by the IU School of Medicine (02-03)

recounts the shortage in Ph.D. level biostatisticians and the difficulties in hiring at that level as one of the impediments for substantially increasing NIH funded research on campus.

## **Other Regional, State, and National Factors**

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Undoubtedly, the current demand for biostatisticians nationally, and in particular in Indiana, far exceeds the supply. In light of the plethora of research and development projects ongoing in Indiana this gap is only expected to widen. Unfortunately, in the midst of this surge of research activities and developments, Indiana's life sciences industries, as well as its research institutions, must import Ph.D. level biostatisticians from out of state—since at the present time, there is no Ph.D. degree program in Biostatistics available anywhere in the state of Indiana. The existing Ph.D. programs in Statistics (PUWL) and in Mathematics (IUB, IUPUI, and PUWL), do not offer the specialized training needed for biostatisticians. However, IUPUI, with its major medical center combining the IU Schools of Medicine, Nursing and Dentistry, and several hospitals, is auspiciously situated in the heart of the state and is uniquely positioned to take a leading role in filling this programmatic void. In the states bordering Indiana, there are five universities that offer a Ph.D. in Biostatistics: University of Illinois at Chicago, University of Michigan, University of Cincinnati, The Ohio State University, and Case Western University (currently there is no Ph.D. program in Biostatistics available in Kentucky). Each of these programs exists in metropolitan areas with major medical centers, very similar to Indianapolis. If Indiana is to have an institution that grants a Ph.D. degree in Biostatistics, as in the surrounding states, then the Indianapolis campus of IU is the logical and the preferred choice.

## **Impact on other Units and Programs at IUPUI and IUB**

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We conceive this proposed program to be a campus-wide program, offered as a new Indiana University degree through the Department of Mathematical Sciences of the School of Science at IUPUI, administered jointly with the Division of Biostatistics of the Indiana University School of Medicine. We believe this program will truly address the multiple needs of the diverse health-and-life related sciences on our campus, locally and the state. As such, it will be highly synergistic in fostering further research and programmatic collaborations amongst all the constituencies of biostatistics and related areas at the university. It is expected that this Biostatistics Ph.D. program will increase faculty research collaboration and will impact interdisciplinary training of students in health-and-life sciences related programs, including, pharmacology and toxicology, epidemiology, genetics, biology, physiology, bioinformatics, public health and health economics, among many others. It is therefore expected that students in this program will take courses in a wide range of cognate areas, to fulfill the minor requirement, and hence, will also contribute to the respective graduate training and research programs of these areas. Similarly, students in other graduate programs would be able to enroll in courses offered in the Ph.D. program and could also designate Biostatistics as a minor.

We envision our program to be inclusive — inviting all interested parties to participate and contribute. In particular, we envision a strong synergistic relationship with the School of Informatics at IUPUI and with the newly created Department of Statistics at the Bloomington campus of IU. The existing Ph.D. program in Informatics, and the planned Ph.D. program in statistics at the Bloomington campus, would likely also benefit from the new Biostatistics Ph.D. program at IUPUI—with students in all these programs mutually benefiting from a wider array of relevant advanced courses, specialized training and faculty expertise. For instance, as was

already presented in a previous section, students in this program will be able to also choose elective courses from the graduate offerings in statistics now being developed at IUB. Likewise, we hope that students in the emerging statistics program at IUB will also be able to take elective courses in the biostatistics program at IUPUI. In all cases, we will strive to collaborate with various schools, departments, and programs, creating a synergy that increases the overall strength of the Biostatistics Ph.D. program within the health and life sciences, and more generally within Indiana University as an institution.

**Letters of support:** Letters in support of the proposed Ph.D. program in Biostatistics at IUPUI have been received from various deans and directors from across campus, as well as from other individuals reflecting strong local and regional interest. These letters include (see Appendix IV) :

- D. Craig Brater  
IU Vice President for Life Sciences  
Dean, IU School of Medicine
- William Bosron, Interim Dean  
Purdue School of Science, IUPUI, and  
IU School of Medicine
- David L. Stocum,  
Purdue School of Science, IUPUI
- Carl C Cowen,  
Purdue School of Science, IUPUI
- Victoria Champion, Associate Dean for Research  
Director of Cancer Control  
IU School of Nursing
- Keith Dunker, Director  
Center for Computational Biology and Bioinformatics  
IU School of Medicine
- Mary Ellen Bock, Head  
Department of Statistics  
Purdue University West Lafayette
- Thomas S. Inui, President and CEO  
Regenstrief Institute
- August M. Watanabe, Chairman of the Board of Directors,  
BioCrossroads
- Timothy Beck, Director, Research & Development  
Roche Diagnostics Operations, Inc.

- Todd Sanger, Director, Global Statistical Sciences  
Eli Lilly and Company
- Karen L. Price, President  
Central Indiana Chapter of the American Statistical Association

## **Student Demand**

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We began by surveying the local community of employees in the health and life sciences industries (primarily employees of Eli Lilly & Company), as well as current and former graduate students of the IUPUI Master's program in applied statistics. The positive response and support for this proposed program has been overwhelming. Over 35 people (to date) have expressed strong interest in actually applying to and completing a Ph.D. program in Biostatistics. Many of these individuals have previously completed a master's degree program in statistics and have desired for some time to pursue the Ph.D., but have been unable to do so because of the lack of such a program in the Indianapolis area. Several of these individuals stated that colleagues have left Indianapolis in order to pursue a Ph.D. in Biostatistics, thus providing anecdotal evidence of the "brain drain" which is negatively affecting the state. As a whole, many of those surveyed expressed the desire to complete the program on a part-time basis, while continuing to work full-time. The structure of the program will thus take this reality of the potential student body into consideration. A significant number of other members of the local community, while not personally interested in pursuing the Ph.D., have indicated that such a program does indeed address an extremely important need in Indianapolis, and in Indiana in general.

## **Planning and Implementation**

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The initial planning for this program started in 2004, when a concept paper describing this program was developed and circulated among the Academic Deans as well as the Office of Dean of the Faculties. The initial strong endorsements that were received from the Dean of Faculties, and the Deans of the IU School of Medicine, the School of Arts and Sciences and the IUPUI School of Science, have led to the further development of this proposal. This programmatic development is now being well synchronized with Indiana's Life and Health Sciences Initiative, and the joining of many of the cognate areas, including the Signature Center for Mathematical Biosciences, at the new Health Information and Translational Sciences Building of the IU School of Medicine.

We are hopeful that we can begin matriculating graduate students into the Ph.D. program in the Fall of 2008. Students who are already admitted into the Master's program in specializing in applied statistics, will be able to take, in anticipation, some of the coursework already in place during the Fall 2007 semester—as courses that would apply towards the Master's program. We are hopeful that the Indiana Commission of Higher Education will receive the Board- approved document by Spring of 2008 and that it would be considered and acted upon within a few months of submission.



Once approved, we will begin small by admitting initially eight Ph.D. students to the program. We anticipate that about one third of the students will be enrolling with a baccalaureate degree and the rest will be entering the program at the post-Master's degree level. The number of full-time students in the program is expected to be small, approximately three students admitted annually, (see Table 1, Enrollment and Completion Data). We arrived at this number by examining the enrollment to the applied statistics concentration of the Master's program and from the size of like programs at the initial stage, trying to estimate the initial demand for the program.

The tuition income stream generated by the program, along with several funded grants in the Department, the CMB and the Division of Biostatistics, will allow the provision of financial support to the full-time Ph.D. students in the program. We assume that all part-time students will be self-supporting or fully sponsored by their employers who will contribute to the costs of their advanced training in Biostatistics. Additionally, the administrators of the program will pursue funding from outside sources, such as the NIH, and Eli Lilly and Company Foundation, to support the training of graduate students in the program. In fact, a proposal to pursue external funding to establish the Lilly-IUPUI fellowship in biostatistics is now under development.

Additionally, as Tables 2A and 2B (Program Costs and Revenue Data) demonstrate, the tuition revenue resulting from new students enrolled in this program will also be sufficient to also offset the incremental cost of faculty efforts resulting from instructing the nine new courses that will be added to the program (aside from seminars and practicum).

## **Evaluation and Assessment**

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The Ph.D. program in Biostatistics will be evaluated through a self-study and a program review process. The systematic five-year program review will be conducted by a committee with members internal and external to IUPUI, and will examine the strengths and weaknesses of the Ph.D. program. The review committee will produce a report and recommendations to the program and university administrators.

The Ph.D. program will also have an Advisory Board with members, internal and external to IUPUI, that will assist in its ongoing programmatic evaluation and will help in its assessment and further development. We intend to invite to this Advisory Board, Todd Sanger, Director, Global Statistical Sciences, Eli Lilly and Company; Prof. John Klein, Head, Division of Biostatistics, Medical College of Wisconsin at Milwaukee; Prof. Roderick Little, Chair, Department of Biostatistics, University of Michigan, Ann Arbor; Prof. Mary Ellen Bock, Head, Department of Statistics, Purdue University at West Lafayette; Prof. Stanley Wasserman, Chair, Department of Statistics, IU Bloomington and Prof. Dipak Dey, Chair, Department of Statistics, University of Connecticut at Storrs. These individuals are well-situated in the profession to provide and share with the program administrators their experience from local, regional, national, as well as academic and industrial, perspectives.

The success of the program will ultimately be assessed for meeting its goals in preparing and training students for independent and successful careers as biostatisticians in any professional health-related or biomedical research environment, for supporting the mission and the strategic

plans of IUPUI, and for serving our state constituencies. Thus, key quality indicators and measures will be collected on an ongoing basis for the program evaluation and assessment, while students are enrolled in the program and also after their graduation. These include (amongst others): standard quality measures for student admission to the program; student performance in the required Ph.D. level courses; student performance in the qualifying examination; student performance in practicum; student total performance in the cognate minor area; student presentation and performance in the advanced topic examination (preliminary examination); the depth and breadth of the proposed research; the successful completion by the Ph.D. candidate of the intended research and all the degree requirements; the quality and level of the journals in which the student's research is published and any related award and recognition. Graduate and employer surveys will be used in the assessment to ascertain the type of employment offered and accepted after graduation; the postdoctoral experience (if any); the level of funding applied/received (if any); the published subsequent research (if any), and the likes.

In all cases, it is hoped that the assessment and evaluation activities will contribute materially to its further improvement and success. IUPUI, the IU School of Medicine, the School of Science, and the Department of Mathematical Sciences, have a long history and experience in program review and assessment that will be useful in successfully implementing the planned assessment of this new Ph.D. program in Biostatistics.

## References

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1. DeMets DL, Anbar D, Fairweather W, Louis TA, O'Neill RT. Training the next generation of biostatisticians. *The American Statistician* 1994; **48**(4):280–284.
2. DeMets DL, Stormo G, Boehnke M, Louis TA, Taylor J, and Dixon D, Training of the next generation of biostatisticians: A call to action in the U.S. *Statistics in Medicine*, 2006; **25**:3415–3429.
3. Zelen M, Biostatisticians, Biostatistical Science and the Future, *Statistics in Medicine*, 2006; **25**:3409–3414.

## Appendices

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### **I. Table 1: Enrollment and Completion Data**

### **II. Tables 2A -- 2B: Cost and Revenue Data**

### **III. Detailed List of Courses**

### **IV. Copies of Letters of Support**

Campus: Indiana University-Purdue University Indianapolis  
 Program: Ph.D. in Biostatistics  
 Date: 20 July 2007

TABLE 1: PROGRAM ENROLLMENTS AND COMPLETIONS  
 Annual Totals by Fiscal Year (Use SIS Definitions)

	<u>Year 1</u> <u>2008-09</u>	<u>Year 2</u> <u>2009-10</u>	<u>Year 3</u> <u>2010-11</u>	<u>Year 4</u> <u>2011-12</u>	<u>Year 5</u> <u>2012-13</u>
A. Program Credit Hours Generated					
1. Existing Courses	114	162	210	210	210
2. New Courses	0	66	132	246	360
Total	114	228	342	456	570
B. Full-time Equivalent (FTEs)					
1. Generated by Full-time Students	2	5	7	9	11
2. Generated by Part-time Students	3	5	8	10	13
Total	5	10	14	19	24
3. On-Campus Transfers	0	0	0	0	0
4. New-to-Campus	5	10	14	19	24
C. Program Majors (Headcounts)					
1. Full-time Students	3	6	9	12	15
2. Part-time Students	5	10	15	20	25
Total	8	16	24	32	40
3. On-Campus Transfers	0	0	0	0	0
4. New-to-Campus	8	16	24	32	40
5. In-State	7	14	21	28	35
6. Out-of-State	1	2	3	4	5
D. Program Completions	0	0	0	0	8

Campus: Indiana University-Purdue University Indianapolis  
Program: Ph.D. in Biostatistics  
Date: 20 July 2007

TABLE 2A:  
TOTAL DIRECT PROGRAM COSTS AND SOURCES OF PROGRAM REVENUE

	Year 1		Year 2		Year 3		Year 4		Year 5	
	FTE	2008-09	FTE	2009-10	FTE	2010-11	FTE	2011-12	FTE	2012-13
A. Total Direct Program Costs										
1. Existing Departmental Faculty Resources	0.0	\$ 0	0.0	\$ 0	0.0	\$ 0	0.0	\$ 0	0.0	\$ 0
2. Other Existing Resources		0		0		0		0		0
3. Incremental Resources (Table 2B)		50,100		100,200		150,300		200,400		250,500
TOTAL		\$ 50,100		\$ 100,200		\$ 150,300		\$ 200,400		\$ 250,500
B. Sources of Program Revenue										
1. Reallocation		\$ 0		\$ 0		\$ 0		\$ 0		\$ 0
2. New-to-Campus Student Fees		36,100		72,200		108,300		144,400		180,500
3. Other (Non-State)										
4. New State Appropriations										
a. Enrollment Change Funding		14,000		28,000		42,000		56,000		70,000
b. Other State Funds		0		0		0		0		0
TOTAL		\$ 50,100		\$ 100,200		\$ 150,300		\$ 200,400		\$ 250,500

Campus: Indiana University-Purdue University Indianapolis  
Program: Ph.D. in Biostatistics  
Date: 20 July 2007

TABLE 2B:  
DETAIL ON INCREMENTAL OR  
OUT-OF-POCKET DIRECT PROGRAM COSTS

	Year 1		Year 2		Year 3		Year 4		Year 5	
	FTE	2008-09	FTE	2009-10	FTE	2010-11	FTE	2011-12	FTE	2012-13
1. Personnel Services										
a. Faculty	0.3	28,500	0.5	42,500	0.7	56,500	0.8	70,500	1.0	84,500
b. Support Staff	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0
c. Graduate Teaching Assistants	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0
Total Personnel Services		28,500		42,500		56,500		70,500		84,500
2. Supplies and Expense										
a. General Supplies and Expense		0		0		0		0		0
b. Recruiting		0		0		0		0		0
c. Travel		0		0		0		0		0
d. Library Acquisitions		0		0		0		0		0
Total Supplies and Expense		0		0		0		0		0
3. Equipment										
a. New Equipment Necessary for Program										
b. Routine Replacement										
Total Equipment		0		0		0		0		0
4. Facilities		0		0		0		0		0
5. Student Assistance										
a. Graduate Fee Scholarships		21,600		57,700		93,800		129,900		166,000
b. Fellowships		0		0		0		0		0
Total Student Assistance		21,600		57,700		93,800		129,900		166,000
Total Incremental Direct Costs	\$	50,100	\$	100,200	\$	150,300	\$	200,400	\$	250,500

## Appendix III

### Required 500 Level Courses

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#### **STAT 512     Applied Regression Analysis**

Inference in simple and multiple linear regression, residual analysis, transformations, polynomial regression, model building with real data, nonlinear regression. One-way and two-way analysis of variance. Use of existing statistical computing package. (3 cr.) P: STAT 511.

#### **BIOS 515     Biostatistics Practicum**

Structured consulting experience on real world problems in biostatistics. A detailed written report and an oral presentation are required. (3 cr.) P: STAT 521.

#### **STAT 519     Introduction to Probability**

Algebra of sets, sample spaces, combinatorial problems, conditional probability, independence, random variables, distribution functions, characteristic functions, special discrete and continuous distributions, distributions of function of random variables, limit theorems. (3 cr.) P: MATH 261.

#### **STAT 525     Intermediate Statistical Methodology**

Generalized linear models, likelihood methods for data analysis, diagnostic methods for assessing model assumptions. Methods covered include multiple regression, analysis of variance for completely randomized designs, binary and categorical response models, and hierarchical log-linear models for contingency tables. (3 cr.) C: STAT 528 or equivalent or consent of instructor.

#### **BIOS 527     Design and Analysis of Clinical Trials**

Topics include types of clinical research, study design, treatment allocation, randomization and stratification, quality control, sample size requirements, patient consent, and interpretation of results. Two of the first four classes are devoted to case studies on the design of superiority and noninferiority studies. Students critique recently published medical literature and write a brief protocol for a study of a clinical question of personal interest. (3 cr.) P: STAT 512.

#### **STAT 528     Mathematical Statistics I**

Sufficiency and completeness, the exponential family of distributions, theory of point estimation, Cramer-Rao inequality, Rao-Blackwell Theorem with applications, maximum likelihood estimation, asymptotic distributions of ML estimators, hypothesis testing, Neyman-Pearson Lemma, UMP tests, generalized likelihood ratio test, asymptotic distribution of the GLR test, sequential probability ratio test. (3 cr.) P: STAT 519.

#### **STAT 536     Introduction to Survival Analysis**

Deals with the modern statistical methods for analyzing time-to-event data. Background theory is provided, but the emphasis is on the applications and the interpretations of results. Provides coverage of survivorship functions and censoring patterns; parametric models and likelihood methods, special life-time distributions; nonparametric inference, life-tables, estimation of cumulative hazard functions, the Kaplan-Meier estimator; one and two-sample nonparametric tests for censored data; semiparametric proportional hazards regression (Cox Regression),

parameters' estimation, stratification, model fitting strategies and model interpretations. Heavy use of statistical software such as Splus and SAS. (3 cr.) P: STAT 517.

### **BIOS 546     Applied Longitudinal Data Analysis**

This course covers modern methods for the analysis of repeated measures, correlated outcomes and longitudinal data, including the unbalanced and incomplete data sets characteristic of biomedical research. Topics include an introduction to the analysis of correlated data, repeated measures ANOVA, random effects and growth curve models, and generalized linear models for correlated data, including generalized estimating equations (GEE). Extensive use of computer software throughout the course. (3 cr.) P: STAT 525.

## **Required 600 Level Courses**

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### **STAT 619     Probability Theory**

Measure theory based course in probability. Topics include Lebesgue measure, measurable functions and integration. Radon-Nikodym Theorem, product measures and Fubini's Theorem, measures on infinite product spaces, basic concepts of probability theory, conditional probability and expectation, regular conditional probability, strong law of large numbers, martingale theory, martingale convergence theorems, uniform integrability, optional sampling theorems, Kolmogorov's Three series Theorem, weak convergence of distribution functions, method of characteristic functions, the fundamental weak compactness theorems, convergence to a normal distribution, Lindeberg's Theorem, infinitely divisible distributions and their subclasses. (3 cr.) P: STAT 519, 528.

### **BIOS 621     Statistical Computing**

A study of computing methods commonly used in statistics. Topics include computer arithmetic, matrix algebra, numerical optimization methods with application to maximum likelihood estimation and GEEs, spline smoothing and penalized likelihood, numerical integration, random number generation and simulation methods, Gibbs sampling, bootstrap methods, missing data problems and EM, imputation, data augmentation algorithms, and Fourier transforms. Students should be proficient with effective implementation of numerical algorithms in one of commonly used computer languages (C, Fortran, S, R or similar). (3 cr.) P: STAT 521, 525, 528.

### **STAT 628     Advanced Statistical Inference**

Real analysis for inference, statistics and subfields, conditional expectations and probability distributions, UMP tests with applications to normal distributions and confidence sets, invariance, asymptotic theory of estimation and likelihood based inference, U-statistics, Edgeworth expansions, saddle point method. (3 cr.) P: STAT 519, 528, C: STAT 619.

### **BIOS 636     Survival Analysis**

Discusses the theoretical basis of concepts and methodologies associated with survival data and censoring, nonparametric tests, and competing risk models. Much of the theory is developed using counting processes and martingale methods. Material is drawn from recent literature. (3 cr.) P: BIOS 628.

## Other Courses

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### **STAT 513     Statistical Quality Control**

Control charts and acceptance sampling, standard acceptance plans, continuous sampling plans, sequential analysis, statistics of combinations, and some non-parametric methods. Use of existing statistical computing packages. (3 cr.) P: STAT 511.

### **STAT 514     Design of Experiments**

Fundamentals, completely randomized design, randomized complete blocks. Latin squares, multi-classification, factorial, nested factorial, incomplete blocks, fractional replications, confounding, general mixed factorial, split-plot and optimum design. Use of existing statistical computing packages. (3 cr.) P: STAT 512.

### **STAT 520     Time Series and Applications**

A first course in stationary time series with applications in engineering, economics, and physical sciences. Stationary, auto-covariance function and spectrum; integral representation of a stationary time series and interpretation; linear filtering; transfer function models; estimation of spectrum; multivariate time series; Kalman filtering, Burg's algorithm. (3 cr.) P: STAT 519.

### **STAT 521     Introduction to Statistical Computing**

A broad range of topics involving the use of computers in statistical methods. Collection and organization of data for statistical analysis; transferring data between statistical applications and computing platforms; techniques in exploratory data analysis; comparison of statistical packages. (3 cr.) P: STAT 511.

### **STAT 522     Sampling and Survey Techniques**

Survey designs, simple random, stratified, cluster and systematic sampling; systems of sampling; methods of estimation, ratio and regression estimates, costs; non-response analysis; spatial sampling. (3 cr.) P: STAT 512 or STAT 511.

### **STAT 523     Categorical Data Analysis**

Models generating binary and categorical response data, two-way classification tables, measures of association and agreement, goodness-of-fit tests, testing independence, large sample properties. General linear models, logistic regression, probit and extreme value models. Log-linear models in two and higher dimensions; maximum likelihood estimation, testing Goodness-of-fit, partitioning Chi-square, models for ordinal data. Model-building, selection and diagnostics. Other related topics as time permits. Computer applications using SAS. (3 cr.) P: STAT 528 or equivalent, or consent of instructor.

### **STAT 524     Applied Multivariate Analysis**

Extension of univariate tests in normal populations to the multivariate case, equality of covariance matrices, multivariate analysis of variance, discriminate analysis and misclassification errors, canonical correlation, principal components, factor analysis (3 cr.) P: STAT 528 or equivalent, or consent of instructor.



**STAT 529     Bayesian Statistics and Applied Decision Theory**

Bayesian and decision theoretic formulation of problems; construction of utility functions and quantification of prior information; choice of prior; methods of Bayesian decision and inference;; Bayesian computations; MCMC methods; empirical Bayes; hierarchical models, Bayes factors; combination of evidence; game theory and minimax rules, Bayesian design and sequential analysis. (3 cr.) C: STAT 528 or equivalent.

**STAT 532     Elements of Stochastic Processes**

A basic course in stochastic models including discrete and continuous time processes, Markov chains and Brownian motion. Introduction to topics such as Gaussian processes, queues and renewal processes and Poisson processes. Applications to economics, epidemic models, birth and death processes, point processes, and reliability problems. (3 cr.) P: STAT 519, or equivalent.

**STAT 533     Nonparametric Statistics**

Binomial test for dichotomous data, confidence intervals for proportions, order statistics, one-sample signed Wilcoxon rank test, two-sample Wilcoxon test, two-sample rank tests for dispersion, Kruskal-Wallis test for one-way layout. Runs test and Kendall test for independence, one and two sample Kolmogorov-Smirnov tests, nonparametric regression. (3 cr.) P: STAT 519 or equivalent.

**BIOS 598     Topics in Statistical Methods**

Directed study and reports for students who wish to undertake individual reading and study on approved topics. (1-3 cr.) P: Consent of advisor.

**BIOS 627     Statistics in Pharmaceutical Research**

An overview of the drug development process, including the various phases of development from pre-clinical to post-marketing, will be provided. Statistical issues in design, study monitoring, analysis, and reporting will be discussed in some detail. Other topics that may be covered include regulatory and statistical aspects of population pharmacokinetics and real world applications. (3 cr.) P: STAT 512, BIOS 527, 546

**BIOS 632     Stochastic Modeling in Biomedical and Health Sciences**

The aim of this course is to develop those aspects of stochastic processes that are relevant for modeling important problems in health sciences. Among the topics to be covered are: Poisson processes, birth and death processes, Markov chains and processes, semi-Markov processes, modeling by stochastic diffusions. Applications will be made to models of prevalence and incidence of disease, therapeutic clinical trials, clinical trials for prevention of disease, length biased sampling, models for early detection of disease, cell kinetics and family history problems. (3 cr.) P: STAT 528, STAT 532.

**BIOS 646     Advanced Longitudinal Data Analysis**

Presents classical and modern approaches to the analysis of multivariate observations, repeated measures, and longitudinal data. Topics include the multivariate normal distribution, Hotelling's  $T^2$ , MANOVA, the multivariate linear model, random effects and growth curve models, generalized estimating equations, statistical analysis of multivariate categorical outcomes, and

estimation with missing data. Discusses computational issues for both traditional and new methodologies. (3 cr.) P: BIOS 546.

**BIOS 695 Seminar in Biostatistics**

Selected presentations and discussion on current research problems and investigation in biostatistics and related areas. (1-3 cr.) P: Consent of advisor.

**BIOS 699 Research Ph.D. Thesis** (1-18 cr.).

## Appendix IV

### Letters of Support

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Letters in support of the proposed Ph.D. program in Biostatistics at IUPUI have been received from various deans and directors from across campus, as well as from other individuals reflecting strong local and regional interest. Included here are copied of letters from:

- D. Craig Brater  
IU Vice President for Life Sciences  
Dean, IU School of Medicine
- William Bosron, Interim Dean  
Purdue School of Science, IUPUI, and  
IU School of Medicine
- David L. Stocum,  
Purdue School of Science, IUPUI
- Carl C Cowen,  
Purdue School of Science, IUPUI
- Victoria Champion, Associate Dean for Research  
Director of Cancer Control  
IU School of Nursing
- Keith Dunker, Director  
Center for Computational Biology and Bioinformatics  
IU School of Medicine
- Mary Ellen Bock, Head  
Department of Statistics  
Purdue University West Lafayette

- Thomas S. Inui, President and CEO  
Regenstrief Institute
- August M. Watanabe, Chairman of the Board of Directors,  
BioCrossroads
- Timothy Beck, Director, Research & Development  
Roche Diagnostics Operations, Inc.
- Todd Sanger, Director, Global Statistical Sciences  
Eli Lilly and Company
- Karen L. Price, President  
Central Indiana Chapter of the American Statistical Association



April 16, 2007

SCHOOL OF MEDICINE

Barry P. Katz, PhD  
Director, Division of Biostatistics  
IU School of Medicine  
IUPUI

Benzion Boukai, PhD  
Chairman, Department of Mathematical Sciences  
School of Science  
IUPUI

Dear Barry and Ben:

I am pleased to support your proposal for a collaborative doctoral program in Biostatistics. I support the creation of this degree program at this time for several reasons. The School of Medicine strategic plan states very clearly that our collective faculty want to take the School to a different level and, in particular, to increase our research activity so that we were in the top ten of public medical schools. Doing so requires at least a doubling of our research funding. When I became Dean of the School of Medicine in 2000, it became my job to facilitate our attaining this lofty goal. Biostatistics is elemental to health science research, and a strong biostatistics group is essential if the School and the IUPUI campus are to successfully compete for funding from NIH and other funding agencies. In addition, there is substantial need for well-trained biostatisticians in Indiana, particularly among the pharmaceutical, medical diagnostics, and medical device industries. This need will continue to increase as the initiatives being undertaken by BioCrossroads begin to reshape our economy.

As I survey the current research efforts of the School of Medicine, I note a distinct change in recent years as more and more studies include microarrays, proteomics, bioinformatics or medical informatics. All of these methods involve huge amounts of data that can yield great insights but, without appropriate biostatistical expertise to analyze the data, can also lead to incorrect and even dangerous conclusions. In Clinical Pharmacology, my own discipline, pharmacogenomics has become a key component of our research efforts. In addition, even the pharmacokinetic and pharmacodynamic models that we use are becoming more complex, requiring new biostatistical methods and expertise. Thus, it is critical that our Biostatistics Division remain at the forefront of these areas, and I hope that this new PhD program will help attract both new faculty members and top notch students who can further the collaborative efforts on this campus.

OFFICE OF THE DEAN

Fesler Hall 302  
1120 South Drive  
Indianapolis, Indiana  
46202-5114

317-274-8157

Drs. Katz and Boukai  
April 16, 2007  
Page 2

The newly opened HITS building affords the opportunity to cluster Biostatistics and Mathematics in the same facility, and that this is an example of the level of collaboration that enhances the potential for a PhD program—it creates a unique multidisciplinary environment, particularly when one also realizes that Bioinformatics is also in the HITS building. The setting is perfect for a PhD program in Biostatistics.

In summary, I strongly support the creation of a doctoral degree program in Biostatistics. I believe that it will be a valuable asset to the school, the campus, Indiana University, and the entire state of Indiana, particularly since there are no other such programs in the state. Thank you and your colleagues for taking the initiative to create this program.

Sincerely,

A handwritten signature in black ink, appearing to be 'D. Brater', written in a cursive style.

D. Craig Brater, M.D.  
Vice President, Indiana University  
Dean and Walter J. Daly Professor,  
Indiana University School of Medicine

DCB/lab

October 29, 2006

Benzion Boukai, Ph.D.  
Chair, Department of Mathematical Sciences  
IUPUI, School of Science  
LD Building, Room 270

Barry Katz, Ph.D.  
Director of Division of Biostatistics  
IUPUI  
RG 4101

SCHOOL OF SCIENCE

IUPUI

Dear Ben and Barry,

I read your proposal for an Indiana University Ph.D. program in Biostatistics and the accompanying letters of support. Deans David Stocum and Carl Cowen of the School of Science indicated a strong endorsement of the proposal and committed the School of Science to the implementation and further development of the program. As Interim Dean of the School of Science, I also lend my strongest support and commitment to the proposal.

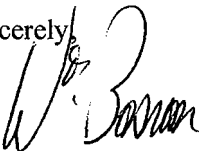
As you know, I have been a faculty member in the School of Medicine for 31 years. From my own research in enzyme kinetics and structural biology, I know the value of statistics in basic science research. In fact, one of my best Biochemistry Ph.D. students did her minor in statistics/mathematics at IUPUI. I have used the collaborative resources of the Division of Biostatistics to prepare grants to the NIH. A recent power analysis done with staff in Biostatistics was very important to the experimental design of a zebrafish model study that was just funded by the National Institute of Alcohol Abuse and Alcoholism. I am very supportive of this collaboration between Mathematical Sciences in the School of Science and the Division of Biostatistics in the Department of Medicine of the School of Medicine.

I believe that the Ph.D. proposal is uniquely possible at IUPUI because of the joint strengths of Mathematics and Biostatistics. I believe that the presence of graduate students in the program will significantly strengthen and keep us at the forefront of life sciences research at IUPUI. I believe that the graduates from this new Ph.D. program will contribute significantly to the growth of life science-related research and businesses in Indiana. I strongly support the proposal for an I.U. Ph.D. in Biostatistics and will do whatever I can to implement the program.

OFFICE OF THE DEAN

Science Building  
LD 222  
402 North Blackford Street  
Indianapolis, Indiana  
46202-3276

317-274-0625  
Fax: 317-274-0628  
science@iupui.edu  
www.science.iupui.edu

Sincerely,  


William F. Bosron, Ph.D.  
Interim Dean, School of Science  
Chancellor's Professor  
Professor of Biochemistry and Molecular Biology, School of Medicine

July 8, 2004

Ben Boukai, Chairman  
Department of Mathematical Sciences  
School of Science  
IUPUI

SCHOOL OF SCIENCE

Barry P. Katz, Director  
Division of Biostatistics  
School of Medicine  
IUPUI



Dear Ben and Barry:

I have read over your proposal to establish a doctoral degree program in Biostatistics at IUPUI. I am very strongly in favor of establishing this program for one reason: the life sciences initiatives on this campus and elsewhere in the state and nation will become increasingly dependent on the pure research in the area of biostatistics and the applications of this research to a multitude of biological and health care areas.

In turn, the services of the graduates of this program will be in great demand in a wide variety of life sciences industries, universities, and government agencies. There is no question that mathematics, particularly statistics, will play an increasingly important role in research on neural networks, genomics, proteomics and systems biology. I myself am part of a Center for Regenerative Biology and Medicine that has generated genomic data that we cannot handle without the aid of a bioinformatic and biostatistical approach.

In summary, I give my highest level of endorsement for this program. It should be implemented immediately so that IUPUI may be a cutting edge leader in the field.

OFFICE OF THE DEAN

Science Building  
LD 322  
North Blackford Street  
Indianapolis, Indiana  
46202-3276

317 274-0625  
fax 317 274-0628

science@iupui.edu  
www.science.iupui.edu

Sincerely,

David L. Stocum  
Dean

November 29, 2004

Ben Boukai, Chair  
Department of Mathematical Sciences  
School of Science  
IUPUI

Barry P. Katz, Director  
Division of Biostatistics  
School of Medicine  
IUPUI

SCHOOL OF SCIENCE



Dear Ben and Barry:

In thinking about IUPUI's role in support of the State of Indiana's economic development and its role in providing outstanding education and ground-breaking research for our region and our nation, I was very pleased to learn about your proposal to establish a doctoral program in Biostatistics at IUPUI. This proposal does a good job of describing the program benefits and its development is an outstanding example of cooperation between the School of Medicine and the School of Science to provide programs that are vital for Indiana.

As you well know, the next few decades will see revolutionary growth in our understanding of fundamental biological mechanisms and these will lead to amazing developments of medical and pharmaceutical protocols and biomedical devices. The mathematical sciences, especially statistics, will be at the center of this revolution, providing the foundation for the discoveries and their rapid exploitation. Bioinformatics generally and genomics and proteomics specifically, systems biology, neuroscience, and drug and treatment protocol creation, development, and certification are just a few of the areas depending on new research in statistics and biostatistics. As this list indicates, the research of the faculty and students associated with the proposed program will be important for the work of other researchers at IUPUI, in the Indianapolis region, and around the world.

In addition, as you know from experience and as recruiters from the local biotech industry and area colleges and universities can testify, PhD statisticians, especially biostatisticians, are in high demand. This program will be of great benefit in providing new graduates for employment in our area to meet the needs of local industry.

I very strongly endorse this proposal. We in the School of Science will do all we can to assist in the implementation and further development of the PhD program in Biostatistics so that it can be a model for creativity and productivity in the field.

Sincerely,

Carl C. Cowen  
Dean

OFFICE OF THE DEAN

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# INDIANA UNIVERSITY



May 27, 2005

## SCHOOL OF NURSING

Barry Katz, PhD  
Director  
Department of Medicine - Division of Biostatistics  
1050 Wishard Blvd., Suite 4101  
Indianapolis, IN 46202

Dear Dr. Katz,

I received the proposal for a PhD in biostatistics. I am very pleased that we are poised to take this step. We have needed a PhD program for many years and this proposal is excellent. All researchers at the School of Nursing are very pleased with our collaborative efforts with biostatistics and support this wonderful opportunity for our University. Please let me know how I can help support this effort. It is very important.

Sincerely,

A handwritten signature in cursive script that reads "Victoria Champion".

Victoria Champion, DNS, RN, FAAN  
Associate Dean for Research  
Mary Margaret Walther/Distinguished Professor of Nursing  
Director of Cancer Control

## CENTER FOR NURSING RESEARCH

1111 Middle Drive  
Indianapolis, Indiana  
46202-5107

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Fax: 317-278-2021

VC:dg

*Located on the campus of  
Indiana University  
Purdue University  
Indianapolis*

INDIANA UNIVERSITY



September 11, 2005

Barry P. Katz, PhD, Director  
Division of Biostatistics  
IU School of Medicine  
IUPUI

Benzion Boukai, PhD, Chairman  
Department of Mathematical Sciences  
School of Science  
IUPUI

SCHOOL OF MEDICINE

Dear Drs. Katz and Boukai,

After a long delay, I finally found to time to go over your proposal for a doctoral program in Biostatistics. I wholeheartedly support your efforts to develop of this program. My views are based self-interest, which is described below.

The Center for Computational Biology and Bioinformatics (CCBB) is seeking several new faculty and we are looking forward to our move to the Medical Information Sciences Building in December 2006. The CCBB has already hired one faculty member whose departmental home is the Division of Biostatistics, and we anticipate that others will follow. Our efforts in the CCBB are directed towards attracting faculty who will collaborate with biologists across campus and who will also lead independent research efforts in their specialties. Having a PhD Program in Biostatistics will be essential for both recruiting the most desirable candidates and for keeping them here after they arrive. From my perspective, a PhD program in biostatistics is not merely desirable, but rather such a program is essential for the future growth and development of the CCBB.

From the intellectual point of view, biostatistics forms one of the cornerstones for both bioinformatics and computational biology. Thus having a strong group of faculty experts in biostatistics and having the necessary associated graduate training program will be important for all of the members of the CCBB, even for those who are not members of the Division of Biostatistics.

As for the Biostatistics PhD program itself, I found it to be well justified in your written document and I also found the course-requirements, organization, etc. to be well designed

That is an essential program. Thank you for your efforts to bring it about.

Sincerely,

A. Keith Dunker  
Director, Center for Computational Biology and Bioinformatics  
Professor, Biochemistry and Molecular Biology  
T-K Lee INGEN Endowed Chair

DEPARTMENT OF BIOCHEMISTRY  
AND MOLECULAR BIOLOGY

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BRTC  
Biotechnology Research  
and Training Center

Biotech Training Program

Biochemistry Biotechnology  
Facility

Proteomics Core

Protein Expression Core

Center for Medical Genomics

1345 West 16th Street  
Room 302  
Indianapolis, Indiana  
46202-2111

317-714-6587  
Fax: 317-278-9739

Professor Barry Katz  
Division of Biostatistics  
410 West Tenth Street  
Indiana University School of Medicine  
Indianapolis, IN 46202

Dear Professor Katz:

I wish to strongly endorse the establishment of a doctoral program in biostatistics at the IUPUI campus as a joint program with the Department of Mathematical Sciences and your division. The close connection of the group to the medical school gives it great advantages for both them and you. It has the ability to greatly enhance the health and life sciences ventures on the campus and in the state. There is a genuine need for such a program and it will be a great advantage to the state. You have my sincere support.

Sincerely,



Mary Ellen Bock  
Professor and Head  
Department of Statistics  
Purdue University  
West Lafayette, IN 47907-2066

Cc: Ben Boukai



# Regenstrief Institute

February 21, 2005

Benzion Boukai, Chair  
Department of Mathematical Science  
IUPUI  
402 Blackford Street  
Indianapolis, IN 46202

Barry P. Katz, Director  
Division of Biostatistics  
IU School of Medicine  
Regenstrief Institute Health Center  
1050 Wishard Blvd., RG 4101  
Indianapolis, IN 46202

Dear Professors Boukai and Katz:

Thank you for circulating the "Concept Paper for a Doctoral Degree in Biostatistics at IUPUI". I enthusiastically support the development of a doctoral-level program in biostatistics on our campus. In my two and one-half years at IU School of Medicine and as President and CEO of Regenstrief Institute, it has become clear to me that the availability of doctoral-level expertise in statistics at IUPUI has sometimes been a rate-limiting resource in the preparation of proposals for interdisciplinary team-based research in health care services for extramural review *and* in the conduct of research itself, once funding has been made available. I believe that a doctoral program in biostatistics will galvanize the development of a significantly larger critical resource of research biostatisticians on the IUPUI campus - through recruitment (of additional faculty and of program graduates) and retention of graduate faculty who value education as well as research. From my perspective, a campus investment in the development of this program would be a high priority strategic action for the good of all programs of research in the life sciences.

Yours sincerely,

Thomas S. Inui, ScM, MD  
President and CEO, Regenstrief Institute  
Sam Regenstrief Professor of Health Services Research  
Associate Dean for Health Care Research, and  
Professor of Medicine Indiana University School of Medicine



May 31, 2005

Craig Brater  
Dean, M.D.  
Indiana University School of Medicine  
Office of Gift Development  
1110 W. Michigan Street LO506  
Indianapolis, IN 46202

Dear Dean Brater:

I have reviewed the proposal to offer a PhD degree in Biostatistics at IUPUI. The biostatistics program in the School of Medicine has matured to the point where this is logical. Several factors make the case for a new PhD program compelling:

1. The Biostatistics Division has grown sufficiently that there is a critical mass of faculty with diverse enough areas of expertise to support such PhD students;
2. The Biostatics program has developed collaborative relationships with other necessary departments;
3. There is interest among students; and
4. There is need in the community commensurate with the growth of the life sciences cluster in Indiana.

Graduates from this program will be in great demand and their presence will directly benefit both academic and private sector-based life sciences efforts.

I personally, and as a spokesperson for BioCrossroads, support creation of this new degree program with high enthusiasm.

Sincerely,

August M. Watanabe, M.D.  
Chairman of the Board of Directors, BioCrossroads



Diagnostics

Indianapolis, 23 April 2007

**Benzion Boukai, PhD**  
Chairman, Department of Mathematical Sciences  
School of Science  
Department of Mathematical Sciences  
IUPUI  
402 N. Blackford Street  
Indianapolis, IN 46202

Dear Dr. Boukai:

I am pleased to hear of the proposal for a doctoral program in Biostatistics in the Indianapolis area. As you know, Roche Diagnostics was a strong proponent for the original Masters in Statistics program that began its offerings through IUPUI in 1990. There are currently several graduates of this program working at Roche Diagnostics, either as employees or as independent contractors.

Clearly, there are several needs for competent graduate level mathematicians and statisticians in our industry. The discipline of Biostatistics allows industries such as ours to recruit people who are multi-disciplined based on the area of their focus. Our specific Business Unit, Diabetes Care, relies on scientists and engineers to create products that can be used at home by people who are managing either their own health, or the health needs of others (children, aging parents, etc.) These products must also support the needs of various health care professionals who diagnose, prescribe, and direct treatment, and who benefit by integration of systems to provide care to the people they serve.

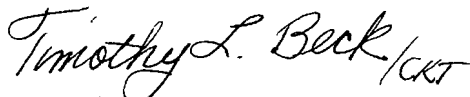
The advanced mathematical and statistical techniques required to produce such products require competent, trained, and committed people who are capable of finding efficient methods to drive

the requisite studies without compromising safety or quality. Challenges in this space include experimental design and sample size calculations that yield sufficient power to provide confidence in the results. The opportunities range from the early design phase, through feasibility studies and proof of performance and clinical claims, to the pre-market introduction studies, which represent final customer and regulatory approval. Additional opportunities exist with respect to scale up, manufacturing, and quality roles including aspects of studying feedback from the field after the introduction into the market.

The combined emphasis on a minor in a scientific discipline and a major in statistics equips the graduate of Biostatistics programs with specific domain knowledge that allows immediate integration of the graduate into the workforce, allowing them to more quickly contribute to the needs of our business.

Thank you for the opportunity to speak on behalf of this program. The central location of such a program would prove beneficial to Indiana and the various industries in the surrounding region. I anticipate and look forward to future opportunities provided by this program, both personally and for Roche Diagnostics.

Yours sincerely,



Timothy L. Beck  
Director, Research & Development  
Dept. of Mathematics and Product IT  
Roche Diagnostics Operations, Inc.

Benzion Boukai, Ph.D.  
Professor and Chair  
Department of Mathematical Sciences, IUPUI  
402 N. Blackford Street  
Indianapolis, IN 46202

Dear Professor Boukai:

I was excited to learn that the Ph.D. program in Biostatistics at IUPUI is proceeding further. As Director of Global Statistical Sciences at Eli Lilly and Company, I am well aware of the need for Ph.D. biostatisticians in central Indiana. Given the importance of data collection and analysis in the pharmaceutical industry, biostatisticians are central to the success of Eli Lilly and Company. We are continuously recruiting Ph.D. biostatisticians, but have had to go out of state to find them. We also have a number of master's level biostatisticians who would greatly benefit from an opportunity to obtain a Ph.D. while working at Lilly.

As a member of the committee which recently reviewed your Department of Mathematical Sciences, I am well aware of the high caliber of your staff as well as Barry Katz's staff in the Division of Biostatistics. I am very confident that this faculty will provide a high quality education to the Ph.D. students.

Please let me know if there is anything I can do to help support the final approval of this Ph.D. program.

Sincerely,

Todd Sanger, Ph.D.  
Director, Global Statistical Sciences  
Eli Lilly and Company



Phone 317 276 2000

March 22, 2005

Barry P. Katz, PhD  
Director, Division of Biostatistics  
IU School of Medicine  
IUPUI

Benzion Boukai, PhD  
Chairman, Department of Mathematical Sciences  
School of Science  
IUPUI

Dear Barry and Ben:

Thank you for the opportunity to review your proposal for a PhD program in Biostatistics at IUPUI. I fully support this program and I look forward with great anticipation to the installation of this program into the IUPUI curriculum. The doctoral program in Biostatistics will be essential to Indiana as the state embarks upon a health and life sciences initiative. The movement toward life sciences cannot happen without highly trained statisticians.

As a statistician at Eli Lilly & Company, I have seen first-hand the importance of statisticians in the drug development process. Many of the Master's level statisticians that I work with are unable to pursue a PhD in Biostatistics as no other programs are available in the state. Many are forced to choose between staying in Indiana and pursuing a higher-level degree in biostatistics in another state. A number of statisticians that I work with would benefit greatly from the opportunity to further their education by pursuing a PhD here in central Indiana.

The program you propose will provide the student with a well-rounded statistical education, focusing applied statistical methodologies, but also providing theoretical foundations. Without doubt, the program will equip graduates with the skills needed to impact the life sciences and will give Indiana a real advantage with regard to its statistical expertise. With so many companies in the area, many statisticians will be able to stay in Indiana and increase their level of statistical education.

With kindest regards,

A handwritten signature in black ink, reading "Karen Price". The signature is written in a cursive style with a large, stylized "K" and "P".

Karen L. Price, PhD  
President, Central Indiana ASA Chapter