Department of Biostatistics and Bioinformatics

Proposal for Graduate Program in Biostatistics

November 2013

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Mission: To educate tomorrow's leaders in the development and application of statistical methods of biomedical research for the continual improvement of human health.

Executive Summary

The Department of Biostatistics and Bioinformatics is proposing a new PhD program to respond to the current shortage of biostatisticians needed for medical research in academia, government, and industry. To be successful, these researchers need a diverse skill set. First, they need a *firm grasp of biostatistical theory and techniques*, including a deep knowledge of probability and statistical inference, in order to develop innovative and methodologically sound solutions to complex problems arising in biomedical research. Second, a core characteristic of biostatistical research is that it is *responsive to inferential problems in medical research*. Thus, an effective biostatistician will have a good grasp of basic biomedical systems and will have the background to understand and translate biomedical problems into a quantitative framework that is amenable to statistical inference. Finally, the need for *effective communication* is pervasive across all biostatistical research, from problem formulation, to articulating a solution, disseminating results, and educating the next generation of biostatistical researchers. Our core curriculum ensures that each student will develop these fundamental competencies.

The following points highlight the features of our program. We begin with the curriculum and for clarity we divide the points into (1) features of the curriculum that are often found in top biostatistics programs, and (2) novel features of the curriculum that extend the training of our students beyond that found in a traditional biostatistics program. We then list other important program features.

Curriculum:

(1) Features of curriculum that are consistent with training found in traditional biostatistics programs:

- Program is comprised of a structured two-year core curriculum, followed by elective courses and a dissertation.
- The core contains a first year, master's level sequence in probability and statistical inference, followed by a second year sequence in measure theoretic probability and advance statistical inference, currently being offered in the Department of Statistical Science (DSS). Please see Appendix A containing a letter of support from Alan Gelfand, Chair of DSS, assuring enrollment in these courses for our students.

- Similar to other PhD programs in Biostatistics, the core contains specialized training in categorical data analysis, survival analysis, generalized linear models, analysis of correlated and longitudinal data, and theory of linear models.
- Throughout the core curriculum, principles of epidemiologic studies are covered in detail.
- The core contains a course emphasizing the ethical issues in the conduct of statistical and medical research.
- Coursework is required in a 'cognate' field, a substantive field outside of biostatistics or statistics. Examples include: epidemiology; biology; biophysics; environmental health; genetics; etc. The cognate field should be complementary to the student's biostatistical area of interest. Appendix A provides letters of support from several supporting programs.

(2) Novel features of the curriculum that extend the training of our students beyond that found in a traditional biostatistics program:

- The core contains a unique first year 'problems in biostatistics' survey seminar. The seminar will involve a gradual progression from required attendance in the first year to active collaborative involvement in the second year, to collaborative presentations in the third year, to independent presentations in fourth and fifth years.
- The core contains a novel course sequence emphasizing biomedical concepts and communication.
- Core contains a novel statistical methods for learning and discovery course which introduces bioinformatic techniques.
- Core contains a novel survey course of modern inferential techniques and theory (to be developed) targeted specifically to advanced graduate students.
- Embedded throughout the curriculum are examples of conflict of interest situations faced by biostatisticians, along with principles of reproducible research and strategies for implementation.

Other academic features of the proposed program:

- Research-oriented experiences, whereby students become affiliated with a faculty member for a period of two to four months to learn about research opportunities and also the practical aspects of a career in biostatistics, are required following the first year of coursework.

- Students will be assigned an initial advisor who will guide the student through selection of faculty affiliations and will mentor the student regarding other issues related to the program.
- Students will engage in the rich academic atmosphere of the department and will be required to attend departmental seminars and to actively participate in departmental journal clubs (clinical trials, statistical genetics, bioinformatics, causal inference).
- Students must pass a comprehensive exam covering the material in the first year core sequence. In order for advanced students to test out of specific first year courses, they must pass the material covered in our first year of theory on the comprehensive exam.
- Students must pass a PhD qualifying exam covering all of the material in the core sequence (typically at the end of their second year).
- In year 3 students take additional electives and select a dissertation advisor, topic, and committee. The committee will consist of the dissertation advisor, at least two faculty members from B&B or DSS, a faculty member from the interdisciplinary cognate program, and, when appropriate, a member of the biomedical area from which the dissertation was derived. Thesis committees will consist of at least four members of the Graduate Faculty in accordance with Graduate School policy.
- Students must typically pass their preliminary exam (dissertation proposal defense) by the end of the third year.
- Dissertation research/writing typically occurs in years 3-5, followed by defense.

Finances

We anticipate enrolling 20-21 masters students and 4 PhD students each year. A brief, **very conservative,** synopsis of the budgeted financial situation at steady state, when fully five cohorts of PhD students have been enrolled, is as follows:

- Tuition revenue from 42 students: approximately $1.5 Million
- Expenses – approximately $1.5 Million
    - Faculty Teaching (including advising): $443,000
    - PhD tuition, fees and stipends: $432,000
    - Director of Graduate Studies: $58,000
    - Masters Scholarships: $150,000
    - Administration: $71,000
    - Other operating: $159,000 (including retreat and G&A)
    - Space: $103,000

This budget anticipates funding four to five PhD students in their second year, with a budgeted contingency of $200,000 per year for backstopping students in year 3 and above, while maintaining a program reserve of $1.1 Million.

I. Rationale for the new program

I.1. Introduction

The Department of Biostatistics and Bioinformatics is proposing a PhD program in Biostatistics. The program will train students to (a) develop innovative new statistical methodology to meet the increasingly complex needs of current medical research; (b) apply existing statistical methodology to biomedical research in a thoughtful and creative manner; and (c) be effective collaborators in today's multidisciplinary biomedical research environment.

The new PhD program responds to the current shortage of biostatisticians who are prepared to meet the demand for multidisciplinary collaboration in academia, government, and industry. Further, the "big data" explosion in genomics and medical informatics (electronic health records, EHR) will increase demand, particularly for biostatisticians who can pioneer new methods research. In addition, Congress recently established the Patient-Centered Outcomes Research Institute for the purposes of extending our understanding and quantifying the sources of variability in patient-reported outcomes, which will add yet another dimension to the EHR. In examining the potential value of "big data" to the world economy, economic analysts contend that a shortage of talent with statistical expertise and machine learning will significantly constrain the ability of government, business and industry to realize its value: (http://www.mckinsey.com/insights/mgi/research/technology_and_innovation/big_data_the_next_frontier_for_innovation).

Additionally, the National Institute of General Medical Sciences, which supports most NIH-funded PhD training, has recently instituted a requirement that students have quantitative training. The most broadly applicable training is in biostatistics, which crosses all disciplinary lines. Through our progressive seminar and our core course in communication, our proposed program will train students who then can teach other biomedical trainees.

Demand is strongest for doctoral-level biostatisticians with a relatively unusual constellation of skills. The first of these includes deep analytical competency, which at the doctoral level includes not just the ability to apply existing methodology but also the ability to develop new methods. The second element of this constellation includes fundamental biomedical knowledge, which is necessary for appropriately translating a research question into a statistical one. The third element is communication, problem-framing and problem-solving.

These skills allow the biostatistician to frame a statistical solution in a fashion that is biomedically sound and mathematically tractable.

Our program will be unique in addressing all three areas described above. Moreover, it builds upon an innovative Masters' program that provides much of the proof of concept for the PhD program. Our vision is that Duke will become recognized as a national leader in training outstanding biomedical statisticians – individuals who combine methodological sophistication with firm grounding in the biomedical disease process, who also have honed leadership and communication skills in order to maximize the impact of their efforts -- toward the ultimate goal of improving public health.

I.1.1. Description of the Department of Biostatistics and Bioinformatics

The Department of Biostatistics and Bioinformatics (B&B) was established in 2000, with the expectation of becoming a national leader in these scientific disciplines. A founding document for the department states: "*As the practice of medicine becomes increasingly evidence-based and the wealth of information within medical and genomic databases grows dramatically, the core disciplines of biostatistics and bioinformatics are becoming increasingly important in medical research and training. Scientists ranging from molecular biologists studying complex diseases such as cancer, diabetes, and dementia to clinicians comparing the effectiveness of treatment regimens must build their research protocols on the concepts and methods of these quantitative disciplines. Duke University Medical Center (DUMC) recognized the importance of an academic home to support these disciplines by creating a Department of Biostatistics and Bioinformatics (B&B) and by making a commitment to become a national leader in areas in which it already had numerous strengths but previously lacked adequate infrastructure*."

B&B currently has approximately 50 full-time PhD-trained faculty members, a significant number of whom teach in the two masters-level programs administered by B&B: the Clinical Research Training Program (CRTP), which awards the Master of Health Sciences in Clinical Research, and the Master of Biostatistics program. The current proposal represents a departmental and School of Medicine priority and builds on our successful experience in developing and administering these programs.

I.2. Description of the Field

I.2.1. Working definition of biostatistics

Biostatistics is the application of statistical principles to biomedical questions. In general, biostatistics uses much the same core sets of probability and inference concepts as does applied

statistics. These concepts include distributions and variation, statistical modeling approaches for analyzing data in the presence of variation, and understanding and testing underlying assumptions. The subject-matter knowledge that the biostatistician must learn in order to be successful is biomedical.

Biostatistics underlies modern medical research in each step of scientific inquiry from the research bench to the hospital bedside to the community. Biostatistics is concerned with the development and proper application of methods for study design, data measurement, data generation, and data analysis. Biostatistical methods are used to help understand data by quantifying variation and by separating signal from noise. The fundamental elements of data and variation are ubiquitous in medical research, being found in such areas as cell regulation, gene expression, genetic susceptibility, pharmacokinetics, response to therapy, assessment of medical treatments and new technology, adherence to guidelines, and program evaluation.

I.2.2. Role of biostatistics

Biostatisticians design studies, oversee their implementation, analyze study data and interpret the results. Importantly, they develop new methodologies in these areas. With grant funding becoming more competitive and grant study sections demanding more statistical rigor, those biostatisticians who perform high-profile methodological research lend name recognition to grant applications on which they are co-investigators. Demand is particularly high for biostatisticians who can become facile with the underlying biomedical content, develop innovative solutions that reflect the unique nature of specific problems, and communicate the results to a variety of audiences, including students. Biostatisticians are needed in academia, industry and government.

I.2.3. Applications of biostatistics

As an illustration of the wide application of biostatistics, some examples are provided. First, in the area of clinical trials, ethical imperatives require extracting as much information from as few patients as possible, placing no more patients than necessary into the group with the least effective intervention, and drawing conclusions as rapidly as possible so that they can then be applied to other patients with the same conditions. These ethical imperatives have led to the development of adaptive designs, and the improvement of such designs is a topical area of inquiry. The statistical issues in question become increasingly complex when genomic information is added.

A second example comes from observational registries of patients who have been diagnosed with certain diseases. Such registries -- now feasible with increases in computing power and

the ability to link datasets – can potentially be used to identify rare adverse events associated with certain therapies and to screen for unexpected drug interactions. The risk of false positive conclusions increases with the number of queries that are performed. Drawing appropriate conclusions in the presence of potential false positive results is an area of ongoing statistical inquiry and is an area where insights from genomic statistics are applicable. With the proliferation of electronic health records, such investigations will expand and provide the infrastructure for the design and analysis of more extensive uses of health data. By developing statistical methodology for mining such databases, insights can be generated to support personalized medicine.

Another use of registries and electronic health records is in comparative effectiveness research, which attempts to determine which interventions are most effective in actual practice. Randomization is absent, and conclusions must take into account the fact that groups can differ not only in characteristics that can be measured, but also in characteristics that are unmeasured. This research requires sophisticated understanding of the developing field of causal inference.

Other types of big data that require new or improved statistical approaches include genetic and genomic data as well as imaging data. The availability of millions of data points on relatively small numbers of patients represents a challenge to classical statistical inference.

These examples illustrate that the demand for biostatisticians is likely to grow; that advancing the field requires fundamental understanding of the biomedical problem being studied and that collaboration and communication skills will be essential.

I.2.4. Benefits to Duke of a PhD program in biostatistics

First, a PhD program would benefit efforts in recruiting and retaining top-level talent to join our biostatistics faculty, by providing the opportunity to teach high-level courses, to mentor and publish with excellent graduate students, and to collaborate with an increasing pool of biostatisticians on methods development. Moreover, the program would remove a disincentive that currently exists when we compete for academic biostatisticians with other institutions that have doctoral programs.

A PhD program would also strengthen the existing Masters in Biostatistics program by enhancing the academic atmosphere. Upper level students are a valuable resource for answering questions and providing advice. They also serve as role models and motivation. A by-product of this enhanced learning environment will be a more valuable masters degree and hence increased name recognition for both B&B and Duke in general.

The demand for PhD-level biostatisticians is particularly acute in industry, especially the pharmaceutical industry, and our program would provide highly trained biostatisticians in positions where critical shortages exist. Our current Masters in Biostatistics program includes on its Professional Advisory Council several biostatisticians from pharmaceutical companies and clinical research organizations. Their guidance has helped us tailor our program to their needs. Further, we are currently working with several pharmaceutical companies who are considering providing scholarships in their names, but without obligations.

An additional benefit to Duke relates to the synergy of this program with the Computational Biology and Bioinformatics (CBB) program and the PhD program in the Department of Statistical Science (DSS). Students enrolled in CBB or DSS will benefit from having access to Biostatistics courses that are potentially relevant to their fields of study.

I.3. Resources at Duke for an innovative program in biostatistics

The Biostatistics and Bioinformatics Department at Duke has created two successful masters programs that not only serve as proof of concept, but also provide the infrastructure for a more advanced degree. We have demonstrated that B&B has a number of faculty members who are willing and capable to teach classes, support and mentor students, and otherwise contribute to the program. Most importantly, Duke has a world-class medical research enterprise, involving close collaboration between biostatisticians and other researchers, and thus providing a wide variety of projects and experiences that can serve as the program's "laboratory".

1.3.1. Master of Health Sciences in Clinical Research

Teaching programs in the Department originated with the Clinical Research Training Program (CRTP), which awards a Master of Health Sciences in Clinical Research degree through the School of Medicine. Its target audience is clinical house staff, faculty, and medical students. One of the first programs of its kind in the country, CRTP has served as a model for similar programs at other institutions and now includes a distance learning component; Clinical fellows and other health professionals at the National Institutes of Health (NIH) in Bethesda, Maryland and the Brazilian Clinical Research Institute (BCRI) in Sao Paulo, Brazil participate in the degree program, taking courses remotely in real time via interactive videoconferencing. Since the program's inception in 1986 as the Biometry Training Program, over 1,150 individual trainees have enrolled in program courses. As of November of 2012, degrees have been awarded to 351 trainees.

Of particular relevance to this document is the number of B&B faculty members that teach in CRTP, 15 during the last two academic years alone. In addition, 26 members of the faculty have served on Examining Committees for degree candidates. The Master of Biostatistics program and our proposed PhD program obtain significant synergies by leveraging this educational infrastructure and experience.

I.3.2. Masters in Biostatistics

Our Masters in Biostatistics program, approved as a professional degree through the Duke School of Medicine, accepted its first class of students in the Fall of 2011. Requirements for admission include good performance in multi-variable calculus, with additional training in areas such as linear algebra and real analysis preferred. Apart from quality of mathematical training, the Admissions Committee also takes into account the school at which training was obtained, a personal statement, and three letters of recommendation. Comparing our 2011-2012 and 2012-2013 students with other masters programs at Duke demonstrates that our new program compares well with these other programs; we are also tightening our requirements.

GRE/UGPA of New Matriculants

	Biostatistics	Biomedical Engineering	Economics	Global Health	Medical Physics
2011-2012					
GRE Verbal	528 [64%]	596 [82%]	569 [77%]	553 [70%]	490 [53%]
GRE Quantitative	764 [82%]	772 [84%]	776 [86%]	692 [60%]	740 [74%]
UGPA	3.4	3.7	3.6	3.5	3.6
2012-2013					
GRE Verbal	593[1]/152[2] 155.5 [65%]	159 [80%]	160 [83%]	158 [77%]	153 [57%]
GRE Quantitative	776[1]/161[2] 161.5 [83%]	162 [85%]	164 [90%]	157 [71%]	162 [85%]
UGPA	3.6	3.6	3.6	3.5	3.7

The success of our program has exceeded our expectations. For the first 5 years of the program we had projected class sizes of 10-15 per year. We have exceeded these projections with class size during year one at 16 (13 fulltime and 3 part-time), class size during year 2 at 24 (22 fulltime), and the application rate for year 3 has doubled that of the previous year.

Our curriculum is patterned after similar masters programs (see Appendix B for specifics of our curriculum). During year one, students take core courses from three two-semester sequences: (a) probability and mathematical statistics; (b) applied data analysis; and (c)

biomedical disease process and communication. These sequences directly map to the 3 core competencies of analytical, biomedical, and communication and have been synchronized with regard to the schedule of topics. Students also take a programming class that teaches skills in the languages of R (the academic standard) and SAS (the industry standard). A qualifying examination is given in August before year 2.

Following their first year of coursework, many students are placed in paid or unpaid internships, with some working full-time during the summer and then part-time during the school year. During year two, students take a novel core course, Statistical Methods for Learning and Discovery, which surveys a number of techniques for high dimensional data analysis useful for data mining, machine learning and genomic applications. They also take a number of elective courses and work on a masters' project (typically, either a thesis-style report of a methodological project directed by a B&B faculty member or a collaborative manuscript from an interdisciplinary project developed as part of their internship). They also take a practicum course focusing on job skills (e.g., developing their curriculum vitae and practicing job interview techniques).

An important component of our curriculum is its experiential learning opportunities, whereby students have the opportunity to practice (under supervision) serving as the statistician for an actual research project. The ideal such experiential learning opportunity is a paid internship that may also serve to provide the topic for a masters' project. For our first class of students, paid internships outside Duke were provided by both FDA and Quintiles. Paid internships within Duke were provided by the Duke Cancer Institute, the Duke Biostatistics Core and the Duke Clinical Research Institute. Additionally, one student obtained part-time work with the National Evolutionary Synthesis Center at Duke. Feedback about student performance has been very positive.

Our first formal review (see Appendix C) of the masters program included an assessment of our curriculum and of student performance to date. The performance of our 13 full-time students has been excellent. Every student from our first class passed the qualifying examination. Two of these students out-competed PhD students from other programs for external internships at the FDA and at Quintiles and all full-time students were placed in internships, 10 of which are paid.

I.3.3. Existing synergistic programs

This proposal capitalizes on our overlap and synergy with two Duke PhD programs: the one in Computational Biology and Bioinformatics (CBB), which emphasizes skills in computation

and machine learning for modeling biological phenomena, primarily at the cellular level, and that given in the Department of Statistical Science (DSS), home to the premier Bayesian faculty in the world. DSS focuses on interdisciplinary methods and applications, but not necessarily related to medicine. It provides a natural continuum and source for elective courses pertaining to statistical methodology. Several of our faculty members serve on graduate committees for these programs and we expect the reverse will be true. In addition, selected courses from both the CBB and the DSS curriculum will be cross-listed in the Biostatistics program and vice versa.

I.4. Integration of basic science and traditional models

Our program will incorporate an integrated learning approach, combining the analytic substance of traditional didactic programs with the "laboratory" experience generally found in the basic sciences and in the existing CBB program. This approach is consistent with the nature of the discipline of biostatistics. The "traditional" component of didactic instruction will allow students to obtain the theoretical and applied background to address multiple types of problems, while the "laboratory" part of the curriculum will allow the student to develop an appreciation for how the details of applying this background will differ from case to case.

II. Relationship to existing programs

II.1. Traditional programs in biostatistics

Most PhD programs in biostatistics reside in schools of public health or colleges of arts and sciences. For those programs, the "natural laboratory" provided by a medical school environment is missing or incompletely integrated. Linking our program with this "natural laboratory" fosters close communication continuously during graduate training and will provide the experiences required to fully achieve the three core competencies. In fact, our graduate students will be encouraged to accompany physicians on rounds and in clinic, and even in the surgical suite, as many of our faculty have done.

II.2. Goals of the proposed graduate program

Biostatisticians must master three core competencies: (a) analysis; (b) biomedical fluency; and (c) communication. These competency goals were determined from interviews with successful statisticians and their non-statistical collaborators, and are consistent with the literature.

The analytic competency is derived from the traditional emphasis of biostatistics, and focuses on both the theoretical and applied aspects of statistical science, statistical modeling, software development and application, and study design. This competency has been achieved when the biostatistician can confidently develop or select and apply appropriate analytical techniques to address the various research questions under study. This competency is primarily acquired through structured didactic instruction, work on the dissertation, and immersion into actual applications.

The biomedical competency requires a sufficient foundation in the biology of diseases and related sciences to be able to understand and appreciate both the principles and the nuances of statistical application to the problem at hand. In addition, current medical research relies on inter-disciplinary collaboration (Begg and Vaughn, 2012[1]). While a biostatistician cannot be expected to become a scientific expert in each area under study, a fundamental level of background knowledge is essential. This competency is acquired not only through our novel didactic course in biomedical disease processes and communication, but also through immersion into the specific scientific milieus, where interdisciplinary interaction is routine.

The communication competency focuses on the unique role of the biostatistician within an increasingly complex and interdisciplinary research enterprise. This competency has been achieved when the biostatistician can effectively rephrase the scientific content into understandable statistical principles, and also embed the underlying biomedical context into the statistical models that are being applied or newly developed. This competency is approached in the first year through our novel course in which students are required to make presentations linking biomedical concepts with statistical thinking; communication is then reinforced and enhanced through affiliations actual faculty projects.

II.3. Uniqueness of the program in comparison with other biostatistics programs

Most programs in biostatistics focus heavily on the analytic competency. The biomedical and communication competencies are generally addressed through specific consulting projects or, in many cases, as on-the-job training. Because of the wealth of medical research opportunities at Duke and the close connections that have already been developed between B&B faculty members and various medical researchers, Duke provides a particularly fruitful environment for focusing on the biomedical competency.

[1] Begg M, Vaughan RD Are Biostatistics Students Prepared to Succeed in the Era of Interdisciplinary Science? (And How Will We Know?) The American Statistician Vol. 65, Iss. 2, 2011

A key feature of our program is exposure to the continuum of contemporary biomedical research. Our students will have basic knowledge in human biology and how the disruption of biologic systems leads to disease. This exposure will greatly facilitate their understanding of how key elements of biomedical systems are measured, leading to a better understanding of the data and better ability to respond to analytic issues presented by emerging technologies.

Our program will be noteworthy in that we focus on biomedical disease processes and communication competencies in addition to the standard analytic competency; and within the analytic competency, we are developing novel courses that will focus on state-of-the-science methodological issues likely to be encountered in 21st century biomedical research. Having an emphasis on all three competencies, supported by the world-class laboratory provided by the Duke biomedical enterprise, will make our program not only innovative, but also unique.

II.4. Comparison between our program and those of other programs at Duke and nationally

Faculty in the B&B Department focus specifically on problems that arise in biomedical research. In fact, most B&B faculty members have their offices located within the area that also houses the biomedical discipline that is their collaborative affiliation, such as cardiovascular disease or cancer. They develop specialized medical knowledge relative to this discipline and collaborate directly with Duke's world class medical investigators. This "natural laboratory" in which our graduates will be trained is a distinguishing feature of our program.

In contrast, faculty in the Department of Statistical Science (DSS) at Duke, renowned for their expertise Bayesian statistics, develop methods and participate in applied research, but are not aligned with any specific partner discipline and their applications span the spectrum of statistical issues that arise in any research context, not necessarily medicine.

The other closely related program at Duke is the Computational Biology and Bioinformatics program, with which we share faculty and students. These scientists use computation for modeling fundamental biology, not necessarily related to medicine; biostatisticians, on the other hand, focus on quantifying and accounting for biological variability in making inferences. Our program will be complementary to both of these established programs.

II.5. Potential overlap with existing programs in the area

As noted above, our proposed program overlaps with and derives synergy from the two existing programs on campus. However, there are unique aspects of our program that distinguish it from the others. In particular, our program differs from Duke's CBB program by its greater emphasis on systematic and didactic instruction and a focus on the inferential rather than the computational aspects of biological systems; the program differs from Duke's Statistical Science program by its emphasis on methods and skills that derive from medical applications and its close affiliation with the school of medicine. Additionally, the program differs from UNC's program in biostatistics because the Duke program is embedded in the Duke School of Medicine, rather than the School of Public Health, and our faculty are totally integrated into the "laboratory" of biomedical research; and the program differs from NCSU's program in statistics in that it is focused on medical issues and NCSU does not have a medical school.

II.5.1. Duke Computational Biology and Bioinformatics (CBB)

The focus of the Biostatistics PhD program is both different from and complementary to the Duke graduate program in CBB offered through the Institute of Genome Sciences and Policy. While several B&B faculty teach and direct dissertation research in the CBB program, students in CBB orient more toward wet lab techniques and algorithmic approaches that are complementary to the inferential statistical approach. Fundamentally, although both programs deal with biomedical data, they are designed to explore different questions, using different methods.

The CBB program seeks to develop research scientists who are fluent in computational science, mathematics, and statistics, with more emphasis on training students through "on the job" training (3 full-semester laboratory rotations) than via methodology classes (only 4 courses are required). Whereas CBB students might attempt to understand the biological mechanisms underlying heart failure, they would be unlikely to design a clinical trial or to assess the comparative effectiveness of two different therapies for heart failure.

In contrast, the B&B PhD program emphasizes a strong methodological foundation and rigorous coursework (14 core courses are required in addition to electives, cognates, and RCR) in theoretical and applied biostatistics. Graduates from the B&B PhD program are expected to be skilled in developing new statistical methods and designs to analyze problems across multiple biomedical disciplines. While the CBB program is suited for students more oriented

toward computation and biology than to statistics, the B&B program is designed for students whose natural interest is in the analytical aspects of statistical theory and inference.

II.5.2. Statistical Science

The graduate program offered by the Department of Statistical Science (DSS) in the Trinity School of Arts and Sciences is a top 10 statistics program nationally, a national top 3 program in research productivity, and the premier Bayesian group in the world. As with B&B, DSS also has an emphasis on application and its students engage in collaborative, application-driven projects. Although some of their faculty members work with investigators in the medical school, medical applications are not their primary focus and they are not generally wholly embedded within the medical environment. Given the synergistic goals of the two programs, mutual benefit can be expected from sharing courses and teaching assistants.

II.5.3. Other Comparative Programs

We have specifically designed our core curriculum to be competitive with those of five of the top Biostatistics PhD programs in the country: UNC, Harvard, University of Washington, Johns Hopkins, and University of Michigan. The table in Appendix D outlines this comparison. As with our program, each of these programs emphasizes two years of theory, with slightly different nomenclature but similar course descriptions, and two years of basic methods/applications. **Because many schools do not offer undergraduate majors in statistics or biostatistics, the first year PhD curriculum is generally coincident with the first year masters curriculum and more advanced students have the option to test out**.

It should be made clear that this is one difference between such a program and the more "basic" programs that are essentially wet or dry lab based. Because biostatisticians spend a good deal of their time collaborating, they need a firm foundation in the topics covered in our core curriculum; they also require a sufficient theoretical background in order to select and engage in an independent research project. Unlike many other fields, our students do not enter the program with the "tools of the trade" and they are not likely to have the experience to select a topic area in their first year.

However, this situation should improve in time. As noted in a recent communication from the American Statistical Association titled "Interest in Statistics still rising:"

> The number of high-school students who took the Advanced Placement (AP) Statistics Exam this year increased to nearly 170,000, a jump of 11% over the 2012 number. The percentage increase is in line with the average annual increases of 12% realized since

2003 and parallels the growth of AP Calculus AB. The strong growth in AP Statistics is considered one factor in the doubling of undergrad statistics degrees over the last five years

As our program matures, we should be in a good position to select for students with an adequate background to enroll immediately in the second year classes.

Among PhD programs in Biostatistics, the UNC Biostatistics program is highly ranked and our closest competitor**.** Our proposed curriculum is very similar to theirs. However, we extend the curriculum in several ways: first, we have added our basic core sequence that focuses on biomedical concepts and communication; we are also developing a new course called "Survey in inferential theory and techniques" (described in section VI), designed to provide the graduate student with the latest techniques in order to keep up with the fast pace of the "big data" explosion. Most importantly, we are embedded within a medical center and our students will be working directly with medical investigators and will be introduced to the entire medical research enterprise. They will be aligned with faculty and research teams that meet regularly to deal with the issues that arise in the process of collaborative medical science. Because the UNC program is embedded within a school of public health rather than a school of medicine, its students are less likely to have the advantages of the "natural laboratory" described above.

The comparison in Appendix D demonstrates that our curriculum is very similar to that of UNC, with the addition of novel features mentioned above and described more fully below. Some programs allow more choice in the additional requisites, while our curriculum is more defined. We have also borrowed the Harvard model, reflected as well in some of the other programs, of requiring a cognate field such as epidemiology. The one substantive difference between our program and the others is that each of the other programs requires a course in epidemiology, while ours embeds epidemiological principles of study design and analysis into our core courses. A six-credit curriculum in epidemiology will be one of the possible cognates. Our program also requires two novel courses that will prepare our students for the big data explosion. In addition, while some programs require one or two semesters of statistical consulting (the Michigan program has a course titled Design and Analysis of Biostatistical Investigation that emphasizes the communication aspect), we require our unique biomedical concepts/communication sequence that is structured to familiarize students with a range of biomedical concepts to the extent that they are fluent communicators. This course prepares them for their second year, in which they engage in three two- to four-month research experiences. Additionally our students will participate in a weekly seminar course, with increasing responsibility as they progress through the program.

Other programs offered locally reside in the UNC and North Carolina State Statistics Departments. The former is a theory-based pure statistics department; the latter is a general statistics department that includes both theory and application orientations, but has no affiliation with a medical entity.

III. Resources

III.1. Business Plan

In collaboration with the Graduate School, a budget has been developed and is attached as Appendix E. Briefly, we anticipate recruiting three to five PhD students each year along with approximately 20-21 masters students for a total incoming class of 25 and a steady state of about 20 PhD students after five years. We anticipate that first-year PhD students will be supported through institutional funds and that the Biostatistics Graduate Program will be responsible for second-year PhD students' tuition remission and stipends. In the third through fifth year these students will be funded through individual faculty grants, traineeships, or graduate assistantships as described in Section III.4. mechanisms that are similar to other biostatistics programs. Other expenses for the entire program include effort for teaching, effort for a DGS, administrative effort, and an academic retreat. Revenue from approximately 42 masters students each year will contribute $1.5M to the Biostatistics Graduate Program. As noted in the Executive Summary, the budget supports PhD students in their second year, and provides a contingency of $200,000 for backstopping students beyond their third year.

- Tuition revenue from 42 students: approximately $1.5 Million
- Expenses – approximately $1.5 Million
    - Faculty Teaching (including advising): $443,000
    - PhD tuition, fees and stipends: $432,000
    - Director of Graduate Studies: $58,000
    - Masters Scholarships: $150,000
    - Administration: $71,000
    - Other operating: $159,000 (including retreat and G&A)
    - Space: $103,000

Contingencies

The financial plan maintains a program reserve of $1.1 Million. We expect no more than 12 students in any year to be in the 3rd to 5th years of study and thus in potential need of departmental backstop. As described below, because of our experience in placing masters interns and our success in attracting both methods and statistical coordinating center grants, we are confident that we will not need to rely on this backstop. In addition, to the extent that we do not access the backstop, it will accumulate.

Although we suspect that we will not be accessing this backstop, the Department has additional contingencies, as confirmed in the letter from the Dean of the School of Medicine, Nancy Andrews (Appendix I). Also, in addition to the many options for funding graduate students, one of our faculty members has obtained provisional assurances from several entities, including pharma and some foreign groups anxious to sponsor graduate students on fellowships. These commitments will not involve any obligation on either the student of the Department's part.

Course development

Four higher-level courses will be required as core courses, three of which will be offered starting in the fall of 2015, as PhD students enter their second year. We have assurances from the former Chair of DSS, Alan Gelfand, that these three core courses are being taught by DSS and will be available to our students (see letter, Appendix A). The current Chair, Merlise Clyde, is in agreement with these plans. The fourth course, a novel survey course of modern inferential techniques and theory will be offered in the fall of 2016 and required of all PhD students and will be developed and taught by Dr. Zhiguo Li.

Director of Graduate Studies

A 25 percent effort for the DGS represents a realistic estimate of the time required to deal with the organizational and academic components of the program.

Students

Although at steady state we anticipate that the program will be admitting mostly advanced students who will test out of some of the first year core courses, our initial budgeting assumes that all students will begin with the year one core courses. Thus, we have assumed that students will take five years to complete the degree rather than four, and are conservatively assuming that all students will need five years of support.

We anticipate that after the first two years in the program each PhD student will be associated with an individual faculty grant or funded project, a traineeship, or a graduate assistantship that will cover the student stipend, as described below.

Inter-program communication

In discussions with the new Chair of the Department of Statistical Science (DSS), we agree that most top programs in statistics and biostatistics are in schools where those departments work closely together. DSS has created a world-renowned PhD program and they have indicated strong support for our proposed PhD program. Dr. Clyde and Dr. DeLong meet regularly to discuss curriculum sharing and best practices and will continue to do so. They will also connect the Directors of Graduate Studies for the two programs program and will encourage them to meet regularly as well. Moving forward, this guidance will be invaluable.

We also have a very strong relationship with the CBB program, as a number of our faculty members teach and supervise dissertations in this program. These faculty members have been and will continue to be a constructive force in shaping the current proposal.

Program evaluation

As suggested by the recent APC review, we anticipate a "review of the PhD program after three years (a formative review) and five years (a summative review) to assess: (a) faculty status and involvement; (b) grants and contracts where B&B faculty are lead PIs (distinct from being lead PIs of subcontracts); (c) student progress toward doctoral degrees (assessed early on by the measurements of the preliminary exam committees according to their evaluation rubrics); (d) self-directed research versus other-directed work by doctoral students; (e) at five years, publications and submissions in the field of biostatistics (or statistics) first-authored by doctoral students.

III.2. Resources available

III.2.1. Operational support

Financial management of the program will continue to be the responsibility of the Business Manager of the Department, assisted by the departmental Grants Administrators, Human Resources Manager, and Staff Assistant.

The current infrastructure that has been established for the Master of Biostatistics and the Clinical Research Training Programs will subsume the operational/management responsibilities for the Ph.D. program. Although the PhD program will incur additional administrative overhead, we benefit from the inherent economies of scale. The administrative and supervisory structure is as follows:

- The Master of Biostatistics Program Coordinator will assume the role of Director of Graduate Studies Assistant (DGSA), for the PhD program, managing the logistics required to matriculate students as appropriate within the standard operating procedures of both the School of Medicine and The Graduate School.
- The Assistant Director of CRTP will extend existing responsibilities for program databases, reporting systems, alumni follow-up, course and program evaluations, and learning management systems (e.g. Sakai) to include the PhD students as appropriate.
- The CRTP Program Coordinator will continue to work with the DGSA in supporting functions common to all three programs such as classroom scheduling, admissions and examining committee meetings, developing new operational procedures (and associated documentation) needed for the additional program, and assist in data entry for the internal databases.

III.2.2. Space

The B&B Department occupies 12,195 square feet on the 11th floor of Hock Plaza, where 20 faculty members have their offices. An additional 2,645 square feet on the ground level house 9 offices, 6 cubes and a conference room. In addition to the multi-functional CRTP classroom on the second floor, there are 2 classrooms with a capacity of 24 students each, and 3 conference/seminar rooms which can accommodate 10 people. Two team meeting rooms are equipped with large monitors so research or student groups can work together on projects, analyses, and presentations.

Two open seating areas provide informal meeting areas for students, faculty, and research staff. In addition, there are three break rooms and a copy/printer room. Workspace available for graduate students includes 13 desks in shared offices, 3 private study rooms, and a computer room which will accommodate 4 desktops for student use.

III.2.3. Computing

Computational and file servers are available for B&B students, faculty, and staff. These servers are housed in the Fitz East Data Center and are maintained by Net Friends in compliance with School of Medicine policies and procedures. The department provides computers and IT support for faculty and staff, including student and postdoc research associates. A computer workstation room will accommodate 3 to 4 desktops and a printer for student use.

III.3. Additional resources needed

Given the infrastructure in place with the two graduate programs being offered through the Biostatistics and Bioinformatics Department, the necessary resources are all available.

III.4. Potential or actual external funding

As described above and included in the budget, funding for students during the first two years of the program will be provided through central institutional and B&B departmental funds.

For years three through five, Biostatistics Departments traditionally offer several opportunities for funding graduate students, in part because the demand for biostatisticians who are trained at the masters level or higher is strong and likely to increase. Because of this increasing demand, fresh PhDs in Biostatistics generally move directly into government, industry, or faculty positions. There are very few who are willing to take a postdoc unless it is with a super star (one of our recently hired faculty members did a postdoc with Susan Murphy at Michigan; she just became a 2013MacArthur Fellow). Given the difficulty of advertising and assessing potential postdocs, selecting an appropriate graduate student, with whom we already have a relationship, is an obvious choice.

Many of our faculty, as well as faculty at other institutions, were trained as recipients of Graduate Research Assistantships, whereby they were funded to use and improve their skills in both biostatistics and communication by serving as members of a statistical team for a large collaborative study. Hence, although R01-type statistical research grants are relatively difficult to obtain, funding for collaborative work remains high and much of this work involves challenging biostatistical problems. Additionally, many of these collaborative projects are ongoing for several years and tend to have multiple statistical issues. Many of our graduate students will have the opportunity for (or will actually prefer) such funding, which represents training that is potentially complementary to the dissertation topic. In many cases the dissertation is derived from a problem that arises in the collaborative study.

This apprenticeship model is common in Biostatistics PhD programs. Many PhD biostatisticians working in both academia and industry were funded and trained through this mechanism, which has the advantage of embedding students in the actual environment where they will spend their careers. Because of the increasing demand for such quantitative skills, students are expected to (and generally eager to) perform at increasingly higher levels. The

DGS will monitor the student's placement and progress to ensure the appropriateness of the student's current biostatistical activities.

Thus, in the third through fifth years of the program, several models for funding will be available:

a. Some students might be funded through the traditional Teaching Assistantship mechanism that is common to graduate programs. In particular, the Department of Statistical Science (DSS) might fund some of our students for this purpose. Although each of our third-year PhD students will be committed to serving one semester as a Teaching Assistant with no compensation, DSS may have additional needs for Teaching Assistants. In discussions with the Chair of DSS, we have agreed to work on an equitable arrangement for supporting these students, should the need arise. We have not counted on this source of funding. Additionally, as our program evolves, we may be able to provide assistantships for our own masters level courses, rather than relying on supplementing the discretionary accounts of our instructors.
b. A second traditional means of graduate student support is through an R01 (or similar) grant on which a B&B faculty member is PI. As a result of a faculty survey, 10 of our faculty members anticipate being able to support a student on such funding and 6 additional faculty members can guarantee funding for a graduate student through a project in which they are involved, but are not the PI. The student will be supported to accomplish some portion of the stated goals of the grant. Of note, our faculty have only recently (since the beginning of the masters program) begun adding graduate student funding to grant applications.
c. A third potential source is a training grant, for which we will apply after we are able to demonstrate a track record.
d. As described above, Biostatistics programs are somewhat unique in that after two years of study, their students have training that is equivalent to that of newly trained masters biostatisticians, who are in great demand. Some students will be offered a Graduate Research Assistantship (GRA) to spend about 20 hours per week working collaboratively as a biostatistician on some medical research project(s). The GRA will be supervised by a B&B faculty member, who will ensure that the student is in a learning environment and is able to gain experience and expertise as he/she progresses through the program. This type of arrangement is typical of other Biostatistics PhD programs and our program has the advantage that our faculty members are embedded in the School of Medicine with access to multiple learning opportunities. Such opportunities will be available through the Duke Clinical Research Institute, the Duke Cancer Institute, the Duke Biostatistics Core, and other groups that employ biostatisticians (for example, NESCENT hired one of our masters students last summer – they might prefer a longer, graduated relationship). The type of experience will

include the range of biostatistical applications such as coordinating center projects (on which several of our faculty are PIs), clinical trials design and analysis, and observational data analysis. In some cases, the dissertation problem will be associated with the GRA project, but in other cases it could be independent.

e. Similar to the GRA, some of our students will obtain internships with industry. As mentioned above, one of our masters students competed successfully for an internship with Quintiles this past summer. In this case, the student will be supervised by both an industry PhD biostatistician and a B&B faculty member and the experience will be monitored to ensure progressively more challenging work.
f. We also anticipate a continued relationship with the FDA, where one of our masters students had an internship this past summer, under the direction of a B&B faculty member.

With only 4 PhD students entering per year, we anticipate no difficulty placing each student in one of the above positions. When the program is in its fifth year and at steady state with 12 PhD students in their third through fifth years of the program, our ability to secure additional funding will have matured to the point that we have developed relationships with a number of funding sources.

Although not necessary for the program's financial viability, we are quite optimistic about the prospects for attracting additional outside financial support which, in turn, can be used for program expansion and enhancement. As an example, the masters' program was able to obtain funding of $25,000 this school year from the Astellas USA Foundation, which we used to support an outstanding student from a historically disadvantaged minority group.

Training grants

The training grant mechanism is a likely funding mechanism for PhD graduate students in the B&B Biostatistics programs. A number of predoctoral training grants, such as the T32, exist through the NIH. Although we will pursue and investigate the T32 and others, the most appropriate and targeted is the National Institute of General Medical Science training grant. The website for this mechanism is:
http://www.nigms.nih.gov/Training/InstPredoc/PredocDesc-Biostatistics.htm.

Our program should be well-positioned to attract an institutional traineeship from this branch of the NIH. As stated on their website:

> "The purpose of these programs is to provide support for predoctoral training in biostatistical theory and evolving methodologies related to basic biomedical research including, but not limited to, bioinformatics, genetics, molecular biology, cellular processes, and physiology, as well as epidemiological, clinical, and behavioral studies. The goal is to ensure 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. Implementation will depend on the integration of biostatistics and basic biomedical sciences to create effective interdisciplinary training grant programs. The aim is to provide students with strong quantitative talents to pursue a wide range of opportunities in biostatistics research.
> … Applications should address the challenges of melding two disparate cultures, statistics and biology, at both the faculty and student levels."

Another grant specifically targeted toward training statisticians is the National Institute for Drug Addiction funded Research Education Grants for Statistical Training in the Genetics of Addiction (R25), which can be found described at: http://grants.nih.gov/grants/guide/pa-files/PAR-08-081.html. Again, this funding mechanism perfectly dovetails with our intended program, as stated on the website:

> "This FOA invites applications focused on research education for the development and testing of new statistical models to address genetics-based research problems in addiction."

In addition, the Integrative Graduate Education and Research Training (IGERT) program through NSF promotes interdisciplinary science and is another potential source of funding. Their website is http://www.nsf.gov/crssprgm/igert/gradopps.jsp.

We anticipate applying for at least one training grant during the first five years of the program. We have not included revenue from a training grant in our initial budget estimate.

Industry

The likelihood of external funding is especially high from participants in the pharmaceutical industry, who heavily rely upon PhD-trained statisticians and have internships designated specifically for them. Members of our Professional Advisory Council have commented that their organizations not only find the premises which underlie our educational program to be appealing, but also that they would be particularly likely to provide support for student

internships. The following links to internships for graduate students in biostatistics provide examples of the availability of such funding on a competitive basis:

http://www.amgen.com/careers/campus.html
http://www.merck.com/careers/explore-careers/students-and-graduates/home.html
http://magazine.amstat.org/blog/2012/12/01/annual-internship-listing/
http://www.amstat.org/education/pdfs/2013AdditionalInternships.pdf
http://www.quintiles.com/careers/global/career-paths/internships/
http://us.gsk.com/html/career/career-summer.html
http://careers.jnj.com/Internship-co-op-programs
http://www.mayoclinic.org/intern-biostats-rst/
http://www.nhlbi.nih.gov/funding/training/redbook/sibsweb.htm

Additionally, some members of our faculty have significant academic interactions with industry, such as presenting workshops on statistical methods. In particular, Dr. Shein-Chung Chow is a well-known author of several books on the design and analysis of pharmaceutical studies and is editor in chief of the *Journal of Biopharmaceutical Statistics*. He has approached several pharmaceutical companies and has obtained tentative commitments for fellowship support. The goal is to create an industrial affiliate program; members will donate funding in the form of student fellowships in the amount of $30,000 for three years, with no obligation on the part of the Department or the students who receive the fellowships.

III.5. Five year student, faculty and resources projections

III.5.1. Faculty

Biostatistics and Bioinformatics faculty number almost 50, of whom 6 are currently teaching the 7 core courses in the Masters in Biostatistics program; one is teaching two core courses and is training a junior faculty member to take one of them. Eight faculty members are teaching the second year masters program electives, two of which are being team taught by a senior faculty member and a junior faculty member.

The graduate program has additional potential teaching faculty drawn from the collaborating faculty from other departments, for example the Center for Human Genetics. Appointments of new teaching faculty to the Program will be made by the Chair of B&B, or his/her designee, on the basis of recommendations of the Graduate Faculty.

Graduate Faculty

Faculty members with long-term commitments to training in the program will be recommended by the Chair of the Department for membership in the Graduate Faculty. The table in Appendix F demonstrates that 30 of the 47 Biostatistics and Bioinformatics faculty members will be affiliated with the PhD program in various substantive roles. The letter T indicates that they are currently teaching courses in the Masters of Biostatistics program. Most of them will continue to teach and others, especially new faculty who have recently joined the department, will likely also teach as the program evolves. For example Zhiguo Li, who joined our faculty after doing a post-doc with Susan Murphy at the University of Michigan, will take responsibility for our novel course in statistical methods for learning and discovery and has already started developing it.

It is of note that, because the B&B Department has only recently initiated a teaching program, and many of our faculty members began their careers at Duke, most cannot list a significant history of mentoring PhD students. However, of the 30 faculty members involved in the program, 12 have been or are currently the primary advisor or co-advisor for a PhD dissertation and an additional 5 have served on dissertation committees. Another two faculty members in the Center for Human Genetics and an adjunct faculty member working part-time at the Durham VA have directed PhD dissertations and are anticipating doing so for the Biostatistics PhD. Many B&B faculty members are also supervising post-docs. All of these Duke faculty members are committed to taking on graduate students while several others, especially recent hires, are anxious to do so, as shown in the table (Role in program = A for being the primary advisor and C for willing to serve on a PhD committee).

As participants in the graduate program, graduate faculty are expected and eager to teach core and elective courses, contribute to curriculum development, serve as dissertation committee members and advisors for program students, and serve on committees associated with the program, including examination committees. Appointment to the graduate program faculty is made with this explicit understanding and expectation.

Faculty Appointments

Among the 20 faculty members who have at minimum served on a dissertation committee, only 7 are either tenured or on the tenure track and the others are active researchers who have been successful in attracting Duke, UNC, and NC State graduate students. Our non-tenure track faculty members have records of scholarship that are commensurate with those of tenure track faculty and they publish in the same journals as faculty of other institutions. In particular, Cliburn Chan is one of our most productive faculty members; he is not on the tenure track, but has a graduate student in Duke's CBB program and has supervised 2 postdocs.

Issues regarding tenure and timelines in the School of Medicine require explanation. Tenure track appointments in the Basic Sciences Departments are on the seven year time clock; those in the Clinical Sciences are given the longer timeline (eleven year clock) because of their "clinical commitments," which have an impact on their research productivity. The Biostatistics and Bioinformatics Department is one of two School of Medicine departments that are classified as both Clinical and Basic. However, B&B faculty members are generally hired in a model more similar to the clinical faculty model than the basic; they are mostly on a non-tenure track and are expected to spend a significant amount of time participating in research initiated by other investigators. Even tenure track faculty are not typically given the protected time or resources needed to establish an independent research career on the shorter timeline. Due to the collaborative nature of these appointments, our faculty members go through the Clinical Sciences APT pathway.

That said, it would be almost impossible to discriminate between our current tenure track and our non-tenure track faculty on the basis of research productivity and independent research. For this reason, and the fact that we would not be able to obtain the requisite number of tenure slots to sufficiently cover all of our current and future faculty members whose accomplishments and promise would warrant a tenure slot, the Biostatistics and Bioinformatics Department has been actively engaged in an initiative to find alternative mechanisms for ensuring a stable faculty, other than the tenure track. In order to enhance our recruitment efforts, we have obtained approval to hire new faculty members and to convert our more productive existing faculty members to extended horizon contracts. This model provides security for those who take the risks expected of an independent researcher, but avoids the additional risk to the University of a lifetime commitment. We are considering this situation our "tenure-equivalent."

We have recently recruited two full professors on the extended track. Both have excellent track records as independent investigators and will be in our pool of potential thesis advisors. Their initial contracts are for five years; after three years, the contracts will convert to a rolling five-year contract which is renewed daily until notice of non-continuance, after which he still has a guaranteed five years. We are currently creating guidelines for determining which current faculty members qualify for these extended contracts. An additional 13 faculty members will most likely be converted to extended horizon within the next few years. In addition to our existing faculty and anticipated new hires, we should have no trouble matching PhD students with advisors.

Those faculty members who are likely to occupy our "tenure-equivalent" slots are active researchers who publish in the field and also attract external funding. Appendix K lists some

of the grants on which B&B faculty members serve as Principal Investigators. Many grants are "owned" by different entities, such as the Duke Cancer Institute, rather than the Department, so this tabulation is relatively crude and incomplete, but it provides a general idea of the ability to attract external funding. Additionally, the activity has steadily increased with more faculty submitting and being awarded grants; a number of grants (that would take considerable effort to tabulate) have been submitted and are pending review.

Note however, that PI status on externally funded grants is not always the best metric of B&B faculty scholarship and/or potential to direct student dissertations. Many of our faculty have leadership roles in large collaborative organization but are not the PIs on the primary funding mechanisms for these groups. We present Dr. Andrew Allen as an example. Though Dr Allen has been the PI of NIH funded methodology grants in the past (K25, R01, etc.), he is currently funded exclusively through collaborative research in which he has COI but not PI status. Never-the-less, these grants fund his postdocs and PhD students and his effort is almost exclusively focused on developing novel statistical methodology addressing problems that emerge from these collaborations.

Faculty Stability

It is worth noting that B&B has never lost a faculty member due to lack of funding. In fact, we have trouble meeting the demand for faculty biostatisticians, partly because of the overwhelming need and partly because of our philosophy of hiring onto our faculty only those with a track record of publications in the field and the potential to contribute to the stature of the department. We have also had success in negotiating with some of our funding partners, such as the Duke Clinical Research Institute, to underwrite protected time for methods research for our faculty who collaborate with them. Additionally, because of the stimulating research environment at Duke, turnover among our faculty is minimal. The table in Appendix F demonstrates these long-term commitments, as well as the number of relatively recent hires. Many of these faculty members have overlapping interests. We anticipate very little attrition among our graduate faculty and, in such case, should have no trouble finding an appropriate replacement for a dissertation advisor.

Student/faculty interactions

Our program is very similar to other PhD programs in biostatistics and our recruitment of students is also similar. Although the School of Medicine Basic Science departments, and possibly those in Arts and Sciences, recruit on an individual level with the intent of matching the background and specific interests of students to advisors who have funding and would like

to take on additional students, incoming biostatistics students are unlikely to have an undergraduate degree in the field or much familiarity with it. Students need an introduction to the various aspects of biostatistics through coursework and internships in order to have an adequate sense of the options.

To ensure consistent student-faculty interaction, we will pair each incoming PhD student with an initial research-oriented advisor/mentor who will meet regularly with the student and will track the student's abilities and interests in order to help guide the student regarding the selection of a dissertation advisor. This initial mentor will serve as the student's gateway to the research environment by having the student read some of his/her manuscripts, by introducing the student to other research-oriented faculty, and by including the student in his/her research meetings.

Students have multiple opportunities to interact with the graduate faculty, in addition to those who are teaching courses. One of our faculty members organizes and facilitates several student/faculty lunches during the school year, during each of which three or four faculty members briefly describe their research interests – followed by open discussion with the students. These sessions have been quite popular. PhD students will also be required to attend at least one of the ongoing journal clubs (Statistical Genetics, Bioinformatics, Clinical Trials, Causal Inference/Predictive Modeling). Additionally, the seminar course, "Problems in Biostatistics" will be attended by faculty members who will at times be presenting.

Further, students will be required to work closely with program faculty members during their two-to-four month research experiences starting at the end of the first year. These experiences will pair students with faculty engaged in methodological research and will allow students to learn more about the graduate faculty and their areas of expertise. Students are required to complete three of these experiences by the end of their second year. Note that this differs fundamentally from the master's internship experience as there is an explicit pairing with a faculty member that could chair a dissertation and the focus is on the development of statistical methodology.

Faculty Development

The Department has had an established program for scientific development of faculty through regular seminars, identification of mentors in specific areas, and publication of technical papers. Pedagogical development is underway as well. Faculty teachers in the Master of Biostatistics program have been able to take advantage of the resources available within the Department through the Clinical Research Training Program (CRTP), as well as those of the Center for Instructional Technology of Duke University Libraries. In addition, the Department

engaged the services of a curriculum and faculty development consultant, Dr. Edward M. Neal, to work with faculty through group workshops and individual consultations on the development and evaluation of their courses. Dr. Neal is the former director of faculty development at the UNC Center for Teaching and Learning, and a regular instructor in Duke Graduate School's Teaching IDEAS workshops. Workshop topics for the Master's program faculty included Designing a College Course, Introduction to Active Learning, and Evaluating Communication Skills. The individual consultations focus on individual course planning, syllabus development, and evaluating student performance.

III.5.2. Administration

Director of Graduate Studies

The Director of Graduate Studies (DGS) is the official departmental or program administrator of the rules and regulations of the Graduate School, the designated advocate of the needs of the graduate program and graduate students, both within the department and in the University, and the initial advisor of all matriculating graduate students. Directors of Graduate Studies are nominated by the department chair or the program director and are appointed by the Dean of the Graduate School for a specified term of service.

Gregory Samsa, PhD has been the DGS for the Masters in Biostatistics program and he will continue in this role for the PhD program. He will devote 25% effort to this position.

III.5.3. Student job placement

Job placement efforts for the first cohort of students focus on building professional networks through internship experiences and student membership in the American Statistical Association (paid for by the Department), as well as formal didactic activities during BIOSTAT 701 Practicum Seminar. The specific aim of the didactic portion of BIOSTAT 701 is to integrate students' internship experiences with guidance and practice in the communication skills required for obtaining professional employment upon graduation from the program. The course consists of 5 two-hour job preparation seminars scheduled to occur throughout the year - - three during the fall semester and two during the spring semester. The course is led by the Program administrative team and includes activities involving human resources staff, department faculty, members of the program's Professional Advisory Council, and career services consultants. The first three sessions included the following topics: Lessons Learned: Debriefing the Internship Experience; Immersion in the Field: Starting to Build Your Professional Network; The Recruiting Process; Looking, Applying, and Interviewing – Stories from the Trenches; and Preparing a Resume. The spring 2013 seminars will focus on preparing

for the interview, including practice through mock interviews. This course will be equally relevant for PhD students, who will be encouraged to attend in their final year of the program.

IV. Students

Our Masters in Biostatistics program has provided the infrastructure and track record for the extension to a PhD program. As indicated above, enrollment has far exceeded projections. Approximately two thirds of our applicants, offers of admission, and matriculants are international, and primarily Asian; about two thirds are women. We offered a full scholarship to one African American student in our first year and were able to attract her; she has proven to be the top student in that cohort. The GRE scores and undergraduate GPAs of our first two years of matriculants compare favorably with the other masters programs at Duke.

In a survey of admitted students who declined our offer, the following schools were listed when asked if they chose to accept another university's offer of admission over ours:

Listed twice:
Columbia University
UNC-Chapel Hill
Yale University

Listed once:
Brown University
Georgetown University
Stanford University
SUNY Upstate Medical University
UC-Irvine
UC-San Diego
University of Minnesota

Entrance requirements for applicants to the PhD program will include more advanced level mathematics or statistics courses and these applicants will be evaluated more rigorously than those applying to the masters program. As with other biostatistics PhD programs, applicants will be required to have taken and received excellent grades in multivariate calculus and linear algebra. Real analysis is recommended. Test scores and letters of recommendation attesting to analytical aptitude are also important. Aside from a higher level of quantitative aptitude, we expect the sources and other characteristics of PhD applicants to be similar to those of our masters applicants.

We will continue to use a study section format for our admissions process, which will be stratified according to whether the applicant is applying to the Masters or the PhD program. Our admissions committee consists of all current teaching faculty and each applicant is evaluated by three reviewers who take into consideration the rigor of the student's curriculum, the GPA, GRE scores, TOEFL scores where applicable, the writing quality and sentiment of the personal statement, and the recommendations. Dr. Elizabeth DeLong, chair of the B&B Department is the chair of the committee and is heavily invested in the success of the program; she will continue in this role until the program is at steady state.

As with other graduate programs, we will invite a select group of applicants for a visit so that there can be a mutual assessment of fit before accepting them. During this visit, they will learn more about our faculty and also potential research areas. We will also continue the practice of inviting students to a recruiting visit (and for PhD students, we will cover the cost of the visit). At that visit, they will have the opportunity to learn about the department and to meet some of the faculty members.

To maximize flexibility in attracting talented students with diverse academic backgrounds, students will enter the PhD program through three potential routes: direct acceptance of outstanding students, provisional acceptance into PhD through masters program with partial scholarship and re-assessment after the first year of course work and comprehensive exam; acceptance from the second year of our Masters program (we actually have four such students currently in our program who would like to continue).

Entering Students will be assigned an initial advisor, who will guide the student through selection of faculty affiliations for research-oriented experiences and will mentor the student regarding other issues related to the program.

Differentiating the curriculum and experience of Masters and the PhD programs

We have configured our program to optimize the experience of both sets of students in the following ways:

- Entering PhD students will each be paired with a research-oriented faculty mentor (not necessarily the eventual thesis advisor) who will ensure that the student is exposed to research in biostatistics.

- The PhD core curriculum will be more demanding through the addition of two advanced level theory courses, an advanced course in theory of linear models, our novel survey course of modern inferential techniques and theory, and the progressive "Problems in Biostatistics" seminar.
- Four currently offered elective courses will be required for the PhD, consistent with the requirements of other PhD programs.
- By the end of the first year, PhD students will be required to select one or more research experiences by apprenticing for a period of time with faculty who have potential dissertation projects. In distinction, Masters students will be placed in internships for up to a full year in order to obtain practical exposure to the environment in which they intend to find employment.
- PhD students will be required to advance through the seminar series to the point of presenting their contributions from their research experiences.
- PhD students will be required to either teach an undergraduate course in the Department of Statistical Science or to serve as a teaching assistant under the supervision of a B&B faculty member for one or more semesters.
- PhD students who, for whatever reason, decide to discontinue pursuit of the PhD, but want to obtain the masters degree, will be required to complete a six-credit masters project during which time they will be required to pay tuition similar to other masters degree students. In essence they will need to fulfill credit requirements for the masters degree.
- PhD and masters students will gain from the associations with each other; advanced PhD students will serve as role models for the masters students and will also have opportunities to mentor and possibly tutor.
- Both types of students will have some classes in other buildings besides Hock Plaza, with an opportunity to interact with other graduate students on campus. In particular, our students will have access to the new Trent Semans Center for Health Education, where graduate students and medical students gather to study and take courses.

Diversity

Our overall strategy for encouraging diversity is to become known as a program that proactively recruits gifted students from under-represented minority groups and provides every encouragement for them to succeed. We are working with Dr. Sherilynn J. Black, Director of the Office of Biomedical Graduate Diversity, to locate potential recruits. Also Dr. Gregory Samsa, the DGS of our Masters in Biostatistics program attends the annual Biomedical Research Conference for Minority Students (ABRCMS). Our first such student was unanimously nominated by the faculty as the most outstanding student among our first graduating class, and received a $25,000 annual scholarship from the Astellas USA Foundation.

V. Degree Requirements

V.1.1. Biostatistics theory and techniques

Any successful biostatistical researcher needs to be well versed in both statistical theory and biostatistical techniques. At the masters level, this requires a course sequence with enough breadth and depth so that the masters level biostatistician can correctly implement an appropriate analysis and interpret results. At the PhD level, a similar breadth of material is required but at a deeper level, so that the PhD level biostatistician is not only able to implement and interpret existing approaches but to modify/extend these techniques or to develop completely new methods for addressing emerging problems in biology and medical research. At the same time we acknowledge that medical research is changing and that there will be a continuing emphasis on extremely large and complex datasets. Thus, in training biostatisticians for the future, our curriculum emphasizes not only traditional biostatistical theory and techniques (Table 1) but also modern inferential approaches that are applicable to emerging high dimensional problems (Table 2).

Table 1: Core courses that are typically found in biostatistics PhD programs

Standard biostatistical methods and theory courses
Introductory Statistical theory (BIOSTAT 604)
Introductory Probability theory (BIOSTAT 601)
Advanced statistical inference (STA 732)
Probability and measure theory (STA 711)
Introductory biostatistical methods I (BIOSTAT 602)
Introductory biostatistical methods II (BIOSTAT 605)
Introductory statistical programming I (BIOSTAT 621)
Introductory statistical programming II (BIOSTAT 622)
Theory of linear models (STA 721)
Generalized linear models (BIOSTAT 719)
Categorical data analysis (BIOSTAT 714)
Survival analysis (BIOSTAT 713)
Analysis of correlated and longitudinal data (BIOSTAT 718)

Table 2: Novel core courses emphasizing modern inferential techniques and theory

Novel biostatistical methods and theory courses
Statistical methods for learning and discovery (BIOSTAT 707)
Survey in modern inferential techniques and theory – de novo

Courses with numbers are all existing courses that are currently taught in either the Statistics PhD program or the Biostatistics masters program. Only the survey course in modern inferential techniques and theory will need to be developed de novo (see Section VI for a detailed description of this course).

Note that the technical depth of the material is at a level that meets or exceeds other top PhD programs in biostatistics. The survey course on modern inferential techniques and theory is novel and covers advanced material that is not covered in most PhD curricula. The theory and techniques covered in this course (empirical process theory, counting processes, semiparametric theory, etc.) are quite powerful and will give our graduates a significant advantage in solving difficult inferential problems during their dissertation research and beyond. For a summary of each of these courses, please see Section VI.0. For an overview of how these courses fit into the educational timeline of typical students, please see Appendix G.

V.1.2. Biology, Disease, and Medical Research

The best methodology research in biostatistics is that which is responsive to pressing inferential needs in medical research. Hence, it is important that the biostatistics researcher have a good handle on the issues that face the various medical disciplines with which they will interact. Having a firm grasp on the human biology of disease processes, and how various biologic quantities are measured is key. Without this background, it is difficult for the biostatistics researcher to translate the biomedical problem into the quantitative framework required to make inferential progress. In the traditional approach to biostatistics education, this material is deferred to on-the-job training and for many, never satisfactorily takes place. To address this deficit, we have developed a unique sequence of courses that provides an introduction to biology at a level suitable for practicing biostatisticians (Table 3). This course emphasizes the translation of the biomedical problem into a statistical framework. In this way, this course serves as a bridge between the biomedical content and the statistical techniques and theories learned in other courses.

V.1.3. Communication

Effective communication skills are essential across all areas of biostatistical research. Biostatisticians need to be effective communicators while formulating the problem that is to be addressed, devising and articulating a solution, and disseminating results. At the PhD level, they also need to be effective educators both to other members of a research team and to the next generation of biostatistical researchers. Unlike other biostatistics programs we explicitly

integrate the development of communication skills into our curriculum. Our novel core course sequence, *Introduction to the practice of biostatistics* (Table 3), explicitly emphasizes the communication aspect of translating biomedical problems into a statistical framework.

In addition, skill building exercises are emphasized in all courses; reports, presentations, and group exercises are present across the curriculum. Second, we will also have an ongoing seminar sequence that introduces students to current problems in biostatistics (see Section VI). This course will be required of all students throughout their tenure at Duke and their participation will evolve with their development. Thus, first year students will largely be attendees, while intermediate PhD students will be required to make presentations on areas related to their emerging research interests and advanced students will present their own methodologic research. The first seminar of each year will be devoted to "How to give a seminar" and will be presented by faculty and advanced graduate students. For student presentations, the final 10 minutes of the session will be dedicated to a constructive critique.

Table 3: Novel core courses emphasizing communication

Novel courses focusing on communication of statistical ideas in medical research
Introduction to the practice of biostatistics I (BIOSTAT 603)
Introduction to the practice of biostatistics II (BIOSTAT 606)
Problems in biostatistics seminar

Note that BIOSTAT 603 & 606 address both biology and communication competencies

V.2. Elective courses

Electives: The program will offer at least 2 electives each academic year on a rotating basis. During the 2012-2013 academic year, we are offering: Statistical genetics and genetic epidemiology (BIOSTAT 710) and Observational studies (BIOSTAT 709). With the approval of the DGS, students can satisfy program requirements by taking courses from allied disciplines including those offered by: Department of Statistical Science, the Computational Biology and Bioinformatics Program, the Umbrella Program in Genetics and Genomics program, the Clinical Research Training Program, and the Global Health program. Students may also be able to take advantage of course offerings at regional universities, i.e., UNC and NCSU. A total of 5 elective courses are required.

Cognate field electives: Students will be required to explore in some depth a selected cognate field, a substantive field outside of biostatistics or statistics. Examples of cognate fields include

biophysics; environmental health; epidemiology; genetics; health policy and management; human development; molecular biology among others. The cognate field should be complementary to the student's biostatistical area of interest. Two of the 5 total electives must be used to satisfy the cognate requirement and should form a coherent set of courses related to the cognate field selected. These courses should be primarily substantive, rather than quantitative, in nature and this requirement will likely be fulfilled in the third year, once the student has chosen a dissertation area.

Each student's cognate program will be customized to the background and interests of the student. Primary faculty members in these supporting programs have expressed enthusiasm for collaborating with us to place students into appropriate sequences of courses (please see letters of support in Appendix A).

To help demonstrate how the cognate requirement could be fulfilled, we highlight three examples:

Student A. Student A's methodology research focuses on a topic in statistical genetics. Student A has an undergraduate degree in mathematics but no genetics training beyond that found in an introductory biology class. Thus Student A would have a cognate program that would address that gap through courses in molecular and population genetics such as UPGEN 687: Complex traits and evolutionary genetics; MGM 532: Human Genetics.

Student B. Student B's methodology research focuses on a topic concerning the analysis of observational data. For this research program, additional training in formal epidemiologic design in addition to topics in global health would form an ideal cognate program. For example, GLHLTH 702: Global health research: Design and Practice and GLHLTH 705: Global Health Research: Introduction to Epidemiologic Methods would give the student a strong background in epidemiologic design, measurement, and analysis.

Student C. Student C's dissertation research focuses on analytic issues in clinical trials. Additional coursework in regulatory issues and research ethics would strongly complement this work and the career path the student is embarking on. For example, students might elect the following set of courses: CRP 253 Responsible Conduct of Research; CRP 254 Research Management; and CRP 262 Systematic Reviews and Meta Analysis.

We note that our program does not explicitly require students to take epidemiology courses as is the case in many (but not all) traditional biostatistics programs. Our approach was instead to imbed universally important epidemiologic principles, quantities, and design in the core

sequence courses and then give students the option to pursue further study in epidemiology through their cognate field requirement (this is entirely similar to Harvard's approach) if it is complementary to the student's area of biostatistical interest. For example, a student conducting dissertation research in statistical methods related to observational analyses would likely find further study in epidemiologic methods useful, while the student conducting research in proteomic analyses may find a cognate course sequence involving molecular biology and protein chemistry more useful.

V.3. Examinations and reasonable progress

First year comprehensive exam: This exam will be based on the first year of core coursework and is equivalent to the masters qualifying exam. It is typically offered in August, prior to the beginning of year 2, with one opportunity to remediate a failing grade. Incoming students who wish to test out of first year coursework will have to pass the theory and methods section of this exam. This exam is useful for counseling students as to the wisdom of pursuing the PhD degree, given that a default masters degree is not an option and will require a masters project. Hence, the second year of coursework could depend on the results of this exam.

Second year qualifying exam: This examination is based primarily on the second year of core coursework and represents a level of rigor beyond that required of masters students. All PhD students must pass the exam at a level sufficient to confirm the ability of the student in these core areas and the preparedness for progression to independent research. The theory exam is set, administered and examined by representatives of the Biostatistics Graduate Faculty. It is typically offered in May of year 2, with one opportunity to remediate a failing grade. Although we have structured our curriculum to be consistent with other similar programs, there is the possibility that a few PhD students will struggle with the typical second year course load. In that case, they will be able to delay some courses and consequently delay the qualifying exam, with permission.

Preliminary Examination: The PhD preliminary examination is administered in accordance with the guidelines set out by the Graduate School. Ordinarily students should pass the preliminary examination by the end of the third year. As part of this examination process, the candidate will submit a short written manuscript on the research area, to be presented and discussed at the exam. The manuscript will usually consist of a literature review and proposal for their anticipated area of thesis research. In addition to addressing the student's readiness to

conduct independent research, the oral preliminary examination features questions and discussion designed to evaluate the competence and preparedness of the student in the broad field as represented by the Biostatistics courses during the preceding two years. Successful completion of the Exam qualifies the student as a PhD candidate in Biostatistics.

Thesis Research and Defense: Following successful completion of the Preliminary examination, students devote most of their time to original research under the supervision of their dissertation advisors and committees. They may also take courses for their Supporting Program, including advanced topics courses or courses outside Biostatistics and of immediate relevance to their thesis research topics. During the third year PhD students also begin to specialize, acquiring the tools and techniques required for their chosen area of expertise. The student, with counsel from the DGS, will select a primary dissertation advisor (if not selected earlier) and a dissertation committee. One member of the student's committee will be either a clinical or a basic science investigator with expertise in subject matter relevant to the dissertation. A faculty member from the cognate field is also recommended. Since the program is tailored to the needs and career goals of each student, the exact program will differ for each student.

During the thesis research period, each student will have routine weekly interactions with the primary advisor, and will meet with the full thesis committee at least twice each semester to review progress, plans, thesis research scope and any other matters arising. Clear research-oriented metrics will be developed so that advisors (and committees) will be guided by uniform standards, both in training doctoral students and in evaluating their progress. The student will complete the thesis research, thesis writing and prepare for the thesis defense as prescribed by the regulations of the Duke Graduate School (available in full at the web site of the Graduate School). It is the expectation of the Biostatistics program that most students will complete their research and successfully defend the PhD within 4 or 5 years.

A student's dissertation topic might or might not be derived directly from a project providing the student's stipend. For example, a student might be funded through the Biostatistics Core that is managed by the B&B Department and the student might be affiliated with the lymphoma research team. However, the student may have chosen a dissertation advisor who is interested in problems related to censoring of data on toxicity. The student would develop methods for the research problem and might possibly use the lymphoma data to provide an example of the methodology.

Each student will be expected to publish or submit at least one first-author paper in the area of biostatistics or statistics, in addition to being included as a co-author on one or more papers

with collaborators. PhD students will also be required to attend the Departmental bi-weekly mentoring session, where both senior and junior faculty members evaluate grant applications that are being prepared by B&B faculty members. For the student's preliminary oral, we will adopt the convention used by the CBB program of requiring that it be in the form of a grant proposal, including an introduction, review of previous work, proposed work and justification regarding its relevance and likelihood of success,

Satisfactory Progress: Each year the student must make Satisfactory Progress toward the PhD degree. The Biostatistics Graduate Faculty meets annually to discuss the progress of each student. When there is a problem, the Director of Graduate Studies will write the student a letter summarizing the faculty's consensus and specifying any deficiencies (academic or otherwise) the student must correct, or any additional requirements the student must meet.

V.4. Other requirements

Responsible Conduct of Research: All basic medical science doctoral students are required to complete 18 hours of training in the Responsible Conduct of Research (RCR). Each biostatistics PhD student will be required to complete one of the following RCR training options to meet this Graduate School requirement:

- Attend GS 710A (12 hours, RCR Orientation at the Beaufort Marine Lab) prior to beginning graduate study and mandatory follow-up RCR training (4 hours, GS713) between Years 3 and 4 of their program; or
- Successful completion of CRP 253 Responsible Conduct of Research offered by the Clinical Research Training Program (22.5 didactic hours). (Please note that GS712 credit approval will be requested for CRP 253 per The Graduate School's instructions as described in "Procedures to Request GS712 Credit Approval for Departmental RCR Training Events")

Seminars: Throughout their participation in the Biostatistics Graduate Program, students are expected to attend B&B research seminars. In addition, they are required to actively participate in at least one of the Department journal clubs: Clinical Trials, Statistical Genetics, Bioinformatics, or Causal Inference. Students are also strongly encouraged to attend research seminars in the CBB, IGSP, Statistics and Decision Sciences and other allied programs as frequently as possible.

Research-Oriented Experiences: Our current masters program provides a mechanism whereby first-year students are introduced to three or four faculty members who describe their research and potential thesis projects during a lunchtime discussion. This introduction will

also serve to familiarize PhD students with the various faculty interests. After the first year of coursework, students will select one or more faculty members with whom to become affiliated to learn about research opportunities and also the practical aspects of a career in biostatistics. These experiences will serve to better acquaint the students with potential dissertation topics as well as funding opportunities.

Teaching experience: Each PhD student will be expected to be a teaching assistant for one semester in the Statistical Science Department.

A timeline for student progression through the program is presented in Appendix G.

VI. New Course Offerings

Current problems in biostatistics (to be developed). Advanced seminar on topics at the research frontiers in biostatistics. This course is comprised of readings of current biostatistical research and presentations by faculty and advanced students of current research in their area of specialization. Required by all students. Course instructor: rotating

Advanced topics in modern inferential techniques and theory. This course provides an introduction to topics that form the theoretical foundation of modern biostatistics and the inferential techniques for solving contemporary biostatistical problems. It covers topics in stochastic processes, weak convergence, semiparametric models and probability limit theory with an emphasis on those needed in biostatistics. Specific topics include stochastic processes, random walks, Markov chains, martingales, counting processes, Hilbert spaces for random vectors, semiparametric models, geometry of efficient score functions and efficient influence functions, the functional delta method, and the theory for M- and Z- estimators. Throughout, the presented theoretical results will be illustrated through application to real problems encountered during the faculty's research. Additional topics including weak convergence and an overview of basic techniques in empirical process theory will be covered. This course provides students a 'tool chest' of advanced techniques for dealing with modern inferential problems. After completing this course, students will be well prepared for the inferential component of dissertation research. Prerequisites: Probability and measure theory (STAT 711) and statistical inference (STAT 732). Course instructor: Dr. Zhiguo Li

VII. Curriculum Vitae of Faculty Who Will Participate In the Program

Please see Appendix H.

VIII. Statement of Support from the Dean of the School of Medicine

Please see Appendix I.

IX. Student Learning Assessment Process Template

Please see Appendix J.

APPENDIX A

Letters of Support

- Department of Statistical Science
- PhD Program in Neurobiology
- PhD Program in Pharmacology and Cancer Biology
- PhD Program in Molecular Genetics and Microbiology
- Department of Molecular Genetics and Microbiology (Email from the Chair)
- University Program in Genetics and Genomics (2 letters)
- PhD Program in Immunology
- PhD Program in Cell Biology
- PhD Program in Molecular Cancer Biology
- PhD Program in Biochemistry
- PhD Program in Cell and Molecular Biology
- Masters Program in Global Health
- Clinical Research Training Program
- PhD Program in Computational Biology and Bioinformatics

(Letters start on next page)

Duke University
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DURHAM, NORTH CAROLINA
27708–0251

DEPARTMENT OF
STATISTICAL SCIENCE

tel: (919) 668-5229
fax: (919) 684–8594
email: *alan@stat.duke.edu*

April 25, 2013

The Graduate School
Duke University
Durham, NC

To whom it may concern,

This letter is a follow up to my letter of January 29, 2013 which is supplied below. I am comfortable with the response of the Department of Biostatistics and Bioinformatics to the recommendations of the Executive Committee of the Graduate Faculty and I remain fully supportive of this new program.

I am delighted to write on behalf of the Department of Statistical Science in support of the proposal by the Department of Biostatistics and Bioinformatics to establish a Ph.D. program in Biostatistics. We concur that the timing is right to go forward with this now. One of the conditions for a world-class biomedical research enterprise at Duke is a vibrant community of biostatisticians which, as a primary component, oversees a well-respected Ph.D. program. Furthermore, we have always felt that a strong research degree program in the Department of Biostatistics and Bioinformatics (B&B) would be an important complement to our outstanding Ph.D. program in Statistical Science. There is clearly a substantial demand for such Ph.D. programs and the rather unique flavor that is being proposed - with the attractive constellation of analytical skills, fundamental biomedical knowledge, and communication with regard to problem-framing and problem-solving - suggests that it will easily find a good share of the demand.

In terms of more explicit support from the Department of Statistical Science (DSS), three of our core courses (Advanced statistical inference, STA 732; Probability and measure theory, STA 711, and Theory of linear models, STA 721) are envisioned as part of the core curriculum for the Ph.D. in Biostatistics. We are committed to making space available in these courses to Ph.D. students from the B&B program who meet the prerequisites. Further, with regard to mutual benefit, we anticipate that some Ph.D. students in B&B will take other research courses that we offer and, reciprocally, that some students in our program might avail themselves of some of the special topics courses that will be offered through B&B.

In summary, we in DSS believe this new Ph.D. initiative has the potential to be a substantial boon

to B&B, to DSS, and to the University as a whole and we enthusiastically support its creation.

Sincerely,

Alan E. Gelfand
Head of Department
J B Duke Professor of Statistical Science and
Professor, Environmental Sciences and Policy,
Nicholas School

DUKE UNIVERSITY MEDICAL CENTER
Department of Neurobiology
Stephen G. Lisberger, PhD
George Barth Geller Professor and Chair
Investigator, Howard Hughes Medical Institute

April 25, 2013

Elizabeth DeLong, PhD, MA
Professor and Chair
Department of Biostatistics and Bioinformatics
Duke Box 2721
Durham, NC 27710

Dear ~~Dr. DeLong~~ Liz:

The Duke PhD program in Neurobiology is very happy to support your initiative to establish a much-needed PhD program in Biostatistics. We also believe that your requirement of a six credit cognate outside of Biostatistics will be quite useful to the student.

I understand that you anticipate enrolling no more than 4 PhD students in any year and these will be distributed among several potential cognate programs. As chair of the department and DGS for the Neurobiology program, we welcome your PhD students to take any of our courses for which they have the required background. We will be glad to work with you and your individual students to ensure that they enroll in the most beneficial combination of courses.

Best wishes.

Yours sincerely,

Stephen G. Lisberger

Stephen G. Lisberger, PhD
George Barth Geller Professor of Neurobiology
Chair, Department of Neurobiology
Investigator, Howard Hughes Medical Institute

Richard ~~Mooney, PhD~~
George Barth Geller Professor of Neurobiology
Director of Graduate Studies

DUKE UNIVERSITY MEDICAL CENTER
Department of Pharmacology and Cancer Biology

Elizabeth DeLong, Ph.D.
Department of Biostatistics and Bioinformatics
Duke University
Durham, NC 27710

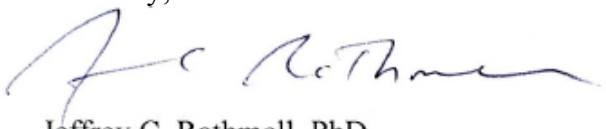
April 25, 2013

Dear Liz,

The Duke PhD program in Pharmacology and Cancer Biology is very happy to support your initiative to establish a much-needed PhD program in Biostatistics. We also believe that your requirement of a six credit cognate outside of Biostatistics will be quite useful to the student.

I understand that you anticipate enrolling no more than 4 PhD students in any year and these will be distributed among several potential cognate programs. As DGS of the Pharmacological Sciences program in the department of Pharmacology and Cancer Biology, I welcome your PhD students to take any of our courses for which they have the required background. I will be glad to work with you and your individual students to ensure that they enroll in the most beneficial combination of courses.

Sincerely,



Jeffrey C. Rathmell, PhD.
Associate Professor
Department of Pharmacology and Cancer Biology
Director of Graduate Studies of Pharmacological Sciences
jeff.rathmell@duke.edu

DUKE UNIVERSITY MEDICAL CENTER
Department of Molecular Genetics and Microbiology
Raphael H. Valdivia, Ph.D.
Director of Graduate Studies

April 28th, 2013

Elizabeth DeLong, Ph.D.
Professor and Chair,
Department of Biostatistics and Bioinformatics
Duke University School of Medicine

Dear Liz

The Duke PhD program in Molecular Genetics and Microbiology (MGM) is very happy to support your initiative to establish a much-needed PhD program in Biostatistics. We have been very impressed with your Master's program students as they are a vibrant and interactive group of individuals. Taking this to the next level with a PhD program is the logical development of your successful training and education efforts.

I understand that you anticipate enrolling approximately 4 PhD students in any year and these will be distributed among several potential cognate programs. As Director for Graduate Studies for the MGM graduate program, I welcome your PhD students to take any of our courses for which they have the required background. These include courses in Gene Regulation, Critical Readings in Genetics, Human Genetics, Virology, Microbial Pathogenesis, and Advanced Topics in Infection Biology. We also believe that your requirement of a six credit outside of Biostatistics will be quite useful to both your students and those in our programs, as "wet-lab" PhD students will benefit from increased interactions with your trainees, who will bring a rigorous statistical perspective to genetic-centered research questions.

I will be glad to work with you and your individual students to ensure that they enroll in the most beneficial combination of courses.

I look forward to continuing to work together as your PhD training program develops and we continue to forge partnerships that build bridges across programs and departments to enrich the opportunities for everyone on campus.

Sincerely,

Raphael H. Valdivia
Associate Professor
Director for Graduate Studies,
Department of Molecular Genetics and Microbiology
Director, Duke Center for the Genomics of Microbial Systems

DUMC 3580 ◆ Durham, NC 27710 ◆ Telephone (919) 668-3831 ◆ Fax: (919) 681-9193 ◆ E-mail: raphael.valdivia@duke.edu

Dear Liz

From my perspective as chair of MGM, and former director of the Duke UPGG program from 2002-2009, including writing two competitive T32 renewals, I am delighted you are moving ahead with establishing a PhD program in your department at Duke. I was very impressed with your masters programs students whom I met at your holiday event, and they are a vibrant and interactive group of engaging and engaged students. Taking this to the next level with a PhD program is the logical development of your terrific training and education efforts and impact. Raphael will send a letter of support as DGS and director of the MGM graduate umbrella program, and my own view is also highly supportive that your students are welcome to register for and matriculate in any courses that they would find of interest for which we are responsible.

I look forward to continuing to work together as your program develops and we continue to forge partnerships that build bridges across programs and departments to enrich the opportunities for everyone on campus.

Best wishes

Joe

Joseph Heitman, MD, PhD

Chair, Department of Molecular Genetics and Microbiology James B. Duke Professor, Departments of Molecular Genetics and Microbiology (MGM), Pharmacology and Cancer Biology, and Medicine Duke University Medical Center
322 CARL Building Box 3546
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DUKE UNIVERSITY MEDICAL CENTER
Department of Molecular Genetics and Microbiology
Douglas A. Marchuk, Ph.D.

Dr. Elizabeth DeLong
Chair
Department of Biostatistics and Bioinformatics
Duke University School of Medicine
Durham, NC 27710

24 April 2013

Dear Liz,

The Duke University Program in Genetics and Genomics (UPGG) is eager to support your initiative to establish a much-needed PhD program in Biostatistics. We are also excited to learn that you will be requiring a six credit cognate program in an area outside of Biostatistics.

I understand that you anticipate enrolling no more than 4 PhD students in any year and these will be distributed among several potential cognate programs. As Program Director of UPGG, I welcome your PhD students to take any of our courses for which they have the required background. Many of the courses in our program will be a natural fit for your students. I and the other leaders of our program (Beth Sullivan, Co-Director; Allison Ashley-Koch, Director of Graduate Studies) will be pleased to work with you and your individual students to ensure that they enroll in the most beneficial combination of courses. We look forward to working together to enhance your new PhD program.

Sincerely yours,

Douglas A. Marchuk, Ph.D.
Professor and Vice Chair; Department of Molecular Genetics and Microbiology
Director: University Program in Genetics and Genomics.

Box # 3175 ◆ Durham, NC 27710 ◆ Telephone (919) 684-1945 ◆ Fax: (919) 684-2790 ◆ E-mail: douglas.marchuk@duke.edu

DUKE center for HUMAN GENETICS

Allison Ashley-Koch, Ph. D.
Professor

April 25, 2013

Elizabeth DeLong
Chair, Biostatistics and Bioinformatics Department
Duke University
2424 Erwin Rd.
Durham, NC 27710

Dear Liz,

The Duke University Program in Genetics and Genomics is eager to support your initiative to establish a much-needed PhD program in Biostatistics. We are also excited to learn that you will be requiring a six credit cognate program in an area outside of Biostatistics. Genetics and genomics are a natural fit with biostatistics. As a genetic epidemiologist I am personally excited about this opportunity.

I understand that you anticipate enrolling no more than four PhD students in any year and these will be distributed among several potential cognate programs. As Director of Graduate Studies for the Program in Genetics and Genomics, I welcome your PhD students to take any of our courses for which they have the required background. I will be glad to work with you and your individual students to ensure that they enroll in the most beneficial combination of courses.

Sincerely,

Allison Ashley-Koch, Ph.D
Professor of Medicine
Director of Graduate Studies
University Program in Genetics and Genomics
Duke University

Duke University Medical Center
DUMC Box 3445 | 595 LaSalle Street | Durham, NC 27710
phone 919-684-1805 | **fax** 919-684-0912 | **email** allison.ashleykoch@duke.edu

DUKE UNIVERSITY MEDICAL CENTER

Yuan Zhuang, Ph.D.
Professor of Immunology
Director, Graduate Studies of Immunology

April. 25, 2013

To: Professor Elizabeth DeLong
Chair
Department of Biostatistics and Bioinformatics
Duke University Medical Center, Box 2721

Dear Liz

The Duke PhD program in Immunology is very happy to support your initiative to establish a much-needed PhD program in Biostatistics. We also believe that your requirement of a six credit cognate outside of Biostatistics will be beneficial to the biostatistics major.

I understand that you anticipate enrolling no more than 4 PhD students in any year and these will be distributed among several potential cognate programs. As the Director of Graduate Studies for the Immunology program, I welcome your PhD students to take any of our courses for which they have the required background. I will be glad to work with you and your students to ensure that they enroll in the most beneficial combination of courses.

Sincerely,

Yuan Zhuang, Ph.D.

329 Jones Bldg. • DUMC 3010 • Durham NC 27710
Telephone (919) 613-7824 • Fax (919) 613-7853 • email: yzhuang@duke.edu

DUKE UNIVERSITY SCHOOL OF MEDICINE

Department of Cell Biology

April 29th, 2013

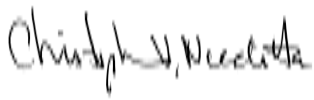
Elizabeth DeLong PhD
DCRI Associate Director
Co-Director, Outcomes Research and Assessment Group
Chair and Professor, Department of Biostatistics and Bioinformatics
Duke University Medical Center
Durham, NC 27710

Dear Liz:

As a follow-up to our discussions re: a PhD program in Biostatistics, I am writing to express our strong support and to say that the PhD program in Cell Biology fully and enthusiastically supports your efforts to establish a PhD program in Biostatistics. Given the nature of the discipline, we very much agree that a requirement for a six-hour credit cognate outside of Biostatistics will benefit the Biostatistics students. On that note, I serve as course organizer for CBI551/CMB551, Molecular Cell Biology - this course is our flagship cell and molecular biology course and is required of all Cell Biology graduate students as well as the graduate students admitted via the T32 Cell and Molecular Biology training grant. This would be an excellent course for your students; they will be exposed to a diversity of fundamental cell and molecular biology research areas as well as key literature in those fields – and will gain a strong appreciation for how, where and why biostatistics is playing an increasingly important role in basic research.

I understand that you anticipate enrolling no more than 4 PhD students in any year and these will be distributed among several potential cognate programs. As DGS for the Cell Biology program, I welcome your PhD students to take any of our courses for which they have the required background. I will be glad to work with you and your individual students to ensure that they enroll in the most beneficial combination of courses.

Sincerely,



Christopher Nicchitta, PhD
Director of Graduate Studies
Professor of Cell Biology and Biochemistry
Duke University Medical Center

Duke University
School of Medicine

Ann Marie Pendergast, Ph.D.
Anthony R. Means Cancer Biology Professor and
Vice Chair of Pharmacology and Cancer Biology

April 25, 2013

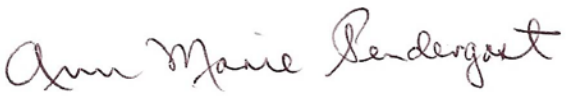
Elizabeth Delong, PhD
Chair and Professor, Department of Biostatistics and
Bioinformatics, DUMC

Dear Liz,

The Duke PhD program in Molecular Cancer Biology is very happy to support your initiative to establish a much-needed PhD program in Biostatistics. We also believe that your requirement of a six credit cognate outside of Biostatistics will be quite useful to the student.

I understand that you anticipate enrolling no more than 4 PhD students in any year and these will be distributed among several potential cognate programs. As Director of Graduate Studies for the MCB program, I welcome your PhD students to take any of our courses for which they have the required background. I will be glad to work with you and your individual students to ensure that they enroll in the most beneficial combination of courses.

Best regards,



Ann Marie Pendergast, Ph.D.
Anthony R. Means Cancer Biology Professor
Vice Chair, Department of Pharmacology and Cancer Biology
Director of Graduate Studies, Molecular Cancer Biology
Duke University School of Medicine
P.O. Box 3813, Medical Center
Durham, NC 27710

BOX DUMC 3813, Durham, NC 27710
LOC C233A LSRC, Research Drive
Durham, NC 27710
TEL 919.681-8086
FAX 919.681.7148
EMAIL ann.pendergast@duke.edu

DukeMedicine

Department of Biochemistry

April 25, 2013

Professor Elizabeth DeLong
Chair, Department of Biostatistics and Bioinformatics
Duke University

Dear Liz,

The Department of Biochemistry and the PhD program are very happy to support your initiative to establish a much-needed PhD program in Biostatistics. We understand that the proposed new degree will require six credit hours outside of Biostatistics. I strongly believe that training in the biostatistics area needs to include this type of classroom and perhaps, in addition, even project experience. As professionals later, it is important that many if not most of PhDs from programs like yours be imbedded in experimental research groups, and this represents early substantive exposure to the scientific environment in which they will likely work.

I understand that you anticipate enrolling about 4 PhD students per year in this new program, and these students will be distributed among several potential cognate programs. As DGS for the Biochemistry program, I welcome your PhD students to take any of our courses for which they have the required background. I will be happy to work with you and your individual students to ensure that they enroll in the most beneficial combination of courses.

Sincerely,

Len Spicer

Leonard D. Spicer
Director of Graduate Studies
Department of Biochemistry
University Distinguished Service Professor

DUMC 3711
Durham, NC 27710

919.684.5326
919.684.8885

www.biochem.duke.edu

Duke University Medical Center

Meta J. Kuehn, PhD
Associate Professor of Biochemistry
Associate Professor of Molecular Genetics and Microbiology

April 25, 2013

Elizabeth DeLong, PhD
Director, Biostatistics Core
Professor and Chair, Department of Biostatistics and Bioinformatics
Co-director, Outcomes Research and Assessment Group, Duke Clinical Research Institute
Duke University Medical Center
Durham, NC 27710

Dear Liz

The Duke PhD program in Cell and Molecular Biology is very happy to support your initiative to establish a much-needed PhD program in Biostatistics. We also believe that your requirement of a six credit cognate outside of Biostatistics will be quite useful to the student.

I understand that you anticipate enrolling no more than 4 PhD students in any year and these will be distributed among several potential cognate programs. As DGS for the CMB program, I welcome your PhD students to take any of our courses for which they have the required background. I will be glad to work with you and your individual students to ensure that they enroll in the most beneficial combination of courses.

Sincerely,

Meta Kuehn, PhD
Director of Graduate Studies,
Cell and Molecular Biology Training Program

DUMC 3711 • DURHAM, NORTH CAROLINA • 27710
mkuehn@biochem.duke.edu • Phone: (919) 684-2545 • Fax: (919) 684-8885

DUKE GLOBAL HEALTH INSTITUTE

April 25, 2013

Dear Liz,

As you know, we at Global Health are very supportive of your proposal to offer a PhD program in Biostatistics. In fact, we have multiple collaborations with faculty in your department and understand the increasing demand for such quantitatively trained individuals.

We are also happy to know that you have proposed a cognate program in Global Health. Your students are certainly welcome to take any of our courses. I will be glad to work with you and Liz Turner, our primary collaborator in B&B, and students interested in Global Health to help select the most appropriate set of courses.

Sincerely,

Michael H. Merson, MD
Director, Duke Global Health Institute
Wolfgang Joklik Professor of Global Health

Duke Global Health Institute • Trent Hall • 310 Trent Drive • Durham, North Carolina 27708
Telephone: (919) 681-7760 • Facsimile: (919) 681-7748 • http://www.globalhealth.duke.edu/

DukeMedicine

Clinical Research Training Program
Department of Biostatistics and Bioinformatics

April 25, 2013

Elizabeth DeLong, PhD
Professor and Chair, Department of Biostatistics and Bioinformatics
Duke University Medical Center
Box 2721
Durham, NC 27710

Dear Dr. DeLong,

I am supportive of and enthusiastic about the proposed development of a PhD in Biostatistics program and the potential for collaborative endeavors between that program and the Clinical Research Training Program. Given that both programs will share the same departmental home, I believe there will some exciting cross-training opportunities for the programs to explore together.

As Director of the Clinical Research Training Program and a statistician myself, I am delighted that the proposed program will require coursework in a 'cognate' field complementary to, but outside of Biostatistics and believe this represents one of several particular strengths of the proposed program. There are multiple elective courses offered by our program (e.g., Research Management, Responsible Conduct of Research, Concepts in Comparative Effectiveness, Meta-analysis) that, I believe, will nicely complement the PhD curriculum and can be combined to serve as a 'clinical research' cognate program for interested PhD students. Students from the PhD program will be welcome to take any of our courses and I will be happy to work with the PhD program leadership and individual students to identify a series of courses that will provide the best fit for their interests.

Best Wishes,

Steven C. Grambow, PhD
Director, Clinical Research Training Program
Assistant Professor of Biostatistics and Bioinformatics
DUMC Box 2721
Durham, NC 27710
Email: steven.grambow@duke.edu
Work: (919) 684-1292

Dear Liz,

The Duke PhD program in Computational Biology and Bioinformatics is very happy to support your initiative to establish a much-needed PhD program in Biostatistics. We also believe that your requirement of a six credit cognate outside of Biostatistics will be quite useful to the student.

I understand that you anticipate enrolling no more than 4 PhD students in any year and these will be distributed among several potential cognate programs. As DGS for the CBB program, I welcome your PhD students to take any of our courses for which they have the required background. I will be glad to work with you and your individual students to ensure that they enroll in the most beneficial combination of courses.

Sincerely,

Scott C. Schmidler
Associate Professor of Statistical Science
and Computer Science
Director of Graduate Studies, Computational
Biology and Bioinformatics Program
Duke University

DUKE INSTITUTE FOR GENOME SCIENCES & POLICY

Duke Institute for Genome Sciences & Policy

Program in Computational Biology and Bioinformatics

Duke University
North Building,
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Durham, NC 27708

T 919-684-0881
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cbbdgs@duke.edu

APPENDIX B

Curriculum Overview and Course Information

CURRICULUM OVERVIEW

Core Courses
Foundational courses required of all full-time Master of Biostatistics students.

BIOSTAT 601: Introduction to Statistical Theory and Methods I (3 Credits)
BIOSTAT 602: Applied Biostatistics Methods I (3 Credits)
BIOSTAT 603: Introduction to the Practice of Biostatistics I (3 Credits)
BIOSTAT 604: Introduction to Statistical Theory and Methods II (3 Credits)
BIOSTAT 605: Applied Biostatistical Methods II (3 Credits)
BIOSTAT 606: Introduction to the Practice of Biostatistics II (3 Credits)
BIOSTAT 707: Statistical Methods for Learning and Discovery (3 Credits)
BIOSTAT 621: Introduction to Statistical Programming I (1 Credit)
BIOSTAT 622: Introduction to Statistical Programming II (1 Credit)
BIOSTAT 701: Biostatistics Practicum (1-3 Credits)

Master's Project
Completed during the second year of study, all full-time Master of Biostatistics students will complete a master's project to demonstrate their mastery of biostatistics.

BIOSTAT 720: Master's Project (6 Credits)

Elective Courses
Full-time Master of Biostatistics students will select five elective courses during the second year of study.

BIOSTAT 708: Clinical Trial Design and Analysis (2 Credits)
BIOSTAT 709: Observational Studies (2 Credits)
BIOSTAT 710: Statistical Genetics and Genetic Epidemiology (2 Credits)
BIOSTAT 713: Survival Analysis (2 Credits)
BIOSTAT 714: Categorical Data Analysis (2 Credits)
BIOSTAT 718: Analysis of Correlated and Longitudinal Data (2 Credits)
BIOSTAT 719: Generalized Linear Models (2 Credits)

COURSE PLANNING

Fall Semester:
BIOSTAT 601: Introduction to Statistical Theory and Methods I (3 Credits)
BIOSTAT 602: Applied Biostatistical Methods I (3 Credits)
BIOSTAT 603: Introduction to the Practice of Biostatistics I (3 Credits)
BIOSTAT 621: Introduction to Statistical Programming I (1 Credit)

Spring Semester:
BIOSTAT 604: Introduction to Statistical Theory and Methods II (3 Credits)
BIOSTAT 605: Applied Biostatistical Methods II (3 Credits)
BIOSTAT 606: Introduction to the Practice of Biostatistics II (3 Credits)
BIOSTAT 622: Introduction to Statistical Programming II (1 Credit)
During the second year of study, full-time Master of Biostatistics students will typically take two core courses, a set of elective courses, and receive credit toward the completion of the master's project. A typical sequence is as follows:

Fall Semester:
BIOSTAT 707: Statistical Methods for Learning and Discovery (3 Credits)
BIOSTAT 720: Master's Project (3 Credits)
BIOSTAT 701: Biostatistics Practicum (1-3 Credits)
Elective Courses (4 Credits)

Spring Semester:
BIOSTAT 720: Master's Project (3 Credits)
BIOSTAT 701: Biostatistics Practicum (1-3 Credits)
Elective Courses (6 Credits)

AY 2012-2013 CORE COURSE DESCRIPTIONS

BIOSTAT 601: Introduction to Statistical Theory and Methods I
This course provides a formal introduction to the basic theory and methods of probability and statistics. It covers topics in probability theory with an emphasis on those needed in statistics, including probability and sample spaces, independence, conditional probability, random variables, parametric families of distributions, sampling distributions, and the central limit theorem. Core concepts are mastered through mathematical exploration, simulations, and linkage with the applied concepts studied in BIOSTAT 604.

Prerequisite(s): 2 semesters of calculus or its equivalent (multivariate calculus preferred). Familiarity with matrix algebra is helpful.
Corequisite(s): BIOSTAT 602, BIOSTAT 603
Credits: 3

Primary Instructor Name: Barry Moser
Semester Offered: Fall
Day(s) of Week Offered: Monday and Wednesday
Start/End Time: 10:00 AM – 11:15 AM

BIOSTAT 602: Applied Biostatistical Methods I
This course provides an introduction to study design, descriptive statistics, and analysis of statistical models with one or two predictor variables. Topics include principles of study design, basic study designs, descriptive statistics, sampling, contingency tables, one- and two-way analysis of variance, simple linear regression, and analysis of covariance. Both parametric and non-parametric techniques are explored. Core concepts are mastered through team-based case

studies and analysis of authentic research problems encountered by program faculty and demonstrated in practicum experiences in concert with BIOSTAT 603. Computational exercises will use the R and SAS packages.

Prerequisite(s): 2 semesters of calculus or its equivalent (multivariate calculus preferred). Familiarity with matrix algebra is helpful.
Corequisites(s): BIOSTAT 601, BIOSTAT 603, BIOSTAT 621
Credits: 3
Primary Instructor Name: Andrew Allen
Semester Offered: Fall
Day(s) of Week Offered: Monday and Wednesday
Start/End Time: 11:30 AM – 12:45 PM

BIOSTAT 603: Introduction to the Practice of Biostatistics I
This course provides an introduction to biology at a level suitable for practicing biostatisticians and directed practice in techniques of statistical collaboration and communication. With an emphasis on the connection between biomedical content and statistical approach, this course helps unify the statistical concepts and applications learned in BIOSTAT 601 and BIOSTAT 602. In addition to didactic sessions on biomedical issues, students are introduced to different areas of biostatistical practice at Duke University Medical Center. Biomedical topics are organized around the fundamental mechanisms of disease from both evolutionary and mechanistic perspectives, illustrated using examples from infectious disease, cancer and chronic /degenerative disease. In addition, students learn how to read and interpret research and clinical trial papers. Core concepts and skills re mastered through individual reading and class discussion of selected biomedical papers, team-based case studies and practical sessions introducing the art of collaborative statistics.

Corequisite(s): BIOSTAT 601, BIOSTAT 602
Credits: 3

Primary Instructor Name: Cliburn Chan
Secondary Instructor Name: Gregory Samsa
Semester Offered: Fall
Day(s) of Week Offered: Tuesday and Thursday
Start/End Time: 11:45 AM – 1:00 PM

BIOSTAT 604: Introduction to Statistical Theory and Methods II
This course provides formal introduction to the basic theory and methods of probability and statistics. It covers topics in statistical inference, including classical and Bayesian methods, and statistical models for discrete, continuous and categorical outcomes. Core concepts are mastered through mathematical exploration, simulations, and linkage with the applied concepts studied in BIOSTAT 605.

Prerequisite(s): BIOSTAT 601 or its equivalent
Corequisite(s): BIOSTAT 605, BIOSTAT 606
Credits: 3

Primary Instructor Name: Kouros Owzar
Semester Offered: Spring
Day(s) of Week Offered: Tuesday and Thursday
Start/End Time: 10:30 AM – 11:45 AM

BIOSTAT 605: Applied Biostatistical Methods II
This course provides an introduction to study design, descriptive statistics, an analysis of statistical models with continuous, dichotomous and survival outcomes, with one or more predictor variables. Topics include mixed effects models, likelihood and Bayesian estimation, generalized linear models (GLM) including binary, multinomial and log-linear models, basic models for survival analysis and regression models for censored survival data, clustered data, and model assessment, validation and prediction. Both parametric and non-parametric techniques are explored. Core concepts are mastered through team-based case study and analysis of authentic research problems encountered by program faculty and demonstrated in practicum experiences in concert with BIOSTAT 606. Computational exercises use the R and SAS packages.

Prerequisite(s): BIOSTAT 602 or its equivalent
Corequisite(s): BIOSTAT 604, BIOSTAT 606, BIOSTAT 622
Credits: 3

Primary Instructor Name: Hussein Al-Khalidi
Semester Offered: Spring
Day(s) of Week Offered: Monday and Wednesday
Start/End Time: 2:00 PM – 3:15 PM

BIOSTAT 606: Introduction to the Practice of Biostatistics II
This course revisits the topics covered in BIOSTAT 603 in the context of high-throughput, high-dimensional studies such as genomics and transcriptomics. The course will be based on reading of both the textbook and research papers. Students will learn the biology and technology underlying the generation of “big data”, and the computational and statistical challenges associated with the analysis of such data sets. As with BIOSTAT 603, there will be strong emphasis on the development of communication skills via written and oral presentations.

Prerequisite(s): BIOSTAT 603
Corequisite(s): BIOSTAT 604, BIOSTAT 605
Credits: 3

Primary Instructor Name: Cliburn Chan
Secondary Instructor Name: Gregory Samsa
Semester Offered: Spring
Day(s) of Week Offered: Tuesday and Thursday
Start/End Time: 8:30 AM – 9:45 AM

BIOSTAT 707: Statistical Methods for Learning and Discovery
This course surveys a number of techniques for high dimensional data analysis useful for data mining, machine learning and genomic applications, among others. Topics include principal and independent component analysis, multidimensional scaling, tree based classifiers, clustering techniques, support vector machines and networks, and techniques for model validation. Core concepts are mastered through the analysis and interpretation of several actual high dimensional genomics datasets.

Prerequisite(s): BIOSTAT 601 through BIOSTAT 606, or their equivalents
Credits: 3

Primary Instructor Name: Kouros Owzar
Semester Offered: Fall
Day(s) of Week Offered: Tuesday and Thursday
Start/End Time: 10:30 AM – 11:45 AM

BIOSTAT 708: Clinical Trial Design and Analysis
Topics include early phase through late phase clinical trials, including two-stage, Simon's optimal design, parallel group, crossover, cluster randomized, and adaptive designs. Objectives such as endpoint selection, dose range, maximum tolerated dose, non-inferiority, surrogate outcomes, and safety will be considered. Methods for group sequential testing, will include fixed group sequential, O'Brien-Fleming, Pocock, one-sided, Tsiatis, Whitehead triangular and other tests. Wang method, repeated confidence intervals, and a range of related topics in monitoring trials.

Prerequisite(s): BIOSTAT 601 and BIOSTAT 604, or permission of the Director of Graduate Studies
Credits: 2

Primary Instructor Name: Bercedis Peterson
Semester Offered: Spring
Day(s) of Week Offered: TBA
Start/End Time: TBA

BIOSTAT 709: Observational Studies
Methods for casual inference, including confounding and selection bias in observational or quasi-experimental research designs, propensity score methodology, instrumental variables, and methods for non-compliance in randomized clinical trials.

Prerequisite(s): BIOSTAT 601 and BIOSTAT 602, or permission of the Director of Graduate Studies
Credits: 2

Primary Instructor Name: Kevin Anstrom
Secondary Instructor Name: Carl Pieper

Semester Offered: Spring
Day(s) of Week Offered: TBA
Start/End Time: TBA

BIOSTAT 710: Statistical Genetics and Genetic Epidemiology
Topics from current and classical methods for assessing familality and heritability, linkage analysis of Mendelian and complex traits, family-based and population-based association studies, genetic heterogeneity, epistasis, and gene-environmental interactions. Computational methods and applications in current research areas. The course will include a simple overview of genetic data, terminology, and essential population genetic results. Topics will include sampling designs in human genetics, gene frequency estimation, segregation analysis, linkage analysis, tests of association, and detection of errors in genetic data.

Prerequisite(s): BIOSTAT 601 and BIOSTAT 604, or permission of the Director of Graduate Studies
Credits: 2

Primary Instructor Name: Andrew Allen
Semester Offered: Spring
Day(s) of Week Offered: TBA
Start/End Time: TBA

BIOSTAT 713: Survival Analysis
Introduction to concepts and techniques used in the analysis of time to event data, including censoring, hazard rates, estimation of survival curves, regression techniques, applications to clinical trials. Interval censoring, informative censoring, competing risks, multiple events and multiple endpoints, time dependent covariates; nonparametric and semi-parametric methods.

Prerequisite(s): BIOSTAT 601 and BIOSTAT 604, or permission of the Director of Graduate Studies
Credits: 2

Primary Instructor Name: Yuliya Lokhnygina
Semester Offered: Fall
Day(s) of Week Offered: Tuesday and Thursday
Start/End Time: 3:00 PM – 4:15 PM

BIOSTAT 714: Categorical Data Analysis
Topics in categorical modeling and data analysis/contingency tables; measures of association and testing; logistic regression; log-linear models; computational methods including iterative proportional fitting; models for sparse data; Poisson regression; models for ordinal categorical data, and longitudinal analysis.

Prerequisite(s): BIOSTAT 601, BIOSTAT 602, BIOSTAT 604, and BIOSTAT 605, or permission of the Director of Graduate Studies

Credits: 2

Primary Instructor Name: Herbert Pang
Semester Offered: Fall
Day(s) of Week Offered: Monday and Wednesday
Start/End Time: 10:15 AM – 11:05 AM

BIOSTAT 718: Analysis of Correlated and Longitudinal Data
Topics include linear and nonlinear mixed models; generalized estimating equations; subject specific versus population average interpretation; and hierarchical model.

Prerequisite(s): BIOSTAT 601, BIOSTAT 602, BIOSTAT 604, and BIOSTAT 605, or permission of the Director of Graduate Studies
Credits: 2

Primary Instructor Name: Paramita Saha Chaudhuri
Secondary Instructor Name: Maragatha Kuchibhatla
Semester Offered: Spring
Day(s) of Week Offered: TBA
Start/End Time: TBA

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

Prerequisite(s): BIOSTAT 601, BIOSTAT 602, BIOSTAT 604, and BIOSTAT 605, or permission of the Director of Graduate Studies
Credits: 2

Primary Instructor Name: Andrzej Kosinski
Semester Offered: Fall
Day(s) of Week Offered: Tuesday and Thursday
Start/End Time: 1:30 PM – 2:45 PM

BIOSTAT 720: Master's Project
Completed during a student's final year of study, the master's project is performed under the direction of a faculty mentor and is intended to demonstrate general mastery of biostatistical practice.

Prerequisite(s): BIOSTAT 601 through BIOSTAT 606
Corequisite(s): BIOSTAT 607
Credits: 6

BIOSTAT 621: Introduction to Statistical Programming I
This class is an introduction to programming, targeted at statistics majors with minimal programming knowledge, which will give them the skills to grasp how statistical software works, tweak it to suit their needs, recombine existing pieces of code, and when needed create their own programs. Students will learn the core of ideas of programming — functions, objects, data structures, input and output, debugging, and logical design — through writing code to assist in numerical and graphical statistical analyses. Students will learn how to write maintainable code, and to test code for correctness. They will then learn how to set up stochastic simulations and how to work with and filter large data sets. Since code is also an important form of communication among scientists, students will learn how to comment and organize code to achieve reproducibility. The class will be taught in both the SAS and R language. Programming techniques and their application will be closely connected with the methods and examples presented in the co-requisite courses.

Corequisite(s): BIOSTAT 602
Credits: 1

Primary Instructor Name: Megan Neely
Semester Offered: Fall
Day(s) of Week Offered: Thursday
Start/End Time: 9:00 AM – 10:15 AM

BIOSTAT 622: Introduction to Statistical Programming II
This class is an introduction to programming, targeted at statistics majors with minimal programming knowledge, which will give them the skills to grasp how statistical software works, tweak it to suit their needs, recombine existing pieces of code, and when needed create their own programs. Students will learn the core of ideas of programming — functions, objects, data structures, input and output, debugging, and logical design — through writing code to assist in numerical and graphical statistical analyses. Students will learn how to write maintainable code, and to test code for correctness. They will then learn how to set up stochastic simulations and how to work with and filter large data sets. Since code is also an important form of communication among scientists, students will learn how to comment and organize code to achieve reproducibility. The class will be taught in both the SAS and R language. Programming techniques and their application will be closely connected with the methods and examples presented in the co-requisite courses.

Corequisite(s): BIOSTAT 605
Credits: 1

Primary Instructor Name: Megan Neely
Semester Offered: Spring
Day(s) of Week Offered: Monday

Start/End Time: 11:45 AM – 1:00 PM

BIOSTAT 701: Biostatistics Practicum
To provide an opportunity to gain practical experience, using acquired competence in statistical analysis, the fundamentals of biology, and the skills of professional communication. This opportunity is used to assess and guide student initiative, leadership, decision-making, and accountability outside the classroom environment. These objectives can be met by an internship or another mechanism approved by the Director of Graduate Studies. This practicum may be continued through successive semesters, earning one credit per semester for up to three credits (credits may not be applied toward required elective credits). Credit amount is contingent upon approval by the Director of Graduate Studies as well as successful completion of the practicum experience.

Prerequisite(s): BIOSTAT 601 through BIOSTAT 606
Credits: 1-3

APPENDIX C

Formal review of the entirety of the Masters in Biostatistics program

November 12, 2012

Note: The curriculum review is limited to the first-year courses, as these are the courses that are being offered for a second, rather than a first, time. For the purposes of this review, the courses are being considered as sequences (e.g., the programming sequence). Its content is based on discussions with Ed Neal PhD, our curriculum consultant.

The reasons that we are evaluating the curriculum include the following:

- Our educational program should be consistent with its advertised program goals
- Our educational program should have a strong likelihood of producing the desired student outcomes
- We need to coordinate the MS and proposed PhD programs – for example, we need to decide whether our first-year MS courses will also be appropriate for PhD students

Our metrics for success include the following:

- Alignment of the curriculum with desired program goals
- Alignment of the curriculum with desired teaching methods
- Alignment of the curriculum with desired student outcomes

How the evaluation has been performed:

- Interviews with instructors
- Review of student performance (e.g., grades, qualifying examination)
- Student feedback

Note: Our program philosophy is one of active-learning-based education. Often, active-learning-based education de-emphasizes rote learning of facts through traditional lecture, and emphasizes active engagement with the material through simulations, group projects, applied problem sets, reports and discussion. Instructors replace “What materials should I cover?” with “What tasks do I expect my students should be able to perform?

Narrative (organized by course sequence):

Probability and mathematical statistics sequence (BIOS201&204):

PhD students in the statistics department are responsible for two sequences of courses on statistical inference. (For the present purposes, a statistical inference sequence is the same as a probability and mathematical statistics sequence.) The first sequence is basic but reasonably thorough, and is taken as an advanced undergraduate. The second sequence is more advanced (e.g., taught from a measure-theoretic perspective), and is usually taken in the first year of graduate school.

Our first-year core sequence is roughly equivalent to the advanced undergraduate sequence taken by students in the statistics department. It is sufficient for students having a terminal masters' degree. It would also adequately prepare our second-year doctoral students to take the first-year inference sequence in the Department of Statistics. Our doctoral students would take that sequence of courses during their second year.

In general, it appears that our current first-year inference sequence won't require significant modification to deliver to doctoral students. Possible modifications are a modest increase in the level of difficulty of the problem sets, and perhaps by moving up one level in textbook (e.g., from Bain & Englehart to Casella & Berger). Separate curricula, separate examinations, and other more substantial changes won't be required.

On the surface, both BIOS201 and BIOS204 are traditional lecture-based courses, covering a standard sequence of material at the level of Bain & Englehart. For example, BIOS201 covers the first 6 chapters of Bain & Englehart, including topics such as probability, random variables, distributions, expectation, moment generating functions and the distribution of functions of random variables.

In reality, however, there is considerable congruence between the teaching methods used in this course sequence and the principles of active-learning-based education. Most notably, both courses are heavily problem-based. Moreover, the assignments and testing are organized in a way that strongly encourages students to keep up with working the problems, and to provide immediate feedback on performance. In

BIOS201, Dr. Moser gives weekly assignments (typically, 10 problems from the end of the chapter) and provides meticulous comments. (He also gives 2 mid-term examinations and a final examination). Dr. Moser also provides practice in how to frame problems – often, using examples from clinical trials.

In BIOS204, Dr. Owzar also assigns numerous problem sets. Lecture notes are provided, and are viewed as a way of working around some of the deficiencies of the text (Bain & Englehart). Although a solid mathematical foundation is assumed (e.g., students need to be familiar with epsilon-delta arguments and definitions of limits), BIOS204 is also designed things in a way to make remediation possible.

The course organization of BIOS204 is designed to ensure that students don't fall behind. Quizzes are provided soon after material is encountered, and much of it is verbatim from what is covered in class. Indeed, including more problems that require applying the course content would probably be helpful, as this could provide a better picture of the facility that students actually have with the material. The grading scale equally weights homework, quizzes, technical reports, a midterm exam and a final exam (these exams being approximately weighted as 60% on previously encountered material, 20% on straightforward extensions of that material, and 20% on more challenging problems).

The instructional method is noteworthy in that the assignments include are two 5-page technical reports on a statistical topic (e.g., the EM algorithm), including an introduction, methods, results, and discussion. These provide directed practice in communicating fundamental concepts of statistical methodology, and would also provide experience in creating the technical appendices that often supplement manuscripts on more applied topics. Such technical reports are unusual for inference courses, a wonderful idea, and something from which other active-learning-based exercises might be based.

Applied data analysis sequence (BIOS202 & 205):

The applied data analysis sequence has a heavy emphasis on comprehension through active exposure to the course materials. The topics are relatively standard. In BIOS202, Dr. Allen starts from square 1 and covers the usual content up to multi-predictor models, for example: central tendency; measures of association; distinction between population and sample; 1- and 2-sample estimation and testing in parametric

and non-parametric contexts; the central limit theorem; analysis of count data using contingency tables and Poisson regression; simple linear regression; and Kaplan-Meier curves and the log-rank test. There is a heavy emphasis on developing an intuitive motivation for the statistical methods in question, and derivations are included. Almost all the methods are illustrated in both R and SAS. Simulation is used to help develop intuition – examples of simulation exercises include a bootstrapping assignment and a permutation test assignment.

Grades are assigned based on weights of 50% weekly quizzes, 30% homework, and 20% final exam. The homework assignments are intended to also offer practice in written communication skills – for example, in producing project reports with introduction, methods, results and conclusions sections. Lecture notes are used rather than a textbook. For the homework assignments students are encouraged to work in groups, but must write up the results on their own.

As with many of the other core courses, the regimented nature of the quizzes and homework assignments is intended to maintain student engagement, and also to identify problems with student performance as early as possible.

In BIOS205, Dr. Al-Khalidi follows roughly the same philosophy. Grades are assigned based on weights of 20% for weekly quizzes, 25% for the mid-term exam, 15% for homework, and 40% for the final exam. The instructor tends to be lenient in grading the quizzes – getting something wrong once isn't a problem but getting something wrong twice is. Students are encouraged to work in groups but write things up on their own. The homework has a standard reporting format (e.g., including a description of the analyses, the results of the analyses, and the interpretation of the results). SAS is used mostly but not entirely. Lecture notes are used rather than a textbook.

Course content is organized around a full-rank matrix-based perspective on linear models, and includes multiple regression, variable selection, 1-way analysis of variance (from a cell viewpoint), 2-way analysis of variance, analysis of covariance, and GLIM (e.g., including logistic regression and proportional odds). There is considerable emphasis on using matrix algebra to develop intuition for simple designs, which is then extended forward to more complicated cases.

PhD students entering with a MS in statistics (or similar training) could probably place out of the applied analysis sequence – otherwise, given its emphasis on comprehension and communication through technical reports, it would probably be valuable for PhD students to take the courses with little or no modification. One idea (equally applicable to the inference sequence) would be to have the first-year masters' qualifying exam also serve as a competency test for doctoral students that wish to place out of first-year courses. Doctoral training should include one additional linear models courses, perhaps taught at a greater level of methodological sophistication than our current second-year electives.

Biology and communication sequence (BIOS203 & 206):

A draft manuscript provides additional detail about this course sequence. Briefly, it is a 3-credit course, taught in two 75-minute sessions per week. The main goals are to teach students to:

- Discuss biology with investigators
- Discuss statistics with investigators
- Finally, to integrate the two

The biological content combines a moderate level of technical sophistication (e.g., detailed knowledge of biochemistry is not required when studying various biological pathways) with a deeper exposure to unifying concepts such as evolution. This training is intended to, among others: (a) put the student in a position to read the medical literature with confidence; and (b) effectively discuss biomedical content with biomedical researchers, statistical colleagues, and others. The statistical content is a systematic treatment of the "art" of statistics – for example, how to design a study, how to formulate an analysis plan, how to interview an investigator, etc.

The presentation of the course content is very much in the style of active-learning based education. Many of the assignments – for example, to formulate responses to the study questions that accompany the day's readings – are first performed individually but processed at the level of the group. Much of the biological content is transmitted by the students in 10-minute PowerPoint presentations. Much of the statistical content involves writing followed by group discussion.

In response to previous student comments, the organization of the class is much more systematic than last year. Also, more of the assignments have been shifted from the

level of the entire class to the level of the work group. The instructors have been quite encouraged by the quality of the student presentations, and also from comments from the previous class of students about how the course content was helpful during their internships.

This course sequence can probably be maintained, as is, for doctoral students.

Programming sequence (BIOS221 & 222):

This is currently a 1-credit course sequence, taught for 1 hour per week. There are 3 main goals.

1. To teach basic proficiency in SAS and R, these skills being key to successful employment after graduation (and also a fruitful internship experience)
2. To teach basic programming ideas (e.g., modularization)
3. To support the applied data an analysis sequence by providing just-in-time information about programming techniques for assignments (e.g., how to perform a bootstrap simulation exploring the robustness of a regression model)

The primary instructional technique is lecture/demonstration during class time, with self-study assignments of increasing difficulty used as homework. Group collaboration is encouraged. The instructional technique is somewhat based on principles of active learning, mostly because of the high level of engagement that students (and groups of students) have with the material.

During orientation week we verify that students have been able to load SAS and R onto their laptop computers.

The programming course begins with an orientation to SAS and R, which is intended to train students to perform basic tasks. It is important that students quickly learn to perform basic tasks in either language, because assignments in their first semester courses use both SAS and R.

Once the basics are completed, the course is divided into an R module and a SAS module. The R module focuses on writing (and using) R functions to perform analytical tasks such as simulations, graphics, and coding of statistical algorithms. The SAS module focuses on data management tasks such as restructuring data sets. Both modules provide practice in applying good programming principles (e.g., modularization) and are intended to provide instruction in how to think about programming in addition to the technical details of coding. Both modules also utilize principles of reproducible programming.

The programming sequence is new, and represents a significant upgrade from last year's programming seminar, which was (among others) less structured.

Whether the programming sequence should be further upgraded – for example, to a 2- or 3-credit course – is an open question (and for which experience with the current course should provide guidance). Of particular importance is the need to provide SAS training at the level of SAS's proficiency testing, as this would enhance the job prospects of our graduates. Developing a detailed competency test to be given at the conclusion of the course would assist in the assessment of competency.

The course sequence intends to combine "higher-level training" in software engineering (i.e., how to think about organizing and documenting a program) with the more mundane tasks of providing just-in-time instruction required to complete assignments from other courses (especially those from the applied data analysis sequence). The integration of these two goals will benefit from tighter collaboration among the course instructors.

Our tentative assessment is that the current course sequence would be adequate (entirely or substantially) for the first two years of doctoral study, but would then need to be supplemented by additional training in "computing", which could include topics such as the technical details of how to perform analyses of large data sets and how to address precision in computationally-intense algorithms.

Outcome metrics:

- Alignment of the curriculum with desired program goals (by sequence)
    - Biology and communication: As two of the three core competencies in the program are biological knowledge and communication skill, the course content is integral to the curriculum.
    - Programming: This sequence is well-aligned with the overall program goals. It will be helpful to determine the degree to which our students would benefit from becoming formally credentialed in SAS, and whether any additional content would be required to obtain those credentials.
    - Probability and mathematical statistics sequence: This sequence provides the intellectual underpinnings of the applied data analysis sequence, and thus is well-aligned with the overall program goals.
    - Analytical methods: This sequence is directed toward the analytical competency, and thus is integral to the curriculum.

- Alignment of the curriculum with desired teaching methods (by sequence)
    - Biology and communication: This sequence is well-aligned with our advertised emphasis on active-learning-based education. It might be noted that these topics are particularly amenable to an active-learning based approach, and that the other core course sequences need not be taught in the same manner to be consistent with the program's core educational principles.
    - Programming: This sequence is reasonably albeit not perfectly aligned with the tenets of active-based learning. A well-designed set of self-study assignments, perhaps designed to develop mastery in content areas that can't be addressed during limited class time, would be consistent with those tenets.
    - Probability and mathematical statistics sequence: This sequence is reasonably aligned with the tenets of active-based learning – especially, their emphasis on learning from solving numerous (albeit standard) problems. The technical reports are a wonderful idea, which might be expanded. Class structure might be expanded beyond the traditional lecture format.
    - Analytical methods: This sequence is well-aligned with the tenets of active-based learning. Class structure might be expanded beyond the traditional lecture format.

- Alignment of the curriculum with desired student outcomes (by sequence)
    - Biology and communication: Although following more quantitative metrics will be helpful in the future, the student outcomes to date have been highly encouraging.
    - Programming: An evaluation of the current version of the course is premature. However, the current version does represent a reconceptualization of a previous seminar that did not produce student proficiency in data management at a level that the program desired.
    - Probability and mathematical statistics: The first-year student evaluations were particularly favorable in their assessment of the dedication and energy that the instructors put into their teaching. Most students appear to be learning as desired, but there are exceptions. The one student that dropped out of the program failed BIOS201. The one student that failed a portion of the qualifying exam failed the BIOS201/204 portion. Perhaps helpful could be an increased emphasis on early skills testing and remediation.
    - Analytical methods: The first-year student evaluations were quite positive. Students tended to do well on the qualifying exam. Students also noted that this sequence helped to prepare them for their internship.

Action items:

Biology and communication:

- Develop more quantitative assessment metrics.
- Revise and submit a manuscript describing the course (this will contribute toward the goal of becoming recognized as a leader in statistical education).

Programming:

- Develop a more detailed syllabus that includes a list of the programming techniques that we wish students to master.
- Compare this list against, for example, the content of the SAS credentialing tests.
- Develop competency tests for SAS and R.

Probability and mathematical statistics:

- More of the assignments might be upgraded to be more challenging – for example, to include elements of problem framing.
- Consider whether a TA could assist in grading.
- Experiment with alternatives to the traditional lecture format.

Applied data analysis:

- BIOS205 would benefit from a TA to assist in grading.
- Experiment with alternatives to the traditional lecture format.

General:

- Develop a map of the overall curriculum

APPENDIX D

Curriculum mapping among competing programs, with reference to B&B proposed PhD program

B&B	UNC	HARVARD	U of WASHINGTON	JOHNS HOPKINS@	U of MICHIGAN
Intro Probability	Prob and Stat Inf I	Probability theory I	Stat Inference***	2-yr theory sequence	Prob and Dist Theory
Intro Biostat Methods	Intermed Stat Meth	Methods I	Biostatistics I	2-yr methods seq	Appl stat I: Lin Regr
Biostat Practice (bio and communication)					Biostatistical Investigations@@
Intro stat computing	Intro stat comput			Statistical computing	
Problems – seminar			Seminar (9 quarters)		
Intro Inference	Prob and Stat Inf II	Stat inference I	Stat Inference***	2-yr theory sequence	Biostat Inference
Intro Methods II	Intermed Lin Models	Methods II	Biostatistics II	2-yr methods seq	
Biostat Practice II					
Stat computing II					
Problems - seminar			Seminar (9 quarters)		
Advanced Probability	Advanced probability and inference	Probability theory and applications II*	Advanced theory of statistical Inference**	2-yr theory sequence	Math stat I
Theory of Linear Models	Theory of Linear Models	Regression and Analysis of Variance*	Theory of Linear Models		
Categorical data			Advanced methods Independent data		
Methods for learning and discovery (novel)					
Problems – seminar	Seminar		Seminar (9 quarters)		
Advanced Inference	Advanced probability and inference II	Statistical Inference II*	Advanced theory of statistical inference**		Math Stat II
Survival analysis	Survival analysis	Failure time data*			
Correlated and Longitudinal	Longitudinal Data Analysis	Multivariate and longitudinal*	Advanced methods dependent data		ANOVA and linear mixed models
Problems – seminar	Seminar		Seminar (9 quarters)		
Advanced inference					

*Harvard requires 4 of 6 courses, 5 of which are analogous to those included in our core requirements

** U of Washington is on quarter system and requires 3 quarters of this named course; **Taught by U of Washington Stat Dept

@ Hopkins is on quarter system and courses have generalized names that are difficult to map

@@ The one course among the five programs that is most similar to our Practice of Biostatistics; it is more concerned with statistical problems than biology

Core requirements not among B&B core requirements

B&B	UNC	HARVARD	U of WASHINGTON	JOHNS HOPKINS	U of MICHIGAN
Biostatistics courses					
B&B Elective	Generalized linear models		Regression modeling project		Generalized linear models
	12 credits upper level Bios courses		6 additional credits Bios courses		15 additional credits Bios courses
	Stat consulting	Consulting seminar	Stat consulting		
	Stat teaching				
	Applied Longitudinal Data Analysis				Advanced Calculus
	Applied Survival				Stochastic processes
Other courses					
	Principles of Epi for Public Health or Fundamentals of Epi	Epidemiologic Methods I or Fundamentals of Epi	9 credits selected from epidemiology list	Principles of Epidemiology	Strategies and Uses of Epidemiology or Principles and Methods of Epidemiology
				Intro to biomedical sciences	
				Public Health Perspectives on Research	

Additional core requirements

B&B	UNC	HARVARD	U of WASHINGTON	JOHNS HOPKINS	U of MICHIGAN
6 credits supporting program	6 credits supporting program	10 credits in a cognate field		18 credits outside the primary department	9 hours in a cognate area
		TA one course per year			

All programs require a course in responsible conduct of research

APPENDIX E

Biostatistics Graduate Program

Description	FY14 BUDGET	FY15	FY16	FY17	FY18	FY19	FY20	FY21
M.B. Tuition and Fees	(1,435,540)	(1,396,270)	(1,458,730)	(1,487,814)	(1,517,480)	(1,547,740)	(1,578,830)	(1,610,312)
Biostat Scholarships - M.B.	273,000	220,000	180,000	150,000	150,000	150,000	150,000	150,000
PhD Tuition and Stipends - PhD 2nd yrs	0	0	175,084	178,585	182,157	232,250	236,895	193,307
PhD Tuition and Stipends - PhD 3+ yrs	0	0	0	200,000	200,000	200,000	200,000	200,000
Operating								
Teaching & course development effort	388,305	414,718	430,433	436,261	442,207	464,021	470,206	476,515
Director of Graduate Studies	62,809	53,810	54,887	55,984	57,104	58,246	59,411	60,599
Program Administration	60,161	66,897	67,961	69,046	70,153	71,282	72,434	73,609
Academic Retreat	0	3,000	4,000	5,000	6,000	7,000	7,000	7,000
Other Operating	131,275	131,000	131,000	131,000	131,000	131,000	132,120	133,262
G&A	19,277	20,083	20,648	20,919	21,194	21,946	22,235	22,530
SOM Space:	92,923	94,781	96,677	98,611	100,583	102,595	104,646	106,739
Contribution to B&B Basic Operations	31,010	75,667	128,936	150,000	150,000	150,000	150,000	150,000
Expenditures	1,058,760	1,079,957	1,289,625	1,495,407	1,510,398	1,588,341	1,604,948	1,573,561
Operating Variance	(376,780)	(316,313)	(169,104)	7,593	(7,083)	40,601	26,118	(36,751)

Biostatistics Education Program Reserve 4310052								
Beginning Balance	(301,659)	(649,712)	(966,024)	(1,135,128)	(1,127,536)	(1,084,618)	(1,044,018)	(1,017,899)
Revenues								
Expenses/(Credits)	24,250				50,000			
Transfers In								
Transfers Out	3,750							
Operating Variance -/(+)	(376,780)	(316,313)	(169,104)	7,593	(7,083)	40,601	26,118	(36,751)
G&A	728							
Repay CRTP								
Ending Balance	(649,712)	(966,024)	(1,135,128)	(1,127,536)	(1,084,618)	(1,044,018)	(1,017,899)	(1,054,650)

APPENDIX F

Graduate Faculty

Faculty Member	Tenure status	Rank	Role in program T=Currently teaching A=Dissertation Advisor C=PhD committee	Number of students as Dissertation Advisor	Number of PhD Committees	Notes	Years at Duke
Al-Khalidi, Hussein	NT	Assoc	T, A, C		7	Came from Industry, but served on Dissertation Committees at University of Cincinnati College of Pharmacy	3
Allen, Andrew	Tenured	Assoc	T, A, C	2	1	Has also supervised two postdocs: Min He (Assistant professor, Duke Center for Human Genome Variation) Chuanhua Xing (Assistant professor, Boston University)"	11
Anstrom, Kevin	NT	Assoc	T, A, C				15
Barnhart, Huiman	Tenured	Full	A, C	4	8	Huiman was a tenured faculty member at Emory prior to coming to Duke	9
Chan, Cliburn	NT	Asst	T, A, C	1	5	Two postdocs: Adam Richardson and Darongsae Kwon; also supervises two scientific programmers working on his research	8
Choudhury, Kingshuk	NT	Assoc	A,C	4	2	Supervised one postdoc: Jian Huang, currently at UCC, Ireland	2
Chow, Shein-Chung	NT	Full	A, C	1	5	Has written several statistics textbooks and supervised several post-docs	7
DeLong, Elizabeth	Tenured	Full	A, C – Director of Admissions	1			33
Engelhardt, Barbara	TT	Asst	A,C	3	5	Also directing 2 post-docs	1
Erkanli, Alaattin	NT	Assoc	A,C				21
Halabi, Susan	Tenured	Full	A, C		1		16
Hauser, Elizabeth	NT	Full	A,C	4	9	Member of Center for Human Genetics	15
Jung, Sin-Ho	Tenured	Full	A,C			Mentored a postdoc investigator, Insuk Sohn, for 3 years. He is working as a bioinformatician at Samsung Medical Center in Korea.	11

Faculty Member	Tenure status	Rank	Role in program T=Currently teaching A=Dissertation Advisor C=PhD committee	Number of students as Dissertation Advisor	Number of PhD Committees	Notes	Years at Duke
Koch, Allison	NT/secondary	Full	A,C	2	3	Member of Center for Human Genetics	15
Kosinski, Andrzej	TT	Assoc	T, A, C	2	7	Andrzej was a tenured faculty member at Emory prior to coming to Duke	9
Kuchibhatla, Maggie	NT	Assoc	T,C				19
Li, Yi-Ju	NT	Assoc	A, C	1	3		12
Li, Zhiguo	NT	Asst	T,A,C				2
Lokhnygina, Yuliya	TT	Asst	T,A,C				8
Moser, Barry	NT	Full	T,A,C	9	See note	I do not have a record of all of the graduate committees I served on as an advisor at Oklahoma State University. My estimate is that I served on one committee in the Statistics Department per year and one committee every other year in the Industrial Engineering Department for a period of 17 years.	10
Neelon, Brian	NT	Asst	A, C		1		3
Neely, Megan	NT	Asst	T, C				1
O'Brien, Sean	TT	Asst	A,C		1		8
Olsen, Maren	NT	Assoc	C				12
Owzar, Kouros	NT	Assoc	T,A,C		3	Supervisor of two post-docs: Faheem Mitha Ivo Shterev	10
Pang, Herbert	TT	Asst	T, A, C			Senior Research Associate: Andrew Dellinger, PhD; Post-doc: Ace Hatch, PhD	4

Faculty Member	Tenure status	Rank	Role in program T=Currently teaching A=Dissertation Advisor C=PhD committee	Number of students as Dissertation Advisor	Number of PhD Committees	Notes	Years at Duke
Pencina, Michael		Full	T, A, C	2	7	**Michael Pencina** has been appointed a Professor in the Department of Biostatistics and Bioinformatics at Duke University's School of Medicine and Director of Biostatistics at Duke Clinical Research Institute, commencing in June 2013. Supervised 3 postdocs.	See Notes
Peterson, Bercedis	NT	Assoc	T				28
Pieper, Carl	NT	Asst	T, C				22
Saha Chaudhuri, Paramita	NT	Asst	T,A,C				1
Samsa, Greg	Tenured	Full	T, C - DGS				24
Turner, Liz	NT	Assistant	T, A, C				1
Wang, Xiaofei	NT	Assoc	A,C	1		Postdoctoral advisor Junling Ma (Shanghai University of Finance)	9
Woolson, Robert	Adjunct	Full	A,C	18	>30	Also directed a post-doctoral training program (T-32) at the University of Iowa for over 20 years and supervised multiple post-docs; currently working part-time at the VA and willing to take students	
Wu, Yuan	NT	Asst	A,C				0

Appendix G

Timeline

Upon entering the PhD program, each student will be assigned an initial advisor/mentor.

Typical First Year Schedule:

Fall semester	*Spring semester*
Probability (BIOSTAT 601)	**Statistical Inference (BIOSTAT 604)**
Biostatistical methods I (BIOSTAT 602)	**Biostatistical methods II (BIOSTAT 605)**
Biostatistical practice I (BIOSTAT 603)	**Biostatistical practice II (BIOSTAT 606)**
Intro to stat computing I (BIOSTAT 621)	**Intro to stat computing II (BIOSTAT 622)**
Problems in biostatistics - seminar	**Problems in biostatistics - seminar**

First Year Examination: At the end of the first year, all students take the methods examination. This exam covers topics spanning the range of core courses available during the first year and must be passed at a level sufficient to confirm the ability of the student in these core areas and, for the PhD student, their preparedness for progression to more advanced courses in the second year. As the material for the exam is taken from that covered in the first year courses, it is expected that students who successfully complete these courses will be well prepared for the exam.

First Year Debrief: At the end of the second semester and after the results from the methods exam are available, the student and their advisor will meet with the DGS to discuss the student's progress, experiences, and interests going forward in the program. This will be an opportunity for the student to both give and receive feedback. Strategies for dealing with areas of weakness will be discussed. The interests and future plans of the student will be explored. If these interests are not consistent with the expertise of their assigned advisor, a new advisor will be assigned. This discussion will also be used to gauge the student's likely course of study and will be used to inform the planning of future elective course offerings.

First Year Summer Research Experience: Students will be required to affiliate with program faculty for a directed research experience beginning the summer of their first year. The student's advisor and the DGS will assist in this process. Having participated in the Problems in Biostatistics seminar during the first year, the students will have been exposed to a range of problem areas, as well as the faculty members working in them, that can provide dissertation topics.

Typical Second Year Schedule:

Fall semester	*Spring semester*
Advanced Probability	**Advanced Statistical Inference**
Theory of linear models	**Generalized linear models (BIOSTAT 719)**
Categorical data analysis (BIOSTAT 714)	**Survival analysis (BIOSTAT 713)**
Statistical methods for learning and discovery (BIOSTAT 707)	**Analysis of correlated and longitudinal data (BIOSTAT 718)**
Problems in biostatistics -seminar	**Problems in biostatistics - seminar**

Second Year Research Experience: During the second year, students will complete two additional faculty directed research experiences (approximately one per semester).

Second Year PhD Theory Examination: At the end of the second year, PhD students take the theory examination. This exam covers topics spanning drawn from the second year core courses available and must be passed at a level sufficient to confirm the ability of the student's preparedness for conducting independent methodological research. Again, as the material for the exam is taken from that covered in the second year core, it is expected that students that successfully complete these courses will be well prepared for the exam.

Second Year Debrief: At the end of the second year and after the results from the theory exam are available, the student and their advisor will meet with the DGS to discuss the student's progress. The interests and future plans of the student will be explored including the likely direction of their research program and courses or experiences needed to round out their education.

Third Year PhD Program (and beyond): During the third year PhD students begin to specialize, acquiring the tools and techniques required for their chosen area of expertise. The student, with counsel from the DGS, will also select a primary dissertation advisor (if not selected earlier) and a dissertation committee. One member of the student's committee will be either a clinical or a basic science investigator with expertise in subject matter relevant to the dissertation. With an advisor selected and a dissertation topic identified, the student and their advisor (with oversight/approval from the DGS) in collaboration with the DGS of the cognate program, will design and implement a cognate program designed to give the student additional background in a substantive area relevant to the students research topic. Since the program is tailored to the needs and career goals of each student, the exact program will differ for each student.

Typical Third Year Schedule (required courses in bold):

Fall semester	*Spring semester*
Advanced topics in inference	Elective
Elective	Elective
Interdisciplinary elective	Interdisciplinary elective
Problems in biostatistics	**Problems in biostatistics**

Preliminary Examination: During the third year, PhD candidates will submit a short written manuscript on the research area to be presented and discussed at the exam, and which will usually be in their anticipated area of thesis research. Successful completion of the Exam qualifies the student as a PhD candidate in Biostatistics.

Yearly Debrief: Each year the student will meet with the student's committee to discuss progress, as described above, with increasing emphasis on the supporting program and the dissertation.

The final oral: The student will present his/her thesis work at a seminar that will serve as the final oral, after which the student's committee will vote to pass the student or to require additional work. Because of the review time (up to two years) involved for some statistical journals, the student will not be required to have the thesis published prior to being approved. However, it is expected that the student will have at least one draft statistical manuscript ready for submission by this time. Additionally, students should have one or more collaborative publications published or in press.

VI.0 New Course Offerings

Current problems in biostatistics (to be developed). Advanced seminar on topics at the research frontiers in biostatistics. This course is comprised of readings of current biostatistical research and presentations by faculty and advanced students of current research in their area of specialization. Required by all PhD students. Course instructor: rotating

Probability and Measure Theory (**Sta 711 or developed de novo**). Introduction to probability spaces, the theory of measure and integration, random variables, and limit theorems. Distribution functions, densities, and characteristic functions; convergence of random variables and of their distributions; uniform integrability and the Lebesgue convergence theorems. Weak and strong laws of large numbers, central limit theorem. Prerequisite: elementary real analysis and elementary probability theory.
Prerequisites: Real Analysis. Instructor: TBD

Statistical Inference (Sta 732 or developed de novo) Classical, likelihood, and Bayesian approaches to statistical inference. Foundations of point and interval estimation, and properties of estimators (bias, consistency, efficiency, sufficiency, robustness). Testing: Type I and II errors, power, likelihood ratios; Bayes factors, posterior probabilities of hypotheses. The

predictivist perspective. Applications include estimation and testing in normal models; model choice and criticism. Prerequisites: STA 611 and STA 721 or equivalent. Instructor: Li, Wolpert

Theory of Linear Models (Sta 721 or developed de novo). Multiple linear regression and model building. Exploratory data analysis techniques, variable transformations and selection, parameter estimation and interpretation, prediction, Bayesian hierarchical models, Bayes factors and intrinsic Bayes factors for linear models, and Bayesian model averaging. The concepts of linear models from Bayesian and classical viewpoints. Topics in Markov chain Monte Carlo simulation introduced as required. Prerequisite: Statistics 213 and 290 or equivalent. Instructor: Clyde

Advanced topics in modern inferential techniques and theory. This course provides an introduction to topics that form the theoretical foundation of modern biostatistics and the inferential techniques for solving contemporary biostatistical problems. It covers topics in stochastic processes, weak convergence, semiparametric models and probability limit theory with an emphasis on those needed in biostatistics. Specific topics include stochastic processes, random walks, Markov chains, martingales, counting processes, Hilbert spaces for random vectors, semiparametric models, geometry of efficient score functions and efficient influence functions, the functional delta method, and the theory for M- and Z- estimators. Throughout, the presented theoretical results will be illustrated through application to real problems encountered during the faculty's research. Additional topics including weak convergence and an overview of basic techniques in empirical process theory will be covered. This course provides students a 'tool chest' of advanced techniques for dealing with modern inferential problems. After completing this course, students will be well prepared for the inferential component of dissertation research. Prerequisites: Probability and measure theory (STAT 711) and statistical inference (STAT 732). Course instructor: Dr. Zhiguo Li

APPENDIX H

Curriculum Vitae of Faculty

Who Will Participate In the Program

(CVs start on next page)

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Hussein R Al-Khalidi, PhD	Associate Professor of Biostatistics
eRA COMMONS USER NAME (credential, e.g., agency login) hushki	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Mustansiriyah University, Baghdad, Iraq	B.S.	06/75	Statistics
Baghdad University, Baghdad, Iraq	M.S.	08/77	Statistics
Texas A&M University, College Station, Texas	Ph.D.	08/88	Statistics

A. Personal Statement

Over the past 25 years, I have been actively conducting research in area of innovative statistical methodology, teaching graduate courses in statistics, serving on graduate thesis committees, developing curriculums, mentoring and serving on departmental committees. For the past 20 years, my main research focus has been on statistical methodology applications to medical sciences and especially to large cardiovascular clinical trials. In addition, I have 17 years of experience in applying innovated statistical methods to clinical trials with variety of composite and recurrent events endpoints. Over the years, I have been reviewer for several statistical and medical professional journals such as Communications in Statistics, Journal of the American Statistical Association, Journal of the American College of Cardiology, Journal of Biopharmaceutical Statistics, and Circulation.

B. Positions and Honors

Positions and Employment

1978-1982 Assistant Lecturer, Department of Statistics, Baghdad University, Baghdad, Iraq
1982-1985 Research Assistant, Department of Statistics, Texas A&M University, College Station, TX
1986-1988 Lecturer, Department of Statistics, Texas A&M University, College Station, TX
1988-1990 Assistant Professor, Department of Statistics, Baghdad University, Baghdad, Iraq
1990-1991 Visiting Research Associate, University of Texas at Tyler, Tyler, TX
1991-1993 Assistant Professor, Department of Epidemiology and Biostatistics, University of Illinois at Chicago, Chicago, IL
1993- Adjunct Associate Professor, College of Pharmacy, University of Cincinnati, Cincinnati, OH
1993-1997 Statistician, Department of Biometrics and Statistical Sciences, Procter & Gamble Pharmaceuticals, Cincinnati, OH
1997-2001 Senior Statistician, Department of Biometrics and Statistical Sciences, Procter & Gamble Pharmaceuticals, Cincinnati, OH
2001-2008 Principal Statistician, Department of Biometrics and Statistical Sciences, Procter & Gamble Pharmaceuticals, Cincinnati, OH
2009-2010 Director of Biostatistics, StatKing Consulting Inc., Cincinnati, OH
2010- Associate Professor, Dept. of Biostatistics and Bioinformatics, Duke University, Durham, NC

Professional Service

1993- Reviewer for Communications in Statistics, Journal of the American Statistical Association, Journal of the American College of Cardiology, American Heart Journal, Journal of Biopharmaceutical Statistics, and Circulation.
2007- Associate Editor, Journal of Biopharmaceutical Statistics.
2009-2010 Secretary/Treasurer, Cincinnati Chapter, American Statistical Association

Professional Memberships
American Statistical Association
Biometric Society
American Heart Association

Professional awards and special recognitions:
Graduate school scholarships from University of Baghdad and Texas A&M University.

C. Selected Peer-reviewed Publications

1. Al-Khalidi HR (1980). Some Notes on Kolmogorov-Smirnov (K-S) test with example. Journal of Economic and Administrative Research, vol. 8, No. 2, 319-330.
2. Al-Khalidi HR (1981). Some measures for stopping simulated war-game by using Lanchester model. Journal of Economic and Administrative Research, vol. 9, No. 1, 141-153.
3. Al-Khalidi HR and Hwang LJ (1991). Some pitfalls of tests of separate families of hypotheses: normality vs. lognormality. Communications in Statistics, Series A, A20, No. 8, 2505-2528.
4. Al-Khalidi HR and Parsa AR (1993). Some aspects of maximum likelihood estimation of multistage cancer dose-response models with application. Communications in Statistics, Series A, A22, No. 12, 3377-3392.
5. Holiday DB, Al-Khalidi HR and McLarty JW (1993). Comparing time trends in a two-arm longitudinal study with an ordinal categorical response. Communications in Statistics, Series A, A22, No. 12, 3569-3590.
6. Al-Khalidi HR (1994). On the misspecification of a lognormal distribution. Communications in Statistics, Series A, A23, No. 8, 2343-2350.
7. Brint S, Al-Khalidi HR, Vatel B and Hier DB (1996). MCA flow asymmetries is a marker for cerebrovascular disease, Neurological Research, 18, 163-167.
8. Al-Khalidi HR and Schnell DJ (1997). Application of a continuous-time Markov chain to a preclinical study. Drug Information Journal, 31(2), 607-613.
9. Shen LZ and Al-Khalidi HR (1997). Application of boundary calculation methodologies to group sequential testing in general parametric models. Communications in Statistics, Series A, A26, No. 9, 2173-2190.
10. Al-Khalidi HR (1997). Interim Analysis in Clinical Trials: A Generalized Spending Function Approach. Bulletin of the International Statistical Institute, Vol. 1, 37-38.
11. Dorian P, Al-Khalidi HR, Hohnloser SH, Brum JM, Dunnmon PM, et al. (2008). Azimilide reduces Emergency Department visits and hospitalizations in patients with an implantable cardioverter-defibrillator in a placebo-controlled clinical trial. Journal of the American College of Cardiology, 52, 1076-83. PMID: 18848141.
12. Corey A, Al-Khalidi HR, Brezovic C, Marcello S, Parekh N, Taylor K and Karam R (1999). Azimilide Pharmacokinetics and Pharmacodynamics upon Multiple Oral Dosing. Biopharmaceutics & Drug Disposition, 20, 59-68. PMID: 10206320.
13. Dorian P, Borggrefe M, Al-Khalidi HR, Hohnloser SH, Brum JM, Tatla DS, et al. (2004). Placebo-controlled, randomized trial of azimilide for prevention of ventricular tachyarrhythmias in patients with an implantable cardioverter defibrillator. Circulation, 110, 3646-3654. PMID: 15533855
14. Pratt CM, Al-Khalidi HR, Brum JM, Holroyde MJ, et al. (2006). Cumulative experience of azimilide-associated torsades de pointes ventricular tachycardia in the 19 clinical studies comprising the azimilide database. Journal of the American College of Cardiology, 48, 471-7. PMID: 16875971.
15. Hohnloser SH, Al-Khalidi HR, Brum JM, Tatla DS, et al. (2006). Electrical storm in patients with an implantable defibrillator: Incidence, features, and preventive therapy. Insights from a randomized trial. European Heart Journal, 27, 3027-3032. PMID: 17050586.
16. Al-Khalidi HR, Hong Y, Fleming TR and Therneau TM (2011). Insights on the robust variance estimator under recurrent-events model. Biometrics, 67, 1564-1572.

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Allen, Andrew S.	Associate Professor, Department of Biostatistics and Bioinformatics, Duke University Medical Center
eRA COMMONS USER NAME allen123	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
University of New Mexico, Albuquerque, NM	B.S.	1992	Mathematics
University of New Mexico, Albuquerque, NM	M.A.	1995	Mathematics
Emory University, Atlanta, GA	Ph.D.	2001	Biostatistics

A. Personal Statement

For this application I will bring expertise in the development and application of statistical methodology that focuses on mapping complex human disease genes. Recent methodological work has included: adjusting for population stratification in case-control studies, testing untyped markers in whole genome association studies, estimating copy-number polymorphisms from intensity data, admixture mapping, and developing haplotype sharing approaches that can deal with computational requirements presented by genome-wide data. The breadth of my experience developing, evaluating, and applying statistical genetic methods in human genetic studies makes me well suited for the role highlighted in this application.

B. Positions and Honors

Positions and employment

1995-1996 Hydrologist, Balleau Groundwater, Inc., Albuquerque, NM.

1996-1997 Senior Statistician, Department of Internal Medicine, University of New Mexico Health Sciences Center, Albuquerque, NM.

1997-2001 Teaching Assistant, Department of Biostatistics, Emory University School of Public Health, Atlanta, GA.

1997-2001 Research Assistant, Department of Biostatistics, Emory University School of Public Health, Atlanta, GA.

2001-2007 Assistant Professor, Department of Biostatistics and Bioinformatics, Duke University Medical Center, Durham, NC.

2007-present Associate Professor, Department of Biostatistics and Bioinformatics, Duke University Medical Center, Durham, NC.

Honors (selected)

Graduate Fellowship-Emory University

Best Student Paper-1999 Joint Statistical Meetings,
ASA Biopharmaceutical Section

C. Selected peer-reviewed publications

1. Lyles RH, Allen AS. Estimating crude or common odds ratios in case-control studies with informatively missing exposure data. Am J Epidemiol 2002;155(3):274-281. PMID: 11821253

2. Allen AS, Rathouz PR, Satten GA. Informative missingness in genetic association studies: case-parent designs. Am J Hum Genet 2003;72(3):671-680. PMCID: PMC1180242

3. Allen AS, Satten GA, Tsiatis AA. Locally-efficient robust estimation of haplotype-disease association in family-based studies. Biometrika 2005;92(3):559-571.

4. Satten GA, Allen AS, Epstein MP. Comment on 'Likelihood-based inference on haplotype effects in genetic association studies' by Lin and Zeng. J Am Stat Assoc 2006;101(473):107-108.

5. Allen AS, Martin ER, Qin X, Li YJ. Genetic Association Tests based On Ranks (GATOR) for quantitative traits with and without censoring. Genet Epidemiol 2006;30(3):248-258. PMID: 16496310

6. Allen AS, Satten GA. Inference on haplotype/disease association using parent-affected-child data: The projection on parental haplotypes method. Genet Epidemiol 2007;31(3):211-223. PMID: 17266114

7. Allen AS, Satten GA. Statistical Models for Haplotype Sharing in Case-Parent Trio Data. Hum Hered 2007;64(1):35-44. PMID: 17483595

8. Epstein MP*, Allen AS*, Satten GA. A Simple and Improved Correction for Population Stratification in Case-Control Studies. Am J Hum Genet 2007;80(5):921-930. PMCID: PMC1852732
*Joint first authors

9. Allen AS, Satten GA. Robust estimation and testing of haplotype effects in case-control studies. Genet Epidemiol 2008;32(1):29-40. PMID: 17948229

10. Allen AS, Satten GA. A novel haplotype-sharing approach for genome-wide case-control association studies implicates the Calpastatin gene in Parkinson's disease. Genet Epidemiol 2009;33(8):657-667. PMID: 19365859

11. Allen AS, Satten GA. SNPs in CAST are associated with Parkinson disease: A confirmation study. Am J Med Genet 2010;153B(4):973-79. PMID: 20127884

12. Allen AS, Epstein MP, Satten GA. Score-based adjustment for confounding by population stratification in genetic association studies. Genet Epidemiol 2010;34(5):383-5. PMID: 20127852. PMCID: PMC 2895686

13. Allen AS, Satten GA, Bray SL, Dudbridge F, Epstein MP. Fast and robust association tests for untyped SNPs in case-control studies. Hum Hered 2010;70(3):167-76. PMCID: PMC2952185

14. Allen AS, Satten GA. Control for confounding in case-control studies using the stratification score, a retrospective balancing score. To appear in the American Journal of Epidemiology 2011.

15. Epstein MP, Duncan R, Broadaway KA, He M, Allen AS, Satten GA. Stratification Score Matching Improves Correction for Confounding by Population Stratification in Case-Control Association Studies. To appear in Genetic Epidemiology 2012.

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Kevin J. Anstrom, Ph.D.	Associate Professor Department of Biostatistics and Bioinformatics Duke Clinical Research Institute
eRA COMMONS USER NAME (credential, e.g., agency login) Anstro001	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Cornell University, Ithaca, NY	B.S.	05/1992	Statistics and Biometry
University of North Carolina, Chapel Hill, NC	M.S.	05/1994	Biostatistics
North Carolina State University, Raleigh, NC	Ph.D.	08/2002	Statistics

A. Personal Statement

Since joining the Duke faculty in the Fall of 2002, my research has been divided into two broad areas: 1) statistical analysis of observational and randomized data to explore the relationships between treatments, and long-term clinical, quality-of-life, and economic outcomes and 2) the design and analysis of randomized clinical trials using appropriate and novel statistical methods applied to idiopathic pulmonary fibrosis and heart failure patient populations.

B. Positions and Honors

Positions and Employment

1993-1995 Research Assistant, School of Public Health, University of North Carolina, Chapel Hill, North Carolina
1995-1997 Research Consultant, Department of Neurological Surgery, University of Washington
1997-2002 Statistician, Outcomes Research and Assessment Group, Duke University Medical Center, Durham, North Carolina
2002-2011 Assistant Professor, Department of Biostatistics and Bioinformatics, Duke University, Durham, North Carolina
2011-Present Associate Professor, Department of Biostatistics and Bioinformatics, Duke University, Durham, North Carolina

C. Selected Peer-reviewed Publications (out of 100+ peer-reviewed manuscripts)

1. **Anstrom KJ**, Tsiatis AA. “Utilizing propensity scores to estimate causal treatment effects with censored time-lagged data.” *Biometrics*. 2001; 57(4): 1207-1218.
2. Grant WC, **Anstrom KJ**. “Minimizing selection bias in randomized trials: A Nash equilibrium approach to optimal randomization.” *Journal of Economic Behavior & Organization*, Volume 66, Issues 3-4, June 2008: 606-624.
3. **Anstrom KJ**, Reed SD, Allen AS, Glendenning GA, Schulman KA. Long-term survival estimates for imatinib versus interferon-alpha plus low-dose cytarabine for patients with newly diagnosed chronic-phase chronic myeloid leukemia. Cancer 2004 Dec 1;101(11):2584-92.
4. Mark DB, Nelson CL, **Anstrom KJ**, Al-Khatib SM, Tsiatis AA, Cowper PA, Clapp-Channing NE, Davison-Ray L, Poole JE, Johnson G, Anderson J, Lee KL, Bardy GH, for the SCD-HeFT Investigators. Cost effectiveness of defibrillator therapy or amiodarone in chronic stable heart failure: results from the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT). Circulation 2006;114(2):135-142.
5. Eisenstein EL, **Anstrom KJ**, Kong DF, Shaw LK, Tuttle RH, Mark DB, Kramer JM, Harrington RA, Matchar DB, Kandzari DE, Peterson ED, Schulman KA, Califf RM. Clopidogrel use and long-term clinical outcomes after drug-eluting stent implantation. JAMA. 2007 Jan 10;297(2):159-68.

6. Curtis LH, Hammill BG, Eisenstein EL, Kramer JM, **Anstrom KJ**. Using inverse probability-weighted estimators in comparative effectiveness analyses with observational databases. Med Care. 2007 Oct;45(10 Supl 2):S103-7.
7. Felker GM, **Anstrom KJ**, Rogers JG. A global ranking approach to end points in trials of mechanical circulatory support devices. J Card Fail. 2008 Jun;14(5):368-72.
8. **Anstrom KJ**, Kong DF, Shaw LK, Califf RM, Kramer JM, Peterson ED, Rao SV, Matchar DB, Mark DB, Harrington RA, Eisenstein EL. Long-term clinical outcomes following coronary stenting. Arch Intern Med. 2008 Aug 11;168(15):1647-55.
9. Mark DB, Pan W, Clapp-Channing NE, **Anstrom KJ**, Ross JR, Fox RS, Devlin GP, Martin CE, Adlbrecht C, Cowper PA, Ray LD, Cohen EA, Lamas GA, Hochman JS; Occluded Artery Trial Investigators. Quality of life after late invasive therapy for occluded arteries. N Engl J Med. 2009 Feb 19;360(8):774-83. PMCID: PMC2724193.
10. Douglas PS, Brennan JM, **Anstrom KJ**, Sedrakyan A, Eisenstein EL, Haque G, Dai D, Kong DF, Hammill B, Curtis L, Matchar D, Brindis R, Peterson ED. Clinical effectiveness of coronary stents in elderly persons: results from 262,700 Medicare patients in the American College of Cardiology-National Cardiovascular Data Registry. J Am Coll Cardiol. 2009 May 5;53(18):1629-41.
11. Brinkley J, Tsiatis A, **Anstrom KJ**. A Generalized Estimator of the Attributable Benefit of an Optimal Treatment Regime. Biometrics. 2009 Jun 9.
12. Zisman DA, Schwarz M, **Anstrom KJ**, Collard HR, Flaherty KR, Hunninghake GW. A controlled trial of sildenafil in advanced idiopathic pulmonary fibrosis. Idiopathic Pulmonary Fibrosis Clinical Research Network, N Engl J Med. 2010 Aug 12;363(7):620-8. PMID: 20484178
13. Idiopathic Pulmonary Fibrosis Clinical Research Network, Raghu G, **Anstrom KJ**, King TE Jr, Lasky JA, Martinez FJ. “Prednisone, azathioprine, and N-acetylcysteine for pulmonary fibrosis.” N Engl J Med. 2012 May 24;366(21):1968-77. Epub 2012 May 20. PubMed PMID: 22607134.
14. Felker GM, Lee KL, Bull DA, Redfield MM, Stevenson LW, Goldsmith SR, LeWinter MM, Deswal A, Rouleau JL, Ofili EO, **Anstrom KJ**, Hernandez AF, McNulty SE, Velazquez EJ, Kfoury AG, Chen HH, Givertz MM, Semigran MJ, Bart BA, Mascette AM, Braunwald E, O'Connor CM; NHLBI Heart Failure Clinical Research Network. “Diuretic strategies in patients with acute decompensated heart failure.” N Engl J Med. 2011 Mar 3;364(9):797-805. PubMed PMID: 21366472.
15. Bart BA, Goldsmith SR, Lee KL, Givertz MM, O'Connor CM, Bull DA, Redfield MM, Deswal A, Rouleau JL, LeWinter MM, Ofili EO, Stevenson LW, Semigran MJ, Felker GM, Chen HH, Hernandez AF, **Anstrom KJ**, McNulty SE, Velazquez EJ, Ibarra JC, Mascette AM, Braunwald E; Heart Failure Clinical Research Network. Ultrafiltration in decompensated heart failure with cardiorenal syndrome. N Engl J Med. 2012 Dec 13;367(24):2296-304. doi: 10.1056/NEJMoa1210357. Epub 2012 Nov 6. PMID: 23131078

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Huiman X. Barnhart	Professor of Biostatistics
eRA COMMONS USER NAME (credential, e.g., agency login) Huiman	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
South China Normal University, P.R. China	B.S.	1983	Mathematics
Jinan University, P.R. China	M.S.	1986	Mathematics
University of Pittsburgh, Pittsburgh, PA	M.A.	1988	Mathematics
University of Pittsburgh, Pittsburgh, PA	Ph.D.	1992	Statistics

A. Personal Statement

As the Principal Investigator of the Drug Induced Liver INjury Data Coordinating Center (DLIN DCC), I am ultimately responsible for the smooth operation of the DCC to meet the goals in the specific aims of DILIN DCC. I over-see the processes for monitoring site data, database validations and quality control efforts. I lead the DCC Statistical team and provide thought leadership and statistical advice on design and conduct of pharmacogenetic and biomarker studies as well as studies with intervention strategies to prevent and treat DILI activities. I also provide support to the network sites and assist the other steering committee members in the design, selection, and implementation of the network protocols.

I am currently a full professor in the department of Biostatistics and Bioinformatics. My research interests include both statistical methodology and disease-specific collaborative clinical research. My statistical expertise areas include methods for assessing reliability/agreement of measurement method, evaluating performance of new medical diagnostic tests, and methods for clinical trials. My work in the area of reliability will be useful for development of a validated, computer-based instruments. I have played pivotal leadership roles in major NIH-funded networks and consortia, and have gained considerable Data Coordinating Center (DCC) experience. I have been actively engaged in simultaneous development of multiple protocols within the network or consortium. I have provided input on the design and implementation of case report forms and databases, performed sample size calculations and re-calculations, advocated and led the implementation of sound statistical designs, overseen interim and final analyses, actively participated in manuscript writing, provided overall study coordination and quality assurance working with various groups within DCRI that supported the network or consortium, and has been an active member in almost all of the committees within the network or consortium. As the sole statistical faculty providing support on quality assessment and quality control for the Duke cardiovascular imaging core lab, I led the effort to revamp the process on assessment and control of quality and reliability on echocardiography measurements.

B. Positions and Honors

Positions and Employment

1992-1998: *Assistant Professor*, Department of Biostatistics, The Rollins School of Public Health, Emory University, Atlanta, GA
1998-2003: *Associate Professor*, Department of Biostatistics, The Rollins School of Public Health, Emory University, Atlanta, GA
2003-2009: *Associate Professor*, Department of Biostatistics and Bioinformatics, Duke University Medical Center, Durham, NC
2009-present: *Professor*, Department of Biostatistics and Bioinformatics, Duke University Medical Center, Durham, NC

C. Selected Peer-reviewed Publications (Selected from 105 peer-reviewed publications)

Most relevant to the current application

1. Huiman X. Barnhart and John M. Williamson. Modeling Concordance Correlation via GEE to Evaluate Reproducibility. *Biometrics*, **57**:931-940, 2001.
2. Huiman X. Barnhart and John M. Williamson. Weighted least squares approach for comparing correlated kappa. *Biometrics*, 58, 1012-1019, 2002
3. Huiman X. Barnhart, Michael Haber and Jingli Song. Overall concordance correlation coefficient for evaluating agreement among multiple observers. *Biometrics*, 58:1020-1027, 2002.
4. Huiman X. Barnhart and Andrzej S. Kosinski. Evaluating medical diagnostic tests at the subunit level in the presence of verification bias. *Statistics in Medicine*, 22:2161-2176, 2003.
5. Huiman X. Barnhart, Jingli Song and Michael Haber. Assessing intra, inter and total agreement with replicated readings. *Statistics in Medicine*, 24: 1371-1384, 2005.
6. Huiman X. Barnhart, Jingli Song and Robert Lyles. Assay validation for left censored data. *Statistics in Medicine*, 24: 3347-3360, 2005.
7. Huiman X. Barnhart, Michael Haber, and Lawrence I. Lin. An overview on assessing agreement with continuous measurements. *Journal of Biopharmaceutical Statistics*, 17(4): 529-569, 2007.
8. Huiman X. Barnhart, Andrzej S. Kosinski and Michael J. Haber. Assessing individual agreement. *Journal of Biopharmaceutical Statistics*, 17(4): 697-719, 2007.
9. Huiman X. Barnhart, Michael Haber, Yuliya Lokhnygina and Andrzej S. Kosinski. Comparions of concordance correlation coefficient and coefficient of individual agreement in assessing agreement. *Journal of Biopharmaceutical Statistics*, 17(4): 721-738, 2007.
10. Huiman X. Barnhart and Daniel P. Barboriak. Applications of the repeatability of quantitative imaging biomarkers: a review of statistical analysis of repeat datasets. *Translational Oncology*, 2:231-235, 2009, 2009.
11. Naga Chalasani, Raj Vuppalanchi, Victor Navarro, Robert. J. Fontana, Herbert Bonkovsky, Huiman Barnhart, David Kleiner, and Jay Hoofnagle. Acute liver injury due to flavocoxid (Limbrel), a medical food for osteoarthritis: A case series. *Annals of Internal Medicine*, 156(12):857-860, 2012.
12. Chia-Cheng Chen and Huiman X. Barnhart. Assessing agreement with intraclass correlation coefficient and concordance correlation coefficient with repeated measures. Computational Statistics and Data Analysis, 60: 132-145, 2013.

Additional publications (in chronological order)

13. Richard S. Legro, Huiman X. Barnhart, William D. Schlaff, Bruce R. Carr, Michael P. Diamond, Sandra A. Carson, Michael P. Steinkampf, Christos Coutifaris, Peter G. McGovern, Nicholas A. Cataldo, Gabriella G. Gosman, John E. Nestler, Linda C. Giudice, Phyllis C. Leppert, and Evan R. Myers, for the Reproductive Medicine Network. Live Birth with Clomiphene and Metformin in Polycystic Ovary Syndrome. *New England Journal of Medicine*, 356:551-566, 2007.
14. Lynda Szczech, Huiman X. Barnhart, Shelly Sapp, G. Michael Felker, Adrian Henandez, Donal Reddan, Robert M. Califf, Jula K. Inrig, Uptal D. Patel, Ajay K. Singh. Patients with heart failure and diabetes mellitus have differential outcomes with treatment for anemia: A secondary analysis of the CHOIR (Correction of Hemoglobin and Outcomes in Renal Insufficiency) Trial. Kidney International, 77: 239–246, 2010.
15. Manesh R. Patel, Richard W. Smalling, Holger Thiele, Huiman X. Barnhart, Yi Zhou, Praveen Chandra, Derek Chew, Marc Cohen, John French, Divaka Perera, E. Magnus Ohman. Intra-aortic balloon counterpulsation and infarct size in patients with acute anterior myocardial infarction without shock: The CRISP AMI Randomized Trial. JAMA, 306(12):1329-1337, 2011.

NAME	POSITION TITLE
Chan, Cliburn Chi Wei	Assistant Professor

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
National University of Singapore, Singapore	MBBS	1986-1991	Medicine
University College London, London, UK	MSc, PhD	1997-2002	Nonlinear Dynamics
Imperial College London, London, UK	Postdoctoral	2002-2004	Immunology
Duke University, Durham, NC, USA	Postdoctoral	2004-2005	Computational Biology

Employment

1992 – 1997 Resident, Singapore General Hospital and Singapore Armed Forces
1999 – 2001 Teaching Assistant, University College London and London School of Economics
2001 – 2004 Postdoctoral Fellow, Hammersmith Hospital, Imperial College London
2004 – 2005 Research Fellow, Statistics and Applied Mathematics Institute (SAMSI)
2005 - Assistant Professor of Biostatistics and Bioinformatics, Duke University
2010 - Director, Biostatistics and Computational Biology Core, Duke Center for Aids Research
2011 - Course director, Introduction to the Practice of Biostatistics I & II

Honors and Synergistic Activities

1998 – 2001 University College London Graduate School Award
1998 – 2001 Overseas Research Award
2002 – 2003 A*STAR (Singapore) International Fellow
2007 - Reviewer for NSF, NIH (for RFA-AI-09-040: Protection of Human Health by Immunology and Vaccines (U01, U19), RFP NIAID-DMID-NIHAI2010091, "Respiratory Pathogens Research Centers (RPRC), (ZAI1-UKS-A-J1), "Centers for AIDS Research' etc)
2008 - Invited speaker, Bioinformatics Summit, DAIDS, NIH; CMI Techniques Standardization for Vaccine Responses Evaluation, Fondation Merieux, Annecy, France; FICCS5 (Flow Informatics and Computational Cytometry Society), Seattle; Mathematics of Immunology and Infectious Diseases, AMS sectional meeting, NCSU; Cancer Vaccine Consortium (CVC) annual meeting, Washington D; CIMT special session on immuno-monitoring, Mainz, Germany.
2009 - Instructor, Summer School on Quantitative and Computational Immunology, Santa Fe, NM, Summer School on Quantitative and Computational Immunology, San Antonio TX.
Feb 2010 Participant, inaugural Duke Course in Scientific Management and Leadership, Durham NC
Jul 2010 Instructor, Summer School on Quantitative and Computational Immunology, San Antonio TX

Publications

1. **Chan C**, Stark J and George AJT, Analysis of cytokine network dynamics in corneal allograft rejection, *Proceedings of the Royal Society B*, 266, (1999), 2217–2223.
2. **Chan C**, George AJT and Stark J, Co-operative enhancement of specificity in a lattice of T cell receptors, *Proceedings of the National Academy of Science USA*, 98, (2001), 5758–5763.
3. Yates A, **Chan C**, Callard RE, George AJT and Stark J, An approach to modelling in im- munology, *Briefings in Bioinformatics*, 2, (2001), 1–13.
4. **Chan C**, George AJT and Stark J, T cell sensitivity and specificity - kinetic proofreading revisited, *Discrete and Continuous Dynamical Systems Series B*, 3, (2003), 343–360.
5. **Chan C**, George AJT and Stark J, Feedback control of T cell receptor activation, *Proceedings of the Royal Society B*, 271, (2004), 931–939.
6. Tan PH, **Chan C**, Xue SA, Kerouedan C, Manunta M, Lombardi G, Larkin DFP, Cheshire N, Wolfe J, Haskard D, Taylor KM and George AJT, Phenotypic and functional differences between human saphenous vein (HSVEC) and umbilical vein (HUVEC) endothelial cells, *Atherosclerosis*, 173, (2004) 171–83.
7. **Chan C**, Lechler RI, George AJT, Tolerance mechanisms and recent progress, *Transplantation Proceedings*, 36, (2004): 561S–569S.
8. Tan PH, Sagoo P, **Chan C**, Yates JB, Campbell J, Beutelspacher SC, Foxwell BM, Lombardi G and George AJ, Inhibition of N-κB and Oxidative Pathways in Human Dendritic Cells by Antioxidative Vitamins Generates Regulatory T Cells, *Journal of Immunology*, (2005) 174:7633–44

9. Tan PH, Yates JB, Xue SA, **Chan C**, Jordan WJ, Harper JE, Watson MP, Dong R, Ritter MA, Lechler RI, Lombardi G and George AJT, Creation of tolerogenic human DC via intra- cellular CTLA4: a novel strategy with potential in clinical immunosuppression, *Blood*, 106, (2005) 2936–43
10. **Chan C**, Stark J and George AJT, The impact of multiple T cell-APC encounters and the role of anergy, *Journal of Computational and Applied Mathematics*, (2005) 184:101–120
11. Tan PH, **Chan C**, George AJT, Bradley JB, The evolving role of gene-based treatment in surgery, *British Journal of Surgery*, (2005), 92:1466–80
12. George AJT, Stark J and **Chan C**, Understanding sensitivity and specificity of T cell recognition, *Trends in Immunology*, (2005), 26:653–9
13. Alam AKMS, Florey O, Weber M, Pillai RG, **Chan C**, Tan PH, Lechler RI, McClure MO Haskard DO and George AJT, Knockdown of mouse VCAM-1 by vector-based siRNA, *Transplantation Immunology*, (2006), 16:185–93
14. Stark J, **Chan C**, George AJT, Oscillations in the immune system, *Immunological Reviews*, (2007), 216:213–31
15. Yates A, **Chan C**, Strid J, Moon S, Callard R, George AJT, Stark J, Reconstruction of cell population dynamics using CFSE, *BMC Bioinformatics*, (2007), 8:196
16. **Chan C**, George AJT, Stark J, Cytotoxic Killing and Immune Evasion by Repair, *Journal of Statistical Physics*, (2007), 128:393–411
17. **Chan C**, Kepler TB, Computational immunology–from bench to virtual reality, *Annals Academy of Medicine Singapore*, (2007), 123–7
18. Kepler TB, **Chan C**, Spatiotemporal programming of a simple inflammatory process, *Immunological Reviews*, (2007), 216:153-63
19. Mitha FH, Lucas TA, Feng F, Kepler TB and **Chan C**, The Multiscale Systems Immunology Project: Software for Cell-Based Immunological Simulation, *Source Code for Biology and Medicine*, (2008), 3:6
20. **Chan C**, Feng F, Ottinger J, Foster D, West M and Kepler TB, Statistical mixture modeling for cell subtype identification in flow cytometry, *Cytometry A*, (2008), 73A:693–701
21. Frelinger, J, Kepler TB and **Chan C**, Flow: Statistics, visualization and informatics for flow cytometry, *Source Code for Biology and Medicine*, (2008), 3:10.
22. Suchard M, Wang Q, **Chan C**, Frelinger F, Cron A and West M, Understanding GPU pro- gramming for statistical computation: Studies in massively parallel massive mixtures. *Journal of Computational and Graphical Statistics*, (2010), 19: 419–438.
23. Manolopoulou I, **Chan C**, West M, Selection Sampling from Large Data Sets for Targeted Inference in Mixture Modeling. *Bayesian Analysis*, (2010), 5:1–22.
24. Frelinger, J, Ottinger J, **Chan C**, Modeling flow cytometry data for cancer vaccine immune monitoring, *Cancer Immunology Immunotherapy*, (2010), 59:1435–41.
25. **Chan C**, Lin L, Frelinger J, Hérbert V, Gagnon D, Landry C, Sékaly RP, Enzor J, Staats J, Weinhold KJ, Jaimes M, West M. Optimization of a highly standardized carboxyfluorescein succinimidyl ester flow cytometry panel and gating strategy design using discriminative information measure evaluation, *Cytometry A*, (2010), 77:1126–36.
26. Snyder LD, Medinas R, **Chan C**, Sparks S, Davis WA, Palmer SM, Weinhold KJ, Polyfunctional cytomegalovirus-specific immunity in lung transplant recipients receiving valganciclovir prophylaxis, *American Journal of Transplantion*, (2011), 11: 553–60.
27. **Chan C**, Billard M, Ramirez SA, Schmidl H, Monson E, Kepler TB, Complex dynamics from chemokine receptor modulation in a minimal spatial model of B cell migration in the follicle and germinal center, *Bulletin of Mathematical Biology*, (2013), 75: 185-205.
28. Shetty G, Beasley GM, Sparks S, Barfield M, Masoud M, Mosca PJ, Pruitt SK, Salama AKS, **Chan C**, Tyler DS, Weinhold KJ, Plasma Cytokine Analysis in Patients with Advanced Extremity Melanoma Undergoing Isolated Limb Infusion (*in press*, *Annals of Surgical Oncology*)
29. Aghaeepour M, Finak G, The Flowcap Consortium1, The Dream Consortium, Hoos H, Mosmann TR, Gottardo R, Brinkman RR, Scheuermann RH, Critical Assessment of Automated Flow Cytometry Analysis Techniques (*in press*, *Nature Methods*)

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Kingshuk Roy Choudhury	Associate Professor
eRA COMMONS USER NAME (credential, e.g., agency login) KRCHOUDHURY	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Indian Statistical Institute, Calcutta, India	B.Stat.(Hons)	06/91	Statistics
Indian Statistical Institute, Calcutta, India	M.Stat.	06/93	Statistics
University of Washington, Seattle, WA, USA	Ph.D.	08/98	Statistics

A. Personal Statement

B. Positions and Honors

Positions and Employment

1998 – 2007 Lecturer, Statistics Department, University College Cork (UCC), Ireland
2007 – 2008 Visiting Professor, Department of Statistics, Stanford University
2008 – 2010 Lecturer, Statistics Department, UCC, Ireland
2011 – Present Associate Professor, Dept. of Radiology, Duke University, Durham, NC, US
2013 – Present Associate Professor, Dept. of Biostatistics and Bioinformatics, Duke University,

Honors and Committee Work

1993 P.C. Mahalanobis Memorial Statistics Symposium Gold Medal
1993 Indian Statistical Institute Alumni Association Gold Medal
2004-2007 Member, Executive committee, Irish Statistical Association
2009-2011 Member, Mathematical Sciences Committee, Royal Irish Academy
2012-Present Member, Metrology committee, Quantitative Imaging Biomarker Alliance, Radiological Society of North America
2013-Present Member, Working Group on Optimization of Medical Imaging Systems and Techniques, American Association for Physicists in Medicine

C. Selected Peer Reviewed Publications (selected from 44 full length journal publications)

1) O'Sullivan, F**., Roy Choudhury, K.**, 2006, A Statistical Measure of Regularity for the Study of Wind-Generated Wave Field Images, J.American Statist.Assoc., 101, 475, 1119 – 1131
2) O'Sullivan, F., Roy Choudhury, K., 2001, An Analysis of the Role of Positivity and Mixture Model
3) **Roy Choudhury, K.**, Crotty, S., 2007, Morphometric analysis for early detection of changes in cellular structure in a toxicological experiment, *Statistics in Medicine*, 26, 29, 5253-5266
4) **Roy Choudhury, K**., Tabirca, S., 2008, A modular CDF approach for the approximation of percentiles, Communications in Statistics – Simulation and Computation, 37, 1948 - 1965
5) Holland, F., **Roy Choudhury, K.**, 2008, Likelihood ratio tests for equality of shape under varying degrees of orientation invariance, Journal of Multivariate Analysis, 99, 8, 1772-1792

6) **Roy Choudhury, K.**, Zheng, L., Mackrill, J., 2010, Analysis of spatial distribution of marker expression in cells using boundary distance plots, *Annals of Applied Statistics*, 4, 1365-1382
7) **Roy Choudhury, K.**, Yagle, K., Swanson, P., Rajendran, J., 2010, A robust automated measure of average antibody staining in immunohistochemistry images, *Journal of Histochemistry and Cytochemistry*, 58 (2): 95-107
8) **Roy Choudhury, K.**, Paik, D., Yi, C., Napel, S., Roos, J., Rubin, G., 2010, Assessing operating characteristics of CAD algorithms in the absence of a gold standard, *Medical Physics*, 37, 1788-1795. PMCID: PMC2864671
9) **Roy Choudhury, K**., Deacon, P., Barrett, R., McDermott, K., 2010, Hypothesis testing for neural cell growth experiments using a hybrid branching process model, Biostatistics, 11, 631-643
10) **Roy Choudhury, K**., Kasman, I., Plowman, G., 2010, Analysis of multi-arm tumor growth trials in xenograft animals using phase change adaptive piecewise quadratic models, Statistics in Medicine, 29, 2399-2409
11) **Roy Choudhury, K.**, O'Sullivan, F., Samanta, M., Caulliez, G., Shrira, V., 2010, Regularized Reconstruction of wave height and slope fields from refracted images of water, Journal of the American Statistical Association, 105, 36–47.
12) **Roy Choudhury, K.,** Pettigrew, C., Parametric scalp mapping and inference via spatially smooth linear models for mismatch negativity studies, 2011, *Journal of Statistical Planning and Inference*, 142, 1, 12 - 24
13) **Roy Choudhury, K.**, O'Sullivan, F., Kasman, I., Plowman, G., 2012, A comparison of least squares and conditional maximum likelihood estimators under volume endpoint censoring in tumor growth experiments, *Statistics in Medicine*, 31(29):4061-73
14) Michel, A., **Roy Choudhury, K**., Firth, A., Ingolia, N., Atkins, J., Baranov, P., 2012, Observation of dually decoded regions of the human genome using ribosome profiling data, *Genome Research*, 22(11):2219-29

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Shein-Chung Chow	Professor, Biostatistics and Bioinformatics
eRA COMMONS USER NAME	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
National Taiwan University, Taipei, Taiwan	B.S.	1978	Mathematics
University of Wisconsin, Madison, Wisconsin	Ph.D.	1985	Statistics

A. Personal Statement

Have more than 25 years experience in pharmaceutical/clinical research and development. Have been working with many clinicians by providing statistical support to clinical studies conducted at early and/or late phases of clinical development across various therapeutic areas. Have published over 230 methodology papers and over 22 books. Have supervised 5 PhDs and 8 MS students. Serve on several editorial boards of leading journals in the area of biostatistics.

B. Positions and Honors

B.1 Positions and Employment

1985 - 1987 Assistant Professor, Department of Mathematics, University of Toledo, Toledo, Ohio
1987 - 1988 Senior Statistician, Ayerst Laboratories, Rouses Point, New York.
1989 - 1989 Senior Statistician, Parke-Davis Pharmaceutical Division, Ann Arbor, Michigan
1989 - 1997 Director, Biostatistics and Data Management, Bristol-Myers Squibb Company, Plainsboro, New Jersey
1992 - 2004 Honorary Affiliate Professor, Department of Statistics, Temple University, Philadelphia, Pennsylvania
1996 - Date Adjunct Professor, Department of Statistics, National Cheng-Kung University, Tainan, Taiwan
1997 - 1998 Executive Director, Statistics and Clinical Programming, Covance, Inc., Princeton, New Jersey
1998 - 2002 President, StatPlus, Inc., Yardley, Pennsylvania
2002 - 2004 Vice President, Biostatistics and Data Management, Millennium Pharmaceuticals, Inc., Cambridge, Massachusetts
2004 - 2005 Distinguished Professor, National Health Research Institutes, Zhunan, Taiwan.
2013 – Date Adjunct Professor, Department of Statistics, North Carolina State University, Raleigh, NC
2005 - Date Professor, Department of Biostatistics and Bioinformatics, Duke University School of Medicine, Durham, NC

B.2 Selected Honors

1995 Fellow, American Statistical Association
1996 The DIA Outstanding Service Award
1996 Extraordinary Achievements Award, International Chinese Statistical Association
1998 Chapter Service Recognition Award, American Statistical Association
1999 Elected Member, International Statistical Institute (ISI)

B.3 Editorial Boards

2002 – Date Editor-in-Chief, Journal of Biopharmaceutical Statistics
1997 - Date Editor-in-Chief, Book series “Biostatistics: A Series of Reference & Textbooks”

Chapman and Hall/CRC, Taylor & Francis.
2013 – Date Academic Editor, European Journal of Pharmaceutical Statistics
2012 – Date Associate Editor, Journal of Bioinformatics and Biometrics
2012 – Date Associate Editor, Journal of Drug Designing
2010 – Date Associate Editor, Biosimilars
2008 – Date Associate Editor, Journal of Probability and Statistics
1994 - Date Advisory Editor, Taylor & Francis.
1999 - 2002 Associate Editor, Statistica Sinica
1990 - 2002 Associate Editor, Journal of Biopharmaceutical Statistics
1996 - 2000 Associate Editor, Journal of Food and Drug Analysis
1996 - 1998 Associate Editor, Drug Information Journal

C. Peer-reviewed Publications

C.1 Selected Books (from over 22 books)

1. **Chow, S.C.** and Liu, J.P. (1995). *Statistical Design and Analysis in Pharmaceutical Science: Validation, Process Control, and Stability*. Marcel Dekker, Inc., New York, New York.
2. **Chow, S.C.** and Shao, J. (2002). *Statistics in Drug Research – Methodologies and Recent Development.* Marcel Dekker,Inc., New York, New York.
3. **Chow, S.C.** and Liu, J.P. (2003). *Design and Analysis of Clinical Trials*. Second Edition, John Wiley & Sons, New York, New York.
4. **Chow, S.C.** and Chang, M. (2006). *Adaptive Design Methods in Clinical Trials*. Chapman and Hall/CRC, Taylor & Francis, New York, New York.
5. **Chow, S.C.** and Liu, J.P. (2008). *Design and Analysis of Bioavailability and Bioequivalence Studies*. Third Edition, Chapman and Hall/CRC, Taylor & Francis, New York, New York.
6. Cosmatos, D. and **Chow, S.C.** (Ed) (2008). *Translational Medicine – Strategies and Statistical Methods*. Chapman and Hall/CRC, Taylor & Francis, New York, New York.

C.2 Selected Publications in Peer-reviewed Journals (from over 230 papers)

1. **Chow, S.C.** and Liu, J.P. (2010). Statistical assessment of biosimilars products. *Journal of Biopharmaceutical Statistics*, 20, 10-30.
2. **Chow, S.C.** and Corey, R. (2011). Benefits, challenges and obstacles of adaptive designs in clinical trials. *The Orphanet Journal of Rare Diseases*, 6:79 doi:10.1186/1750-1172-6-79.
3. **Chow, S.C.** (2011). Quantitative evaluation of bioequivalence/biosimilarity. *Journal of Bioequivalence and Bioavailability*, Suppl. 1-002, 1-8, http://dx.doi.org/10.4172/jbb s1-002.
4. **Chow, S.C.**, Corey, R., and Lin, M. (2012). On independence of data monitoring committee in adaptive clinical trial. *Journal of Biopharmaceutical Statistics*, 22, 853-867.
5. **Chow, S.C.**, Yang, L.Y., Starr, A., and Chiu, S.T. (2013). Statistical methods for assessing interchangeability of biosimilars. *Statistics in Medicine*, 32, 442-448.

D. PhD Students Supervised

Dr. Wenping Wang (Temple University, 1995) – Co-advisor under special permission of Dean at Temple University
Dr. Li Li (Temple University, 2004) – Co-advisor under special permission of Dean at Temple University
Dr. Lan-Yan Yang (National Cheng-Kung University, 2011) – Co-advisor under special permission of dean at National Cheng-Kung University, Tainan, Taiwan
Ms. Ying Lu (Beijing Technology University, 2011 – Date) – Co-advisor under special permission of Dean of the university
Ms. Aijing Zhang (North Carolina State University, 2012 – Date) – Co-advisor since I was appointed as adjunct professor since March 1, 2013.

BIOGRAPHICAL SKETCH

NAME: Elizabeth Ray DeLong Ph.D.	POSITION TITLE Professor of Biostatistics & Bioinformatics
eRA COMMONS USER NAME: DELON001	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
University of North Carolina, Chapel Hill, NC	Ph.D.	05/1979	Biostatistics
University of Maine, Onoro, ME	M.A.	05/1970	Mathematics
University of Maine, Onoro, ME	B.A.	05/1969	Mathematics

Personal Statement

As Chair of the Department of Biostatistics and Bioinformatics, Duke University Medical Center and Co-Director of the Cardiovascular Outcomes Research group in the Duke Clinical Research Institute (DCRI), I participate directly in the selection of curriculum, course instructors, and advisors for our graduate programs. My research interests are in the field of comparative effectiveness with regard to cardiovascular outcomes and quality-of-care, with emphasis on risk adjustment methodology, assessment of risk prediction models, and provider profiling. With more than 20 years of biostatistics, clinical research, and bioinformatics experience, my responsibilities have included administrative and data analytic functions, as well as statistical methods development. I have held government grants studying statistical issues in Validating Risk Prediction Models in Cardiology and also Features of Managed Care Affecting Quality for Cardiovascular Disease and am currently the Principal Investigator for the analysis center for the ASCERT GO grant, a unique collaboration between the American College of Cardiology Foundation (ACCF) and The Society for Thoracic Surgeons (STS). I have taught several Biostatistics courses in the Medical School, including statistics for medical students, survival analysis, and a capstone course for the Clinical Research Training Program (CRTP).

Professional Positions

2009 – Present Chair, Department of Biostatistics and Bioinformatics, DUMC, Durham, North Carolina
2008 – 2009 Interim Chair, Department of Biostatistics and Bioinformatics, DUMC, Durham, North Carolina
2005 – Present Professor, Department of Biostatistics and Bioinformatics, DUMC, Durham, North Carolina
1997 – 2005 Associate Professor, Department of Biostatistics and Bioinformatics, DUMC, Durham, North Carolina
1996 - 1998 Chief, Division of Biostatistics and Clinical Outcomes, Department of Anesthesiology, Duke University Medical Center, Durham, North Carolina.
1994 - Present Co-Director Outcomes Research and Assessment Group, DUMC, Durham, North Carolina
1991 - 1997 Assistant Professor, Division of Biometry and Medical Informatics, Department of Community and Family Medicine, DUMC, Durham, North Carolina
1991 - 1994 Director Ischemic Heart Disease PORT, DUMC, Durham, North Carolina
1987 - 1991 Director of Biostatistics, Quintiles, Inc., Chapel Hill, North Carolina
1987 - 1991 Consulting Assistant Professor, Division of Biometry and Medical Informatics, Department of Community and Family Medicine, Duke University Medical School, Durham, North Carolina
1984 - 1987 Biostatistician, Health Services Research and Development Field Program, VA Medical Center, Durham, North Carolina
1979 - 1987 Assistant Professor, Division of Biometry and Medical Informatics, Department of Community and Family Medicine, Duke University Medical School, Durham, North Carolina
1979 - 1984 Biostatistician, Comprehensive Cancer Center, Duke University, Durham, North Carolina

Service Positions

2012 Grant Review Study Section, Ancillary Studies in Clinical Trials - National Heart, Lung and Blood Institute (NHLBI)
2012 National Quality Forum (NQF) Composite Measure Framework Assessment Expert Panel, Co-Chair.
2012 The Joint Commission: Development of Risk Adjusted Outcome Measures in the EHR

	Environment Conference
2012 -	Duke, MAESTRO Care – Research Advisory Executive Council
2011	NIH Review of Program Project grant application (P01)
2011 –	Duke Implementation Science Initiative and Advisory Committee
2011	National Institute of Health (NIH), National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel
2008 – 2009	Editorial Board, Circulation: Cardiovascular Quality and Outcomes
2007 – 2009	Composite Measure Steering Committee for the National Quality Forum (NQF),
2007 – 2010	ACC/AHA Task Force on Performance Measures
2006 – 2007	Composite Technical Advisory Panel (TAP), The National Quality Forum, National Voluntary Consensus Standards for Hospital Care: Additional Priorities
2006	NHLBI Strategic Planning Group: Cardiovascular Bioinformatics and Computational Biology
2003 – 2008	Editorial Board, Journal of the American College of Cardiology
2003 – 2006	Clinical Faculty Academic Council, Duke University School of Medicine
2002 – 2003	Faculty Women's Committee, Duke University School of Medicine
1999 – 2012	Editorial Board, American Heart Journal
1999 – 2007	Steering Committee, Scientific Forum on Assessment of Healthcare Quality in Cardiovascular Disease and Stroke, American Heart Association
1997 – 1999	Associate Editor, American Heart Journal
1997 – 1998	Treasurer, University of North Carolina Biostatistics Alumni Association
1996 – 1998	Treasurer, Health Policy Statistics Section, American Statistical Association

C. SELECTED PEER – REVIEWED PUBLICATIONS (IN CHRONOLOGICAL ORDER).

1. **DeLong ER,** Sen PK. Estimation of P (X > Y) based on progressively truncated versions of the Wilcoxon Mann Whitney statistics. Commun Statist Theor Meth 1981;A10:963 81.
2. **DeLong ER**, Sen PK. The extended two sample problem: Progressively truncated estimation of P (X > Y). Statistics and Decisions 1983;1:147 170.
3. **DeLong ER**, Maile MC, Grufferman SG. Climate, socioeconomic status and Hodgkin's disease mortality in the United States. J Chronic Dis 1984;37:209 213.
4. **DeLong ER,** Vernon WB, Bollinger RR. Sensitivity and specificity of a monitoring test. Biometrics 1985;41:947 958.
5. DeLong DM, **DeLong ER**, Wood PD, Lippel K, Rifkind BM. A comparison of methods for the estimation of plasma low and very low density lipoprotein cholesterol: The Lipid Research Clinics Prevalence Study. JAMA 1986;256:2372 2377.
6. **DeLong ER**, DeLong DM, Clarke Pearson DL. Comparing the areas under two or more correlated receiver-operating characteristic curves; a nonparametric approach. Biometrics 1988;44:837 845.
7. **DeLong ER**, Peterson ED, DeLong DM, Muhlbaier LH, Hackett S, Mark DB. Comparing risk-adjustment methods for provider profiling. *Statistics in Medicine* 1997;16:2645-2664. PMID: 9421867 [PubMed - indexed for MEDLINE]
8. Parker CB, **DeLong ER**. A diagnostic for Cox regression with discrete failure-time models. *Biometrics* 2000; 56:996-1001.) PMID: 11213761 [PubMed - indexed for MEDLINE]
9. **DeLong ER**, Nelson CL, Wong JB, Pryor DB, Peterson ED, Lee KL, Mark DB, Califf RM. Using observational data to estimate prognosis: an example using a coronary artery disease registry. *Statistics in Medicine* 2001; 20(16).
10. **DeLong ER,** Coombs, LP, Ferguson TB, Peterson ED. The evaluation of Treatment when Center-Specific Selection Criteria Vary with Respect to Patient Risk. *Biometrics* 2005, 61(4)942-949. PMID: 16401267 [PubMed - indexed for MEDLINE]
11. O'Brien SM, **DeLong ER**, Dokholyan RS, Edwards FH, Peterson ED. Exploring the behavior of hospital composite performance measures: an example from coronary artery bypass surgery. *Circulation.* Dec 2007; 116(25):2969-2975. PMID: 18056529 [PubMed - indexed for MEDLINE]
12. O'Brien SM, **DeLong ER**, Peterson ED. Impact of case volume on hospital performance assessment. *Arch Intern Med.* 2008;168(12)1277-1284. PMID: 18574084 [PubMed - indexed for MEDLINE]
13. Olsen M, **Delong E**, Oddone E, Bosworth H. Strategies for analyzing multilevel cluster-randomized studies with binary outcomes collected at varying intervals of time. *Stat Med*. 2008 Dec 20;27(29):6055-71. PMID: 18825655 [PubMed - indexed for MEDLINE]

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Barbara E Engelhardt	Assistant Professor
eRA COMMONS USER NAME (credential, e.g., agency login) ENGELHARDT	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Stanford University, USA	BS	06/99	Symbolic Systems
Stanford University, USA	MS	06/99	Computer Science
University of California, Berkeley, USA	PhD	12/07	Computer Science
University of Chicago, USA	Postdoctoral	8/12	Human Genetics

A. Personal Statement

With a background in machine learning and statistics as applied to large biological data sets, I am uniquely qualified to develop and validate the statistical models required of the proposed research. I will develop the statistical methodology and analyze the results in a biological framework. I have experience with developing statistical models and software for genomics applications, including the development of the software SIFTER (supervised by Drs Michael I Jordan and Stephen E Brenner) to predict protein molecular function in protein families, and the development of sparse factor analysis models (supervised by Dr Matthew Stephens) to capture population structure using genotype data. More recently, I have completed work on several pharmacogenomic studies involving complex, high-dimensional phenotypes and gene expression data. In particular, I developed methodologies to perform association mapping with complex phenotypes associated with drug response, including models to identify differential expression quantitative trait loci (eQTLs). I am currently developing statistical models to build directed gene networks from gene expression data by incorporating available biological covariates (e.g., cis-eQTLs), and to identify individual-specific levels of mRNA isoforms from RNA-seq data in the independent phase of an R00. My new group at Duke University is focused on statistical methodologies for use in eQTL and association studies, joining forces with biologists to collect high-throughout biological and genomic data, and developing the appropriate statistical analysis to gain the most insight from jointly considering these diverse data.

B. Positions and Honors

Positions

1999-2001 Technical Staff, Artificial Intelligence Group, Jet Propulsion Laboratory, NASA
2001-2007 Graduate Student, Department of Computer Science, University of California, Berkeley
2007-2008 Scientist, 23andMe, Inc., Mountain View, California
2008-2011 Postdoctoral scholar, Department of Computer Science, University of Chicago
2011-2012 Postdoctoral scholar, Department of Human Genetics, University of Chicago
2012-present Assistant Professor, Department of Biostatistics & Bioinformatics, Duke University

Honors/Awards/Professional Activities

2001-2005 National Science Foundation Graduate Research Fellowship
2004 Walter M. Fitch Prize from Society for Molecular Biology and Evolution (SMBE)
2005-2006 Google Anita Borg Scholarship

C. Peer-reviewed publications

Engelhardt BE, Jordan MI, Muratore KE, Brenner SE (2005). Protein molecular function prediction by Bayesian phylogenomics. *PLoS Computational Biology* 1(5):e45. PMC1246806

Engelhardt BE, Jordan MI, Brenner (2006). A graphical model for predicting protein molecular function. *Proceedings of the International Conference on Machine Learning*.

Pickrell JK, Marioni JC, Pai AA, Degner JF, **Engelhardt BE**, Nkadori E, Veyrieras JB, Stephens M, Gilad Y, Pritchard JK (2010). Understanding mechanisms underlying human gene expression variation with RNA sequencing. *Nature* 464:768-772. PMC3089435

Engelhardt BE, Stephens M. Analysis of population structure: a unifying framework and novel methods based on sparse factor analysis (2010). *PLoS Genetics* 6(9):e1001117. PMC2940725

Engelhardt BE, Jordan MI, Srouji JR, Brenner SE (2011). Genome-scale phylogenetic function annotation of large and diverse protein families. *Genome Research* 21(11):1969-1980. PMC3205580

Hart AE**, Engelhardt BE,** Wardle MC, Sokoloff G, Stephens M, de Wit H, Palmer AA (2012). Genome-Wide Association Study of *d*-Amphetamine Response in Healthy Volunteers Identifies Putative Associations, Including Cadherin 13 (CDH13). *PLoS One*;7(8):e42646. PMC3429486

BIOGRAPHICAL INFORMATION (SHORT BIOSKETCH)

Date: March 12, 2013
Name: **Alaattin Erkanli**
Degree**: Ph.D.**
Gender: Male

1. EDUCATION (Begin with baccalaureate degree and include postdoctoral training, if applicable.)

Institution and Location	Degree	Year Conferred	Scientific Field
Middle East Technical University, Ankara, Turkey	B.S.	1981	Applied Statistics
Middle East Technical University, Ankara, Turkey	M.S.	1984	Mathematics
London School of Economics and Political Sciences London, England		1986-1987	British Council Research Scholar
Carnegie Mellon, Pittsburgh, P A	M. S.	1988	Statistics
Carnegie Mellon, Pittsburgh, P A	Ph.D.	1991	Statistics

2. PERSONAL STATEMENT

I am a statistician who strives for finding sound methodological solutions to complex problems arising from real applications. I have over twenty years of on hand experience in providing statistical support to Duke Faculty and other collaborators. I routinely provide extensive power calculations for NIH/NIMH and similar grant applications using cutting edge statistical techniques. My research focus is in the applications of Bayesian and frequentist methodology to psychiatric epidemiology, mental health services, genetic epidemiology, multi-stage optimal designs, hierarchical generalized linear models, meta-analysis, structural equations (SEM), latent class models, item-response theory, non-parametric statistics, reliability, clinical cancer research, response adaptive randomization, and medical diagnostic testing. I made some important methodological contributions to statistical literature, and, through collaborative research with some of the best scientists in the world, I also made important contributions to psychiatric epidemiology literature.

2. EXPERIENCE.

1991-1993	Visiting Assistant Professor, Institute of Statistics and Decision Sciences, Duke University
1993-1994	Research Associate, Developmental Epidemiology Program, Department of Psychiatry and Behavioral Sciences, Duke University School of Medicine
1995-1999	Assistant Professor, Developmental Epidemiology Program, Department of Psychiatry and Behavioral Sciences, Duke University School of Medicine
1999-2006	Assistant Professor of Biostatistics, Department of Biostatistics and Bioinformatics, Duke University School of Medicine
2006-	Associate Professor of Biostatistics, Department of Biostatistics and Bioinformatics, Duke University School of Medicine

3. **SELECTED PEER-REVIEWED PUBLICATIONS**. List (in chronological order)of representative publications

Erkanli, A. (1994). Laplace approximations for posterior expectations when the mode occurs on the

boundary of the parameter space, Journal of the American Statistical Association, 89, 250-258.

Federman, E., Costello, E., Angold, A., Farmer, E., & **Erkanli, A**. (1997). Great Smoky Mountains Study: Development of substance use and psychiatric comorbidity in an epidemiologic study of white and American Indian young adolescents. Drug and Alcohol Dependence, 44, 69-78.

Erkanli, A., Costello E., & Soyer, R. (1999). Bayesian Inference for prevalence in longitudinal two-phase studies. Biometrics, 55, 1145-1150.

Costello, E**., Erkanli, A**., Federman, E., & Angold, A. (1999). The development of psychiatric comorbidity with substance abuse in adolescents: Effects of timing and sex. Journal of Clinical Child Psychology, 28,298-311.

Erkanli, A., Soyer, R. & Angold, A. (2001). Bayesian analysis of longitudinal binary data using Markov regression models of unknown order. Statistics in Medicine, 20, 755-770.

A. Erkanli, D. D. Taylor, D. Dean, F. Eksir, D. Egger, J. Geyer, B. H. Nelson, B. Stone, H. A. Fritsche, and R. B.S. Roden (2006) Application of Bayesian modeling of autologous antibody responses against ovarian tumor-associated antigens to cancer detection. Cancer Research, 66, 1792-1798.

Erkanli, A., Sung, M, Costello, E., and Angold A. Bayesian semi-parametric ROC analysis. (2006). Statistics in Medicine, 25(22):3905-28.

Goldston, D., Walsh, A., Arnold, E., Reboussin, B., Daniel, S., **Erkanli, A**., Nutter, D., Hickman, E., Palmes, G., Snider, E., Wood, F. (2007). Reading problems, psychiatric disorders, and functional impairment from mid- to late adolescence. Journal of the American Academy of Child and Adolescent Psychiatry. 46(1), 25-32.

Soyer, R., **Erkanli, A**. and Merrick, J. R. (2008). Accelerated Life Tests: Bayesian Models. Encyclopedia of Statistics in Quality and Reliability, Wiley, NY.

Goldston, D., Daniel, S., Reboussin, B., **Erkanli, A.,** Frazier, P., Mayfield, A., Treadway, S. (2009). Psychiatric diagnoses as proximal risk factors for suicide attempts among adolescents and young adults: Developmental changes. Journal o/Consulting and Clinical Psychology; 77, 281-290.

Costello, E., **Erkanli, A**., Copeland W., Angold A. (2010) Association of family income supplements in adolescence with development of psychiatric and substance use disorders in adulthood among an American Indian population. JAMA, 1954-1960.

Copeland WE, Shanahan L, Costello EJ**, Erkanli A**, & Angold A. (2011) Cumulative Prevalence of Psychiatric Disorders by Young Adulthood. Journal of the American Academy of Child and Adolescent Psychiatry. 50(3): 252-261.

Angold, A**, Erkanli, A**, Copeland, W, Goodman, R, Fisher, P.W. F, and Costello, E. J, (2012) Psychiatric diagnostic interviews for children and adolescents: A comparative study. Journal of the American Academy of Child and Adolescent Psychiatry, **51**(5): 506-517

E. Jane Costello et al. (2013). Genes, Environments, and Developmental Research: Methods for a Multi-Site Study of Early Substance Use. Twin Research and Human Genetics, first view.

Suarez, C. E., Schramm-Sapyta, N. L., Hawkins, T. V., and **Erkanli A.** (2013). Depression inhibits the anti-inflammatory effects of leisure time physical activity and light to moderate alcohol consumption. Brain, Behavior and Immunity. In press.

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Susan Halabi, Ph.D.	Professor with Tenure
eRA COMMONS USER NAME (credential, e.g., agency login) Shalabi	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
American University of Beirut	B.S.	6/82	Biostatistics
American University of Beirut	M.P.H.	6/84	Health Services Admin
The University of Texas Health Science Center at Houston, TX	Ph.D.	5/94	Biometry

A. Personal Statement

Since 1996, I have been actively engaged within the Geni-urinary Committee (GU) of the Alliance (formerly Cancer and Leukemia Study Group B). I have provided statistical support for investigators where I have been involved in study design, monitoring, study conduct, analyses, and manuscript writing. The collaboration was very productive and resulted in over several dozen publications in leading medical journals including the *Journal of Clinical Oncology and Journal of the National Cancer Institute*. In this application, I will collaborate with study chairs with the GU committee in the design, conduct and analysis of trials and correlative sciences studies. In addition, I have a tremendous interest and I maintain a research portfolio in prostate cancer, especially in developing and validating prognostic models. I have led multiple meta-analyses in prostate cancer and recently co-edited a book on clinical trials in oncology. Currently, I am a PI on a funded R01 award to develop prognostic models of clinical outcomes in men with castration resistant prostate cancer. I am also a PI on funded U01 award entitled 'Validation of prognostic and pathway signatures in lethal prostate cancer. In summary, I have a demonstrated record of successful and productive research as a statistician and as an independent researcher within the GU committee.

B. Positions and Honors

List in chronological order previous positions, concluding with the present position. List any honors. Include present membership on any Federal Government public advisory committee.

7/94 -12/96	Assistant Professor, Department of Biostatistics and Epidemiology, Tulane University Assistant Director, Office of Clinical Research, Tulane Cancer Center, Tulane University
12/96-2/05	Assistant Professor, Department of Biostatistics and Bioinformatics, Duke University
3/05-9/30/12	Associate Professor, Department of Biostatistics and Bioinformatics, Duke University
10/01/12-present	Professor, Department of Biostatistics and Bioinformatics, Duke University
12/96-present	Faculty Statistician, The Genitourinary Committee, Cancer and Leukemia Group B
6/03- 06/06	Member, Central IRB (CIRB), NCI
6/03-6/06	Reviewer, Cancer Biomarker Study Section (CBSS), NCI
2007-2008	*Ad hoc* Member, Subcommittee H, NCI
08-present	Member, GU Steering Committee, NCI
08-present	Member, Prostate Cancer Task Force, NCI
2008-2011	Special Government Employee, General and Plastic Surgery Devices Panel, Food and Drug Administration
2009-present	Member, Editorial Board, *Journal of Clinical Oncology*
2009-present	American Joint Committee on Cancer, Modeler Group
2008-2011	Member, Grant Selection Committee, American Society of Clinical Oncology
2011-2015	Member, Board of Directors, Society of Clinical Trials
2012-2013	Member and Director of Biostatistics Track (2013), American Society of Clinical Oncology Scientific Program Committee
11/11-present	Associate Editor, *Clinical Trials*

C. Selected Peer-reviewed Publications (Selected from over 150 peer-reviewed publications)

1. Halabi S, Small EJ, Kantoff PW, Kattan MW, Kaplan EB, Dawson NA, Levine EG, Blumenstien BA, Vogelzang NJ. Prognostic model for predicting survival in men with hormone-refractory metastatic prostate cancer. *Journal of Clinical Oncology* 21:1232-1237, 2003.

2. Halabi S, Vogelzang NJ, Kornblith AB, Ou SS, Kantoff PW, Dawson NA, Small EJ. Pain predicts overall survival in men with metastatic castrate refractory prostate cancer (CRPC). *Journal of Clinical Oncology* 26:2544-9, 2008. PMID: 18487572

3. Cole BF, Logan RF, Halabi S, Benamouzig R, Sandler RS, Grainge MJ, Chaussade S, Baron JA (2009). Aspirin for the chemoprevention of colorectal adenomas: Meta-analysis of the randomized trials. *Journal of the National Cancer Institute* 101:256-66. PMID: 19211452

4. Halabi S, Vogelzang NJ, Ou SS, Owzar K, Archer LA, Small EJ. Progression-free survival as a predictor of overall survival in men with castrate resistant prostate cancer (CRPC). *Journal of Clinical Oncology* 27:2766-71, 2009. PMID: 19380448

5. Rini BI, Halabi S, Rosenberg JE, Stadler WM, Vaena DA, Archer L, Atkins JN, Picus J, Czaykowski P, Dutcher J, Small ES. A phase 3 study of bevacizumab plus interferon-alpha versus interferon-alpha monotherapy in patients with metastatic renal cell carcinoma-final results of CALGB 90206. *Journal of Clinical Oncology* 28:2137-43, 2010. PMID: 20368558

6. Garber JE, Halabi S, Tolaney SM, Kaplan E, Archer L, Atkins JN, Edge S, Shapiro CL, Dressler L, Paskett EM, Kimmick G, Orcutt J, Scalzo A, Winer E, Levine E, Rotche R, Shahab N, Berliner N. Factor V Leiden mutation and the risk of thromboembolic events in women receiving adjuvant tamoxifen for breast cancer: Results from CALGB 9872. *Journal of the National Cancer Institute* 102:942-9, 2010. PMID: 20554945

7. Kelly WM, Halabi S, Carducci M, George D, Mahoney JF, Stadler WM, Morris M, Kantoff P, Monk P, Small EJ. Randomized, double-blind, placebo-controlled phase III trial comparing docetaxel and prednisone with or without bevacizumab in men with metastatic castration-resistant prostate cancer: CALGB 90401. *Journal of Clinical Oncology* 30(13): 1534-40, 2012. PMID: 22454414

8. Armstrong AJ, George DJ, Halabi S. Serum lactate dehydrogenase predicts for overall survival benefit in patients with metastatic renal cell carcinoma treated with inhibition of mammalian target of rapamycin**.** *Journal of Clinical Oncology* PMID: 22891270 [Epub ahead of print]

9. Halabi S, Wun CC, Davis BR. Analysis of survival data with missing measurements of a time-dependent binary covariate. *Journal of Biopharmaceutical Statistics* 13:253-270, 2003.

10. Halabi S, Singh B. Sample size determination for comparing several survival curves with unequal allocations. *Statistics in Medicine* 23:1793-1815, 2004.

11. Singh B, Halabi S, Schell M. Sample size selection in clinical trials when population means are subject to a partial order. *Journal of Applied Statistics* 35: 583-600, 2008.

12. Liu C, Liu A, Halabi S. A min-max combination of biomarkers to improve diagnostic accuracy. *Statistics in Medicine* 30:2005–2014, 2011. PMID: 21472763

13. Halabi S, Moser BK (2012). Estimation and testing of the relative risk of disease in case-control studies with a set of k matched controls per case with known prevalence of disease. *Statistics in Medicine* 31(1):29-44.PMID: 22162127

14. Korn EL, Freidlin B, Abrams JS, Halabi S (2012). Design issues in randomized phase II/III trials. *Journal of Clinical Oncology* 30(6): 667-71,2012. PMID: 22271475

15. Halabi S. Adjustment on the type I error rate for a clinical trial monitoring for both intermediate and primary endpoints. *Journal of Biostatistics and Bioinformatics* 2155-6180, S7-S15, 2012.

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Elizabeth R. Hauser, Ph.D.	Professor
eRA COMMONS USER NAME (credential, e.g., agency login) Elizabeth.Hauser	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Ripon College, Ripon, WI	AB	05/1982	Biology
The Johns Hopkins University, Baltimore, MD	MHS	08/1985	Genet. Epidemiology
University of Michigan, Ann Arbor, MI	MS	05/1992	Biostatistics
University of Michigan, Ann Arbor, MI	PhD	05/1998	Biostatistics

A. Personal Statement

I have a long-standing interest in understanding effects in cardiovascular disease and the relationship between cardiovascular disease, biomarkers for cardiovascular disease and genetic models for both cardiovascular disease and biomarkers. We have had tremendous success in the identification of genetic effects in the GENECARD study of early-onset coronary artery disease and we have recently turned our attention to understanding preclinical markers of cardiovascular risk in a cohort of individuals from the Duke Catheterization Lab. I am very excited about the emphasis of our ongoing studies to metabolomics biomarkers because this new direction allows for the potential for translation of our genetic and biomarker findings to treatments for coronary artery disease. My recent statistical methods development projects) in the setting of genetic heterogeneity (i.e. multiple genetic causes) has provided me an opportunity to explore the quantitative trait model, such as might be seen for genetic effects in metabolite profiles and the gene-by-covariate interaction models. Finally, I am familiar with the logistical aspects of performing a high-throughput genetic and genomics study. I direct the Duke Center for Human Genetics and supervise the Center for Human Genetics informatics group and as such I have been involved in the establishment of our WGA informatics and sequence analysis pipeline.

B. Positions and Honors

Positions and Employment

1985-1987 Research Assistant, The Health Services Research and Development Center, The Johns Hopkins University School of Hygiene and Public Health
1987-1988 Research Associate, Dept. Epidemiology and Preventive Medicine, University of Maryland at Baltimore School of Medicine
1988-1990 Research Associate, Dept. Pediatrics, The Johns Hopkins School of Medicine
1990-1997 Graduate Student Research Assistant, Dept. Biostatistics, University of Michigan School of Public Health
1998-2004 Assistant Research Professor, Section Medical Genetics, Dept. Medicine, Duke University Medical Center (DUMC), Durham, NC
2001-2004 Assistant Research Professor of Biostatistics and Bioinformatics, DUMC
2004-2010 Associate Professor, Division of Medical Genetics, Dept. Medicine, DUMC
2004-2010 Associate Research Professor of Biostatistics and Bioinformatics, DUMC
2007-present Adjunct Associate Professor, Dept. Statistics, College of Physical and Mathematical Sciences, NC State University, Raleigh, North Carolina
2007-present Associate Research Professor in Nursing, DUMC
2008-present Associate Research Professor in Statistical Science, Dept. of Statistical Science, Duke University, Durham, NC
2010-present Statistician, Durham VAMC, Durham, NC
2010-present Professor, Division of Medical Genetics, Dept. Medicine, DUMC
2010-present Research Professor of Biostatistics and Bioinformatics, DUMC

C. Selected peer-reviewed publications most relevant to this application (in chronological order from more than 85)

1. **Hauser ER,** Mooser V, Crossman D, Haines J, Jones C, Winkelmann B, Schmidt S, Scott WK, Roses A, Pericak-Vance M, Granger C, Kraus W. Design of the genetics of early onset cardiovascular disease (GENECARD) study. Am Heart J 145:602-613, 2003.
2. **Hauser ER**, Crossman DC, Granger CB, Haines JL, Jones CJH, Mooser V, McAdam B, Winkelmann BR, Wiseman AH, Muhlestein JB, Bartel AG, Dennis CA, Dowdy E, Estabrooks S, Eggleston K, Francis S, Roche K, Clevenger PW, Huang L, Pedersen B, Shah S, Schmidt S, Haynes C, West S, Asper D, Booze M, Sharma S, Sundseth S, Middleton L, Roses A, Hauser MA, Vance JM, Pericak-Vance MA, Kraus WE. A genome wide scan for early-onset coronary artery disease in 438 families: the GENECARD study. Am J Hum Genet 75(3):436-437, 2004.
3. Schmidt S, Schmidt MA, Qin X, Martin ER, **Hauser ER**. Linkage analysis with gene-environment interaction: model illustration and performance of ordered subset analysis. Genet Epidemiol Jul;30(5):409-22, 2006.
4. Connelly JJ, Wang T, Cox JE, Haynes C, Wang L, Shah SH, Crosslin DR, Hale AB, Nelson S, Crossman DC, Granger CB, Haines JL, Jones CJH, Vance JM, Goldschmidt-Clermont PJ, Kraus WE, **Hauser ER**, Gregory SG. GATA2 is associated with familial early onset coronary artery disease. PLoS Genet. Aug 25;2(8):e139, 2006.
5. Sutton BS, Crosslin DR, Shah SH, Nelson SC, Bassil A, Hale AB, Haynes C, Goldschmidt-Clermont, PJ, Vance JM, Kraus WE, Gregory SG, **Hauser ER**. Comprehensive genetic analysis of the platelet activating factor acetylhydrolase (PLA2G7) gene and cardiovascular disease in case/control and family datasets. Human Molecular Genetics, 2008, 17(9), 1318-1328, PMCID: PMC2652668.
6. Shah SH, Freedman MD, Zhang L, Crosslin DR, Stone DH, Haynes C, Johnson J, Nelson S, Wang L, Connelly J, Muehlbauer M, Ginsburg GS, Crossman DC, Jones CJH, Vance J, Sketch MH, Granger CB, Newgard CB, Gregory SG, Goldschmidt-Clermont PJ, Kraus WE, **Hauser ER**. Neuropeptide Y gene polymorphisms confer risk of early-onset atherosclerosis, PLoS Genet 2009 5(1): e1000318. doi:10.1371/journal.pgen.1000318, PMCID: PMC2602734.
7. Wang T, Furey TS, Connelly JJ, Ji S, Nelson S, Heber S, Gregory SG, **Hauser ER**. A general integrative genomic feature transcription factor binding site prediction method applied to analysis of USF1 binding in cardiovascular disease. Hum Genomics. 2009 Apr;3(3):221-35, PMCID: PMC2742312
8. Shah SH, Bain JR, Muehlbauer MJ, Stevens RD, Crosslin DR, Haynes C, Dungan J, Newby LK, **Hauser ER**, Ginsburg GS, Newgard CB, Kraus WE. Association of a peripheral blood metabolic profile with coronary artery disease and risk of subsequent cardiovascular events. Circ Cardiovasc Genet. 2010 Apr;3(2):207-14.
9. Crosslin DR, Qin X, **Hauser ER**. Assessment of LD Matrix Measures for the Analysis of Biological Pathway Association. Stat Appl Genet Mol Biol. 2010;9(1):Article35. Epub 2010 Oct 2.
10. Zhang L, Connelly JJ, Peppel K, Brian L, Shah SH, Nelson S, Crosslin DR, Wang T, Allen A, Kraus WE, Gregory SG, **Hauser ER**, Freedman NJ. Aging-related atherosclerosis is exacerbated by arterial expression of tumor necrosis factor receptor-1: evidence from mouse models and human association studies. Hum Mol Genet. 2010 Jul 15;19(14):2754-66. PMCID: PMC2893804
11. Qin X, **Hauser ER**, Schmidt S. Ordered subset analysis for case-control studies. Genet Epidemiol. 2010;34(5):407-17. PMCID: 2937265.
12. Orlando LA, Hauser ER, Christianson C, Powell KP, Buchanan AH, Chesnut B, Agbaje AB, Henrich VC, Ginsburg GS. Protocol for implementation of family health history collection and decision support into primary care using a computerized family health history system. BMC Health Serv Res. 2011 Oct 11;11(1):264. [Epub ahead of print]
13. Shah AA, Craig DM, Sebek JK, Haynes C, Stevens RC, Muehlbauer MJ, Granger CB, Hauser ER, Newby LK, Newgard CB, Kraus WE, Hughes GC, Shah SH. Metabolic profiles predict adverse events after coronary artery bypass grafting. J Thorac Cardiovasc Surg. 2012 Apr;143(4):873-8. Epub 2012 Feb 4.
14. Xiong Q, Ancona N, **Hauser ER**, Mukherjee S, Furey TS. Integrating genetic and gene expression evidence into genome-wide association analysis of gene sets. Genome Res. 2012 Feb;22(2):386-97. Epub 2011 Sep 22. PMCID:PMC3266045
15. Nolan DK, Sutton B, Haynes C, Johnson J, Sebek J, Dowdy E, Crosslin D, Crossman D, Sketch MH Jr, Granger CB, Seo D, Goldschmidt-Clermont P, Kraus WE, Gregory SG, **Hauser ER**, Shah SH. Fine mapping of a linkage peak with integration of lipid traits identifies novel coronary artery disease genes on chromosome 5. BMC Genet. 2012 Feb 27;13:12. PMCID:PMC3309961

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Hyslop, Terry	Associate Professor
eRA COMMONS USER NAME	
tmh102	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Drexel University, Philadelphia, PA	B.S.	1981	Mathematics
Temple University, Philadelphia, PA	Ph.D.	2001	Statistics

A. Personal Statement

I am the Director of Thomas Jefferson University's Division of Biostatistics and the Director of the Biostatistics Core of Jefferson's NCI-designated Kimmel Cancer Center. As of 1/2014, I will be the Director of Biostatistics for the Duke Cancer Institute, and Professor (pending final appointment) in the Department of Biostatistics and Bioinformatics at Duke. I have had more than 10 years of experience in cancer research, with a focus on estimation of and modeling of biomarkers, including mRNA, microRNAs and in situ tumor protein levels. I have NCI funding to support statistical investigations of quantification of biomarkers from q-RT-PCR. My current research focuses on sophisticated approaches to models of prognosis that utilize multiple biomarkers. I serve as the study biostatistician on several major collaborative cancer grants. For instance, a $ 6.7 million Komen Promise grant on breast cancer (quantitative in situ protein marker profiling and outcome, clinical trial) was the result of several years of weekly interactions with Dr. Hallgeir Rui (PI of Komen grant) and a multidisciplinary consortium of translational and clinician scientists.

B. Positions and Honors.

Positions and Employment

1991 - 2001 Promotion to Principal Biostatistician, Thomas Jefferson University, Department of Medicine, Philadelphia, PA
2001 - 2005 Assistant Professor, Thomas Jefferson University, Division of Biostatistics, Department of Pharmacology and Experimental Therapeutics
2003 - 2006 Assistant Director of Biostatistics Core, Thomas Jefferson University, Kimmel Cancer Center
2005-2013 Associate Professor, Thomas Jefferson University, Division of Biostatistics, Department of Pharmacology and Experimental Therapeutics
2006-2013 Director of Biostatistics Core, Thomas Jefferson University, Kimmel Cancer Center
2006-2013 Director, Division of Biostatistics, Thomas Jefferson University
2014-present Professor, Department of Biostatistics and Bioinformatics, Duke University
Director of Biostatistics, Duke Cancer Institute

Other Professional Experience

Reviewer, NCI Scientific Study Section (PARs-03-098, 099, SEP)	2003
Reviewer, NCI Scientific Study Section (PARs-01-104, 105, 106, 107)	2003-2006
Reviewer, NCI Parent Committee, Cancer Centers, Initial Review Group, ad-hoc	2007-2009
Reviewer, NCI SPORE (Specialized Programs of Research Excellence)	2007-present
applications in Breast, Gynecologic, Genitourinary, and Prostate Cancers	2007-present
Reviewer, NCI P01 Molecular Studies	2009-present
Reviewer, NCI Clinical Oncology (CONC)	2008-2009
Member, ASCO Scientific Program Committee	2009-present
Permanent Member, NCI, Subcommittee A, Cancer Centers	2009-2012
Reviewer, NCI Parent Committee, Cancer Centers, Initial Review Group, ad-hoc	2013-present
Statistical Adviser, Nature Publishing Group	2013-present

C. Selected peer-reviewed publications (in chronological order).

(Publications selected from >70 peer-reviewed publications)

1. Heron DE, Komarnicky-Kocher LT, **Hyslop T**, Schwartz GF, Mansfield CM. Bilateral breast cancer - Risk factors and outcomes in synchronous and metrachronous patients. *Cancer*, 2000; 88 (12):2739-50.
2. Calin GA, Sevignani C, Dumitru CD, **Hyslop T**, Noch E, Yendamuri S, Shimizu M, Rattan S, Bullrich F, Negrini M, Croce CM. Human microRNA genes are frequently located at fragile sites and genomic regions involved in cancers, *Proceedings National Academy Sciences*, 2004; 101(9):2999-3004.
3. Cornfield DB, Palazzo JP, Schwartz GF, Goonewardene SA, Kovatich AJ, Chervoneva I, **Hyslop T**, Schwarting R. The prognostic significance of multiple morphologic features and biologic markers in ductal carcinoma in situ of the breast. A study of a large cohort of patients treated with surgery alone, *Cancer*, 2004; 100(11): 2317-2327.
4. Chervoneva I, Iglewicz B, **Hyslop T**. A general approach for two-stage analysis of multi-level clustered non-Gaussian data, *Biometrics*, 2006; 62, 752-759.
5. Schulz S, **Hyslop T**, Haaf J, Bonaccorso C, Nielsen K, Witek ME, Palazzo J, Weinberg D, Waldman SA. A validated quantitative assay to detect occult micrometasteses by RT-PCR of Guanylyl Cyclase C in patients with colorectal cancer, *Clinical Cancer Research*, 2006; 12(15):4545-4552.
6. Sevignani C, Calin GA, Nnadi SC, Shimizu M, Davaluri RV, **Hyslop T**, Demant P, Croce CM, Siracusa L. MicroRNA genes are frequently located near mouse cancer susceptibility loci, *PNAS*, 2007;104(19):8017-8022.
7. Calin G, Liu C-G, Ferracin M, **Hyslop T**, Spizzo R, Sevignani C, Fabbri M, Cimmino A, Lee EJ, Wojcik SE, Shimizu M, Tilli E, Rossi S, Taccioli C, Pichiorri F, Liu X, Zupo S, Herlea V, Gramantieri L, Lanza G, Alder H, Rassenti L, Volina S, Schmittgen TD, Kipps TJ, Negrini M, Croce CM. Ultraconserved Regions Encoding ncRNAs are Altered in Human Leukemias and Carcinomas. *Cancer Cell* ,12, Issue 3, 215-229.
8. Chervoneva I, Li Y, Waldman SA, **Hyslop T**. Relative quantification based on logistic models for individual polymerase chain reactions, *Statistics in Medicine*, 2007; 26(30):5596-611.
9. Waldman SA, **Hyslop T**, Schulz S, Barkun A, Nielsen K, Haaf J, Bonaccorso C, Li Y, Weinberg DS. Association of GUCY2C Expression in Lymph Nodes and Time to Recurrence and Disease-Free Survival in pN0 Colorectal Cancer, JAMA, 2009; 301(7):745-752. PMID: 17473304, NIHMSID 137712
10. Liu M, Casimiro MC, Wang C, Shirley LA, Jiao X, Katiyar S, Ju X, Li Z, Yu Z, Zhou J, Johnson M, Fortina P, **Hyslop T**, Windle JJ, Pestell RG. p21CIP1 attenuates Ras- and c-Myc-dependent breast tumor epithelial mesenchymal transition and cancer stem cell-like gene expression in vivo. Proc Natl Acad Sci U S A. 2009 Nov 10;106(45):19035-9.
11. Sato T, Neilson LM, Peck AR, Liu C, Tran TH, Witkiewicz A, **Hyslop T**, Nevalainen MT, Sauter G, and Rui H. Signal transducer and activator of transcription-3 and breast cancer prognosis. American Journal of Cancer Research 1:347-355, 2011.
12. Peck AR, Witkiewicz AK, Liu C, Stringer GA, Klimowicz AC, Pequignot E, Freydin B, Tran TH, Yang N, Rosenberg AL, Hooke JA, Kovatich AJ, Nevalainen MT, Shriver CD, **Hyslop T**, Sauter G, Rimm DL, Magliocco AM, Rui H. Loss of Nuclear Localized and Tyrosine Phosphorylated Stat5 in Breast Cancer Predicts Poor Clinical Outcome and Increased Risk of Anti-Estrogen Therapy Failure. J Clin Oncol, 18, 2448-53, 2011. *Subject of Editorial*: Tweardy D, Chang JC. Stat5: from breast development to cancer prognosis, prediction, and progression. J Clin Oncol. 29, 2443-4, 2011.
13. Peck AR, Witkiewicz AK, Liu C, Klimowicz AC, Stringer GA, Pequignot E, Freydin B, Yang N, Ertel A, Tran TH, Girondo MA, Rosenberg AL, Hooke JA, Kovatich AJ, Shriver CD, Rimm DL, Magliocco AM, **Hyslop T** and Rui H. Low levels of Stat5a protein in breast cancer are associated with tumor progression and unfavorable clinical outcomes. Breast Cancer Research, 14:R130, 2012 (16 pages).
14. Sato T, Tran TH, Peck AR, Girondo MA, Liu C, Goodman CR, Neilson LM, Freydin B, Chervoneva I, **Hyslop T**, Kovatich AJ, Hooke JA, Shriver CD, Fuchs SY and Rui H. Prolactin suppresses a progestin-induced CK5-positive cell population in luminal breast cancer through inhibition of progestin-driven BCL6 expression, Oncogene, in press, 2013.
15. Yang N, Liu C, Peck AR, Girondo MA, Yanac AF, Tran TH, Utama FE, Tanaka T, Freydin B, Chervoneva I, **Hyslop T**, Kovatich AJ, Hooke JA, Shriver CD, and Rui H. Prolactin-Stat5 signaling in breast cancer is potently disrupted by acidosis within the tumor microenvironment. Breast Cancer Research, 2013, 15:R73.

DUKE UNIVERSITY MEDICAL CENTER
BIOSKETCH

Date Prepared: 3/11/2013

Name: Sin-Ho Jung, Ph.D.
Primary academic appointment: Professor (tenured)
Primary academic department: Department of Biostatistics and Bioinformatics

Education:	**Institution**	**Date [year]**	**Degree**
College	Seoul National University	1982	B.A.
Graduate or professional school	Seoul National University	1984	M.S.
	University of Wisconsin-Madison	1992	Ph.D.

Professional training and academic career: [chronologically, beginning with first postgraduate position]

1. Academic Appointments

Institution	Position/Title	Dates
Mayo Medical/Graduate School	Assistant Professor	1994-1995
Hallym University	Assistant Professor	1995-3/99
University of Wisconsin-Madison	Visiting Assistant Professor	1/98-7/98
Indiana University (IU) School of Medicine	Associate Professor	8/98-9/01 (with tenure)
IU School of Public Health	Adjunct Faculty	8/99-9/00
Duke University	Associate Professor	10/01-5/31/06
	Professor	6/1/06-present

2. Administrative Positions

Institution	Position/Title	Dates
IU Cancer Center	Biostatistics Core Director	8/98-9/01
American College of Surgeons Oncology Group	Acting Group Statistician	4/02-4/03
Cancer & Leukemia Group B	Director, Biostatistics Unit	1/08-present
Duke Cancer Institute	Interim Director, Biostatistics	4/11-present

3. Collaboration/Committee

Institution	Position/Title	Dates
Mayo/North Central Cancer Treatment Group	Faculty Statistician	1992-1995
Hoosier Oncology Group	Faculty Statistician	1999-2001
IU Cancer Center, Scientific Review Committee		8/98-9/01
Mary Margaret Walther Program, Internal Advisory Committee		5/99-9/01
IU General Clinical Research Center, Advisory Committee		5/01-9/01
IU School of Medicine, IRB-02 and IRB-04		7/01-9/01
American College of Surgeons Oncology Group	Faculty Statistician	10/01-4/04
Cancer and Leukemia Group B	Faculty Statistician	5/04-present
North Central Cancer Treatment Group	Faculty Statistician	1/11-present

4. Professional Activities

Institution	Position/Title	Dates
NICHD, NIH	Visiting Scientist	7/95-8/95
NSABP, Pittsburgh University	Research Scholar	1/96-1/96
NICHD, NIH	Visiting Scientist	7/96-8/96
NSABP, Pittsburgh University	Research Scholar	1/97-1/97

NCI Lymphoma Steering Committee, Member, 3/2010-present.
NCI DLBCL Working Group, Member, 12/2010-present.

Publications:

Peer-Reviewed Papers (selected among N=139):

1. Ying Z, **Jung SH**, Wei LJ. Survival analysis with median regression models. J Am Stat Assoc 1995; 90(429):178-84.
2. **Jung SH**. Quasi-Likelihood for median regression models. J Am Stat Assoc 1996; 91:251-57.
3. **Jung SH**. Regression analysis for long-term survival rate. Biometrika 1996; 83:227-32.
4. **Jung SH**, Ying Z. Rank-based regression with repeated measurements data, Biometrika 2003; 90: 732-740.
5. **Jung SH**. Sample size for FDR-control in microarray data analysis, Bioinformatics, 2005; 21 (14): 3097-3104.
6. Owzar K, **Jung SH**, Sen PK. A copula approach for detecting prognostic genes associated with survival outcome in microarray studies, Biometrics, 2007; 63: 1089-1098.
7. **Jung SH**. Randomized phase II trials with a prospective control, Statistics in Medicine, 2008; 27: 568-583
8. Jeong JH, **Jung SH**, Costantino JP. Nonparametric inference on median residual life function, Biometrics, 2008; 64: 157-163.
9. **Jung SH**, Jeong JH, Bandos H. Regression on median residual life. Biometrics, 2009; 65: 1203-1212. [PMCID: PMC3050018]
10. Pang H and **Jung SH**. Sample size considerations of prediction-validation methods in high-dimensional data for survival outcomes. Genetic Epidemiology, to appear.

Chapters in books:

1. Jung SH, Owzar K, George SL. "Associating microarray data with a survival endpoint." In Methods of Microarray Data Analysis IV, edited by Shoemaker and Lin. Norwell, MA: Kluwer Academic Publishers, 2005; 109--120.
2. Jung SH. "Generalized estimating equations (GEE) method: Sample size calculation." Encyclopedia of Biopharmaceutical Statistics (EBS), 2006.
3. Jung SH. "Two-stage design: Phase II cancer clinical trials." EBS, 2006.
4. Jung SH, Lee TY, DeLong L. "Sample Size Calculation for Observational Studies." In Analysis of Observational Health-Care Data Using SAS, SAS Press, 2010.
5. Jung SH. "Sample Size and Power Calculation for Molecular Biology Studies." In Statistical Methods in Molecular Biology. Bang, H, Zhou, XK, Van Epps, H, Mazumdar, M. (Editors). Humana Press. To be published in 2010.

Books:

1. Ko ER, Park BJ, Jung SH. Statistical Methods for Clinical Trials, 2nd ed, 1997 (in Korean).
2. Jung SH. Randomized Phase II Clinical Trials in Oncology. CRC, expected to be in market in April 2013.

Editorials, position and background papers

1. Associate editor, Journal of Modern Applied Statistical Methods, Aug/01-present.
2. Associate editor, Journal of Biopharmaceutical Statistics, Feb/06-present.
3. Editorial board, Clinical and Translational Science, May/07-present.
4. Editorial board, Open Statistics & Probability Journal, Oct/08-present.
5. Guest editor (with Terry Hyslop), Journal of Biopharmaceutical Statistics, 2009; 19(3).
6.

Areas of research interest:

Statistical methods for cancer clinical trials, Survival analysis, Longitudinal data analysis, Design and analysis of phase II clinical trials, Bioinformatics, Clustered data analysis.

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Allison Ashley-Koch	Associate Professor
eRA COMMONS USER NAME AAK001	

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
University of North Carolina, Chapel Hill	B.S.	05/1992	Biology
Emory University, Atlanta, GA	Ph.D.	08/1997	Genetics & Molecular Biology
Centers for Disease Control and Prevention, Atlanta, GA	Postdoctoral	06/1998	Genetic Epidemiology
Duke University Medical Center, Durham, NC	Postdoctoral	12/2000	Genetic Epidemiology

A. Personal Statement.

I am a genetic epidemiologist with over 15 years of experience in the genetic dissection of complex and Mendelian traits. I have a long-standing interest in the identification of gene*gene and gene*environment interactions and have applied a number of biostatistics and genetic analytic techniques to a host of human disease phenotypes, including neurologic, hematologic and opthalmic. I have also been involved with methods development, particularly more recently to deal with the large dimensionality that is often present in genetic and genomic studies. With a wealth of applied projects, as well as methodologic projects, I can provide trainees with a rich professional perspective and internship possibilities. I have been involved in teaching at all levels (elementary and high school through postdoctoral and fellowships), through both didactic and one on one settings. I have a strong commitment to education and am also the Director of Graduate Studies for the Duke University Program in Genetics and Genomics since August of 2012. I have a secondary academic appointment in the Department of Biostatistics and Bioinformatics and am happy to be a part of such an important mission to train and engage future biostatisticians.

B. Positions and Honors.

Positions and Employment

1997-1998 ATPM Fellow, Office of Genetics and Disease Prevention, Centers for Disease Control and Prevention, Atlanta, GA.
1998-2000 Research Associate, Department of Medicine, Division of Neurology, Duke University Medical Center, Durham, NC.
2001-present Assistant Medical Professor, Department of Medicine, Section of Medical Genetics, Duke University Medical Center, Durham, NC.
2001-2007 Assistant Professor in Biostatistics and Bioinformatics, Section of Medical Genetics, Department of Medicine, Duke University Medical Center, Durham, NC.
2007-present Associate Professor, Department of Medicine, Section of Medical Genetics, Duke University Medical Center, Durham, NC.

Other Experience and Professional Memberships

1993-present Member, American Society of Human Genetics
2002-present Member, International Genetic Epidemiologic Society
2002 Reviewer, Mental Disorders Panel, Pennsylvania Department of Health
2006-2007 Reviewer, Special Emphasis Panel (ZMH1-ERB-S-06), NIH
2006 Reviewer, Italian Telethon Foundation
2007-present Member, American Society of Human Genetics Program Committee
2007-present Member, Chiari and Syringomyelgia Foundation Scientific Board
2007 Reviewer, CPDD Study Section, NIH
2008 Reviewer, Mental Disorders Panel, Pennsylvania Department of Health
2009 Reviewer, Special Emphasis Panel (Z-DCI-SRB-R), NIH
2010 Reviewer, Study Section (ZES1-TN-J-R), NIH/NIEHS
2010 Reviewer, Special Emphasis Panel (ZDE1-VH [02]), NIH/NIDCR

Honors

1996 Sigma Xi Graduate Student Research Award, Emory University, Atlanta, GA

1997	Associations of Teachers of Preventive Medicine “Genetics in Preventive Medicine,” Postdoctoral Fellowship, Centers for Disease Control and Prevention, Atlanta, GA
1998	Student Travel Award, Advanced Linkage Course, Rockefeller University, New York, NY
2010-present	Admissions Committee, University Program in Genetics and Genomics, Duke University
2011-present	Vice Chair, Scientific and Education Advisory Board, Chiari and Syringomyelia Foundation.

C. Selected peer-reviewed publications (in chronological order, out of over 95).

1. Züchner S, Cuccaro ML, Tran-Viet KN, Cope H, Krishnan R, Pericak-Vance MA, Wright HH, **Ashley-Koch AE**. SLITRK1 mutations in trichotillomania. Mol Psychiatry. 11(10):888-9, 2006.
2. **Ashley-Koch AE**, Jaworski J, Ma DQ, Mei H, Ritchie MD, Skaar DA, Delong GR, Worley G, Abramson RK, Wright HH, Cuccaro ML, Gilbert JR, Martin ER, Pericak-Vance MA. Investigation of potential Gene-gene interactions between APOE and RELN contributing to autism risk. Psychiatr Genet. (4): 221-6, 2007.
3. **Ashley-Koch AE**, Elliott L, Kail ME, De Castro LM, Jonassaint J, Jackson TL, Price J, Ataga KI, Levesque MC, Weinberg JB, Orringer EP, Collins A, Vance JM, Telen MJ. Identification of genetic polymorphisms associated with risk for pulmonary hypertension in sickle cell disease. Blood. 111(12):5721-6, 2008. PMCID: PMC2424164
4. McClernon FJ, Fuemmeler BF, Kollins SH, Kail ME, **Ashley-Koch AE**. Interactions between genotype and retrospective ADHD symptoms predict lifetime smoking risk in a sample of young adults. Nicotine Tob Res. 10(1):117-27, 2008.
5. Stamm DS, Siegel DG, Mehltretter L, Connelly JJ, Trott A, Ellis N, Zismann V, Stephan DA, George TM, Vekemans M, **Ashley-Koch A**, Gilbert JR, Gregory SG, Speer MC; NTD Collaborative Group. Refinement of 2q and 7p loci in a large multiplex NTD family. Birth Defects Res A Clin Mol Teratol. 82(6):441-52, 2008.
6. Kollins SH, Garrett ME, McClernon FJ, Lachiewicz AM, Morrissey-Kane E, FitzGerald D, Collins AL, Anastopoulos AD, **Ashley-Koch AE**. Effects of postnatal parental smoking on parent and teacher ratings of ADHD and oppositional symptoms. J Nerv Ment Dis. 197(6):442-9, 2009.
7. Taylor WD, Steffens DC, **Ashley-Koch A**, Payne ME, MacFall JR, Potocky C, Krishnan KR. Angiotensin receptor gene polymorphisms and two-year change in cerebral hyperintense lesion volume in men. Molecular Psychiatry. 15(8):816-22, 2010. PMCID: PMC2891956
8. Solovieff N, Milton JN, Hartley SW, Sherva R, Sebastiani P, Dworkis DA, Klings ES, Farrer LA, Garrett ME, **Ashley-Koch A**, Telen MJ, Fucharoen S, Ha SY, Li CK, Chui DH, Baldwin CT, Steinberg MH. Fetal hemoglobin in sickle cell anemia: genome-wide association studies suggest a regulatory region in the 5' olfactory receptor gene cluster. Blood. 115(9):1815-22, 2010. PMCID: PMC2832816
9. Markunas CA, Quinn KS, Collins AL, Garrett ME, Lachiewicz AM, Sommerd JL, Morrissey-Kane E, Kollins SH, Anastopoulos AD, **Ashley-Koch AE**. Genetic variants in SLC9A9 are associated with measures of Attention-deficit/hyperactivity disorder symptoms in families. Psychiatr Genet. 20(2):73-81, 2010, PMCID: PMC3085270.
10. Bidwell LC, Garrett ME, McClernon FJ, Fuemmeler BF, Williams RB, **Ashley-Koch AE**, Kollins SH. A Preliminary Analysis of Interactions Between Genotype, Retrospective ADHD Symptoms, and Initial Reactions to Smoking in a Sample of Young Adults. Nicotine Tob Res. 2011 Jul 20. [Epub ahead of print], PMID:21778150
11. **Ashley-Koch AE**, Okocha EC, Garrett ME, Soldano K, De Castro LM, Jonassaint JC, Orringer EP, Eckman JR, Telen MJ. MYH9 and APOL1 are both associated with sickle cell nephropathy. British J Haematol 2011 Nov;155(3):386-94.
12. Wang L, **Ashley-Koch A**, Steffens DC, Krishnan KR, Taylor WD. Impact of BDNF Val66Met and 5HTTLPR polymorphism variants on neural substrates related to sadness and executive function. Genes Brain Behav. 2012 Jan 6.
13. McDonald KK, Stajich J, Blach C, **Ashley-Koch AE**, Hauser MA. Exome analysis of two limb-girdle muscular dystrophy families: mutations identified and challenges encountered. PLoS One. 2012;7(11):e48864. doi: 10.1371/journal.pone.0048864. Epub 2012 Nov 14. PMID: 23155419.
14. Zhu B, Dunson DB, **Ashley-Koch AE**. Adverse subpopulation regression for multivariate outcomes with high-dimensional predictors. Stat Med. 2012 Dec 20;31(29):4102-13. doi: 10.1002/sim.5520. Epub 2012 Jul 24. PMID: 22825854.
15. Lu Y, Vitart V, Burdon KP, Khor CC, Bykhovskaya Y, Mirshahi A, Hewitt AW, Koehn D, Hysi PG, Ramdas WD, Zeller T, Vithana EN, Cornes BK, Tay WT, Tai ES, Cheng CY, Liu J, Foo JN, Saw SM, Thorleifsson G, Stefansson K, Dimasi DP, Mills RA, Mountain J, Ang W, Hoehn R, Verhoeven VJ, Grus F, Wolfs R, Castagne R, Lackner KJ, Springelkamp H, Yang J, Jonasson F, Leung DY, Chen LJ, Tham CC, Rudan I, Vatavuk Z, Hayward C, Gibson J, Cree AJ, Macleod A, Ennis S, Polasek O, Campbell H, Wilson JF, Viswanathan AC, Fleck B, Li X, Siscovick D, Taylor KD, Rotter JI, Yazar S, Ulmer M, Li J, Yaspan BL, Ozel AB, Richards JE, Moroi SE, Haines JL, Kang JH, Pasquale LR, Allingham RR, **Ashley-Koch** A; NEIGHBOR Consortium, Mitchell P, Wang JJ, Wright AF, Pennell C, Spector TD, Young TL, Klaver CC, Martin NG, Montgomery GW, Anderson MG, Aung T, Willoughby CE, Wiggs JL, Pang CP, Thorsteinsdottir U, Lotery AJ, Hammond CJ, van Duijn CM, Hauser MA, Rabinowitz YS, Pfeiffer N, Mackey DA, Craig JE, Macgregor S, Wong TY. Genome-wide association analyses identify multiple loci associated with central corneal thickness and keratoconus. Nat Genet. 2013 Jan 6. doi: 10.1038/ng.2506. [Epub ahead of print] PMID: 23291589

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Kosinski, Andrzej Stanislaw	Associate Professor of Biostatistics
eRA COMMONS USER NAME (credential, e.g., agency login) AKosinski	

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
AGH University of Science and Technology, Krakow, Poland	B.S/M.S.	05/1983	Applied Mathematics
University of Oxford, Oxford, England	M.Sc.	11/1984	Applied Statistics
University of Washington, Seattle	Ph.D.	12/1990	Biostatistics

A. Personal Statement

While at the Emory University Rollins School of Public Health I was involved as the primary biostatistician on several major clinical trials. Since joining Duke University and the Duke Clinical Research Institute (DCRI) 9 years ago, I have become involved in the NIH sponsored Data Coordinating Centers for the PROMISE trial and the GUIDE-IT trial. I have been actively engaged in protocol development, overseen analyses, participated in the DSMB meetings, and collaborated in manuscript writing.

I have also been active in the comparative effectiveness research through the Duke Evidence-based Practice Center. Currently I am part of the Data Coordinating Center for the Drug Induced Liver Injury Network (DILIN) with focus on manuscript preparation, and I participate in analyses and manuscript preparation based on the Society of Thoracic Surgeons (STS) Database.

In addition to my collaborative research activities I have been active in statistical research. I have been principal investigator (PI) of statistical methodology research grants funded by the American Heart Association, a co-investigator on a NIH grant related to agreement methods, and PI of an internal Duke grant for statistical methodology research in the area of longitudinal analysis. I have advised severa; graduate students and have taught graduate biostatistics courses.

B. Positions and Honors

Positions and Employment

1990-1998 Assistant Professor, Department of Biostatistics, Emory University, Atlanta, GA
1999-2003 Associate Professor (tenure), Department of Biostatistics, Emory University, Atlanta, GA
2003- Associate Professor, Dept. of Biostatistics & Bioinformatics, Duke University, Durham, NC

Other Experience and Professional Memberships

2005-2007 Member, Data Safety Monitoring Boards
1999-2012 Member, NIH Peer Review Committees: ad hoc reviewer

Honors

1983 Tuition scholarship from Vice Chancellors and Principals of the Universities of United Kingdom
1988 First prize at the student paper competition of 9th meeting of Society of Clinical Trials
1996-1998 NSF junior researcher travel support: Amsterdam, 1996; Istanbul 1997; Cape Town 1998

C. Selected Peer-reviewed Publications (selected from 85 peer-reviewed publications)

Most relevant to the current application

1. **Kosinski, A.S.** A procedure for the detection of multivariate outliers. Computational Statistics and Data Analysis, 1999; 29(2):145-161.
2. **Kosinski, AS,** Barnhart H.X. Accounting for non-ignorable verification bias in assessment of diagnostic test. Biometrics, 2003; 59: 163-171.
3. Hlatky MA, Boothroyd DB, Bravata DM, Boersma E, Booth J, Brooks MM, Carrié D, Clayton TC, Danchin N, Flather M, Hamm CW, Hueb WA, Kähler J, Kelsey SF, King SB, **Kosinski, AS**, Lopes N, McDonald KM, Rodriguez A, Serruys P, Sigwart U, Stables RH, Owens DK & Pocock SJ. Coronary artery bypass surgery compared with percutaneous coronary interventions for multivessel disease: a collaborative analysis of individual patient data from ten randomised trials. Lancet, 2009; 373(9670):1190-1197.
4. **Kosinski AS**, Chen Y & Lyles RH. Sample size calculations for evaluating a diagnostic test when the gold standard is missing at random. Statistics in Medicine 2010 29(15): 1572-1579. DOI: 10.1002/sim.3899.
5. **Kosinski AS.** A weighted generalized score statistic for comparison of predictive values of diagnostic tests. Statistics in Medicine, 2013 (in press; published online) DOI: 10.1002/sim.5587

Additional publications (in chronological order)

1. King SB 3rd, Lembo NJ, Weintraub WS, **Kosinski AS**, Barnhart HX, Kutner MH, Alazraki NP, Guyton RA, Zhao XQ. "A randomized trial comparing coronary angioplasty with coronary bypass surgery. Emory Angioplasty versus Surgery Trial." New England Journal of Medicine, 1994; 331(16):1044-50.
2. King SB 3rd, **Kosinski AS**, Guyton RA, Lembo NJ, Weintraub WS. Eight-year mortality in the Emory Angioplasty versus Surgery Trial (EAST). Journal of the American College of Cardiology, 2000; 35 (5): 1116-1121.
3. **Kosinski AS**, Barnhart HX. A global sensitivity analysis of performance of a medical diagnostic test when verification bias is present. Statistics in Medicine, 2003; 22 (17): 2711-2721.
4. **Kosinski AS,** Flanders WD. Evaluating the exposure and disease relationship with adjustment for different types of exposure misclassification: A regression approach. Statistics in Medicine, 1999; 18:2795-2808.
5. Crawford, S.B., **Kosinski, A.S.**, Lin, H.M., Williamson, J.M., & Barnhart, H.X. Computer programs for the concordance correlation coefficient. Computer Methods & Programs in Biomedicine, 2007; 88(1):62-74,
6. Feldmann E. Wilterdink JL. **Kosinski AS**. Lynn M. Chimowitz MI. Sarafin J. Smith HH. Nichols F. Rogg J. Cloft HJ. Wechsler L. Saver J. Levine SR. Tegeler C. Adams R. Sloan M and SONIA Trial Investigators. "The Stroke Outcomes and Neuroimaging of Intracranial Atherosclerosis (SONIA) trial". Neurology. 68(24):2099-106, 2007 Jun 12.
7. Barnhart HX, **Kosinski AS**, Haber MJ. Assessing individual agreement. [Journal Article. Research Support, N.I.H., Extramural] Journal of Biopharmaceutical Statistics. 17(4):697-719, 2007.
8. Majidi, M., **Kosinski, A.S**., Al-Khatib, S.M., Lemmert, M.E., Smolders, L., van Weert, A., Reiber, J.H., Tzivoni, D., Bar, F.W., Wellens, H.J., Gorgels, A.P. & Krucoff, M.W. Reperfusion ventricular arrhythmia 'bursts' predict larger infarct size despite TIMI 3 flow restoration with primary angioplasty for anterior ST-elevation myocardial infarction. European Heart Journal, 2009; 30(7):757-64
9. Boffa DJ, **Kosinski AS**, Subroto P, Mitchell JD, Onaitis MW. Lymph Node Evaluation by Open or Video-Assisted Approaches in 11,500 Anatomic Lung Cancer Resections. Annals of Thoracic Surgery, 2012;94:347-353. doi:10.1016/j.athoracsur.2012.04.059 (**Richard E. Clark Award**).
10. Ceppa DP, **Kosinski AS**, Berry MF, Tong BC, Harpole DH, Mitchell JD, D'amico TA, Onaitis MW. Thoracoscopic lobectomy has increasing benefit in patients with poor pulmonary function: a Society of Thoracic Surgeons database analysis. Ann Surg. 2012; 256(3):487-93.

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Kuchibhatla, Maragatha	Associate Professor
eRA COMMONS USER NAME (credential, e.g., agency login) MAGGIEK	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
St. Francis College, Hyderabad, India	B.S.	06/79	Mathematics & Physics
Osmania University, Hyderabad, India	M.S.	12/81	Statistics
Texas A & M University, College Station, TX	Ph.D.	12/92	Statistics

A. Personal Statement

As a faculty statistician, the majority of the studies I am involved in are with Department of Psychiatry, and the Duke Center for the Study of Aging. My primary statistical methodological interest, as evident from my publications, is longitudinal data analysis. I have acquired statistical expertise with regards to issues and modeling of cross- sectional and longitudinal analysis. I was a PI on a recently completed grant from the Duke Translational Medicine Institute on an application of a newer alternate statistical methodology on repeated measures data from a drug trial.

As a statistical investigator on several cycles of Conte Center for Neurosciences, a Center grant with the department of Psychiatry, and with the Duke Aging Center's PEPPER Center grant, I am involved in a number of longitudinal analyses. I am also the primary statistician for a number of completed as well as ongoing drug and behavioral trials sponsored by both NIH and industry. The proposed study involves survival analyses and cross-sectional analysis of biomarkers. I have worked on similar studies and the analyses are straight forward.

B. Positions and Honors

Positions and Employment

1982-1987 Research Officer, Department of Statistics, National Institute of Rural Development, Hyderabad, India.
1987-1992 Graduate Assistant (Teaching and Research), Department of Statistics, Texas A & M University, College Station, Texas.
1993-1993 Statistician, Institute of Urban Affairs, North Carolina State University, Raleigh, NC.
1993-1996 Statistician, Center for Aging and Human Development, DUMC, Durham, NC.
1996-2008 Assistant Professor, Department of Biostatistics and Bioinformatics, DUMC, Durham, NC.
2008- Associate Professor, Department of Biostatistics and Bioinformatics, DUMC, Durham, NC.

Other Experience and Professional Memberships

1995 Member, American Statistical Association (ASA)
2000 Member, Gerontological Association of America (GSA)
2004 Affiliate, American Association of Geriatric Psychiatry (AAGP)
2009 Associate Editor - Journal of Nutrition for the Elderly

Honors

2008-2010 Grant reviewer – Alzheimer's Association
2008 Duke Pepper Center's Pilot Award on Statistical Methodology
2009 Biostatistical Methodology Grant from CTSA (Clinical and Translational Sciences Award)

C. Selected Peer-reviewed Publications

Barber MD, **Kuchibhatla MN**, Pieper CF, Bump RC. Psychometric evaluation of 2 comprehensive condition-specific quality of life instruments for women with pelvic floor disorders. American Journal of Obstetrics and Gynecology. 2001;185(6): 1388-1395.

Kuchibhatla MN, Fillenbaum GG. Alternative statistical approaches to identifying dementia in a community- dwelling sample. Aging and Mental Health. 2003;7(5): 383-389.

Kuchibhatla MN, Fillenbaum GG. Modeling association in longitudinal binary outcomes: A brief review. Aging and Mental Health. 2005;9(3): 196-200.

Kuchibhatla MN, Fillenbaum GG. Trajectory classes of depression in a randomized depression trial of Heart Failure Patients: A Reanalysis of the SADHART-CHF Trial. Am J Geriatr Pharmacother. 2011 9(6):483-494. PMCID: PMC3526974

Kuchibhatla MN, Fillenbaum GG. Hybels CF, Blazer DG. Trajectory classes of depressive symptoms in a community sample of older adults. Acta Psychiatr Scand. 2012;125(6):492-501. PMCID: PMC3539152

Additional recent publications of importance to the field (in chronological order)

Steffens DC, O'Conner CM, Pieper CF, **Kuchibhatla MN**, Arias RM, Look L, Davenport C, Krishnan RR. The effect of major depression on functional status in patients with coronary artery disease. Journal of American Geriatric Society. 1999;47(3):319-322.

Bosworth HB, Steffens DC, **Kuchibhatla MN**, Jiang WJ, Arias RM, O'Connor CM, Krishnan RR. The relationship of social support, social networks, and negative events with depression in patients with coronary artery disease. Aging and Mental Health. 2000;4(3): 253-258.

Jiang W, Alexandra J, Christopher E, **Kuchibhatla MN**, Gaulden LH, Cuffe MS, Blazing MA, Davenport C, Califf RM, Krishnan RR, O'Connor CM. Relationship of depression to increased risk of mortality and rehospitalization in patients with congestive heart failure. Arch Intern Med. 2001;161(15): 1849-1856.

Beyer JL, **Kuchibhatla MN**, Looney C, Engstrom E, Cassidy F, Krishnan R. Social support in elderly patients with bipolar disorder. Bipolar Disorders. 2003;5(1): 22-27.

Colon-Emeric C, **Kuchibhatla MN**, Pieper C, Hawks W, Fredman L, Magaziner J, Zimmerman S, Lyles KW. The contribution of hip fracture to risk of subsequent fractures: data from two longitudinal studies. Osteoporosis International. 2003;14(11): 879-883.

Debellis M, **Kuchibhatla MN.** Cerebellar volumes in pediatric maltreatment-related posttraumatic stress disorder. Biol Psychiatry. 2006;60(7): 697-703.

O'Connor CM, Jiang W, **Kuchibhatla MN**, Mehta RH, Clary GL, Cuffe MS, Christopher EJ, Alexander JD, Califf RM, Krishnan RR. Antidepressant use, depression, and survival in patients with heart failure. Arch Intern Med. 2008;168(20):2232-2237. http://archinte.jamanetwork.com/article.aspx?articleid=414601

Taylor WD, **Kuchibhatla MN**, Payne ME, Macfall JR, Sheline YI, Krishnan KR, Doraiswamy PM. Frontal white matter anisotropy and antidepressant remission in late-life depression. PLoS ONE. 2008;24;3(9):e3267. PMCID: PMC2533397

Fillenbaum GG, **Kuchibhatla MN**, Whitson HE, Batch BC, Svetkey LP, Pieper CF, Kraus WE, Cohen HJ, and Blazer DG. Accuracy of self-reported height and weight in a community-based sample of older African Americans and Whites. J Gerontol A Biol Sci Med Sci/ J Gerontol A Biol Sci Med Sci. 2010; 65(10): 1123-1129. PMCID: PMC2949332

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Yi-Ju Li	**ASSOCIATE PROFESSOR**
eRA COMMONS USER NAME YIJU.LI	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Chung-Yuang Christian University, Taiwan	B.S.	06/1991	Mathematics
North Carolina State University, Raleigh, NC	M.S.	12/1994	Statistics & Genetics
North Carolina State University, Raleigh, NC	Ph.D.	12/1996	Statistics & Genetics

A. Personal Statement

I am a statistical geneticist with over 13 years of research experience in genetic studies of human complex diseases. My expertise includes genetic association method development, genetic data analysis, study design, and decision making for gene mapping research of complex diseases. I have devoted a significant part of my career in genetic studies of Alzheimer disease, Parkinson diseases, myopia, Fuchs Endothelial Cornea Dystrophy, and several clinical outcomes for patients underwent non-emergent coronary artery bypass grafting with cardiopulmonary bypass. In addition, my collaborators and I have developed a number of family-based association methods. I have also mentored graduate students by either serving as a thesis advisor or committee member, postdoctoral fellows, and a junior MD faculty by serving as a co-mentor for the K23 grant. As a faculty member in the Biostatistics and Bioinformatics Department, I am in strong support for the Ph.D. program and will be happy to mentor students from the proposed Ph.D. graduate program.

B. Positions and Honors

1996-1997	Postdoctoral Research Associate, Department of Dairy Science, Virginia Polytechnic Institute & State University, Blacksburg, Virginia
1998-2000	Research Associate, Department of Biosystems, The Graduate University for Advanced Studies, Hayama, Kanagawa, JAPAN
Oct 2000 - July 2002	Research Associate, Center for Human Genetics, Department of Medicine, Duke University Medical Center, Durham, North Carolina
Aug 2002 - Oct 2002	Instructor, Center for Human Genetics, Department of Medicine, Duke University Medical Center, Durham, North Carolina
Nov 2002 – Jan 2010	Assistant Professor, Track 5, Center for Human Genetics Department of Medicine, Duke University Medical Center, Durham, North Carolina
Mar 2007 – Jan 2010	Assistant Professor, Department of Biostatistics and Bioinformatics, Duke University Medical Center, Durham, North Carolina
Mar 2007 – present	Adjunct Assistant Professor, Department of Statistics, North Carolina State University, Raleigh, North Carolina
Sept 2008 – Oct 2010	Adjunct Assistant Professor, Department of Community, Occupational & Family Medicine, National University of Singapore, Singapore
Feb 2010 – present	Associate Professor, Track 5, Center for Human Genetics Department of Medicine, Duke University Medical Center, Durham, North Carolina
Feb 2010 – present	Associate Professor, Track 5, Department of Biostatistics and Bioinformatics, Duke University Medical Center, Durham, North Carolina
Nov 2010 – present	Adjunct Associate Professor, Duke-National University of Singapore Graduate Medical School, Singapore

<u>Other Experience and Professional Services</u>

2003 – present	Reviewer for Alzheimer's Association Research Grants.
2005 – 2006	Ad hoc reviewer for NINDS, NSD-K Study Section
2005	Reviewer for National Eye Institute, ZEY1 VSN Study Section
2005	Reviewer for Gene Variation & Evolution Study Section, Special Emphasis Panel ZRG1 GGG-H (60)

2007	Reviewer for GEI Study Investigators RFA 033, National Human Genome Research Institute Special Emphasis Panel
2007 – present	External Reviewer for Research Grants Council of Hong Kong, China
2008 – 2012	Associate Editor, *Molecular Biology and Evolution (MBE)*
2011 – present	Editorial Board Member, *Journal of Biometrics & Biostatistics*
2011- present	Editorial Board Member, *ISRN Biomathematics*
2013	Reviewer for 2013/05 ZRG1 BCMB-A (51) R for RFA RM11-006

C. Selected peer-reviewed publications (out of 76 publications)

1. **Li YJ,** Scott WK, Hedges DJ, Zhang F, Caskell C, Nance MA, et al. (2002) Age-at-Onset in two common neurodegenerative diseases is genetically controlled. *Am J Hum Genet* 70: 985-993. PMCID: PMC379130
2. **Li YJ**, Oliveira SA, Xu P, Martin ER, Stenger JE, Hulette C, et al. (2003) Glutathione S-Transferase modifies age-at-onset of Alzheimer Disease. *Hum Mol Genet* (12) 24: 3259-671.
3. Allen AS, Martin ER, Qin XJ, **Li YJ**. (2006) Genetic association tests based on ranks (GATOR) for quantitative traits with and without censoring. *Genet Epidemiol* 30(3): 248-258.
4. Chung RH, Morris RW, Li Z, **Li YJ**, Martin ER. (2007) X-APL: An improved family-based test of association for the X chromosome. *Am J Hum Genet* 80:59-68. PMCID: PMC1785309
5. Zhang L, Martin ER, Chung RH, **Li YJ**, Morris RW. (2008) X-LRT: A likelihood approach to estimate genetic risks and test association with X-linked markers using a case-parents design. *Genet Epidemiol* 32(4):370-80.
6. Zhang L, Martin ER, Morris RW, **Li YJ**. (2009) Association test for X-linked QTL in family-based designs. *Am J Hum Genet* 84(4):431-444. PMCID: PMC2667970
7. **Li YJ**, Guggenheim JA, Bulusu A, Metlapally R, Abbott D, Malecaze F, Calvas P, Rosenberg T, Paget S, Creer RC, Kirov G, Owen MJ, Zhao B, White T, Mackey DA, Young TL. (2009) An international collaborative family-based whole genome linkage scan for high-grade myopia. *Invest Ophthalmol Vis Sci* 50(7):3116-27. NIHMSID: NIHMS130444
8. Dellinger AE, Saw SM, Goh LK, Seielstad M, Young TL, **Li YJ**. (2010) Comparative analyses of seven algorithms for copy number variant identification from single nucleotide polymorphism arrays. Nucleic Acids Res. 38(9):e105. PMCID: PMC2875020
9. Macgregor S, Hewitt AW, Hysi PG, Ruddle JB, Medland SE, Henders AK, Gordon SD, Andrew T, McEvoy B, Sanfilippo PG, Carbonaro F, Tah V, **Li YJ**, Bennett SL, Craig JE, Montgomery GW, Tran-Viet KN, Brown NL, Spector TD, Martin NG, Young TL, Hammond CJ, Mackey DA. (2010) Genome-wide association identifies ATOH7 as a major gene determining human optic disc size. *Human Molecular Genetics*. 19(13):2716-24. PMCID: PMC2883339
10. Hysi PG, Young TL, Mackey DA, Andrew T, Fernández-Medarde A, Solouki AM, Hewitt AW, Macgregor S, Vingerling JR, **Li YJ**, Ikram MK, Fai LY, Sham PC, Manyes L, Porteros A, Lopes MC, Carbonaro F, Fahy SJ, Martin NG, van Duijn CM, Spector TD, Rahi JS, Santos E, Klaver CC, Hammond CJ. (2010) A genome-wide association study for myopia and refractive error identifies a susceptibility locus at 15q25. *Nat Genet.* 42(10):902-5.
11. **Li YJ**, Minear MA, Rimmler J, Zhao B, Balajonda E, Hauser MA, Allingham RR, Eghrari AO, Riazuddin SA, Katsanis N, Gottsch JD, Gregory SG, Klintworth GK, Afshari NA. Replication of TCF4 through Association and Linkage Studies in Late-Onset Fuchs Endothelial Corneal Dystrophy. (2011) *PLoS One.* 6(4):e18044 PMCID: PMC3080358
12. **Li YJ**, Goh L, Khor CC, Fan Q, Yu M, Han S, Sim X, Ong RT, Wong TY, Vithana EN, Yap E, Nakanishi H, Matsuda F, Ohno-Matsui K, Yoshimura N, Seielstad M, Tai ES, Young TL, Saw SM. (2010) Genome wide association studies reveal genetic variants in CTNND2 for high myopia in Singapore Chinese. *Ophthalmology.* 118(2):368-75. PMCID: PMC3052933 [Available on 2/1/2012]
13. Abbott D[*], **Li YJ[*],** Guggenheim JA, Metlapally R, Malecaze F, Calvas P, Rosenberg T, Paget S, Zayats T, Mackey D, Feng S, Young TL. (2012) An International Collaborative Family-based Whole Genome Quantitative Trait Linkage Scan for Myopic Refractive Error. *Molecular Vision, 18:720-9.* **[[*]Joint First Author]** PMCID: PMC3324362
14. Verhoeven VJ, Hysi PG, Saw SM, Vitart V, Mirshahi A, Guggenheim JA, Cotch MF, Yamashiro K, Baird PN, Mackey DA, Wojciechowski R, Ikram MK, Hewitt AW, Duggal P, Janmahasatian S, Khor CC, Fan Q, Zhou X, Young TL, Tai ES, Goh LK, **Li YJ**, et al. (2012) Large scale international replication and meta-analysis study confirms association of the 15q14 locus with myopia. The CREAM consortium. *Human Genetics. June 5.* PMCID: PMC3418496

BIOGRAPHICAL SKETCH

NAME Zhiguo Li	POSITION TITLE Assistant Professor of Biostatistics and Bioinformatics
eRA COMMONS USER NAME (credential, e.g., agency login)	

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Xiangtan University, CHINA	B.S.	1993	Statistics
Wuhan University, CHINA	M.S.	1996	Statistics
University of Michigan, Ann Arbor, MI	PhD	2008	Biostatistics
University of Michigan, Ann Arbor, MI	postdoc	2008-2010	Biostatistics

A. Personal Statement

My experience in clinical trials started when I was a postdoctoral research fellow at the University of Michigan, when I provided consultation to psychiatrists on the design of their clinical trials. During the same time, I also developed novel methodology for clinical trial design. As an assistant professor of Biostatistics and Bioinformatics at Duke University, I have been heavily engaged in cancer clinical trials especially clinical trials in hematological malignancies and statistical methods research related to cancer. With my extensive training and experience in clinical trials and statistical methodology, I am confident that I can achieve the goals of the proposed project.

B. Positions and Honors:

1989-1993	Department of Mathematics, Xiangtan University. CHINA
1993-1996	Department of Mathematics, Wuhan University. CHINA
1996-2002	Lecturer, Medical School of Peking University. CHINA
2002-2004	Department of Statistics, Florida State University. Tallahassee, FL
2004-2008	Department of Biostatistics, University of Michigan, Ann Arbor, MI
2008-2010	Postdoctoral Research Fellow, Institute for Social Research, University of Michigan, Ann Arbor, MI
2010-present	Assistant Professor, Dept. of Biostatistics and Bioinformatics, Duke University Medical Ctr., Durham, NC
2003	Best First Year Student Award, Department of Statistics, Florida State University
2008	Distinguished Student Paper Award, ENAR Spring Meeting

C. Selected peer-reviewed publications (in chronological order):

1. Taylor J.M.G., Braun T.M., Li Z. Comparing an experimental agent to a standard agent: relative merits of a one-arm or randomized two-arm Phase II design. Clinical Trials 2006;3(4):335-348. PMID: 17060208.
2. Taylor J.M.G., Wang L., Li Z. Analysis on binary responses with ordered covariates and missing data. Statistics in Medicine 2007 Aug 15;26(18):3443-3458. PMID: 17219376.
3. Li Z., Gilbert P., Nan B. Weighted likelihood method for grouped survival data in case-cohort studies, with application to HIV vaccine trials. Biometrics 2008 Dec:64(4):1247-1255. PMID: 19032178.
4. Li Z., Taylor J.M.G., Nan B. Construction of confidence intervals and regions for ordered binomial probabilities. The American Statistician, 2010, 64(4): 291-298.
5. Rizzieri DA, Crout C, Storms R, Golob J, Long GD, Gasparetto C, Sullivan KM, Horwitz M, Chute J, Lagoo AS, Morris A, Beaven A, Yang Y, Peterson B, Li Z, Chao NJ. Feasibility of low dose interleukin-2 therapy following T cell-depleted non-myeloablative allogeneic hematopoietic stem cell transplantation from HLA matched or mismatched family member donors. Cancer Investigation 2011; 29(1):56-61. PMID: 21166499.

6. Klymenko SV, Belyi DA, Ross JR, Owzar K, Jiang C, Li Z, N Minchenko J, N Kovalenko A, Bebeshko VG, J Chao N. Hematopoietic cell infusion for the treatment of nuclear disaster victims: New data from the Chernobyl accident. International Journal of Radiation Biology 2011; 87(8):846-850. PMID: 21406047.
7. Li Z., Murphy S.A. Sample size formulae for two-stage randomized trials with survival outcomes. Biometrika, 2011; 98(3):503-518.
8. Li Z., Nan B. Relative risk regression for current status data in case-cohort studies. Canadian Journal of Statistics, 2011; 39(4):557-577.
9. Li Z., Pfeiffer N.P., Hoggatt K., Zivin K., Downing K., Ganoczy D., Valenstein M. Development of anxiety after antidepressant use among depressed veterans. *Journal of Clinical Therapeutics*. 2011; 33(12):1985-1992.
10. Kanda J., Horwitz M.E., Long G.D., Gasparetto C., Sullivan K.M., Chute J.P., Morris A., Hennig, T., Li Z., Chao N.J., Rizzieri D.A. Outcomes of a 1-day nonmyeloablative salvage regimen for patients with primary graft failure after allogeneic hematopoietic cell transplantation. *Bone Marrow Transplantation* 2012; 47(5):700-705
11. Lanasa M.C., Davis R.N., Datto M., Li Z., Gockerman J.P., Moore J., DeCastro C.M., Friedman D.R., Rehder C., Cook H., Daugherty F.J., Matta, K.B., Weinberg J.B., and Rizzieri D. Phase II study of cenersen, an antisense inhibitor of p53, in combination with fludarabine, cyclophosphamide, and rituximab for high risk CLL. *Leukemia and Lymphoma*. 2012; 53(2):218-224.
12. Owzar K., Li Z., Cox N., Jung S.H. Power and sample size calculations for SNP association studies with censored time-to-event outcomes. Genetic Epidemiology 2012; 36(6):538-48.
13. Brennan T.V., Lin L., Huang X., Chao N.J., Li Z., Yang Y. Heparan sulfate, an endogenous TLR4 agonist, promotes acute GVHD following allogeneic stem cell transplantation. *Blood*. 2012 accepted.
14. Morris T.A., DeCastro C.M., Diehl L.F., Gockerman J.P., Lagoo A.S., Li Z., Moore J.O., Rizzieri D.A., Rao A.V. Re-induction Therapy Decisions Based on Day 14 Bone Marrow Biopsy in Acute Myeloid Leukemia. Leukemia Research 2012. Accepted.
15. Zhou D., Deoliveira D., Kang Y., Choi S.S., Li Z., Chao N.J., Chen B.J. Insulin-like growth factor 1 mitigates hematopoietic toxicity post lethal total body irradiation. International Journal of Radiation Oncology*Biology*Physics 2012. Accepted.
16. Lunsford K.E., Baird B.J., Sempowski G.D., Cardona D.M., Weinhold K.J., Sudan D.L., Li Z., Brennan T.V. Up-Regulation of IL-1β, IL-6, and CCL-2 by a Novel Mouse Model of Pancreatic Ischemia-Reperfusion Injury. Transplantation 2012. Accepted.

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Yuliya Lokhnygina	Assistant Professor of Biostatistics
eRA COMMONS USER NAME (credential, e.g., agency login) lokhn001	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Moscow Institute of Physics & Technology (MIPT), Moscow, Russia	BSc	1997	Control Theory & Operations Research
MIPT, Moscow, Russia	MSc	1999	Control Theory& Operations Research
Cornell University, Ithaca, NY	MSc	2001	Operations Research & Industrial Engineering
North Carolina State University, Raleigh, NC	PhD	2004	Statistics

A. Personal Statement

As a PhD-trained biostatistician with over 8 years of experience, I will bring the necessary statistical expertise to this project. I will help develop the appropriate statistical hypotheses to address clinical research questions, advise on the appropriate analytic methods, help interpret the results and contribute to reporting of the study findings in the manuscripts.

B. Positions and Honors

Positions and Employment

1999-2001	Teaching Assistant, Dept of Operations Research and Industrial Engineering, Cornell University, New York
2001-2003	Teaching Assistant, Dept of Statistics, North Carolina State University, North Carolina
05/2003-08/2003	Intern, BioOncology Statistics group, Genentech, Inc.
09/2003-08/2004	Intern, CT Statistics, Duke Clinical Research Institute, Durham, North Carolina
09/2004-present	Assistant Professor of Biostatistics, Duke Clinical Research Institute and Department of Biostatistics and Bioinformatics, Duke University
09/2005-10/2006	Biostatistician, Duke General Clinical Research Center
10/2006-present	Biostatistician, Biostatistics Core, Duke Translational Medicine Institute
09/2010-present	Associate Director, Biostatistics Core, Duke Translational Medicine Institute

Other Experience and Professional Memberships
American Statistical Association, International Biometric Society (ENAR)

Honors
Mu Sigma Rho
William Mendenhall Teaching Scholarship (2002)

C. Selected Peer-reviewed Publications (from 36 peer-reviewed publications)

1. White HD, Kleiman NS, Mahaffey KW, **Lokhnygina Y**, Pieper KS, Chiswell K, Cohen M, Harrington RA, Chew D, Petersen JL, Berdan LG, Aylward PEG, Nessel CC, Ferguson JJ, Califf RM. Efficacy and safety of enoxaparin compared with unfractionated heparin in high-risk patients with non-ST-segment elevation acute coronary syndrome undergoing percutaneous coronary intervention in the Superior Yield of the New Strategy of Enoxaparin, Revascularization and Glycoprotein IIb/IIIa Inhibitors (SYNERGY) trial. Am Heart J 2006;152(6):1042-1050. PMID: 17161049
2. **Lokhnygina Y**, Helterbrand J. Cox regression methods for two-stage randomization designs. Biometrics 2007;63(2):422-428. PMID: 17425633

3. Barnhart HX, Haber M, **Lokhnygina Y**, Kosinski AS. Comparison of Concordance Correlation Coefficient and Coefficient of Individual Agreement in Assessing Agreement. J Biopharm Stat 2007;17(4):721-738. PMID: 17613650
4. Tricoci P, **Lokhnygina Y**, Berdan LG, Steinhubl SR, Gulba DC, White HD, Kleiman NS, Aylward PE, Langer A, Califf RM, Ferguson JJ, Antman EM, Newby LK, Harrington RA, Goodman SG, Mahaffey KW. Time to Coronary Angiography and Outcomes among Patients with High- risk Non–ST-segment Elevation Acute Coronary Syndromes: Results from the SYNERGY Trial. Circulation 2007;116(23):2669-2677. PMID: 18025532
5. Thomas KL, Al-Khatib SM, **Lokhnygina Y**, Solomon SD, Kober L, McMurray JJV, Califf RM, Velazquez EJ. Amiodarone Use After Acute Myocardial Infarction Complicated by Heart Failure and/or Left Ventricular Dysfunction May Be Associated with Excess Mortality. Am Heart J 2008;155(1):87-93. PMID: 18082495
6. **Lokhnygina Y**, Tsiatis AA. Optimal two-stage group-sequential designs. J Stat Planning and Inference 2008;138(2):489-499.
7. Califf RM, **Lokhnygina Y**, Velazquez EJ, McMurray JJV, Leimberger JD, Lewis EF, Diaz R, Murin J, Pfeffer MA. Usefulness of Beta Blockers in High-Risk Patients After Myocardial Infarction in Conjunction With Captopril and/or Valsartan (from the VALsartan In Acute Myocardial Infarction [VALIANT] Trial). Am J Cardiol 2009;104(2):151-157. PMID: 19576338
8. Califf RM, **Lokhnygina Y**, Cannon CP, Stepanavage ME, McCabe CH, Musliner TA, Pasternak RC, Blazing MA, Giugliano RP, Harrington RA, Braunwald E. An update on the IMProved reduction of outcomes: Vytorin Efficacy International Trial (IMPROVE-IT) design. Am Heart J 2010;159(5):705-9. PMID: 20435175
9. Mahaffey KW, Pieper KS, **Lokhnygina Y**, Califf RM, Antman EM, Kleiman NS, Goodman SG, White HD, Rao SV, Hochman JS, Cohen M, Col JJ, Roe MT, Ferguson JJ, for the SYNERGY Investigators. The Impact of Postrandomization Crossover of Therapy in Acute Coronary Syndromes Care. Circ CV Quality Outcomes 2011;4(2):211-19. PMID: 21304094.
10. Tricoci P, Huang Z, Held C, Moliterno DJ, Armstrong PW, Van de Werf F, White HD, Aylward PE, Wallentin L, Chen E, **Lokhnygina Y**, Pei J, Leonardi S, Rorick TL, Kilian AM, Jennings LH, Ambrosio G, Bode C, Cequier A, Cornel JH, Diaz R, Erkan A, Huber K, Hudson MP, Jiang L, Jukema JW, Lewis BS, Lincoff AM, Montalescot G, Nicolau JC, Ogawa H, Pfisterer M, Prieto JC, Ruzyllo W, Sinnaeve PR, Storey RF, Valgimigli M, Whellan DJ, Widimsky P, Strony J, Harrington RA, Mahaffey KW; the TRACER Investigators. Thrombin-receptor antagonist vorapaxar in acute coronary syndromes. NEJM 2012 Jan 5;366(1):20-33. PMID: 22077816.
11. Roe MT, White JA, Kaul P, Tricoci P, **Lokhnygina Y**, Miller CD, Van't Hof AW, Montalescot G, James SK, Saucedo J, Ohman EM, Pollack CV Jr., Hochman JS, Armstrong PW, Giugliano RP, Harrington RA, Van de Werf F, Califf RM, Newby LK. Regional patterns of use of a medical management strategy for patients with non-ST-segment elevation acute coronary syndromes: Insights from the EARLY ACS trial. Circ Cardiovas Qual Outcomes 2012;5(2):205-13. PMID: 22373905.
12. Chan MY, Sun JL, Newby LK, **Lokhnygina Y**, White HD, Moliterno DJ, Theroux P, Ohman EM, Simoons ML, Mahaffey KW, Pieper KS, Giugliano RP, Armstrong PW, Califf RM, Van de Werf F, Harrington RA. Trends in clinical trials of non-ST-segment elevation acute coronary syndromes over 15 years. Int J Cardiol 2012 Feb 16. [Epub ahead of print] PMID: 22341697.
13. Piccini JP, White JA, Mehta RH, **Lokhnygina Y**, Al Khatib SM, Tricoci P, Pollack CV Jr, Montalescot G, Van de Werf F, Gibson CM, Giugliano RP, Califf RM, Harrington RA, Newby LK. Sustained ventricular tachycardia and ventricular fibrillation complicating non-ST-segment elevation acute coronary syndromes. Circ 2012;126(1):41-49. Epub 2012 May 29. PMID: 22645292
14. Roe MT, Armstrong PW, Fox KA, White HD, Prabhakaran D, Goodman SG, Cornel JH, Bhatt DL, Clemmensen P, Martinez F, Ardissino D, Nicolau JC, Boden WE, Gurbel PA, Ruzyllo W, Dalby AJ, McGuire DK, Leiva-Pons JL, Parkhomenko A, Gottlieb S, Topacio GO, Hamm C, Pavlides G, Goudev AR, Oto A, Tseng CD, Merkely B, Gasparovic V, Corbalan R, Cinteza M, McLendon RC, Winters KJ, Brown EB, **Lokhnygina Y**, Aylward PE, Huber K, Hochman JS, Ohman EM: the TRILOGY ACS Investigators. Prasugrel versus clopidogrel for acute coronary syndromes without revascularization. N Engl J Med 2012;367(14):1297-309. Epub 2012 Aug 25. PMID: 22920930
15. Patel MR, Hellkamp A, **Lokhnygina Y**, Zhang Z, Mohanty S, Singer DE, Hacke W, Breithardt G, Halperin JL, Hankey GJ, Piccini JP, Becker RC, Nessel CC, Berkowitz SD, Fox KAA, Califf RM, Mahaffey KW. Outcomes of discontinuing rivaroxaban compared with warfarin in patients with nonvalvular atrial fibrillation: analysis from the ROCKET AF trial. J Am Coll Cardiol [in press 2012 September].

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed for Form Page 2.
Follow the sample format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Barry K. Moser, Ph.D.	Associate Research Professor

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Illinois Benedictine College, Chicago IL	B.S.	1973	Mathematics
Purdue University, W. Lafayette, IN	M.S.	1975	Statistics
Purdue University, W. Lafayette, IN	Ph.D.	1985	Statistics

A. Personal Statement

My areas of expertise are in biostatistics theory and applications, particularly in the areas of cancer and transplant clinical trials research and global health initiatives. I have published a graduate level Statistical Linear Models textbook and published numerous statistical methodology papers in respected national journals. I have also published many collaborative research papers in areas such as: T cell diversity and T cell function in long-term human SCID chimeras, Partner-Assisted Emotional Disclosure for Patients with GI Cancer, Diagnosis of Genital Ulcer Disease in Malawi, and Racial Differences in Analgesic/Anti-inflammatory Medication Use. I am a faculty biostatistician with thirty-five years of methodological and collaborative experience. I am, or have been, the faculty statistician or the co-PI on various grants in several health related fields. I have been teaching Statistics at the graduate level since 1985 and I have been the major advisor for 9 PhD and 7 Masters' degrees in Statistics.

B. Positions and Honors

Positions and Employment:

1985-1990 Assistant Professor, Department of Statistics, Oklahoma State University
1991-1997 Associate Professor, Department of Statistics, Oklahoma State University
1997-2002 Professor, Department of Statistics, Oklahoma State University
2002-present Associate Professor, Biostatistics and Bioinformatics, Duke University Medical Center

Organizations and Participation:

Member, American Statistical Association
Member, Society of Clinical Trials

Professional Awards and Special Recognitions:

Nominee for the AMOCO Foundation Award for Teaching Excellence, 1990
Nominee for the Burlington Northern Faculty Achievement Award, 1992
Nominee for the Graduate Student Association Outstanding Teaching Award, 1996
Graduate Student Association Outstanding Teaching Award, 1997
Oklahoma State University Celebrity for Outstanding Commitment to Teaching, 1997
Nominee for the Oklahoma Medal for Excellence in Teaching and Administration, 1998

C. Selected Peer-Reviewed Publications

Moser, B.K. and Coombs, L.P., (2004), "Odds Ratios for a Continuous Outcome Variable Without Dichotomizing," *Statistics in Medicine,* (23)12, 1843-1860.

Moser, B.K. and Tebbs, J.M., (2004), "An Interim Monitoring Tool for Group Sequential Methods in Clinical Trials", *Communications in Statistics: Theory and Methods,* 33 (1), 153-164.

Moser, B.K. and Coombs, L.P., (2004), "Odds Ratios for a Continuous Outcome Variable Without Dichotomizing," *Statistics in Medicine,* (23)12, 1843-1860.

Moser, B.K. and George, S.L. (2005), "A general formulation for a one-sided group sequential design," *Clinical Trials*, 2(6), 519-528.

Moser, B.K. and McCann, M. H., (2008), "Reformulating the hazard ratio to enhance communication with clinical investigators," *Clinical Trials,* 5(3), 248-252.

Stone R.M., **Moser B.**, Sanford B., Schulman P., Kolitz J.E., Allen S., Stock W., Galinsky I., Vij R., Marcucci G., Hurd D., Larson R.A.; Cancer and Leukemia Group B, (2011), "High dose cytarabine plus gemtuzumab ozogamicin for patients with relapsed or refractory acute myeloid leukemia: Cancer and Leukemia Group B study 19902," *Leukemia Research*, 35(3), 329-333. PMCID:PMC3023007 [Available on 2012/3/1]

Powell B.L., **Moser B.**, Stock W., Gallagher R.E., Willman C.L., Stone R.M., Rowe J.M., Coutre S., Feusner J.H., Gregory J., Couban S., Appelbaum F.R., Tallman M.S., Larson R.A., (2010), "Arsenic trioxide improves event-free and overall survival for adults with acute promyelocytic leukemia: North American Leukemia Intergroup Study C9710," *Blood*, 116(19), 3751-3757. PMCID:PMC2981533

Moser B.K., Halabi S., (2012), "Estimation and testing of the relative risk of disease in case-control studies with a set of k matched controls per case with known prevalence of disease," *Statistics in Medicine,* 31(1), 29-44.

Moser, B.K., Halabi, S. (2012), "Sample size requirements and length of study for testing main effects and interactions in completely randomized clinical trials with time-to-event outcomes," in press, *Communications in Statistics: Theory and Methods*.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed on Form Page 2.
Follow this format for each person. DO NOT EXCEED FOUR PAGES.

NAME	POSITION TITLE
Neelon, Brian H	Assistant Professor
eRA COMMONS USER NAME bneelon	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Duke University, Durham, NC	BA	12/88	Philosophy
University of North Carolina at Chapel Hill	Teaching Certificate	06/93	Mathematics
University of North Carolina at Chapel Hill	PhD	05/05	Biostatistics
Harvard Medical School, Boston, MA	Post-Doctoral Fellowship	06/07	Biostatistics

A. Personal Statement

As an Assistant Professor in the Department of Biostatistics and Bioinformatics at Duke University School of Medicine, Dr. Neelon divides his time between the Nicholas School of the Environment and the HSR&D Division at the Durham VA Medical Center. In this capacity, he provides statistical support for grant applications, conducts data analysis, and contributes to the development of new statistical methodology. His research focuses on Bayesian methods, longitudinal data analysis, cluster randomized trials, finite mixture models, zero-inflated models, and spatial statistics, with application to children's health, chronic disease prevention, and health services research. He has published or co-authored numerous applied and methodological papers in these areas, and has served as Co-Investigator on several NIH-funded grants. Prior to his position at Duke, Dr. Neelon was a post-doctoral fellow in the Department of Health Care Policy at Harvard Medical School, where he developed new methods for analyzing health care utilization and medical expenditure data. Since arriving at Duke in 2009, he has collaborated closely with investigators from the Nicholas School and the Durham VA on several published manuscripts and recently funded grants.

B. Positions and Honors

Positions and Employment

1998-2004 Graduate Research Assistant, Lineberger Comprehensive Cancer Research Center, University of North Carolina at Chapel Hill
2001-2003 Student Temporary Employee, Biostatistics Branch, National Institute of Environmental Health Sciences
2005-2007 Faculty Statistician, Center for Health Promotion and Disease Prevention, University of North Carolina at Chapel Hill (Joint Appointment with Department of Biostatistics)
2006-2007 Research Assistant Professor, Department of Biostatistics, University of North Carolina at Chapel Hill
2007-2009 Postdoctoral Fellow in Statistics, Department of Health Care Policy, Harvard Medical School
2009-2011 Associate in Research, Children's Environmental Health Initiative, Nicholas School of the Environment, Duke University
2012- Statistician, Durham VA Medical Center, Durham, North Carolina
2012- Assistant Professor, Department of Biostatistics and Bioinformatics, Duke University Medical Center

Honors

1998 Special Commendation: MS qualifying exams, Department of Biostatistics, University of North Carolina at Chapel Hill
1999 Delta Omega Society (National Public Health Honor Society)
1997-2007 NIEHS Predoctoral Training Grant, 1997–2001.
2001-2003 NIEHS Student Temporary Employee Fellowship

2004 Kupper Dissertation Award (awarded by the University of North Carolina Department of Biostatistics for the best dissertation publication)
2012 Biometrics Showcase Selection, Joint Statistics Meeting, August 2012, San Diego, CA
2012 Guest Editor of forthcoming special issue in *Statistical Methods in Medical Research* entitled, "Spatial Methods in Health Policy Research"

C. Selected Peer-Reviewed Publications

1. Dunson DB and **Neelon B**. Bayesian Inference on Order Constrained Parameters in Generalized Linear Models. *Biometrics*. 2003. 59;286-295.

2. **Neelon B** and Dunson DB. Bayesian Isotonic Regression and Trend Analysis. *Biometrics*. 2004;60,177-191.

3. Ward DS, Linnan L, Vaughn A, **Neelon B**, Martin SL, Fulton JE. Characteristics associated with US Walk to School programs. International *Journal of Behavioral Nutrition and Physical Activity*. 2007,19;4-67.

4. Evenson KR, **Neelon B**, Ball SC, Vaughn A, Ward DS. Validity and reliability of a school travel survey. *Journal of Physical Activity and Health*. 2008,5;1-15.

5. Busch AB, Huskamp HA, **Neelon B**, Manning T, Normand S-L, and McGuire TG. Longitudinal racial/ethnic disparities in antimanic medication use in bipolar-I disorder. *Medical Care*. 2009,47(12):1217-28.

6. **Neelon B** and O'Malley AJ. Bayesian Analysis Using Power Priors with Application to Pediatric Quality of Care. *Journal of Biometrics and Biostatistics*. 2010;1:103 doi: 10.4172/2155-6180.1000103

7. **Neelon B**, O'Malley AJ, Normand S-L. Bayesian Models for Repeated Measures Zero-Inflated Count Data with Application to Mental Health Services Utilization. *Statistical Modelling*. 2010;10(4): 421-439.

8. Miranda ML, Edwards SE, Swami GK, Paul CJ, and **Neelon B**. Blood Lead Levels among Pregnant Women: Historical Versus Contemporaneous Exposures. *International Journal of Environmental Research and Public Health*. 2010;7(4):1508-19.

9. **Neelon B**, O'Malley AJ, Normand S-L. A Bayesian Two-Part Latent Class Model for Longitudinal Medical Expenditure Data: Assessing the Impact of Mental Health and Substance Abuse Parity. *Biometrics*. 2010; doi: 10.1111/j.1541-0420.2010.01439.

10. Busch AB**, Neelon B**, Zelevinsky K, He Y, Normand S-L. Accurately predicting bipolar disorder mood outcomes—implications for the use of electronic databases. *Medical Care*. 2011;50(4),311-319.

11. **Neelon, B**, Swamy GK, Burgette LF, and Miranda ML. A Bayesian growth mixture model to examine maternal hypertension and birth outcomes. *Statistics in Medicine*. 2011;30,2721-2735.

12. Montagna S, Tokdar ST, **Neelon B**, Dunson DB. Bayesian latent factor regression for functional and longitudinal data. *Biometrics*. 2012; 68,1064-1073.

13. **Neelon B**, Anthopolos RA, Miranda ML. A spatial bivariate probit model for correlated binary data with application to adverse birth outcomes. *Statistical Methods in Medical Research*. Published online ahead of print, May 8, 2012. doi:10.1177/0962280212447152.

14. Bhaumik DK, Amatya A, Normand S-L, Greenhouse J, Kaizar E, **Neelon B**, Gibbons RD. Meta-analysis of binary rare adverse event data. *Journal of the American Statistical Association*. 2012; 107,555-567.

15. **Neelon B**, Ghosh P, Loebs PF. A spatial Poisson hurdle model for exploring geographic variation in emergency department visits. *Journal of the Royal Statistical Society: Series A*. 2013; 176,389-413.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Megan L. Neely	Assistant Professor Department of Biostatistics and Bioinformatics Duke University Medical Center
eRA COMMONS USER NAME (credential, e.g., agency login)	

EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Clemson University, Clemson, SC	BS	2001-	Mathematical Sciences
Clemson University, Clemson, SC	MS	2005-	Mathematical Sciences
North Carolina State University, Raleigh, NC	PhD	2006-	Statistics

A. Personal Statement

I currently teach two courses in the Masters program: BIOS 221 and 222, Introduction to Statistical Programming I and II. These courses are co-requisites for BIOS 202 and 205, respectively. In BIOS 221, I focus on programming in R. The course establishes a sound foundation in programming logic and the implementation of statistical simulations. In BIOS 222, I focus on programming in SAS. The course establishes good practices in data management and introduces computing approaches that reinforce reproducibility. Through my collaborative work at the Duke Clinical Research Institute, I have exposure to a wide variety of statistical methodological issues that arise when applying current approaches to data from both observational and clinical trial data (e.g. the need to tweak an existing method or develop a new approach). Thus, I think could serve as a co-chair or as a committee member for a PhD student.

B. Positions and Honors

Positions and Employment

2011 – Present	Assistant Professor, Department of Biostatistics & Bioinformatics, Duke University, Durham, NC
2010 – 2011	Statistical Intern, Clinical Trials SIGMA Group, Duke Clinical Research Institute, Durham, NC
2007 – 2010	Adjunct Instructor, Department of Mathematics, Wake Technical Community College, Raleigh, NC
2004 – 2006	Research Assistant, Greenville Hospital University Medical, Greenville, SC

Other Experience and Professional Memberships

2011 – Present	Statistical Editor, Journal of the American College of Cardiology Heart Failure
2009 – Present	Member, Eastern North American Region of the International Biometric Society
2008 – Present	Member, American Statistical Association

Honors

2009	Gertrude M. Cox Academic Achievement Award: Outstanding PhD Candidate, NC State University
2006 – 2010	NIH Fellowship: Biostatistics Training in the Omics Era, NC State University
2005	President's Award: 4.0 Career GPA, Clemson University
2005	Summa cum Laude, Clemson University
2005	Martin Academic Achievement Award: Top Graduating Senior, Clemson University

C. Selected Peer-reviewed Publications and Abstracts

1. Leonardi S, Truffa AMA, **Neely ML**, Tricoci P, White HD, Gibson CM, Wilson M, Stone GW, Harrington RA, Bhatt DL, Mahaffey KW. A novel approach to systematically implement the universal definition of myocardial infarction: insights from the CHAMPION PLATFORM trial. Heart (2013).

2. Gurbel PA, Erlinge D, Ohman EM, Neely B, **Neely M**, Goodman SG, Huber K, Chan MY, Cornel JH, Brown E, Zhou C, Jakubowski JA, White HD, Fox KA, Prabhakaran D, Armstrong PW, Tantry US, Roe MT. Platelet Function During Extended Prasugrel and Clopidogrel Therapy for Patients With ACS Treated Without Revascularization: The TRILOGY ACS Platelet Function Substudy. Journal of the American Medical Association 308.17 (2012): 1785-1794.
3. Fiuzat M, **Neely ML**, Starr AZ, Kraus WE, Felker GM, Donahue M, Adams K, Piña IL, Whellan D, O'Connor CM. Association between adrenergic receptor genotypes and beta-blocker dose in heart failure patients: analysis from the HF-ACTION DNA substudy. European Journal of Heart Failure (2012).
4. Parikh NI, Honeycutt EF, Roe MT, **Neely ML**, Rosenthal EJ, Mittleman MA, Carrozza JP, and Ho KL. Left and Codominant Coronary Artery Circulations Are Associated With Higher In-Hospital Mortality Among Patients Undergoing Percutaneous Coronary Intervention for Acute Coronary Syndromes Report From the National Cardiovascular Database Cath Percutaneous Coronary Intervention (CathPCI) Registry. Circulation: Cardiovascular Quality and Outcomes 5.6 (2012): 775-782.
5. Leonardi S, Thomas L, **Neely ML**, Tricoci P, Lopes RD, White HD, Armstrong PW. Comparison of the Prognosis of Spontaneous and Percutaneous Coronary Intervention–Related Myocardial Infarction. Journal of the American College of Cardiology 60.22 (2012): 2296-2304.
6. Halim SA, **Neely ML**, Pieper K, Shah S, Kraus W, Hauser E, Califf R, Granger C, and Newby LK. Simultaneous Analysis of Multiple Protein Biomarkers Identifies Independent Markers of Long-term Risk for Death or Myocardial Infarction. Journal of the American College of Cardiology 59.13s1 (2012): E1476-E1476 [abstract].
7. Pongpanic M, **Neely ML**, Tzeng JY. On the Aggregation of Multimarker Information for Marker-set and Sequencing Data Analysis: Genotype Collapsing vs. Similarity Collapsing. Frontiers in Genetics 2 (2011).
8. **Koehler ML**, Bondell HD, Tzeng JY. Evaluating Haplotype Effects in Case-control Studies via Penalized-likelihood Approaches: Prospective or Retrospective Analysis? Genetic epidemiology 34.8 (2010): 892-911.

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Sean M. O'Brien	Assistant Professor of Biostatistics
eRA COMMONS USER NAME OBRIE027	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Haverford College, Haverford, PA	BA	1992	Religion
Southern College of Technology, Marietta, GA		1995	Computer Science
University of North Carolina, Chapel Hill, NC	MS	1998	Biostatistics
University of North Carolina, Chapel Hill, NC	PhD	2002	Biostatistics

A. Personal Statement

My career has focused on advancing statistical methodology and outcomes research within the Department of Biostatistics and Bioinformatics, the Duke Clinical Research Institute, and nationally. My scientific contributions are in the areas of health care performance evaluation, clinical risk prediction, and multi-center observational studies. I currently serve as the Statistical Director of the Society of Thoracic Surgeons (STS) Data Warehouse and Analysis Center at DCRI, a data warehouse that collects detailed clinical data from over 250,000 surgical patients annually from over 1000 sites. I am also Co-Principal Investigator of the Statistical and Data Coordinating Center for the NHLBI-funded ISCHEMIA Trial which has a planned enrollment of 8000 patients in 40 countries. Additionally, I have been an investigator on 4 federal grants and contracts that involved linking clinical registries with administrative data in order to study comparative effectiveness of cardiovascular interventions. My statistical expertise includes the analysis of multicenter observational data, development of risk prediction and propensity models, and Bayesian analysis. I also work on the development of quantitative methods for healthcare provider performance assessment, including the development of new composite measurement methodology used by Consumer Reports and the Society of Thoracic Surgeons for evaluating adult cardiac surgery providers. I have served on 12 thesis committees including 2 as chair. I am co-author of a textbook published by CRC press called "Exercises and Solutions in Biostatistical Theory" and of a forthcoming textbook called "Exercises and Solutions in Statistical Theory" to appear in 2013. My background includes a Ph.D. in biostatistics from the University of North Carolina at Chapel Hill and fellowship training in Bayesian methodology at the National Institute of Environmental Health Sciences.

B. Positions and Honors

Positions and Employment

1992-1993	Intern / Consultant, United Nations Institute for Training and Research (UNITAR), Geneva, Switzerland.
1993	Intern, World Health Organization, Geneva, Switzerland.
1993-1994	English Teacher, Hong Ren High School and Joeshan Institute, Chiayi Taiwan
1995-2002	Graduate Research Assistant / Statistician II, UNC Lineberger Cancer Research Center, University of North Carolina, Chapel Hill
1996&1999	Teaching Intern, Department of Biostatistics, University of North Carolina, Chapel Hill
2002–2004	Research Fellow, National Institute of Environmental Health Sciences, Research Triangle Park, NC
2004–Pres	Assistant Professor, Biostatistics and Bioinformatics, Duke University Medical Center, Durham NC

C. Selected Peer-reviewed Publications

1. **O'Brien SM** and Dunson DB. (2004), "Bayesian Multivariate Logistic Regression." Biometrics, 60, 739746.
2. **O'Brien SM.** Cutpoint selection for categorizing a continuous predictor. Biometrics. 2004;60:504-9.

3. **O'Brien SM**, Kupper LL, Dunson DB. Performance of tests of association in misspecified generalized linear models. Journal of Statistical Planning and Inference. 2006;136:3090-3100.
4. **O'Brien SM**, DeLong ER, Dokholyan RS, Edwards FH, Peterson ED. Exploring the behavior of hospital composite performance measures: an example from coronary artery bypass surgery. Circulation. 2007;116(25):2969-75.
5. **O'Brien SM**, Shahian DM, DeLong ER, Normand SL, Edwards FH, Ferraris VA, Haan CK, Rich JB, Shewan CM, Dokholyan RS, Anderson RP, Peterson ED. Quality measurement in adult cardiac surgery: part 2--Statistical considerations in composite measure scoring and provider rating. Ann Thorac Surg. 2007;83(4 Suppl):S13-26.
6. **O'Brien SM**, Jacobs JP, Clarke DR, Maruszewski B, Jacobs ML, Walters HL 3rd, Tchervenkov CI, Welke KF, Tobota Z, Stellin G, Mavroudis C, Hamilton JR, Gaynor JW, Pozzi M, Lacour-Gayet FG. Accuracy of the aristotle basic complexity score for classifying the mortality and morbidity potential of congenital heart surgery operations. Ann Thorac Surg. 2007 Dec;84(6):2027-37; discussion 2027-37.
7. **O'Brien SM**, Clarke DR, Jacobs JP, Jacobs ML, Lacour-Gayet FG, Pizarro C, Welke KF, Maruszewski B, Tobota Z, Miller WJ, Hamilton L, Peterson ED, Mavroudis C, Edwards FH. An empirically based tool for analyzing mortality associated with congenital heart surgery. J Thorac Cardiovasc Surg. 2009;138(5):1139-53.
8. **O'Brien SM**, Shahian DM, Filardo G, Ferraris VA, Haan CK, Rich JB, Normand SL, DeLong ER, Shewan CM, Dokholyan RS, Peterson ED, Edwards FH, Anderson RP. The Society of Thoracic Surgeons 2008 cardiac surgery risk models: part 2--isolated valve surgery. Ann Thorac Surg. 2009;88(1 Suppl):S23-42.
9. Boehme CC, Nabeta P, Hillemann D, Nicol M, Shenai S, Krapp F, Allen J, Tahirli R, Blakemore R, Rustomjee R, Milovic A, Jones M, **O'Brien SM**, Persing DH, Ruesch-Gerdes S, Gotuzzo E, Rodrigues C, Alland D, Perkins MD. Molecular detection of tuberculosis and rifampin resistance at point-of-treatment. New England Journal of Medicine. 2010 Sep 9;363(11):1070-1.
10. Bennett-Guerrero E, Zhao Y, **O'Brien SM**, Ferguson TB, Peterson ED, Gammie JS, Song HK. Variation in Use of Blood Transfusion in Coronary Artery Bypass Graft Surgery. JAMA. 2010 Oct 13;304(14):1568-75. PMID: 20940382
11. Jacobs JP, Edwards FH, Shahian DM, Haan CK, Puskas JD, Morales DL, Gammie JS, Sanchez JA, Brennan JM, **O'Brien SM**, Dokholyan RS, Hammill BG, Curtis LH, Peterson ED, Badhwar V, George KM, Mayer JE Jr, Chitwood WR Jr, Murray GF, Grover FL. Successful linking of the society of thoracic surgeons adult cardiac surgery database to centers for medicare and medicaid services medicare data. Ann Thorac Surg. 2010 Oct;90(4):1150-6. PMID: 20868806.
12. Yang HX, **O'Brien SM**, Dunson DB. "Nonparametric Bayes stochastically ordered latent class models". JASA. 2011 Sep; 106 (495): 807-817.
13. Shah BR, Cowper PA, **O'Brien SM**, Jensen N, Patel MR, Douglas PS, Peterson ED. Association between physician billing and cardiac stress testing patterns following coronary revascularization. JAMA. 2011 Nov 9;306(18):1993-2000.
14. Weintraub WS, Grau-Sepulveda MV, Weiss JM, **O'Brien SM**, Peterson ED, Kolm P, Zhang Z, Klein LW, Shaw RE, McKay C, Ritzenthaler LL, Popma JJ, Messenger JC, Shahian DM, Grover FL, Mayer JE, Shewan CM, Garratt KN, Moussa ID, Dangas GD, Edwards FH. Comparative effectiveness of revascularization strategies. N Engl J Med. 2012 Apr 19;366(16):1467-76. PMID: 22452338.
15. Badhwar V, Peterson ED, Jacobs JP, He X, Brennan JM, **O'Brien SM**, Dokholyan RS, George KM, Bolling SF, Shahian DM, Grover FL, Edwards FH, Gammie JS. Longitudinal outcome of isolated mitral repair in older patients: results from 14,604 procedures performed from 1991 to 2007. Ann Thorac Surg. 2012 Dec;94(6):1870-7.

BIOGRAPHICAL SKETCH

NAME Maren K. Olsen, PhD	POSITION TITLE Associate Research Professor
eRA COMMONS USER NAME Olsen008	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Johns Hopkins University, Baltimore	B.S.	1994	Mathematical Sciences
Pennsylvania State University, University Park	M.A.	1996	Statistics
Pennsylvania State University, University Park	Ph.D.	1999	Statistics

A. Personal Statement.

I have been the Director of the Durham VAMC Health Services Research Biostatistics Unit since June 2003. In this role, I supervise and mentor 5 masters-level statisticians and coordinate biostatistics support all of the research protocols in our center. My research activities have primarily focused on collaborative statistical methodology within the field of health services research. In these endeavors I have continued to apply and build expertise in three broad methodological areas: complicated longitudinal data structures (including clustered, longitudinal data), multiple imputation of missing data, and two-part models for longitudinal health data.

B. Positions and Honors.

Positions and Employment

2000-2010 Assistant Professor, Duke University Medical Center.
2000-present Biostatistician, Health Services Research & Development, VA Medical Center, Durham, NC
2003-present Director, Biostatistics Unit, Health Services Research & Development, VA Medical Center, Durham, NC
2010-present Associate Professor, Duke University Medical Center

Other Experience and Professional Memberships

2001-2002 Course Co-Director, Introduction to Statistical Methods, Clinical Research Training Program, Duke University Medical Center, Durham, NC
2003, 2005 Ad Hoc reviewer of the VA Scientific Review and Evaluation Board (SREB) Study Section
2009-2011 Course Co-Director, Clinical Research Seminar, Clinical Research Training Program, Duke University Medical Center, Durham, NC

Honors

1994 Mathematical Sciences Achievement Award, Johns Hopkins University
2004 Second author on paper awarded "Best of JGIM": Edelman D, Olsen MK, Dudley TK, Harris AC, Oddone EZ. 2004. Utility of Hemoglobin A1c in Predicting Diabetes Risk. *J Gen Intern Med* 19(12): 1175-1180.
2011 Second author on "Top 5 Poster" awarded at *Chest October 2011*. Chiarchiaro J, Olsen MK, Steinhauser KE, Tulsky JA. ICU Impact on Trajectories of Well-being in Patients With Advanced Chronic Illness *Chest October 2011 140:4 Meeting Abstracts 262A; doi:10.1378/chest.1116539*

C. Selected peer-reviewed publications (in chronological order).

Most relevant to the current application

1. **Olsen MK**, DeLong ER, Oddone EZ, Bosworth HB. (2008). Strategies for analyzing multilevel cluster-

randomized studies with binary outcomes collected at varying intervals of time. *Statistics in Medicine*. 27, 6055-6071 PMID: 18825655

2. Powers BJ, **Olsen MK**, Smith VA, Woolson RW, Bosworth HB, Oddone EZ. Measuring blood pressure for decision making and quality reporting: where and how many measures? *Annals of Internal Medicine*. 2011 Jun 21;154(12):781-8, W-289-90.
3. Maciejewski ML, Liu CF, Kavee AL, **Olsen MK**. How price responsive is the demand for speciality care? *Health Economics*. 2011. Jul 14.
4. **Olsen MK**, Stechuchak KM, Edinger JD, Ulmer C, Woolson RW. Move over LOCF: principled methods for handling missing data in sleep disorder trials. *Sleep Medicine*. 2012 Feb;13(2):123-32.
5. Jackson GL, Edelman D, **Olsen MK**, Smith VA, Maciejewski ML. Benefits of Participation in Diabetes Group Visits After Trial Completion (Research Letter). Archives of Internal Medicine (in press 10/15/12).

Additional recent publications of importance to the field (in chronological order)

1. **Olsen, MK** and Schafer, JL. 2001. A two-part random-effects model for semicontinuous longitudinal data. *Journal of the American Statistical Association*. 96, 730-745.
2. Yancy WS, **Olsen MK**, Guyton JR, Bakst RP Westman EC. 2004. A randomized, controlled trial of a low-carbohydrate, ketogenic diet versus a low-fat diet for obesity and hyperlipidemia. *Annals of Internal Medicine*. 140: 769-777.
3. Yancy WS, **Olsen MK**, Curtis LH, Schulman KA, Cuffe MS, Oddone EZ. 2005. Variations in coronary procedure utilization depending on body mass index. *Archives of Internal Medicine*. 165: 1381-1387.
4. Edelman DE, Oddone EZ, Liebowitz RS, Yancy WS, **Olsen MK**, Jeffreys AS, Moon SD, Harris AD, Smith LL, Quillien-Wolever RE, Gaudet TW. 2006. A Multidimensional Integrative Medicine Intervention to Improve Cardiovascular Risk. *Journal of General Internal Medicine*. 21(7):728-34.
5. Edinger JD, **Olsen MK**, Stechuchak KM, Means MK, Lineberger MD, Kirby A, Carney CE. 2009. Cognitive Behavioral Therapy for Patients with Primary Insomnia or Insomnia Associated Predominantly with Comorbid Depression and Anxiety Disorders: A Randomized Clinical Trial. *Sleep.* 32(4): 499-510.
6. Tulsky JA, Arnold RM, Alexander SC, **Olsen MK**, Jeffreys AS, Rodriguez KL, Skinner CS, Farrell D, Abernathy AP, Pollak KI. Enhancing Communication between Oncologists and Patients with a Computer-Based Training Program. *Annals of Internal Medicine*. 2011 Nov 1;155(9):593-601
7. Bosworth, HB, Powers BJ, **Olsen MK**, McCant F, Grubber JM, Smith VA, Gentry PW, Rose C, Van Houtven CH, Wang V, Goldstein MK, Oddone EZ. Can home blood pressure management improve blood pressure control: results from a randomized controlled trial. *Archives of Internal Medicine*. 2011 Jul 11;171(13):1173-80.
8. Bosworth HB, **Olsen MK**, Grubber JM, Neary AM, Orr MM, Powers BJ, Adams MB, Svetkey LP, Reed SD, Li Y, Dolor RJ, Oddone EZ. 2009. Two self-management interventions to improve hypertension control: A randomized trial. *Annals of Internal Medicine*. Nov 17; 151(10):687-95.
9. Edinger JD, Wyatt JK, Stepanski EJ, **Olsen MK**, Stechuchak MK, Carney CE, Chiang A, Crisostomo MI, Lineberger MD, Means MK, Radtke RA, Wohlgemuth WK, Krystal AD. Testing the reliability and validity of DSM-IV-TR and ICSD-2 insomnia diagnoses: results of a multi-method/multi-trait analysis. *Archives of General Psychiatry*. 2011 Jun 6.
10. Jackson GL, Oddone EX, **Olsen MK**, Powers BJ, Grubber JM, McCant F, Bosworth HB. 2012. Racial differences in the effect of a telephone-delivered hypertension management program. J Gen Intern Med. Aug 3.

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Kouros Owzar	Associate Professor of Biostatistics and Bioinformatics
eRA COMMONS USER NAME (credential, e.g., agency login) KOWZAR	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Lehigh University, Bethlehem, PA	B.S.	1994	Statistics
Lehigh University, Bethlehem, PA	M.S.	1996	Mathematics
University of Chicago, Chicago, IL	M.S.	1998	Statistics
University of North Carolina, Chapel Hill, NC	Ph.D.	2002	Statistics

A. Personal Statement

As the lead statistician for the Pharmacology and Population Pharmacokinetics committee of the Alliance for Clinical Trials in Oncology (formerly the Cancer and Leukemia Group C; CALGB), have over nine years of experience in designing and analyzing candidate marker and genome-wide pharmacogenomics studies in cancer. Four notable examples are GWAS studies CALGB 80303 (pancreas), 40101 (breast), 90401 (prostate) and 80405 (colon). I also have a proven record of designing and conducting clinical trials in oncology. Two notable studies are CALGB 100104, which assessed the effect of maintenance therapy in multiple myeloma (McCarthy et al; NEJM 2012), and ACOSOG Z9001 which assessed the effect of adjuvant imantinib in GIST (DeMatteo et al, Lancet 2009).

My main statistical research focus is the development of survival analysis methodology for genome-wide data. I am interested in diverse censoring mechanisms including singly and doubly interval, grouped and informative censoring. I conduct research in both the large and finite-sample size inference. This work started in the context of microarrays, later shifted to the GWAS setting and now has ventured in to the next generation sequencing realm.

I have been active in the research arena by developing open source technology Notable applications include from tools for conducting association studies using stream computing technologies (permPGU), tools for managing GWAS data (SNPpy) and tools for designing discovery and validation GWAS studies (survSNP).

As the director of the Bioinformatics Unit of the Alliance and the Biostatistics Core of the Radiation Countermeasures Centers of Research Excellence (RadCCORE), I have extensive experience in the administrative and scientific mentorship of research staff. Furthermore, as the lead instructor of the three courses offered at Duke University, I have extensive expertise in teaching.

In summary, I have a demonstrated record of successful and productive genomic research in the clinical trial setting. My leadership, technical and mentoring will stand me in good stead to lead the proposed research.

B. Positions and Honors:

1993-1996	Department of Mathematics, Lehigh University. Bethlehem, PA
1996-1998	Department of Statistics, University of Chicago. Chicago, IL
1996	MET, Harrisburg Area Community College. Harrisburg, PA
1998	Department of Statistics, University of North Carolina. Chapel Hill, NC
1999	Clinical Pharmacology Data Sciences, Glaxo Wellcome. RTP, NC
2002-present	Assistant Professor, Dept. of Biostatistics and Bioinformatics, Duke University Medical Ctr., Durham, NC
2002-present	Faculty Statistician, The Cancer and Leukemia Group B (CALGB), Duke University Medical Center, Durham, NC
2002-2006	Faculty Statistician, ACOSOG, Duke University Medical Center, Durham, NC
2006-present	Director, Biostatistics and Computational Biology Core of RadCCORE
2006-present	Director, CALGB Bioinformatics Unit

2009-Present Adjunct Assistant Professor, Division of Pharmacotherapy and Experimental Therapeutics, University of North Carolina, Chapel Hill NC.

C. Selected peer-reviewed publications (in chronological order):

Most relevant to methods and software development for statistical genomics

1. Jung, S.-H., **Owzar, K**., George, S. L. A multiple testing procedure to associate gene expression levels with survival. Statistics in Medicine 2005; 24(20):3077-3088
2. **Owzar K**, Jung SH, Sen PK. A Copula Approach for Detecting Prognostic Genes Associated With Survival Outcome in Microarray Studies. Biometrics. 2007 May 2.
3. Sohn I, **Owzar K**, George SL, Kim S, Jung SH. A permutation-based multiple testing method for time-course microarray experiments. BMC bioinformatics 10:336, 2009. PMCID:PMC2772858
4. Sohn I, **Owzar K**, George SL, Kim S, Jung SH. Robust test method for time-course microarray experiments. BMC Bioinformatics 2010:391. PMCID:PMC2910023
5. Shterev ID, Jung SH, George SL, **Owzar K**. permGPU: Using graphics processing units in RNA microarray association studies. BMC Bioinformatics 2010.:329. PMCID:PMC2910023
6. Mitha F, Herodotou H, Borisov N, Jiang C, Yoder J, **Owzar K**. SNPpy--database management for SNP data from genome wide association studies. PLoS One 2011; 6(10):e24982. PMCID: PMC3198468
7. Sohn I, **Owzar K**, Lim J, George SL, Mackey Cushman S, Jung SH. Multiple testing for gene sets from microarray experiments. BMC Bioinformatics 2011.:209. PMCID: PMC3131260
8. **Owzar K**, Li Z, Cox N, Jung SH. Power and Sample Size Calculations for SNP Association Studies With Censored Time-to-Event Outcomes. Genet Epidemiol 2012 Jun 8.

Most relevant to analysis of genomic data

9. Innocenti F**, Owzar K**, Cox NL, Evans P, Kubo M, Zembutsu H, Jiang C, Hollis D, Mushiroda T, Li L, Friedman P, Wang L, Glubb D, Hurwitz H, Giacomini KM, McLeod HL, Goldberg RM, Schilsky RL, Kindler HL, Nakamura Y, Ratain MJ. A genome-wide association study of overall survival in pancreatic cancer patients treated with gemcitabine in CALGB 80303. Clin Cancer Res 2012 Jan 15; 18(2):577-84. PMCID: PMC3412624
10. Wheeler HE, Gamazon ER, Wing C, Njiaju UO, Njoku C, Baldwin RM, **Owzar K**, Jiang C, Watson D, Shterev I, Kubo M, Zembutsu H, Winer EP, Hudis CA, Shulman L, Nakamura Y, Ratain MJ, Kroetz D, Cox NJ, Dolan ME. Integration of cell line and clinical trial genome-wide analyses supports a polygenic architecture of paclitaxel-induced sensory peripheral neuropathy. Clin Cancer Res. 2012 Nov 30.
11. Baldwin RM, **Owzar K**, Zembutsu H, Chhibber A, Kubo M, Jiang C, Watson D, Eclov RJ, Mefford J, McLeod HL, Friedman PN, Hudis CA, Winer EP, Jorgenson EM, Witte JS, Shulman LN, Nakamura Y, Ratain MJ, Kroetz DL. A genome-wide association study identifies novel loci for paclitaxel-induced sensory peripheral neuropathy in CALGB 40101. Clin Cancer Res. 2012 Sep 15;18(18):5099-109

Most relevant to the current application in terms of design and conduct of clinical trials

12. Jung, S.-H., Lee, T., **Owzar, K**., George, S. L. P-value calculation for multistage phase II cancer clinical trials. Journal of Biopharmaceutical Statistics 2006; 16(6):765-75; discussion 777-83
13. **Owzar K**, Jung S-H. Designing Phase II Studies in Cancer with Time-to-Event Endpoints. Clinical Trials 2008; Vol. 5, No. 3, 209-221
14. DeMatteo RP, Ballman KV, Antonescu CR, Make RG, Pisters PWT, Demetri GD, Blackstein ME, Blanke CD, von Mehren M, Brennan MF, Patel S, McCarther MD, Polikoff, JA, Tan BR, **Owzar K**. Adjuvant imatinib mesylate after resection of localised, primary gastrointestinal stromal tumour: a randomised, double-blind, placebo-controlled trial. Lancet 2009 28;373(9669):1097-104.PMID: 19303137. PMCID:PMC2915459

15. McCarthy PL, **Owzar K**, Hofmeister CC, Hurd DD, Hassoun H, Richardson PG, Giralt S, Stadtmauer EA, Weisdorf DJ, Vij R, Moreb JS, Callander NS, Van Besien K, Gentile T, Isola L, Maziarz RT, Gabriel DA, Bashey A, Landau H, Martin T, Qazilbash MH, Levitan D, McClune B, Schlossman R, Hars V, Postiglione J, Jiang C, Bennett E, Barry S, Bressler L, Kelly M, Seiler M, Rosenbaum C, Hari P, Pasquini MC, Horowitz MM, Shea TC, Devine SM, Anderson KC, Linker C. Lenalidomide after stem-cell transplantation for multiple myeloma. N Engl J Med 2012 May 10; 366(19):1770-81.

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Pang, Herbert	**Assistant Professor, Department of Biostatistics and Bioinformatics, Duke University School of Medicine**
eRA COMMONS USER NAME (credential, e.g., agency login) oxbert	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
University of Oxford, England	B.A.	2002	Mathematics and Computer Science
Yale University, New Haven, CT	Ph.D.	2008	Biostatistics

A. Positions and Honors.

Positions and Employment

9/03 – 12/03 Teaching Fellow, Department of Epidemiology and Public Health, Yale University School of Medicine, New Haven, CT
9/04 – 12/04 Teaching Fellow, Department of Epidemiology and Public Health, Yale University School of Medicine, New Haven, CT
8/08 – present Assistant Professor, Department of Biostatistics and Bioinformatics, Duke University School of Medicine, Durham, NC
8/08 – present Faculty Statistician, Alliance for Clinical Trials in Oncology (formerly Cancer & Leukemia Group B), Statistics and Data Center, Duke Cancer Institute, Durham, NC

Honors and Awards

2002 – 2006 Graduate Fellowship, Yale University
2006 Travel Award, 1st Annual NIH National Graduate Student Research Festival
2011 Burroughs Wellcome Fund Collaborative Research Travel Grant

Other Experience and Professional Memberships

2003 – present Member, American Statistical Association
2009 – present Member, American Association for Cancer Research
2010 – present Editorial Board, Journal of Biometrics and Biostatistics
2011 – present Editorial Board, International Journal of BioSciences and Technology
2012 – present Editorial Board, Bioinformatics and Biometrics
2012 – present Editorial Board, Journal of Clinical Oncology

B. Selected peer-reviewed publications (in chronological order).

H. Pang, A. Lin, M. Holford, B. E. Enerson, B. Lu, M.P. Lawton, E. Floyd, H. Zhao (2006), Pathway analysis using random forests classification and regression. Bioinformatics 22:2028-2036.

H. Pang, and H. Zhao (2008), Building Pathway Clusters from Random Forests Classification using Class Votes. BMC Bioinformatics 9:87. PMCID: PMC2335306

H. Pang, I. Kim, H. Zhao (2008), Pathway-Based Methods for Analyzing Microarray Data. In F. Emmert-Streib & M. Dehmer (Eds.), Analysis of Microarray Data: Network based Approaches (pp. 355-384). Weinheim, Germany: Wiley-VCH.

H. Pang, T. Tong, H. Zhao (2009), Shrinkage-based Diagonal Discriminant Analysis and its Applications in High-dimensional Data. Biometrics 65:1021-1029. PMCID: PMC2794982

H. Pang, D. Datta, H. Zhao (2010), Pathway Analysis using Random Forests with Bivariate Node-split for Survival Outcomes. Bioinformatics 26:250-258. PMCID: PMC2804301

H. Pang, K. Ebisu, E. Watanabe, L. Sue, T. Tong (2010), Analysing breast cancer microarrays from African Americans using shrinkage-based discriminant analysis. Human Genomics 5:5-16. PMCID: PMC3042882

H. Pang, and T. Tong (2011), Testing the equality of means when one sample has only a standalone sample. Advances and Applications in Statistical Sciences 5:53-62.

H. Pang, M. Hauser, S. Minvielle (2011), Pathway-based identification of SNPs predictive of survival. European Journal of Human Genetics 19:704-709. PMCID: PMC3110054

N. Ready, A. Dudek, **H. Pang**, L. Hodgson, S. Graziano, M. Green, E. Vokes (2011), Cisplatin, Irinotecan and Bevacizumab for Untreated Extensive Stage Small Cell Lung Cancer: CALGB 30306 A Phase II Study. Journal of Clinical Oncology 29:4436-4441. PMCID: PMC3221525

T. Kong, K. Joe, **H. Pang** (2012), Relationship type, condom use and HIV/AIDS risks among men who have sex with men in six Chinese cities. AIDS Care. 24:517-528.

H. Pang, T. Tong (2012), Recent Advances in Discriminant Analysis for High-dimensional Data Classification. Journal of Biometrics and Biostatistics 3:e106.

I. Kim, **H. Pang**, H. Zhao (2012), Semiparametric Regression Models for Evaluating Pathway Effects on Clinical Continuous and Binary Outcomes. Statistics in Medicine 31:1633-51.

W. Syn, K. Agboola, M. Swiderska, G. Michelotti, **H. Pang**, G. Xie, G. Philips, I. Chan, G. Karaca, T. Pereira, Y. Chen, Z. Mi, P. Kuo, S. Choi, C. Guy, M. Abdelmalek, A.M. Diehl (2012), NKT cells stimulate hedgehog and osteopontin production to drive fibrogenesis in nonalcoholic fatty liver disease. Gut 61:1323-9.

H. Pang, S. George, K. Hui, T. Tong (2012), Gene Selection using Iterative Feature Elimination Random Forests for Survival Outcomes. IEEE/ACM Transactions on Computational Biology and Bioinformatics 9:1422-1431. PMCID: PMC3495190

M. Kelley, J. Bogart, L. Hodgson, R. Ansari, J. Atkins, **H. Pang**, M. Green, E. Vokes (2013), Phase II study of induction cisplatin and irinotecan followed by concurrent carboplatin, etoposide, and thoracic radiotherapy for limited stage small cell lung cancer: CALGB 30206. Journal of Thoracic Oncology 8:102-108. PMCID: PMC3524334

N. Balajonda, T. Bisanar, J. Mathew, **H. Pang**, C. Voils (2013), Determinants of a Subject's Decision to Participate in Clinical Anesthesia Research. Anesthesia & Analgesia 116:448-454.

H. Pang, S. Jung (2013), Sample Size Considerations of Prediction-Validation Methods in High-Dimensional Data for Survival Outcomes. Genetic Epidemiology Mar 7: Epub.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME **Michael J. Pencina**	POSITION TITLE **Professor of Biostatistics and Bioinformatics**
eRA COMMONS USER NAME **pencina.michael**	

EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, such as nursing,*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
University of Warsaw, Warsaw, Poland	**M.A.**	**1998**	**Mathematics**
Boston University, Boston, MA	**Ph.D.**	**2003**	**Statistics**

A. Personal Statement

The goal of this research is to develop and expand the existing methodology to address the problem of heterogeneity of treatment effects in randomized trials and registry studies. I have the expertise, leadership and motivation necessary to successfully carry out the proposed work. I have worked on topics related to risk assessment and treatment personalization in the field of cardiovascular disease prediction among participants enrolled in the Framingham Heart Study for the last 10 years. Construction of risk scores and evaluation of their performance is the area of my primary research interest. New methods proposed in my recent publications have been widely adopted as the most promising statistical tools in the assessment of model performance. Recent guidelines from the American Heart Association suggest reporting of results that utilizes metrics and presentation suggested in my work. My ongoing collaborations with thought leaders in the fields of cardiovascular risk prediction, imaging and assessment of usefulness of new markers further strengthen my ability to carry out this research. My publications record includes more than 150 manuscripts published in peer-reviewed journals. These experiences make me uniquely positioned to fulfill my role on this application.

B. Positions and Honors

Positions and Employment

1999 – 2003 Research Assistant, Teaching Assistant, Boston University, Statistics and Consulting Unit, Department of Mathematics and Statistics, Boston, MA
2003 - 2008 Research Assistant Professor, Boston University, Department of Mathematics and Statistics, Boston, MA
2007 - 2010 Senior Consulting Statistician, Harvard Clinical Research Institute, Boston, MA
2008 - 2013 Associate Professor, Boston University, Department of Biostatistics, Boston, MA
2011 - 2013 Director, Statistical Consulting, Harvard Clinical Research Institute, Boston, MA
2013 - Professor Duke University, Biostatistics and Bioinformatics, Durham, NA
2013 - Director, Duke Clinical Research Institute Biostatistics, Durham, NA

Other Experience and Professional Memberships

2012 - Associate Editor, Statistics in Medicine
2007 - 2011 Assistant Editor, Statistics in Medicine
2005 - Member, American Heart Association

C. Selected peer-reviewed publications (Selected from over 100 publications)

Most relevant to the current application

1. Polak JF, **Pencina MJ**, O'Leary DH, D'Agostino RB. Common carotid artery intima-media thickness progression as a predictor of stroke in multi-ethnic study of atherosclerosis. Stroke. 2011 Nov;42(11):3017-21. Epub 2011 Sep 1. PubMed PMID: 21885840; PubMed Central PMCID: PMC3202068.
2. Polak JF, **Pencina MJ**, Pencina KM, O'Donnell CJ, Wolf PA, D'Agostino RB Sr. Carotid-wall intima-media thickness and cardiovascular events. N Engl J Med. 2011 Jul 21;365(3):213-21. PubMed PMID: 21774709; PubMed Central PMCID: PMC3153949.
3. **Pencina MJ**, D'Agostino RB, Vasan RS. Statistical methods for assessment of added usefulness of new biomarkers. Clin Chem Lab Med. 2010 Dec;48(12):1703-11. Epub 2010 Aug 18. Review. PubMed PMID: 20716010; PubMed Central PMCID: PMC3155999.
4. **Pencina MJ**, D'Agostino RB Sr, Larson MG, Massaro JM, Vasan RS. Predicting the 30-year risk of cardiovascular disease: the framingham heart study. Circulation. 2009 Jun 23;119(24):3078-84. Epub 2009 Jun 8. PubMed PMID: 19506114.
5. **Pencina MJ**, D'Agostino RB Sr, D'Agostino RB Jr, Vasan RS. Evaluating the added predictive ability of a new marker: from area under the ROC curve to reclassification and beyond. Stat Med. 2008 Jan 30;27(2):157-72; discussion 207-12. PubMed PMID: 17569110.

Additional recent publications of importance to the field (in chronological order)

1. Lee DS, **Pencina MJ**, Benjamin EJ, Wang TJ, Levy D, O'Donnell CJ, Nam BH, Larson MG, D'Agostino RB, Vasan RS. Association of parental heart failure with risk of heart failure in offspring. N Engl J Med. 2006 Jul 13;355(2):138-47. PubMed PMID: 16837677.
2. **Pencina MJ**, D'Agostino RB Sr, Steyerberg EW. Extensions of net reclassification improvement calculations to measure usefulness of new biomarkers. Stat Med. 2011 Jan 15;30(1):11-21. doi: 10.1002/sim.4085. Epub 2010 Nov 5. PubMed PMID: 21204120.
3. Lieb W, **Pencina MJ**, Wang TJ, Larson MG, Lanier KJ, Benjamin EJ, Levy D, Tofler GH, Meigs JB, Newton-Cheh C, Vasan RS. Association of parental hypertension with concentrations of select biomarkers in nonhypertensive offspring. Hypertension. 2008 Aug;52(2):381-6. Epub 2008 Jun 23. PubMed PMID: 18574071; PubMed Central PMCID: PMC2574605.
4. Parikh NI, **Pencina MJ**, Wang TJ, Benjamin EJ, Lanier KJ, Levy D, D'Agostino RB Sr, Kannel WB, Vasan RS. A risk score for predicting near-term incidence of hypertension: the Framingham Heart Study. Ann Intern Med. 2008 Jan 15;148(2):102-10. PubMed PMID: 18195335.
5. Ingelsson E, **Pencina MJ**, Tofler GH, Benjamin EJ, Lanier KJ, Jacques PF, Fox CS, Meigs JB, Levy D, Larson MG, Selhub J, D'Agostino RB Sr, Wang TJ, Vasan RS. Multimarker approach to evaluate the incidence of the metabolic syndrome and longitudinal changes in metabolic risk factors: the Framingham Offspring Study. Circulation. 2007 Aug 28;116(9):984-92. Epub 2007 Aug 13. PubMed PMID: 17698726.
6. Steg PG, Bhatt DL, Wilson PW, D'Agostino R Sr, Ohman EM, Röther J, Liau CS, Hirsch AT, Mas JL, Ikeda Y, **Pencina MJ**, Goto S; REACH Registry Investigators. One-year cardiovascular event rates in outpatients with atherothrombosis. JAMA. 2007 Mar 21;297(11):1197-206. PubMed PMID: 17374814.
7. **Pencina MJ**, Larson MG, D'Agostino RB. Choice of time scale and its effect on significance of predictors in longitudinal studies. Stat Med. 2007 Mar 15;26(6):1343-59. PubMed PMID: 16955538.
8. Polak JF, **Pencina MJ**, Herrington D, O'Leary DH. Associations of edge-detected and manual-traced common carotid intima-media thickness measurements with Framingham risk factors: the multi-ethnic study of atherosclerosis. Stroke. 2011 Jul;42(7):1912-6. Epub 2011 May 5. PubMed PMID: 21546477; PubMed Central PMCID: PMC3169166.
9. **Pencina MJ**, D'Agostino RB, Beiser AS, Cobain MR, Vasan RS. Estimating lifetime risk of developing high serum total cholesterol: adjustment for baseline prevalence and single-occasion measurements. Am J Epidemiol. 2007 Feb 15;165(4):464-72. Epub 2006 Nov 20. PubMed PMID: 17116649.
10. Wilson PW, Nam BH, **Pencina M,** D'Agostino RB Sr, Benjamin EJ, O'Donnell CJ. C-reactive protein and risk of cardiovascular disease in men and women from the Framingham Heart Study. Arch Intern Med. 2005 Nov 28;165(21):2473-8. PubMed PMID: 16314543.

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Bercedis L. Peterson	Associate Research Professor
eRA COMMONS USER NAME (credential, e.g., agency login) bpeter	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Southern Illinois University	B.A	12/73	English Literature
Southern Illinois University	M.S.	6/77	Measurement and Stats
University of North Carolina, Chapel Hill	M.S.	8/82	Biostatistics
University of North Carolina, Chapel Hill	Ph.D.	8/86	Biostatistics

A. Personal Statement:

I am fully funded by grants within the Cancer Institute where I have worked since 1991. I collaborate with Cancer Institute members in the design of grants, clinical trials, retrospective research projects, biomarker studies, and laboratory studies. If a project is funded I serve as the faculty statistician on the grant. From 1991 to 2008 I worked on the Leukemia and Breast Committees of the Cancer and Leukemia Group B, designing, monitoring, analyzing, and publishing Phase I, II and III clinical trials for CALGB. While there is currently limited opportunity for me to work on Phase III clinical trials at Duke, I make up for this by working with members of the Cancer Prevention, Detection, and Control division of the Cancer Institute to design and run complex randomized intervention studies.

B. Positions and Honors:

2005-present	Associate Research Professor, Department of Biostatistics and Bioinformatics, DUMC
2000-2005	Assistant Research Professor, Department of Biostatistics and Bioinformatics, DUMC
	Assistant Professor, Department of Community and Family Medicine, Division of Biometry and Medical Informatics, DUMC
1984-88	Biostatistician, Behavioral Medicine Research Center, DUMC
1983	Graduate Research Assistant, EPA, Clinical Studies, University of North Carolina
1980-82	Graduate Research Assistant, Institute of Research in Social Sciences; UNC
1977-79	Staff Researcher, Computing Affairs Research and Evaluation Center, Computer Center, Southern Illinois University

C. Selected Peer-reviewed Publications from over 100.

1. Peterson, BL, Harrell, FE. Partial proportional odds model for ordinal response variables. *Journal of the Royal Statistical Society C* 39:205-21, 1990.

2. Peterson, BL, George, SL. Sample size requirements and length of study for testing interaction in a 2xk factorial design when time-to-failure is the outcome. *Controlled Clinical Trials* 14:511-211, 1993.

3. Rai KR, Peterson BL, Appelbaum FR, Kolitz J, Elias L, Shepherd L, Hines J, Threatte GA, Larson RA, Cheson BD, Schiffer CA. Fludarabine compared with chlorambucil as primary therapy for chronic lymphotcytic leukemia. *New England Journal of Medicine* 343:1751-1759, 2000.

4. Potthoff RF, Peterson BL, George SL. Detecting treatment-by-center interaction in multi-center clinical trials. *Statistics in Medicine* 20:193-213, 2001.

5. Silverman LR, Demakos EP, Peterson BL, plus 11 others. A randomized controlled trial of azacitidine in patients with the myelodysplastic syndrome: A study of the Cancer and Leukemia Group B. *Journal of Clinical Oncology* 20:2429-2440, 2002.

6. Sartor CI, Peterson BL, Woolf S, FitzGerald TJ, Laurie F, Turrisi AJ, Bogart J, Henderson IC, Norton L. Effect of addition of adjuvant paclitaxel on radiotherapy delivery and locoregional control of node positive breast cancer: CALGB 9344. *Journal of Clinical Oncology 23*:30-40, 2005.

7. Scales C, Norris R, Keitz S, Peterson BL, Preminger G, Vieweg G, Dahm P. A Critical Assessment of the Quality of Reporting of Randomized, Controlled Trials in the Urology Literature. *The Journal of Urology* 177:1090-1095, 2006.

8. Demark-Wahnefried W, Clipp EC, Lipkus IM, Lobach D, Snyder DC, Sloane R, Peterson BL, Macri JA, Rock CL, McBride CM, Kraus WE. Main Outcomes of the FRESH START Trial: A Sequentially-Tailored, Diet and Exercise, Mailed Print Intervention Among Breast and Prostate Cancer Survivors. *Journal of Clinical Oncology* 26: 2709-2718, 2007.

9. Gollob JA, Rathmell W., Richmond TM, Marino CB, Miller EK, Grigson G, Watkins C, Gu L, Peterson BL, Wright JJ. Phase II Trial of Sorafenib Plus Interferon Alpha-2b as First- or Second-Line Therapy in Patients with Metastatic Renal Cell Cancer. *Journal Clinical Oncology* 28:3288-3295, 2007.

10. Swamy GK, Roelands JJ, Peterson BL, Lyna P, Brouwer RJ, Fish LJ, Oncken CA, Pletsch PK, Myers ER, Pollak KI. Predictors of adverse events among pregnant smokers exposed in a nicotine replacement therapy trial. *American Journal of Obstetrics and Gynecology* 201(4):354.e1-7, 2009. PMCID: PMC2755600

11. Morey MC, Snyder DC, Sloane R, Cohen HJ, Peterson B, Hartman TJ, Miller P, Mitchell D, and Demark- Wahnefried D. Effects of Home-Based Diet and Exercise on Functional Outcomes Among Older, Overweight Long-Term Cancer Survivors: The RENEW: Randomized Clinical Trial. *Journal of the American Medical Association* 301:1883-1891, 2009. PMCID: PMC2752421

12. Rizzieri DA, Crout C, Storms R, Golob J, Long GD, Gasparetto C, Sullivan KM, Horwitz M, Chute J, Lagoo AS, Morris A, Beaven A, Yang Y, Peterson B, Li Z, Chao NJ. Feasibility of low-dose interleukin-2 therapy following T-cell-depleted nonmyeloablative allogeneic hematopoietic stem cell transplantation from HLA-matched or -mismatched family member donors. *Cancer Investigation* 29(1):56-61, 2011.

13. Beasley GM, Riboh JC, Augustine CK, Zager JS, Hochwald SN, Grobmeyer SR, Peterson BL, Royal R, Ross MI, Tyler DS. A Prospective Multi-Center Phase II Trial of Systemic ADH-1 in Combination with Melphalan via Isolated Limb Infusion (M-ILI) in Patients with Advanced Extremity Melanoma. *Journal of Clinical Oncology* 29(9):1210-5, 2011.

14. Woyach JA, Ruppert AS, Heerema NA, Peterson BL, Gribben JG, Morrison VA, Rai KR, Larson RA, Byrd JC. Chemoimmunotherapy with fludarabine and rituximab produces extended overall survival and progression-free survival in chronic lymphocytic leukemia: long-term follow-up of CALGB study 9712. *Journal of Clinical Oncology* 29(10):1349-55, 2011. PMCID: PMC3084002

15. Herold CI, Chadaram V, Peterson BL, Marcom PK, Hopkins J, Kimmick GG, Favaro J, Hamilton E, Welch RA, Bacus S, Blackwell KL. Phase II Trial of Dasatinib in Patients with Metastatic Breast Cancer Using Real-Time Pharmacodynamic Tissue Biomarkers of Src Inhibition to Escalate Dosing. *Clinical Cancer Research* 17(18):6061-70, 2011.

16. Østbye T, Peterson BL, Krause K, Lovelady CL, Swamy GK. Predictors of postpartum weight change among overweight and obese women: Results from the Active Mothers Postpartum (AMP) study. Journal of Women's Health, 21, 215-222, 2012.

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Pieper, Carl	Assistant Professor
eRA COMMONS USER NAME (credential, e.g., agency login) CARLPIEPER	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Duke University	BA	05/75	Psychology
Columbia University	MPH	05/81	SocioMed. Sciences
Columbia University	DrPH	05/91	Biostatistics

A. Personal Statement.

I have worked as an applied biostatistician in gerontology and aging for over 20 years – directing the Computing and Statistics Laboratory for the Center on Aging and Human Development at Duke, and as a faculty member in the Duke Clinical Research Institute, for that entire time. The research I have participated in spans from macro sociological studies to cellular. In that capacity, my lab and I have provided design and analytic consultation on a wide variety of studies dealing with issues in aging, including clinical trials, analysis of longitudinal epidemiologic studies, pilot studies, meta-analysis, and administration Center grants. I list over 250 publications in refereed journals, many of which deal with analysis of exercise, function and performance data, and issues of aging. I have directed analysis and data management cores for Duke's Older American Independence Center (Pepper OAIC) for three 5 year cycles, including work on the analytic issues in the study of metabalomic and physiologic biomarkers as they relate to aging, physical performance, and function.

I have served as the core director for numerous other center grants, including PI of the Data Analysis and Management core for Duke's Bryan Alzheimers Disease Center, PI of the Analysis and Data Management core for Duke's department of Psychiatry's Conte Center for the study of depression in the elderly for 2 cycles, and I was also PI for a twenty five million dollar contract for NIDA for the data management center for the Institute's Clinical Trials Network, directing the data management activities for all clinical trials on drug abuse conducted within the network.

My substantive research interests include psychometric/data aggregation methodology specific to metabolomics, analysis of function and performance, and methodological issues in methods for repeated measures designs, methods for data reduction, and issues in the assessment of reliability. I have been the lead statistician in works on aging in a variety of NIH projects (clinical trials, cross sectional, longitudinal, observational, and meta-analyses of secondary data sources). In addition, I have mentored students on K-awards and post-doctoral work, mostly dealing with issues in aging, on PhD committees providing statistical guidance on issues in physical performance and other aging problems, and as a statistical advisor on over 40 master’s essays in the Clinical Research Training Program (CRTP) in Duke Medical Center. I am a expert in reliability, clinical trials, design and longitudinal data analysis – having published both methodologic and substantive pieces in these areas, as well as teaching courses in the CRTP program in both psychometrics and longitudinal data analysis as well as Observational Data Analysis in the Biostatistics and Bioinformatics masters program.

Positions and Honors

1984-87	Adjunct Instructor in Biostatistics, School of Health Sciences, Hunter College, City U. of NY
1984-89	Adjunct Lecturer, Division of Biostatistics, Columbia University School of Public Health.
1990	Adjunct Assistant Professor, Div. of Biostatistics, Columbia Univ. School of Public Health
1990-91	Assistant Professor of Statistics in Medicine, Dept. of Medicine, NY Hosp/Cornell Medical Ctr
1991-Pres.	Director, Computing and Statistical Laboratory Aging Center, Duke Univ. Med. Ctr.
1991-2001	Asst. Professor, Dept. Community & Family Medicine, Div. of Biometry, Duke Univ. Med. Ctr
1994-Pres.	Senior Fellow, Duke University Center for Aging and Human Development
2001-Pres.	Assistant Professor, Dept. of Biostatistics and Bioinformatics, Duke Univ. Med. Ctr

C. Selected Peer-reviewed Publications (Selected from 250+ peer reviewed publications)

Most relevant to the current application

1. **Pieper.CF**, Redman,LM, Racette,SB, Roberts,SB, Bapkar,M, Rochon,J, Martin,CK, Kraus,WE, Das,S, Williamson,D, Ravussin,E 'Development of Adherence Metrics for Caloric Restriction Interventions', Clinical Trials, 2011: 8(2), 155-164. PMCID: PMC3095229 (Available 2012/3/8)
2. Nahm ML, **Pieper, C**, Cunningham MM. Quantifying data quality for clinical trials using electronic data capture. PLoS ONE 2008; 3(8): e3049. PMCID: PMC2516178.
3. Pan, JJ, Nahm,M, Wakim,P, Cushing,C, Poole,L, Tai,B, **Pieper,C**, 'A centralized informatics infrastructure for the National Institute on Drug Abuse Clinical Trials Network' Clinical Trials Journal of the Society for Clinical Trials, 2009: 6(1), 67-75. PMCID: PMC2962616
4. Rostami,R Nahm, M, **Pieper,CF** 'What can we learn from a decade of database audits? The Duke Clinical Research Institute experience, 1997–2006', Controlled Clinical Trials, 2009: 6(2), 141-150. PMCID: PMC - in process
5. Racette, SB Das,SK, Bhapkar,M, Hadley,EC, Roberts,SB, Ravussin,E, **Pieper,C**, DeLany,JP, Kraus,WE, Rochon,J, Redman,LM for the CALERIE Study Group. 'Approaches for quantifying energy intake and % calorie restriction (CR) during CR interventions in humans: the multicenter CALERIE study' American Journal of Physiology - Endocrinology and Metabolism, 2012, 302(4), E441-E448.

Additional recent publications of importance to the field

6. Stewart, TM, Bhapkar,M, Das,S, Galan,K, Martin,CK, McAdams,L, **Pieper,C**, et al, for the CALERIE Study Group, 'Comprehensive Assessment of Long-Term Effects of Reducing Intake of Energy Phase 2 (CALERIE Phase 2) Screening and Recruitment: Methods and Results', Controlled Clinical Trials, 2013, 34(1), 10-20.
7. Redman, LM, Kraus, WB, Huffman, KM, Landerman, LR, **Pieper, CF,** et al., 'Effect of caloric restriction with and without exercise on metabolic intermediates in non-obese men and women' The Journal of Clinical Endocrinology & Metabolism, 2011: 96(2) E312-E321. PMCID: PMC3048325
8. Lyles, KW, Colón-Emeric, CS, Magaziner, JS, Adachi, JD, **Pieper, CF** et al., for the HORIZON Recurrent Fracture Trial, 'Zoledronic Acid in Reducing Clinical Fracture and Mortality after Hip Fracture' New England Journal of Medicine, 2007: 357(18), 1799-1809. (nihpa40967) PMCID: PMC2324066
9. Synder, DC, Morey,MC, Stull,V, Sloane,R, Cohen, HJ, Peterson,B, **Pieper,C**, et al., 'Reach Out to Enhance Wellness in Older Cancer Survivors (RENEW): Design, Methods and Recruitment Challenges of a Home-based Exercise and Diet Intervention to Improve Physical Function among Long-term Survivors of Breast, Prostate, and Colorectal Cancer' Psycho-Oncology, 2009: 19(4), 429-439. PMCID: PMC4748788
10. Morey,MC, Peterson,MJ, **Pieper,CF**, Sloane,R, Crowley,GM, Cowper,PA, McConnell,ES, Bosworth,HB, Ekelund,CC, Pearson,MP, The Veterans Learning to Improve Fitness and Function in Elders Study: A Randomized Trial of Primary Care Based Physical Activity Counseling For Older Men, Journal of the American Geriatrics Association, 2009: 57(7), 1166-1174. PMCID: PMC2757328
11. Huffman, K, Redman,L, Landerman,L, **Pieper,C**, Stevens,R, Muehlbauer,M, Wenner,B, Bain,J, Kraus,V, Newgard,C, Ravussin,E, Kraus,W, "Caloric Restriction Alters the Metabolic Response to a Mixed-Meal", PLoS ONE, http://dx.plos.org/10.1371/journal.pone.0028190.
12. Joseph,AM, Arikian,NJ, An,LC, Nugent, SM, Sloane,RJ, **Pieper,CF**, and the GIFT Research Group 'GIFT Results of a randomized controlled trial of intervention to implement smoking guidelines in Veterans Affairs medical centers: Increased use of medications without cessation benefits.' Medical Care, 2004: 42 (11), 1100-1110.
13. Demark-Wahnefried, W, Clipp, EC, Morey, MC, **Pieper,CF**, et al., Lifestyle Intervention Development Study to Improve Physical Function in Older Adults with Cancer: Outcomes from Project LEAD, Journal of Clinical Oncology, 2006: 24(21); 3465-3473. PMCID: PMC1532928
14. Purser,J, **Pieper,C**, Duncan,P, et al.,'Reliability of Physical Performance tests in Four Different Randomized Clinical Trials', Archives of Physical Medicine and Rehabilitation, 1999: 80(5), 557-561.
15. Morey,MC, Peterson,MJ, **Pieper,CF** et al., The Veterans Learning to Improve Fitness and Function in Elders Study: A Randomized Trial of Primary Care Based Physical Activity Counseling For Older Men, Journal of the American Geriatrics Association, 2009: 57(7), 1166-1174. PMCID: PMC2757328

BIOGRAPHICAL SKETCH

NAME Paramita Saha Chaudhuri	POSITION TITLE Assistant Professor of Biostatistics
eRA COMMONS USER NAME CHAUDHURI001	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Presidency College, Kolkata, India	BSc	1999	Statistics
Indian Statistical Institute, Kolkata, India	MStat	2001	Statistics
University of Washington, Seattle, WA	MS	2005	Biostatistics
University of Washington, Seattle, WA	PhD	2009	Biostatistics

A. Personal statement

My research interest includes risk prediction, assessment of prediction accuracy, efficient design for observational studies and gene by environment interaction in longitudinal setting. I am experienced in analysis of observational studies with epidemiological, correlated, and survival data, in particular registry data (cardiac surgery registry) and electronic health records (diabetes).

B. Positions and Honors

Positions and Employment

2001 – 2003	Research Fellow, Theoretical Statistics and Mathematics Unit, Indian Statistical Institute, Delhi, India.
2004 – 2009	Research Assistant, Teaching Assistant and Consultant, University of Washington, Seattle, WA.
2009 – 2011	Research Fellow, National Institute of Environmental Health Sciences, Research Triangle Park, NC.
2011 – Present	Assistant Professor, Biostatistics and Bioinformatics, Duke University Medical Center, Durham NC.
2011 – Present	Faculty Statistician, Outcomes Research and Assessment Group, Duke Clinical Research Institute, Durham, NC.

Other Activities

2004 – Present	Member, American Statistical Association
2006 – 2009	Member, Western North American Region, International Biometric Society
2009 – Present	Member, Eastern North American Region, International Biometric Society
2009 – Present	Member, Society for Epidemiologic Research
Reviewer	American Journal of Epidemiology, Biometrical Journal, Biometrics, Biostatistics, BMC Medical Research Methodology, International Journal of Biostatistics, International Statistical Review, Journal of American Medical Association, Lifetime Data Analysis, Statistical Methodology, Statistics and Probability Letters, Statistics in Medicine.

C. Selected Peer-reviewed Publications (chronological order)

1. Das A, Dey A, **Saha P***. Small asymmetric fractional factorial plans for main effects and specified two-factor interactions. Metrika 62 : 33-52, 2005. (* Authors are listed alphabetically by convention.)

2. Robinson TE, Long FR, Raman P, **Saha P**, Emond MJ, Reinhardt JM, Raman R, Brody A. An airway parenchymal phantom to standardize CT acquisition in multicenter clinical trials. Academic Radiology 16 (9) : 1134-1141, 2009.

3. **Saha P**, Heagerty PJ. Time-dependent predictive accuracy in the presence of competing risks. Biometrics 66 (4): 999-1011, 2010.

4. Cupul-Uicab LA, Baird DD, Skjaerven R, **Saha-Chaudhuri P**, Eggesbo M, Haug K, Longnecker MP. In utero exposure to maternal tobacco smoking and women's risk of pregnancy loss later in life in the Norwegian Mother and Child Cohort (MoBa). Human Reproduction 26 (2): 458-465, 2011. PMCID: PMC3024897

5. **Saha-Chaudhuri P**, Umbach DM, Weinberg CR. Pooled exposure analysis for matched case-control studies. Epidemiology 22 (5): 704-712, 2011. PMCID:PMC3160274

6. French B*, **Saha-Chaudhuri P***, Ky B, Cappola TP, Heagerty PJ. Evaluating the predictive accuracy of multiple biomarkers and clinical variables. (*Joint first authors) In Press, Statistical Methods in Medical Research. PMCID:PMC3467353

7. **Saha-Chaudhuri P**, Heagerty PJ. Non-parametric estimation of a time-dependent predictive accuracy curve. In Press, Biostatistics. PMCID:PMC3520498

8. **Saha-Chaudhuri P**, Weinberg CR. Specimen pooling for efficient use of bio-specimens in studies of time to a common event. In Press, American Journal of Epidemiology.

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Samsa, Gregory	Associate Professor
eRA COMMONS USER NAME (credential, e.g., agency login) gsamsa	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
University of North Carolina, Chapel Hill, NC	B.A.	1979	Mathematics
University of North Carolina, Chapel Hill, NC	M.S.	1981	Statistics
University of North Carolina, Chapel Hill, NC	Ph.D.	1988	Biostatistics

A. Personal Statement

I am an applied statistician with interests in information synthesis, practice improvement and system design, randomized trials, outcomes research, and most particularly in improving the link between evidence and practice. I have published on both the theory and practice of quality improvement and practice improvement research, and has served as the lead statistician on numerous studies that have developed and assessed the impact of putative improvements to health care systems. I am also committed to mentorship – for example, in my role as Director of Graduate Studies in the Department of Biostatistics and Bioinformatics, and through my work with various junior investigators.

B. Positions and Honors

1980-1988 Statistician, Department of Infectious Diseases, University of North Carolina
1988-1995 Senior Research Scientist, Department of Veterans Affairs Medical Center, Durham NC
1988-1998 Assistant Professor, Duke University Division of Biometry, Dept of Community and Family Medicine
1993-2009 Associate Director, Duke University Center for Health Policy Research and Education
1991-present Assistant Research Professor, Duke University Division of General and Internal Medicine, Dept of Medicine
1998-present Associate Professor, Duke University Division of Biometry, Dept of Biostatistics and Bioinformatics
2009-present Director of Graduate Studies, Duke University Division of Biometry, Dept of Biostatistics and Bioinformatics

C. Selected Peer-reviewed Publications (from approximately 200, 25 first-authored)

Samsa G, Matchar D. Can continuous quality improvement be assessed using randomized trials? **Health Services Research** 2000;35(3):689-702.

Samsa GP, Matchar DB. Have randomized trials of neuroprotective drugs been underpowered? An illustration of three statistical principles. **Stroke** 2001;32:669-674.

Samsa GP, Oddone EZ, Horner R, K, Daley J, Henderson W, Matchar DB. To what extent should quality of care decisions be based upon health outcomes data? Application to carotid endarterectomy. **Stroke** 2002;33:2944-2949.

Samsa G, Matchar DB, Dolor RJ, Wiklund I, Hedner E, Wygant G, Hauch O, Marple CB, Edwards G. A new instrument for measuring anticoagulation-related quality of life: development and preliminary validation. **Health and Quality of Life Outcomes** (online journal) 2004 2:22. DOI:10.1186/1477-7525-2-22.

Samsa, GP, Thomas L, Lee LS, Neal EM. An active learning approach to teach advanced multi-predictor modeling to clinicians. **Journal of Statistics Education**. 2012; 20(1):1-31.

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Turner, Elizabeth	Medical Instructor, Duke Global Health Institute and Department of Biostatistics and Bioinformatics, Duke University, USA
eRA COMMONS USER NAME ELTURNER16	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Warwick University, UK	BSc	07/00	Mathematics
McGill University, Canada	MSc	10/02	Statistics
McGill University, Canada	PhD	10/07	Statistics

A. Personal statement:

The key experiences and abilities that I offer include a depth and breadth of analytical skills including cluster-randomized trials, longitudinal cohort data, mediation and moderator analyses of both trial and observational data, and a range of outcome measures including anthropometric, cognitive, educational, psychological and socioeconomic measures.

As research fellow in the Department of Medical Statistics at the LSHTM, my role as collaborative research statistician with six main research groups has led to the development and honing of the key skills outlined above. These include Preventive Cardiology, through Imperial College London, with a focus on the European cluster randomized trial of a family-based preventive cardiology programme (ISRCTN 71715857); Public Health Entomology with a focus on prevention of malaria transmission through innovative transmission prevention strategies in Tanzania; International Centre for Eye Health with a focus on disease burden estimation, particularly due to cataract blindness, which led to the development of new statistical methodology (manuscript in review); European Huntington's Disease Network with the goal to use longitudinal registry data to inform clinical trial design; Stroke Research, through University College London, with a focus on the International Carotid Stenting RCT. In recognition of my analytical and collaborative skills, I was invited to become statistician to the Health and Literacy Intervention study (HALI; NCT00878007), a cluster-randomized trial of 5100 children in 101 schools in Kenya. HALI aims to evaluate a school-based malaria treatment to improve educational achievement.

B. Positions and Honors

Positions and Employment

2003-2007 Research Assistant, Lady Davis Institute for Medical Research, Montreal
2007-2012 Research Fellow, Department of Medical Statistics, Faculty of Population Health, London School of Hygiene and Tropical Medicine, London, UK
2012- Medical Instructor, Duke Global Health Institute and Department of Biostatistics and Bioinformatics, Duke University, US

Honors and awards

2000-2001 Entente Cordial Scholarship, France (declined)
2000-2001 Canada Memorial Foundation Scholarship
2001-2003 Institut des Sciences Mathématiques Scholarship, Canada

2003-2005 Commonwealth Scholarship, Canada
2003-2006 McGill Major Scholarship, Canada (declined first two years)
2005 One of top three presentations, Research Students Conference, Cambridge

Committees and Memberships

2007- Member, Royal Statistical Society, UK
2011- Member, International Biometric Society

C. Selected peer-reviewed publications (last 5 years)

1. Halliday KE, Karanja P, Turner EL, Okello G, Njagi K, Dubeck MM, Jukes MCH, Brooker S (2012). *Plasmodium falciparum*, anaemia and cognitive and educational performance among school children in an area of moderate malaria transmission: baseline results of a cluster randomised trial on the coast of Kenya. *Tropical Medicine and International Health* 17, 532-549.
2. Mng'ong'o FC, Sambali JJ , Sabas E, Rubanga J, Magoma J, John A, Turner EL, Nyogea D, Ensink J, Moore SJ (2011). Repellant plants provide affordable natural screening to prevent mosquito house entry in tropical rural settings - Results from a pilot efficacy study. *PLoS ONE*, 6(10): e25927.
3. Turner EL, Perel P, Edwards P, Clayton TC (2012). Covariate adjustment increased power in randomized controlled trials: an example in traumatic brain injury. *Journal of Clinical Epidemiology,*65(5): 474-481.
4. Shah SP, Gilbert CE, Rezzavi H, Turner EL, Lindfield RJ (2011). Variation in pre-operative visual acuity among cataract patients reflects levels of social deprivation at the population level: a global study. *Bulletin of the WHO,* 89: 749-756.
5. Limmathurotsakul D, Turner EL, Wuthiekanun V, Thaipadunpanit J, Suputtamongkol Y, Chierakul W, Smythe LD, Day NPJ, Cooper BS, Peacock SJ. (2012). Fool's Gold: Why imperfect reference tests are undermining the evaluation of novel diagnostics: A reevaluation of 5 diagnostic tests for Leptospirosis. *Clinical Infectious Diseases*, Advance access online doi: *10.1093/cid/cis403.*

Additional recent publications of importance to the field

1. Kotseva K, Jennings CS, Turner EL, Mead A, Connolly S, Jones J, Bowker T, Wood DA on behalf of the ASPIRE-2-PREVENT Study Group. ASPIRE-2-PREVENT: A survey of lifestyle, risk factor management and cardioprotective medication in coronary patients and people at high risk of developing cardiovascular disease in the UK. *Heart*, 865-871.
2. Connolly S, Holden A, Turner EL, Fiumicelli G, Stevenson J, Hunjan M, Mead A, Kotseva K, Jennings C, Jones J, Wood D A (2011). MyAction – an innovative approach to the prevention of cardiovascular disease in the community. *British Journal of Cardiology*, 18(4): 171-176.
3. Turner EL, Dobson, JA, Pocock, SJ (2010). Categorisation of continuous risk factors in epidemiological publications: a survey of current practice. *Epidemiologic Perspectives & Innovations*, 7:9.
4. Turner EL, Hanley JA (2010). Cultural imagery and statistical models of the force of mortality: Addison, Gompertz and Pearson. *Journal of the Royal Statistical Society, Series A.*173(3): 483-499.
5. Hanley JA, Turner EL (2010). Age in medieval plagues and pandemics: Dances of Death or Pearson's bridge of life? *Significance* 7(2): 85-87.

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Xiaofei Wang, PhD	Associate Professor of Biostatistics
eRA COMMONS USER NAME (credential, e.g., agency login) xiaofei.wang	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
East China Normal University, Shanghai, China	BS	1990	Computer Science & Psychology
Peking University, Beijing, China	MS	1993	Cognitive Sciences
University of North Carolina at Chapel Hill	MS	1999	Biostatistics
University of North Carolina at Chapel Hill	PhD	2003	Biostatistics

A. Personal Statement

I have strong research interests in developing innovative study designs and related statistical methods for the discovery and validation of biomarkers and classifiers based on high dimensional molecular, genetic and imaging data. My statistical methodology research have been funded by a NIH R03 grant on statistical methods for cancer screening, the Duke-NCSU-UNC cancer methodology P01 grant and Duke CTSA internal methodology grants. My methodology works have been published on influential statistical and medical journals. In the past years, I have also served in Duke CRTP master thesis committees and am advising master thesis projects of several Duke B&B master students as well as PhD dissertation of a UNC Biostatistics student. I am interested in teaching master and PhD level courses as well as supervising the incoming Duke B&B PhD students on their dissertations.

B. Positions, Honors and Professional Activities

Nov 2012-	Associate Professor of Biostatistics, Department of Biostatistics and Bioinformatics Duke University Medical Center, Durham, NC
2004-Oct 2012	Assistant Professor of Biostatistics, Department of Biostatistics and Bioinformatics Duke University Medical Center, Durham, NC
2011-present	Co-Lead Statistician, Respiratory Committee, Alliance (CALGB/NCCTG/ACOSOG)
2004-2011	Faculty Statistician, Respiratory Committee, Cancer and Leukemia Group B (CALGB)
1996-2003	Graduate Research Assistant, Biometrics Consulting Laboratory, Department of Biostatistics, School of Public Health, University of North Carolina, Chapel Hill, NC
1993-1994	Lecturer, Department of Psychology Beijing University, Beijing, China

1999 Delta Omega, Honor Society of American Public Health
2003 ENAR Student Paper Competition Award, International Biometrics Society

Reviewer: Biometrics, Biostatistics, Computational Statistics and Data Analysis, Journal of Biopharmaceutical Statistics, Journal of Clinical Oncology, Journal of Multivariate Statistics, Lung Cancer, International Journal of Cancer, Statistics in Medicine, Statistics in Biopharmaceutical Research, and Statistica Sinica,
Special Emphasis Panel for National Institute of Neuroological Disorders and Stroks (ZNS1 SRB-G58) reviewed U01 applications respond to the FOA PAR-12-097
Advisor panel for the NCI funded research on Oncology Clinical Trial Accrual Study (OCTAS)
Treasurer for North Carolina Chapter, American Statistical Association

C. Selected Peer-reviewed Publications

- **Wang XF**, Zhou HB (2006). A semiparametric empirical likelihood method for biased sampling schemes in epidemiologic studies with auxiliary covariates. *Biometrics*, 62, 1149-1160.

- Socinski MA, Blackstock AW, Bogart J, **Wang XF**, Rosenman JG, Gu L, Green M, Vokes EE from the Cancer and Leukemia Group B, Chicago, IL (2007) Induction followed by Concurrent Chemotherapy and Dose-escalated Thoracic Conformal Radiotherapy (74 Gy): A Randomized Phase II Trial of the Cancer and Leukemia Group B (CALGB 30105). *Journal of Clinical Oncology*. 26(15): 2457-2463.
- Rudin CM, Salgia R, **Wang XF**, Hodgson LD, Grubbs S, Johnson BE, Vokes EE (2007). A randomized phase II study of carboplatin and etoposide with or without oblimersen, antisense bcl-2, for extensive stage small cell lung cancer. *Journal of Clinical Oncology*. 26(6):870-876.
- Edelman M, Watson D, **Wang XF**, Morrison C, Kratzke R, Jewell S, Hodgson L, Mauer AM, Graziano SL, Masters GA, Bedor M, Green MJ, Vokes EE (2007). Eicosanoid modulation in advanced lung cancer: COX-2 expression is a positive predictive factor for celecoxib + chemotherapy. *Journal of Clinical Oncology*. 26(6):848-855.
- Govindan R, **Wang XF**, Baggstrom MQ, Hodgson L, Green MR, Vokes EE for the Cancer and Leukemia Group B (2009). A phase II study of carboplatin, etoposide, and exisulind in patients with extensive small cell lung cancer: CALGB 30104. *Journal of Thoracic Oncology*. 4(2): 220-226.
- **Wang XF**, Pang H, Schwartz T (2009). Statistical issues in validation of cancer biomarkers*. Chance.* 22(2), 55-62.
- Aupérin A, Le Péchoux C, Rolland E, Curran WJ, Furuse K, Fournel P, Belderbos J, Clamon G, Ulutin HC, Paulus R, Yamanaka T, Bozonnat MC, Uitterhoeve L, **Wang XF**, Stewart L, Arriagada R, Burdett S, Pignon JP (2009). Meta-analysis of concomitant versus sequential radiochemotherapy in locally advanced non-small-cell lung cancer. *Journal of Clinical Oncology*. 28(13), 2181-2190.
- Graziano SL, Gu L, **Wang XF**, Tatum AH, Vollmer RT, Strauss GM, Kratzke R, Dudek AZ, Green MR, Vokes EE (2010). Prognostic Significance of Molecular Markers and Clinical Factors in State IB Non-SmallCell Lung Cancer: a Laboratory Companion Study to CALGB 9633. *Journal of Thoracic Oncology*. 5(6), 810-817.
- **Wang XF**, Wu YG, Zhou HB (2009). Outcome- and Auxiliary-Dependent Subsampling and Its Statistical Inference. *Journal of Biopharmaceutical Statistics*. 19(6), 1132-1150.
- Lilenbaum R, **Wang X**, Gu L, Kirshner J, Lerro K, Vokes E. (2009). A Randomized Phase II Trial of Docetaxel Plus Cetuximab or Docetaxel Plus Bortezomib in Patinets with Advanced Non-small Cell Lung Cancer and a Performance Status of 2 - CALGB 30402. *Journal of Clinical Oncology*. 27, 4487-4491; PMCID:PMC2754901
- **Wang XF**, Zhou HB (2010). Design and Inference for Cancer Biomarker Study with an Outcome/Auxiliary-Dependent Subsampling. *Biometrics.* 66(2):502-511; PMCID:PMC2891224
- Partridge H, Archer L, Kornblith AB, Gralow J, Grenier D, Perez E, Wolf AC, **Wang XF**, Kastrissios H, Berry D, Hudis C, Winer E, Muss H (2010). Adherence and Persistence with Oral Adjuvant Chemotherapy in Older Women with Early Stage Breast Cancer. *Journal of Clinical Oncology*. 28(14), 2418-2422; PMCID:PMC2881723
- Kawaguchi A, Koch GG, **Wang XF** (2011). Stratified Multivariate Mann-Whitney Estimators for the Comparison of Two Treatments with Randomization Based Covariance Adjustment. *Statistics in Biopharmaceutical Research,* 3(2), 217-231.
- Govindan R, Bogart J, Stinchcombe T, **Wang XF**, Hodgson L, Kratzke R, Garst J, Brotherton T, Vokes EE for the Cancer and Leukemia Group B (2011). A Randomized Phase II Study of Pemetrexed, Carboplatin and Thoracic Radiation with or without Cetuximab in Patients with Locally Advanced Unresectable Nonsmall Cell Lung Cancer: Cancer and Leukemia Group B Trial 30407. Journal of Clinical Oncology 29(23), 3120-3125; PMID: 21747084; PMCID:PMC3157978 [Available on 2012/8/10]
- Wu YG, **Wang XF** (2011). Optimal Weight in Estimating the Receiver Operating Characteristic Curve Area. *Biometrical Journal* Epub 2011 August 1; PMID: 21805488
- PA J¨anne, **XF Wang**, MA Socinski, J Crawford, M Capelletti, M Edelman, MA Villalona-Calero, R Kratzke, E Vokes and VA Miller (2012). Randomized Phase II trial of erlotinib (E) alone or in combination with carboplatin/paclitaxel (CP) in never or light former smokers with advanced lung adenocarcinoma: CALGB 30406. Journal of Clinical Oncology 2012 Apr 30. Epub ahead of print; PMID: 22547605.
- **XF Wang**, JL Ma, SL George (2012). RUC Curve Estimation Under Test-Result-Dependent Sampling. Biostatistics doi: 10.1093/biostatistics/kxs020

BIOGRAPHICAL SKETCH

NAME	POSITION TITLE
Robert F. Woolson	Adjunct Professor of Biostatistics, Duke University; Professor Emeritus of Biostatistics, University of Iowa & MUSC
eRA COMMONS USER NAME (credential, e.g., agency login) woolson	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
University of Delaware, Newark	BA	1967	Mathematics (Statistics)
University of North Carolina, Chapel Hill	PhD	1972	Biostatistics (Epidemiology)

Personal Statement

I have a continuing interest in statistical methods for the design and analysis of neurological clinical trials and for epidemiologic studies. My statistical work has included the development of techniques for the analysis of longitudinal studies, including those with missing data. I have collaborated in a number of clinical research areas with longstanding interests in neurological clinical trials, especially stroke treatment clinical trials. I currently serve as consultant and adviser to the DSMB statisticians for the ALIAS and IMS-3 multi-center ischemic stroke trials. While at the University of Iowa (UI) I was Principal Investigator (PI) for the TOAST stroke trial's Statistical and Data Management Center; was PI for several NIH statistical methodology development grants; and directed an NIMH T-32 Post-doctoral and Pre-doctoral Training Program in Psychiatric Epidemiology and Biostatistics - a program I directed for twenty years. After retirement from UI, and at MUSC I collaborated with several neurological research groups including the stroke trial group (e.g. ALIAS and IMS-3) and with the Parkinson's disease methodology group, principally with Professor Peng Huang on methods for global statistic assessments in neurological trials. Other research work includes methodological research on informative censoring and joint modeling of survival and longitudinal data with two of my former doctoral students, Professors M. Mori (University of Oregon) and M. Jaffa (AUB).

Positions

1967 – 1968	Research Associate in Biostatistics, University of North Carolina, Chapel Hill, NC
1968 – 1970	Statistician/Commissioned Officer, US Public Health Service, NIMH, Bethesda, MD
1970 – 1972	Research Associate in Biostatistics, University of North Carolina, Chapel Hill, NC
1972 – 1977	Assistant Professor of Biostatistics, Dept. of Preventive Medicine & Environmental Health, University of Iowa, Iowa City, IA
1977 – 1981	Associate Professor of Statistics, Dept. of Statistics, University of Iowa, Iowa City, IA
1977 – 1981	Associate Professor of Biostatistics, Dept. of Preventive Medicine & Environmental Health, University of Iowa, Iowa City, IA
1979 – 1980	Visiting Fellow, Dept. of Biomathematics, Wolfson College, University of Oxford, England
1981 – 1985	Professor of Biostatistics, Dept. of Preventive Medicine & Environmental Health, University of Iowa, Iowa City, IA
1981 – 2002	Professor of Statistics, Dept. of Statistics, University of Iowa, Iowa City, IA
1985 – 1999	Professor and Director of Biostatistics Division, Dept. of Preventive Medicine & Environmental Health, University of Iowa, Iowa City, IA
1999 – 2002	Professor & Head, Dept. of Biostatistics, College of Public Health, University of Iowa, Iowa City, IA
2000 – 2002	Associate Dean for Research, College of Public Health, University of Iowa, Iowa City, IA
2002 – Present	Emeritus Professor, Departments of Biostatistics, Epidemiology & of Statistics, University of Iowa

2002 – 2009	Professor, Dept. of Biostatistics, Bioinformatics & Epidemiology, Medical University of South Carolina, Charleston, SC (Division of Biostatistics & Epidemiology in the Dept. of Medicine effective July 2009)
2009 – Present	Emeritus Professor, Division of Biostatistics & Epidemiology, Department of Medicine, Medical University of South Carolina
2009- Present	Adjunct Professor, Department of Biostatistics & Bioinformatics, Duke University, Durham, ,NC; Senior Statistical Consultant, Center for Health Services Research in Primary Care, Durham VA, Durham, NC

Awards & Research Service

1973	Delta Omega Society (Honorary Public Health Society)
1979	Foundations' Fund for Research in Psychiatry Scholar Award—Sabbatical Award to Oxford University
1981	Mortimer Spiegelman Gold Medal Recipient, American Public Health Association
1989	(elected) Fellow, Royal Statistical Society
1990	(elected) Fellow, American Statistical Society
1999	Regents Award for Faculty Excellence, University of Iowa
2003	Centennial Distinguished Graduate Alumnus, Graduate College, UNC at Chapel Hill
1980-2012	Multiple committee appointments including: FDA Advisory Committees, NIH Study Sections

Representative Publications (from 200 +)

1. The TOAST Study Group. Results of a randomized, placebo-controlled trial of the low molecular weight heparinoid, ORG 10172, in improving outcome after acute ischemic stroke. *JAMA* 1998; 279:1265-72.
2. Carter RE, **Woolson RF**. Statistical design considerations for pilot studies transitioning therapies from the bench to the bedside. *J Transl Med* 2004; 2(1): 37.
3. Huang P, Tilley B, **Woolson RF**, Lipsitz S. Adjusting O'Brien's test to central type I error for the generalized nonparametric Behrens-Fisher problem. *Biometrics* 2005; 61: 532-539.
4. Carter R, **Woolson RF**. Safety assessment in pilot studies when zero events are observed. *J Transl Med* 2005; 2: 37-39.
5. Wang W, **Woolson RF**, Clarke W. Estimating and testing treatment effects on two binary endpoints in clinical trials. *Communications in Statistics* 2005; 34(3): 751-769.
6. Lackland DT, **Woolson RF**. Clinical hypertension research tools: the randomized clinical trial (RCT). *J Clin Hypertens* 2006; 8(6): 427-433.
7. Huang P, **Woolson RF** and O'Brien PC. A Rank-Based Sample Size Method for Multiple Outcomes in Clinical Trials. *Statistics in Medicine* 27: 3084-3104; 2008.
8. Jaffa MA, **Woolson RF**, and Lipsitz SR. Slope estimation for bivariate longitudinal outcomes adjusting for informative right censoring using discrete survival model: application to the renal transplant cohort. *Journal of the Royal Statistical Society Series A (Statistics in Society)* **174:** 387-402*;* 2011.
9. Jaffa M A, Lipstiz SR and **Woolson RF**. Slope estimation for informatively right censored longitudinal data, modeling the number of observations using geometric and Poisson distributions. *Statistical Methods in Medical Research* (Published Online December 4, 2011; In Press 2012).
10. Powers BJ, Olsen MK, Smith VA, **Woolson RF**, Bosworth HB, Oddone EZ. Measuring blood pressure for decision-making and quality reporting: where and how many measures? *Ann Intern Med* 21;154(12):781-8, W-289-90, 2011.
11. Sherrill JT, Sommers DI, Nierenberg AA, Leon AC, Arndt S, Bandeen-Roche K, Greenhouse J, Guthrie D, Normand SL, Phillips KA, Shear MK, **Woolson R**. Interpreting statistical and clinical research elements in intervention-related grant applications: a summary from an NIMH workshop. *Acad Psychiatry* 33(3):221-8, 2009.
12. Olsen MK, Stechuchak KM, Edinger JD, Ulmer CS, **Woolson RF**. Move over LOCF: Principled methods for handling missing data in sleep disorder trials. *Sleep Med* 13(2):123-132, 2012.
13. Coffman, CJ, Allen KD, **Woolson RF**. Mixed-effects regression modeling of real-time momentary pain assessments in osteoarthritis (OA) patients. *Health Services Outcomes Research Methods* 12:200-218, 2012.
14. Carter RE and **Woolson RF**. Monitoring of clinical trials: interim monitoring, data monitoring committees and group sequential methods applied to neurology. In *Clinical Trials in Neurology: Design, Conduct Analysis,* edited by Ravina B, Cummings J, McDermott M and Poole M. Cambridge University Press, Cambridge, England , 2012.
15. **Woolson RF,** Clarke, WR. *Statistical Methods for the Analysis of Biomedical Data*, 2nd Edition John Wiley and Sons, New York, 2002; 678 pp.

BIOGRAPHICAL SKETCH

NAME: Yuan Wu	POSITION TITLE Assistant Professor of Biostatistics and Bioinformatics
eRA COMMONS USER NAME YUANWU	

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	YEAR(s)	FIELD OF STUDY
North West University, China	BS	1998	Computational Mathematics
North West University, China	MS	2001	Mathematics
University of Iowa	MS	2008	Biostatistics
University of Iowa	PhD	2010	Applied Mathematics

I am a PhD biostatistician with research interests in survival analysis, categorical data analysis, non-parametric analysis and statistical computing. March 2013 I joined Duke University as an assistant professor of biostatistics and bioinformatics and currently I am working on multiple clinical cancer studies. I received my PhD from the University of Iowa with thesis topic on bivariate survival analysis. Prior to the current position, from July 2011 to February 2013 I was a postdoctoral scientist of the Division of Biomedical Informatics at the University of California San Diego and working on multiple medical and biomedical research topics, from July 2010 to June 2011 I was a postdoctoral scholar of the Department of Epidemiology at the University of Iowa and serving as a biostatistician for multiple health care related projects.

Positions and Honors

Employment and Experience

2013.3 – present Assistant professor, Department of Biostatistics and Bioinformatics, Duke University
2011.7 – 2013.2 Postdoctoral scientist, Division of Biomedical Informatics, UCSD
2010.7 – 2011.6 Postdoctoral scholar, Department of Epidemiology, U. of Iowa

Awards and Honors

2012 Best Student Award Finalist, AMIA Annual Symposium
2009 Graduate Summer Fellowship, U. of Iowa
2007, 2008 Summer Merit Fellowship, AMCS Program, U. of Iowa
2003.8 – 2003.12 Graduate Fellowship, Idaho State University

Professional Societies

International Biometric Society Eastern North American Region (ENAR), American Statistical Association (ASA)

A. Publications (in reverse chronological order)

1. **Wu Y**, Zhang Y. Partially Monotone Tensor Spline Estimation of the Joint Distribution Function with Bibariate Current Status Data. The Annals of Statistics, 40 1609-1636, 2012.
2. **Wu Y**, Jiang X, Kim J, Ohno-Machado L. Grid binary LOgistic REgression (GLORE): Building Shared Models Without Sharing Data. Journal of the American Medical Informatics Association, 19 758-764, 2012.
3. **Wu Y**, Jiang X, Ohno-Machado L. Preserving Institutional Privacy in Distributed Binary Logistic Regression. AMIA Annual Symposium Proceedings (Accept), 2012.

4. Ramirez M, **Wu Y**, Kataoka S, Wong M, Yang J, Peek-Asa C, Stein B. Youth violence across multiple dimension: A study of violence, absenteeism and suspensions among middle school children. The Journal of Pediatrics, 161 542-546, 2012.
5. Jiang X, Kim J, **Wu Y**, Ohno-Machado L. Selecting Cases for Whom Additional Tests Can Improve Prognostication. AMIA Annual Symposium Proceedings (Best Student Award Finalist), 2012.
6. **Wu Y**, Jiang X, Kim J, Ohno-Machado L. I-spline Smoothing for Calibrating Predictive Models. AMIA Joint Summits on Translational Science Proceedings, 39-46, 2012.
7. **Wu Y**, Gao X. Sieve Estimation with Bivariate Interval Censored Data. Jounal of Statistics: Advances in Theory and Applications, 2011; 5: 37-61.

Duke University
School of Medicine

Nancy C. Andrews, M.D., Ph.D.
Dean, Duke University School of Medicine
Vice Chancellor for Academic Affairs

November 5, 2013

Elizabeth DeLong, PhD
7010 North Pavilion
DUMC Box 3850

Dear Liz,

I am writing in strong support of your proposal for a new PhD program in Biostatistics. I am, in particular, writing in response to one of the questions raised by the Academic Programs Committee (APC) last week.

Understanding that faculty members in your department (and throughout the School of Medicine) generally do not have a large portion of their salary fixed as compensation for teaching, they asked whether funding would be available to support the faculty time devoted teaching, mentoring and student supervision needed for a successful PhD program. I assured the APC that the School of Medicine has provided you access to ample funds for this purpose – in fact, far more than I can imagine you would need to cover faculty effort associated with the PhD program, even if the program grew substantially over time. You and I have discussed this recently, and it was documented in the confidential letter I sent last week to ask you to serve an additional five year term as Chair of Biostatistics and Bioinformatics.

In addition to this source of support, we anticipate that revenues from your successful professional Master's degree program will also be used to support the PhD program.

I hope that this letter provides the APC, the Provost, and the Executive Committee of the Academic Council with the information requested.

Sincerely,

Nancy C. Andrews, MD, PhD
Dean, Duke University School of Medicine
Vice Chancellor for Academic Affairs

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Duke University
School of Medicine

Nancy C. Andrews, M.D., Ph.D.
Dean, Duke University School of Medicine
Vice Chancellor for Academic Affairs

26 April, 2013

Paula McClain, Ph.D., Dean
John Klingensmith, Ph.D., Associate Dean for Academic Affairs,
The Graduate School
Duke University

Dear Paula and John,

I am writing to provide my continued strong endorsement for Liz DeLong's proposed PhD program in Biostatistics and to assure you that I am comfortable with the revised document.

I am happy to report that the proposal for this new program has been endorsed by both our Basic Sciences and Clinical Sciences Faculty Standing Committees. It was presented to the Medical Center Executive Committee earlier this year, and unanimously supported by the voting members.

I would like to point out that Biostatistics and Bioinformatics has an outstanding faculty, well prepared for educating PhD student. In contrast to departments in other schools of the university, there is little correlation between tenured/tenure track appointments and scholarship in Biostatistics and Bioinformatics. The department is relatively young, and has very few tenure slots available. Nonetheless, it has recruited an extremely capable faculty, using long-term contracts and other mechanisms in lieu of tenured/tenure track appointments. Medical schools across the country (particularly those schools we compare ourselves to) tend to put much less emphasis on traditional tenure than other disciplines. I feel strongly that this cultural difference should not be an impediment to the formation of this important Ph.D. program.

I am very hopeful that we will be in a position to matriculate our first class in the fall of 2014. Please let me know if there is anything I can do to help this go swiftly through the remaining approval processes.

Sincerely,

Nancy C. Andrews, M.D., Ph.D.
Dean of the School of Medicine
Vice Chancellor for Academic Affairs

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APPENDIX J

Excerpt from Master of Biostatistics Program Assessment Plan (SACS format)

Table 1: Program Objectives and Student Learning Outcomes

1. Objective: To develop students who acquire the analytical, biological, and communication competencies required to perform the following core functions by the time they graduate:
   Outcomes:
   A. Graduates will integrate knowledge of the scientific issues well enough to communicate with the scientific investigators, and to propose protocol changes if needed.
   B. Graduates will be able to perform standard analyses, including descriptive analyses, linear regression, analysis of variance, analysis of covariance, logistic regression, and straightforward survival analysis.
   C. Graduates will be able to identify non-standard situations requiring additional input from senior statisticians and investigators.
   D. Graduates will be able to perform/oversee data management.

2. Objective: To prepare students who desire to enter the labor force, success in finding high-quality jobs in the field.
   A. Students so identified will be invited to continue internship positions after their first semester of employment as a student.
   B. Students so identified will receive letters of recommendation for employment from internship sites.
   C. Fifty percent of students so identified will receive offers of employment from internship sites.

3. Objective: To prepare students who desire to pursue doctoral level training for admission to high-quality graduate programs.
   Outcomes:
   A. Students so identified will complete the qualifying examination without condition or re-examination at the end of year one.
   B. Students so identified will earn a grade of H in at least 75% of their coursework.
   C. Students so identified will be admitted to a PhD program within one year of completing the Master's degree program.

Table 2: Student Outcomes Assessment Plan

Objective 1: To develop students who acquire the analytical, biological, and communication competencies required to perform core functions by the time they graduate.

Outcome	Evidence of Outcome	Frequency of Collection	Semesters Report Due
Graduates will integrate knowledge of the scientific issues well enough to communicate with the scientific investigators, and to propose protocol changes if needed.	Masters Project and Defense	Annually	Spring
Graduates will be able to perform standard analyses, including descriptive analyses, linear regression, analysis of variance, analysis of covariance, logistic regression, and straightforward survival analysis.	Performance in courses and qualifying examination results	Annually	Fall semester
Graduates will be able to identify non-standard situations requiring additional input from senior statisticians and investigators.	Employer reports	1 year out from graduation for each cohort	Spring
Graduates will be able to perform/oversee data management.	Employer reports	1 year out from graduation for each cohort	Spring

Objective 2: To prepare students who desire to enter the labor force, success in finding high-quality jobs in the field.

Outcome	Evidence of Outcome	Frequency of Collection	Semesters Report Due
Students so identified will be invited to continue internship positions after their first semester of employment as a student.	Internship site reports and evaluation forms.	Annually	Fall
Students so identified will receive letters of recommendation for employment from internship sites.	Copies of letters in student dossiers.	Annually	Spring
Fifty percent of students so identified will receive offers of employment from internship sites.	Internship site reports and evaluation forms.	Annually	Summer

Objective 3: To prepare students who desire to pursue doctoral level training for admission to high-quality graduate programs.

Outcome	Evidence of Outcome	Frequency of Collection	Semesters Report Due
Students so identified will complete the qualifying examination without condition or re-examination at the end of year one.	Qualifying examination report	Annually	Fall
Students so identified will earn a grade of H in at least 75% of their coursework.	Student academic record and dossiers.	Annually	Fall
Students so identified will be admitted to a PhD program within one year of completing the Master's degree program.	Correspondence from admitting program.	Annually	Fall

Table 3: Partial Analytical Report - AY2013

(At this time, we are six months in advance of the graduation of our first cohort. Hence the analytical report is based primarily on the end-of-semester debriefings attended by faculty members and program staff.)

Selected Outcomes	Evidence collected	Finding and evaluation	Resultant action
Ability to perform standard analyses, including descriptive analyses, linear regression, analysis of variance, analysis of covariance, logistic regression, and straightforward survival analysis.	Performance in courses and internship reports.	Faculty reports of performance during the internship experience have been positive to date. The only source of concern was from one of the internships in the private sector, noting that our training in computer programming could be upgraded.	1. First year computer programming course has been restructured. 2. Students interested in obtaining SAS certification may apply for funding from department for training fee. 3. The restructured programming course will be revisited at the end of the academic year for consideration of expansion to 2 credits and/or implementation of competency test.
Complete the qualifying examination without condition or re-examination at the end of year one.	Qualifying exam reports.	All of our full-time students passed the qualifying exam in August, 2012.	

APPENDIX K — Grants on which B&B Faculty are Principal Investigators

Name	Project Role	Sponsor	Prime Sponsor	Annual Directs	Project Start	Project End	PI Name	Proposal Title
Anstrom, Kevin J.	PI	NIH	NIH	375,223	6/8/12	4/30/17	Anstrom, Kevin J.	GUIDing Evidence Based Therapy Using Biomarker Intensified Treatment (DCC)
Anstrom, Kevin J.	PI	NIH	NIH	3,826,431	1/1/12	12/31/18	Anstrom, Kevin J.	Heart Failure Clinical Research Network Coordinating Center
Anstrom, Kevin J.	PI	NIH	NIH	4,660,745	5/1/05	4/30/14	Anstrom, Kevin J.	Idiopathic Pulmonary Fibrosis Clinical Research Network
Anstrom, Kevin J.	PI	UCSF	NIH	189,587	8/1/13	5/31/16	Anstrom, Kevin J.	IPF Wrap
Barnhart, Huiman x.	PI	NIH	NIH	907,495	9/3/13	6/30/18	Barnhart, Huiman x.	Coordinating Center for the Drug Induced Liver Injury Network (DILIN)
Chan, Cliburn C.	Core Director	NIH	NIH	100,221	7/15/10	6/30/15	Chan, Cliburn C.	Biostatistics and Computational Biology Core
Chan, Cliburn C.	PI	Leiden University	Wallace Coulter	167,349	4/1/12	3/31/15	Chan, Cliburn C.	Standardization of Immune Monitoring - phase II
Delong, Elizabeth	Consortium PI	Tufts University	PCORI	133,667	6/1/13	5/31/16	Delong, Elizabeth	Integrating Causal Inference, Evidence Synthesis, and Research Prioritization Methods
Erkanli, Alaattin	PI	NIH	NIH	714,549	4/1/11	3/31/16	Ramanujam, Nirmala	A Novel Optical Spectral Imaging System for Rapid Imaging of Breast Tumor Margins
George, Stephen L.	PI	UNC-CH	NIH	-	4/1/10	3/31/15	Stephen George	Statistical Methods for Cancer Clinical Trials
Gordan, Raluca M.	PI	PhRMA Foundation	PhRMA Foundat	60,000	1/1/13	12/31/13	Gordan, Raluca M.	Understanding the complex interplay among members of a transcription factor family
Gordan, Raluca M.	PI	March of Dimes	March of Dimes	136,364	2/1/13	1/31/15	Gordan, Raluca M.	Using high-throughput protein binding microarray data to identify DNA sequence polymorphisms
Halabi, Susan	PI	NIH	NIH	148,920	7/6/11	5/31/15	Halabi, Susan	Prognostic Models of Clinical Outcomes In Men With Castration Resistant Prostate Cancer
Halabi, Susan	PI	Cedars Sinai Medical Center	NIH	26,367	9/12/12	6/30/14	Halabi, Susan	Expression Profiling of Renal Cell Carcinoma Utilizing Tissue from CALGB 90206
Halabi, Susan	PI	Mayo Clinic	Mayo Clinic	10,000	6/1/13	5/31/14	Halabi, Susan	Statistical Analysis of Overall Survival in Complex Situations of Phase II Clinical Trials
Hasselblad, Victor	PI	NIH	NIH	347,341	6/25/08	3/31/15	Hasselblad, Victor	BRIDGE DCC
Jung, Sin-Ho	PI	Roswell Park Cancer Institute	NIH	23,147	2/1/12	1/31/14	Jung, Sin-Ho	Diet Change Among Prostate Cancer Patients Under Expectant Management
Jung, Sin-Ho	PI	UNC-CH	NIH	18,901	4/1/10	3/31/15	Stephen George	Methods for Missing and Auxiliary Data in Cancer Clinical Trials
Jung, Sin-Ho	PI	UNC-CH	NIH	39,406	4/1/10	3/31/15	Stephen George	Methods for Pharmacogenomics and Individualized Therapy Trials
Lee, Kerry L.	PI	NIH	NIH	1,087,692	2/1/09	1/31/15	Lee, Kerry L.	CABANA-AF Trial
Lee, Kerry L.	PI	Eli Lilly and Company	Eli Lilly and Com	324,132	12/1/08	4/30/14	Lee, Kerry L.	Lilly Stats Project
Lee, Kerry L.	PI	NIH	NIH	560,496	9/29/09	11/30/14	Lee, Kerry L.	PROMISE Trial: SDCC
Lee, Kerry L.	PI	Mount Sinai School of Medicine	NIH	172,178	3/1/13	2/28/14	Lee, Kerry L.	TACT-Trial to Assess Chelation Therapy Data Coordinating Center NCE
Li, Zhiguo	PI	NIH	NIH	169,670	9/30/09	6/30/14	Li, Zhiguo	Biostatistical Core
Li, Zhiguo	PI	UNC-CH	NIH	9,845	4/1/10	3/31/15	Stephen George	Methods for Discovery and Analysis of Dynamic Treatment Regimes
Martin, Barbara E.	PI	NIH	NIH	158,599	9/6/11	6/30/15	Martin, Barbara E.	Statistical Models to Investigate Long-Distance QTL Transcription Regulation
Niedzwiecki, Donna	PI	Dana-Farber Cancer Institute	NIH	18,296	7/1/10	5/31/14	Niedzwiecki, Donna	The Influence of Diet and Lifestyle on Patients with Advanced Colorectal Cancer
O'Brien, Sean M.	PI	STS	STS	40,118	8/1/12	12/31/13	O'Brien, Sean M.	Linking the Congenital Heart Surgery Database of the STS with the CHSS Database
O'Brien, Sean M.	Consortium PI	North Carolina State University	NIH	97,648	6/1/13	5/31/14	O'Brien, Sean M.	Statistical Methods for Complex Data in Cardiovascular Disease
O'Brien, Sean M.	PD/PI	NIH	NIH	2,677,897	7/22/11	10/31/18	Harrington, Robert A.	The ISCHEMIA Trial - SDCC
Owzar, Kouros	PI	NIH	NIH	70,066	8/1/10	7/31/15	Owzar, Kouros	Bioinformatics
Owzar, Kouros	PI	UNC-CH	NIH	16,259	4/1/10	5/31/15	Stephen George	Computational Resources and Dissemination Core
Owzar, Kouros	PI	Roswell Park Cancer Institute	NIH	25,732	1/1/13	12/31/13	Owzar, Kouros	Genome-Wide Predictors of Treatment-related Toxicities
Owzar, Kouros	PI	University of Chicago	NIH	52,771	7/16/10	6/30/15	Owzar, Kouros	PAAR Pharmacogenomics of Anticancer Agents Research Group
Pang, Herbert H.	PD/PI	NIH	NIH	131,937	8/1/13	5/31/15	Wang, Xiaofei F.	Translational meta-analysis for elderly lung cancer patients
Pieper, Carl F.	Core Leader	NIH	NIH	-	9/15/06	6/30/16	Pieper, Carl F.	RC1
Reddy, Timothy E.	PI	Northwestern University	NIH	151,785	7/1/13	5/31/14	Reddy, Timothy E.	Genetics and Evolution of Fetal Human Fat Accretion During Development
Roy Choudhury, Kingsh	Co-PI	North Carolina Biotechnology Center		300,000	2/1/13	1/31/15	Palmer, Gregory M.	Imaging, Modeling and Modulating Stromal Cell Roles in Tumor Growth and Therapy
Wang, Xiaofei F.	PD/PI	NIH	NIH	131,937	8/1/13	5/31/15	Wang, Xiaofei F.	Translational meta-analysis for elderly lung cancer patients