The major goal of the Department of Biostatistics, achieved through education, research and professional practice, is to enhance and promote effective statistical reasoning and its application in health research and ultimately, to advance the public's health. This document summarizes the major initiatives in research, education and professional practice that the Department proposes to pursue in the next few years. The initiatives in research and education were developed at a two-day retreat on September 21-22, 2001 attended by faculty, students and staff. The departmental proposals are an outgrowth of, and therefore consistent with, the School-wide strategic plan that was completed last year.

**Research:** The School’s strategic plan accentuates two areas of particular importance to Biostatistics: genomics and informatics. Within that context, the department has identified the following four areas for growth in our research program:

* Genetics: The faculty proposes to continue to build research strength in statistical methods for genetics, including genetic epidemiology, statistical genetics and bioinformatics. We propose the formation of the **Hopkins Genome Biometry Laboratory (GBL)** to develop and apply advanced methods in bioinformatics/biostatistics that support molecular biology/genetics research at our medical institutions and beyond. The GBL will provide physical space integrated within the department and the requisite computational resources for faculty and students to pursue computational and statistical issues in the design and analysis of data from genomic studies. The department has a strong group of young faculty interested in this area and plans to recruit new faculty members with expertise in computational statistics and/or bioinformatics. The group will closely collaborate with the departments of Biochemistry and Molecular Biology and Molecular Microbiology and Immunology and School of Medicine colleagues in Oncology and the Institute for Human Genetics. It will have joint responsibility for building the bioinformatics team for the Malaria Initiative. A key opportunity will be fostering closer collaborations with colleagues at the Institute for Genomic Research (TIGR).

The department will also continue to build its strength in statistical genetics, collaborating closely with colleagues in Epidemiology and at the NIH Center for Inherited Disease Research (CIDR). Hopkins will be a leader in statistical methods for genetics with a broad spectrum of applications from molecular to population genetics.

* Health Surveillance: The department plans to expand and coordinate the development and application of a set of related statistical methods for: tracking epidemics; environmental health studies; and longitudinal studies. We will refer to these, collectively, as problems of "health surveillance." In simplest terms, the novel designs and analyses we develop here will enable more effective monitoring of the health of a population. A key issue common to these problems is how best to integrate and interpret complex information possibly derived from multiple sources.

The department faculty will focus on statistical issues that arise in diverse settings, including the surveillance of:

- **epidemics** (HIV; Alzheimers disease; bioterrorist outbreaks of anthrax or smallpox);
environmental risk factors (smoking, air pollution and weather) and the resulting morbidity, mortality and medical expenditures;
- chronic diseases such as cardiovascular disease, cancer and mental disorders (schizophrenia and depression);
- natural processes such as aging;
- medical services and their consequences.

The diversity of the aforementioned problems demonstrates the potential for an innovation to have a major impact.

We propose to move novel methods directly to creative web platforms so that they can be widely used by the public health community. Doing so will create new models for surveillance.

* Clinical and Community Trials: The department will continue to specialize in the design and analysis of clinical and community studies -- in particular, randomized trials. Working with the Johns Hopkins Center for Clinical Trials (JHCCI), our faculty proposes to develop better designs and better methods for the successful conduct of studies and analysis of data from randomized trials. Modern clinical trials are producing increasingly complex markers of disease status including images and gene expression arrays. Investigators seek to go beyond traditional intent-to-treat methods to estimate the biological efficacy of therapies, account for non-compliance, and deal more successfully with study drop-outs. As genetic typing advances, clinical scientists will seek to identify subgroups for which particular treatments are most effective. Ultimately, we will attempt to predict the efficacy of a new treatment for each individual using genetic and other biomarkers.

In community trials, similar questions pertain. In addition, distinguishing the contributions of personal, family, neighborhood, and regional influences on health using multi-level designs and analyses is of interest.

* Foundations of Research Methodology: The design and analysis of data from empirical studies to draw valid scientific inferences is the central methodology of public health and biomedical research. The department plans to further strengthen our research on the foundations of scientific inferences focusing on novel approaches to the design and analysis of observational studies, the cornerstone of epidemiologic research. We will build on the department’s tradition established by William Cochran and Jerome Cornfield and led in recent years by Richard Royall. Key research areas are likelihood inference, Bayesian biostatistics, and causal inference from observational data. Recent additions to the faculty bring strength for future research on foundations.

Each of the four initiatives introduced above critically depends on a state-of-the-art statistical computing environment including hardware, software, and personnel. We plan to recruit additional faculty and staff with interests in databases and web-based technologies including one person to take responsibility for leading the department's educational program in database management and statistical computing, replacing Bill Rising.

Our faculty is also interested in becoming increasingly involved in behavioral science studies and in the translation of our work for public policy. We recognize opportunities for doing so in each of the four specific initiatives above. To strengthen ourselves and the school in this essential component of public health, the department is considering a special opportunity.
recruitment of a full professor who is an international leader and has research focus in scientific policy issues.

**Education:** The department will continue to focus on its educational mission, including: doctoral education in biostatistics; instruction in statistical reasoning and methods to students in other departments; and an expanded set of short courses for public health and biomedical scientists and professionals, both onsite and via distance education. The excellence of our PhD and other degree programs must be maintained.

* PhD Program: We propose to expand the enrollment of funded PhD students from the current level of 25-30 to 35-40. This will require additional training grants and expanded numbers of applicants who are eligible for NIH grant support as well as private support for foreign students. We will continue to strengthen learning opportunities for students, including more student-led seminar courses and enhanced opportunities for students to gain professional statistical experience, such as consulting apprenticeships in the Biostatistics Center.

* MHS in Bioinformatics: We propose to develop a new MHS program in bioinformatics in partnership with the departments of MMI and BCMB. This new program will be attractive to students earning a PhD in one of these departments and to MD researchers in the School of Medicine. The program will complement current offerings in statistical genetics and genetic epidemiology.

The faculty has re-affirmed that its greatest collective impact on public health is likely achieved through statistical instruction of public health students in our introductory courses. Several of the initiatives below are directed at the goal of further strengthening the quality of student learning in these courses.

* Coordination of Introductory Courses: The Department of Epidemiology is currently reconsidering its offering of first-year courses. We propose to take advantage of this unique opportunity between departments to better coordinate the content and sequencing of course materials in the introductory courses in biostatistics and epidemiology.

* Education Methods Research: We propose to further develop our research on how to most effectively teach introductory biostatistics concepts and methods to public health and biomedical scientists and professionals. Each student has an individualized way of learning statistics. We seek to provide multiple learning opportunities that optimize each student’s experience. The current randomized trial comparing three different learning techniques in Biostatistics 621-622 is our first step in this direction. We will also be able to compare student performance in onsite versus distance education with the current offering of Biostatistics 611-12 this year.

* Modularize Course Materials: We propose to consider the departmental adoption of a common technology for creating and offering courses and, in particular, to modularize our course materials so that we can more flexibly create new courses or modify existing courses. Such a system (possibly web-based) would allow us to more easily create specialized short courses for health professionals and scientists, both in our School institutes and beyond.

* Courses for Special Groups: Recognizing that there are several student groups with specific needs, we propose to develop several new courses. These include an introductory
methods course sequence for students focusing on the laboratory sciences; an introductory course for undergraduate public health majors; and short courses in the School institutes.

**Professional Practice:** The faculty and students recognize the importance of the practice of biostatistics and the ever-growing demand for biostatistical support of biomedical and public health research at Johns Hopkins. Faculty members are engaged in many professional activities, including editing journals, serving on academic, government and industry expert panels, consulting, and lecturing at professional societies. Another key outlet for our professional practice is scholarly, longer-term collaborations with scientists at Hopkins and beyond. Collectively, faculty members spend roughly 50% of their time in such collaborations. In addition, three years ago the Department established the Hopkins Biostatistics Center, which provides shorter-term consultation to internal clients and others from government and industry.

Over the last two years, the center has spent a substantial fraction of its energy on the U.S. Justice Department's suit against the tobacco industry. As this work comes to an end, the department has an opportunity to plan future directions for this professional service component. Over the next year, we propose to re-examine the center’s role in the University and School, addressing the following questions:

- How should the center be staffed to provide the best possible professional service to its clients?
- Should the center focus on internal or external clients?
- How can the center best support the professional development of students and junior faculty?

**Recruitments:** Figure 1 shows the projected growth of the Department of Biostatistics faculty, staff and students. We propose to add five new tenure-track faculty over the next 5 years growing to about 20. The new faculty will likely include one full professor and 4 assistant professors. While our searches will not be restricted to narrowly-defined research areas, we hope to add strength in each of the major topics discussed above. It is likely one of the persons will focus on malaria bioinformatics as part of the Genome Biometry Laboratory.

We also propose to add 4 non-tenure track faculty who will work on specific research projects and in the Biostatistics Center. The addition of 4 staff will be largely in the Center. Finally, we must grow the numbers of PhD students from 30 to 40 to meet the growing demands for research assistants on School research projects and for teaching assistants in the increasing number of introductory courses.

**Space:** Figure 2 shows the projections for numbers of offices necessary for the department over the next 5 years. In addition to offices, the department will require the following special rooms: library, computing center/terminal room, conference room, Biostatistics Center consulting room, and Genomics Biometry Laboratory. Only the last is an addition to our current space.
Figure 1. Projected Growth in Faculty, Staff and Students for the Biostatistics Department and Center

Figure 2. Projected Space Requirements for the Biostatistics Department and Center