

Baylor Research Institute: 2003 update

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The research being conducted through Baylor Research Institute (BRI) is one of Dallas' best-kept secrets. Few people know that physicians and scientists in Baylor Health Care System have almost 500 active protocols. The focus is to move advances from the bench to the bedside, with programs in basic science, mechanisms of disease, clinical effectiveness, clinical efficacy, and health care quality improvement. The 2 basic science programs are in immunology—which relates to the clinical areas of cancer, infectious diseases, allergy, transplantation, and autoimmune diseases—and metabolic disease, which relates to the diagnosis and treatment of inherited errors of metabolism. Other major clinical research con-

centrations include asthma, gastroenterology, diabetes, cardiovascular disease, orthopaedics, and dermatology.

BRI exists to improve the medical care and well-being of our community—nationally and internationally—through innovative, clinically relevant research that is consistent with the mission, vision, and values of Baylor Health Care System. The institute provides administrative support to investigators in areas such as education, finances, and quality assurance and ensures compliance with federal and state regulations. It has divisions devoted to research quality and safety, sponsored research, research subject protection, clinical trials, financial management, and the BioScience Center (Figure 1). In this article, I review BRI's activities in 2002 and outline goals for 2003.

ACCOMPLISHMENTS IN 2002

In fiscal year 2002, Baylor embarked on 148 new studies, supported by \$8 million in new research awards, including 76 new industry research contracts totaling \$5.5 million. A \$5 million grant was obtained from the Caruth Foundation via the Communities Foundation for a chair in transplant immunology. This donation was matched by another \$5 million from the Baylor Health Care System Foundation. Paul Grayburn, MD, was re-

cruited to the Paul J. Thomas Endowed Chair in Cardiology. Dr. Hal Urschel was appointed to the newly endowed chair in cardiothoracic surgical research.

Several strategic initiatives were completed during the year. First, a certified institutional review board (IRB) professional, Elizabeth Cothran, was recruited to lead the Office of Research Subject Protection. The reporting lines changed: the IRB became a committee of the BRI board of trustees to better serve the entire Baylor Health Care System. A database system was developed in Access to more efficiently track IRB actions and to provide more complete reports for investigators, medical staff, and administrators. Further, in 2002, BRI registered as an early adopter for accreditation by the Partnership for Human Research Protection and also began an application for accreditation by the Association for Accreditation of Human Research Protection Programs. Accreditation is expected this year. Through the Office of Research Subject Protection, BRI began a credentialing initiative, making an online program available in October 2002.

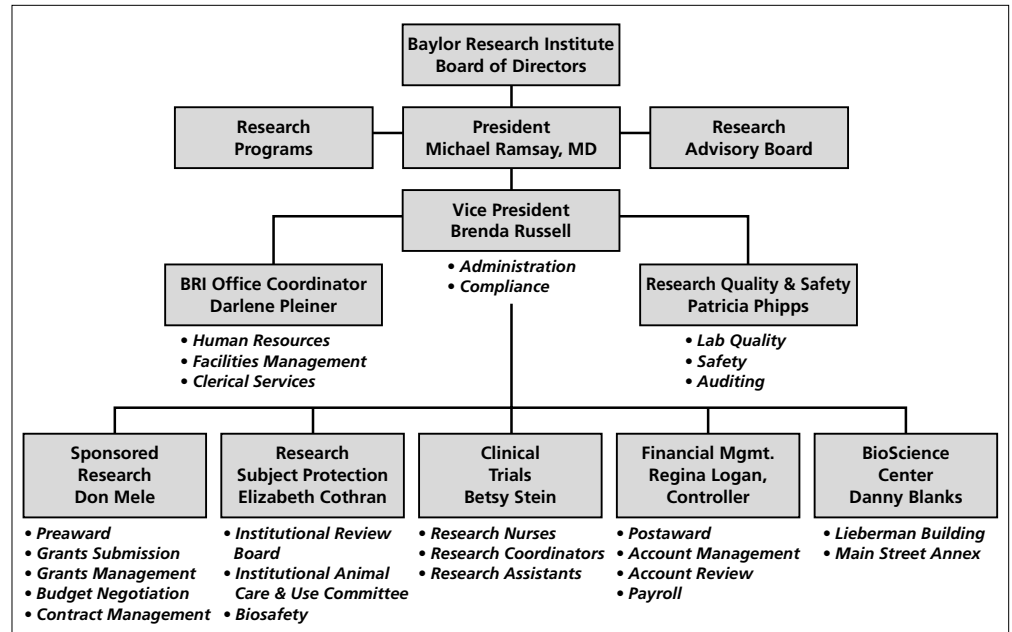


Figure 1. Current organizational structure of Baylor Research Institute.

From Baylor Research Institute, Dallas, Texas.

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Figure 2. Cover of informational booklet for prospective subjects.

To date, 231 investigators, 22 coordinators, and 23 IRB and staff members have become credentialed.

Second, BRI opened a Clinical Trials Office, which coordinated 20 trials in 10 specialties and contracted for over \$1 million in revenue during its first year. This office makes available a number of resources for investigators: education and training; operating procedures for trials; biostatistical assistance; preparation of documents for the IRB; budget development; screening, registration, and coordination of study patients; completion of case report forms; and liaison with study sponsors. The office also introduced the Study Manager electronic management system, which includes a contact database and screens for scheduling, visit tracking, budget tracking, document tracking, and patient recruitment and screening. The program is being used at 24 sites in Baylor Health Care System, from the Clinical Cardiology Research Center and the Institute of Metabolic Disease to the Hereditary Cancer Risk Program and the Howard Center at Baylor Medical Center at Irving. Finally, the office produced and distributed an informational booklet for those considering participating in clinical trials (*Figure 2*).

Third, BRI opened a Research Quality and Safety Division. This division has 3 aims. It maintains the quality assurance program, which focuses on process improvement, document and process control, and compliance. It audits clinical trials and surveys research subjects to ensure research subject protection. It also ensures laboratory quality by reviewing quality control efforts, reviewing standard operating procedures, auditing, and providing training in good manufacturing processes. Research billing compliance is one example of BRI compliance efforts. A team defined the billing process, provided research coordinators

Table. Research goals for 2003

- Install the chair in gastrointestinal diseases, C. Richard Boland, MD
- Open a pancreatic islet cell transplant laboratory
- Enhance chair endowments in cardiovascular surgery and cardiology
- Appoint a chair in transplant immunology
- Drive the centennial research fund initiative
- Strongly support Baylor Health Care System Foundation initiatives for philanthropy in research.
- Publicize research at Baylor
- Develop a start-up biotech company
- Encourage National Institutes of Health and other grant support
- Attract industry support
- Enhance the integrity of research through quality assurance, safety, and education
- Elevate the research subject protection program through credentialing and institutional review board accreditation
- Continue to develop and expand clinical trials
- Work on potential joint initiatives with the University of Texas at Dallas, Baylor College of Dentistry–Texas A&M University System Health Science Center, and M. D. Anderson Cancer Center

with formal procedures and forms, and offered training in billing compliance beginning in June 2002.

Fourth, in 2002, the Caruth Surgical Laboratories were renamed the BioScience Center to reflect the technology and diverse range of services. The center is located in the Zelig H. Lieberman Research Building.

A final area of accomplishment in 2002 was a focus on collaboration with diverse institutions. Baylor began to work with Southern Methodist University to jointly recruit a specialist in biostatistics and bioinformatics. BRI has multiple joint research projects with the University of Southwestern Medical Center and Rockefeller University in New York. In addition, Baylor University Medical Center collaborates with Baylor University in Waco to offer a doctorate program.

PLANS FOR 2003

Plans for 2003 are outlined in the *Table*. One of the most exciting is the possibility of starting a biotech company to manage BRI's business ventures and intellectual property. A consultant has been approached to consider the cost of commercialization, the revenue stream, and the business plan. The time seems ripe for a biotech company in the Dallas area.

BUMC Proceedings will focus on specific areas of research in future issues, highlighting some work in progress. It is clear that successful research at Baylor supports the entire health care system. It attracts top physicians and staff, increases patient referrals, provides financial support, and offers the ability to provide patients leading-edge medicine.