



FROM THE GUEST EDITOR'S DESK

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As an academic medical center, Ochsner Clinic Foundation has a strong commitment to patient care, research, and education. In the past, the Ochsner Journal has featured articles that demonstrate the diverse clinical, educational, and research interest that have evolved at this institution. Prior to August 29, 2005, this issue of the Ochsner Journal was planned to highlight the inter-relationships between clinical research, clinical practice, and graduate medical education. At that time, the issues seemed straightforward, the opportunities clear and the challenges predictable. And then hurricane Katrina and its aftermath decimated areas of New Orleans and its surrounding parishes. Within 48 hours, the world as we knew it had dramatically changed. Ochsner Clinic Foundation was fortunate not only in its location, but also in its excellent leadership. In stabilizing the critical components of the medical enterprise (i.e., patient care, medical education, and research), rapid decision-making and concerted efforts were required in the aftermath of the hurricane. A command post, if you will, was established at the Ochsner Clinic in Baton Rouge. In less than a week after the hurricane, Dr. Pinsky and I had established communication with the majority of our investigators and developed a system for all Ochsner patients to communicate with Ochsner. A 1-800 number was established, and a telephone triage system directed patients to research personnel who could assist with their questions and concerns regarding their research study. For patients unable to access Ochsner via the telephone, a website was available with key information along with an email address (research@ochsner.org). We established a database to capture patients' contact information as well as their concerns and any adverse events. Access to the resources developed prior to the hurricane and coordinated through the Clinical/Outcomes Research Department, Research Administration, and the IRB contributed to our success: OMIS registration of clinical trial patients, investigator and coordinator Groupwise database for email communication, research education database, and the IRB database linking investigators to current research protocols. In addition, access to the electronic medical record spearheaded by Dr. Lynn Witherspoon provided critical information regarding patient clinical status and contact information. Dr. Joseph Breault, Chairman of the IRB, worked with Dr. Pinsky to communicate in a timely and effective manner with the regulatory organizations (e.g., FDA, OHRP) and sponsors regarding the status of the clinical research

activities at Ochsner and the attention being given to protections of human subjects. Investigators and staff with large research programs in departments such as Oncology, Cardiology, and Transplant mobilized quickly and were positioned to respond to patients' needs. Through these and other efforts, Ochsner was able to facilitate patients' continuation in their studies and communication with their investigators as needed. Ochsner received positive responses from federal officials regarding its response to the disaster.

It became clear that for many patients, their clinical care was defined by clinical research. It was a rewarding experience to be part of the immediate response team for the clinical research areas. The inter-dependence between patient care, medical education, and clinical research was never as apparent as in the aftermath of the hurricane when coordination among administrators, clinicians, research personnel, and trainees was so critical. Opportunities for improving Ochsner's response to disasters were identified including, but not limited to, registering patients' email addresses in addition to telephone numbers in electronic systems; moving information systems out of state; enhancing sponsor and federal agency databases to facilitate communication; preparing investigators and CRCs to have ready access to relevant study and study patient information in the event of disaster; and securing key information on portable databases.

This issue of the Ochsner Journal will highlight current issues, opportunities, and challenges in clinical research while taking into account the impact of catastrophic events. The issue is divided into four sections: 1) overview of the role of academics in healthcare, 2) administrative and regulatory issues, 3) examples of clinical research programs at Ochsner, and 4) reflections on hurricane Katrina.

In the first section, Drs. Re, Frohlich, and Wilson provide an overview of academics with the focus on research in health centers. Dr. Richard Re, Scientific Director, describes the many challenges and opportunities in medical research which influence medical practices while using Ochsner as a point of reference. Dr. Edward Frohlich, Alton Ochsner Distinguished Scientist, explores current challenges in clinical investigation from an investigator's viewpoint. In his article, Dr. Frohlich describes how advances in science have

changed the face of medicine, how errors in research conduct have led to changes in practice that enhance ethical research methods, and how important the mentor-mentee relationship is in the development and growth of an investigator. The last article in the first section is by Dr. Michael Wilson, former Chairman of the Graduate Medical Education Committee. He describes the three-legged stool of academic medicine's teaching, patient care, and research, and the related challenges of balancing the stool in graduate medical education training programs.

The second section of this issue describes and summarizes the regulatory requirements and the need for oversight and education to ensure appropriate protection of human subjects and adherence to federal and state rules. Dr. Joseph Breault provides a thorough overview of the role of the IRB, infamous research that drove development of a regulatory infrastructure designed to protect human research subjects, current controversies, and future directions in human subject protections. Ms. Wendy Portier and Dr. Claire Dunne, Compliance Officers, describe the value of a research compliance program designed to assist institutions and investigators work through the "regulatory maze." In their paper, they highlight challenges and opportunities in clinical research compliance and key issues targeted by federal and state regulators. Hot topics in compliance include informed consent, protocol deviations, drug and device accountability, inadequate medical records, need for IRB approval, clinical trial billing, HIPAA regulations, and conflict of interest. They reflect that the root causes of non-compliance rest in poor record keeping and inadequate training. In the last article in this section, I describe Ochsner's approach to clinical research education in the new era. The program is designed to overcome many barriers to education and to provide core training to all research personnel to facilitate proper conduct of research and adherence to regulatory requirements.

In the third section, Drs. Kardinal and Lavie are the primary authors in articles highlighting two vibrant research programs at Ochsner. Dr. Kardinal and Marilyn Bateman describe the establishment and accomplishment of the Ochsner Community Clinical Oncology Program (CCOP) sponsored by the National Cancer Institute (NCI) and housed in the Ochsner Cancer Institute (OCI). Ochsner received one of the first CCOP awards in 1983 and has been continuously funded since. Over the years, this program has placed over 3,000 patients in NCI cancer treatment trials and over 1,200 patients in cancer control protocols. This program has also provided an avenue for scholarly activity for the investigators in the OCI in the form of publications and presentations. The opportunities for training future physicians with an appreciation for clinical research are also made possible by Ochsner's participation in CCOP. Dr. Lavie and colleagues review some of the preventive cardiology and non-invasive research performed at the Ochsner Heart and Vascular Institute in New Orleans: Cardiac Rehabilitation and Exercise Training (CRET) programs, heart failure and cardiopulmonary laboratory, and Cardiovascular Information Systems (CVIS) which looks at clinical and laboratory data to predict prognosis for cardiovascular disease.

The last section includes several authors' reflections on hurricane Katrina. Ochsner's leadership, investigators, and staff responded

quickly to a rapidly changing and challenging environment. Through these tireless efforts, all components of Ochsner's academic enterprise remained intact. Many opportunities have been identified for enhancing the integrity of our programs and for responding to catastrophic events.

As in the past, we feature publications by Ochsner investigators. In addition, this issue highlights R01 grants in excess of 3.3 million dollars in direct costs awarded to Ochsner researchers by the National Institutes of Health in 2005. I hope you find this a motivating issue published at an interesting time at Ochsner. We welcome your participation in future issues of the Journal.