CFRI serves as research enterprise lynchpin

Le Bonheur Children's Hospital is host to numerous research activities being conducted under the auspices of the Children's Foundation Research Institute (CFRI). The CFRI functions as the “glue” that holds the research enterprise together and moves it forward in a coordinated and efficient manner. At its helm are Scientific Director Dennis Black, MD, and Administrative Director Sheon Lynch. The CFRI provides investigators with expertise, services, equipment and resources to conduct research.

Research Matters is a new, quarterly newsletter designed to feature some of the interests and accomplishments of our researchers and the ongoing projects at the CFRI.

Research Topics

Congratulations to CFRI junior faculty members who have recently been awarded Le Bonheur grants. These funds will augment resources available to perform state-of-the-art studies in a variety of exciting areas of research. The goal is to help these young investigators establish their research careers. Some of the awardees and their projects include:

- Bindiya Bagga, MD, assistant professor in Infectious Diseases: “Investigating the mucosal immune response in human RSV infection”
- Ramesh Krishnan, MD, assistant professor in Neonatology: “Prevention of bronchopulmonary dysplasia and importance of growth factors in lung development”
- Benedetta Pallante, PhD, assistant professor in the departments of Pediatrics and Physiology: “Role of NMYC in oxygen-regulated lung and heart dysmorphogenesis”
- Andreas Schwingshackl, MD, assistant professor in Critical Care Medicine: “Stretch-activated ion channels regulate inflammatory mediator release in the lung”
- Emma Tillman, PharmD, assistant professor in Pediatrics and Clinical Pharmacy: “Fish oil in parenteral nutrition-associated liver disease”
- Dr. Tillman also won the Bea Gerber Award for highest score

New Appointments

The CFRI is pleased to welcome two new faculty members who will join the ranks this summer. Assistant professor of Pediatrics Teeradache Viangteeravat, or “Dr. Tee,” will serve as the technical director of the CFRI Bioinformatics Core Unit. The unit will develop informatics tools and resources to support the research needs of individual investigators as well as multidisciplinary research teams and programs. Informatics will help to build a bridge between clinical research and translational science.

Dr. C. Akunna Emeremni, assistant professor of Pediatrics, with a joint appointment in the Department of Preventive Medicine, will serve as biostatistician for the CFRI. Akunna has research interests that encompass statistical methods in clinical trials, survival analysis, causal inference and analysis of missing data. She will assist investigators with study design, power and sample size calculation, data management and statistical analysis, among other things.

Renovation work continues

Le Bonheur is currently cleaning and repainting the laboratory research areas on the Third and Fourth floors of the Research Center. The project is expected to take several months. Phase one involves mostly vacant offices and temporary storage areas. Information about phases two through five will be disseminated as plans are finalized. With careful communication and timely preparation, the disruption of laboratory operations will be kept to a minimum. Please contact Sheon Lynch at (901) 287-6208 with questions or concerns.
The Pediatric Clinical Research Unit (PCRU) is updating its process for the review and approval of new clinical studies at Le Bonheur Children’s Hospital. Investigators interested in clinical research, either industry-sponsored or investigator-initiated, should contact the PCRU Clinical Manager Neya Rhoads at (901) 287-6207.

Industry-sponsored Clinical Research

- Investigators complete a confidentiality agreement, which is forwarded to the PCRU Clinical Manager for processing. The appropriate research administrator – Methodist Foundation or UTHSC Research Administration – reviews and signs the confidentiality agreement. Review by the PCRU Oversight Committee may be requested to provide guidance and prioritization when competing studies are being considered and there is limited availability of research personnel and/or resources.
- The sponsor sends the investigator the study protocol, clinical study agreement and budget template, which are forwarded to the clinical manager who assigns research personnel to work with the investigator to:
  - prepare and submit the IRB application
  - contact any hospital departments that may be required to perform procedures or tests
  - work with the administrative director of the CFRI on budget analysis of the protocol and comparison to the sponsor budget

Investigator-initiated Clinical Study

- A short protocol synopsis is submitted to the chair of the PCRU Oversight Committee, which reviews the scientific merit and feasibility of completing the proposed study and provides a preliminary estimate of the resources required. Priority is given to studies deemed to have a high potential for attracting extramural funding and that are part of a planned research program for the investigator.
- If the PCRU Oversight Committee approves the protocol synopsis, the investigator submits a complete protocol for review. The protocol should follow ICH GCPs, which generally include the following sections: General Information, Background, Trial Objectives & Purpose, Trial Design, Selection and Withdrawal of Subjects, Treatment of Subjects, Assessment of Efficacy & Safety, Statistics, Direct Access to Source Documents, Quality Control & Assurance, Ethics, Data Handling, Financing & Insurance, and Publication Policy. Review online at http://ichgcp.net/6-clinical-trial-protocol-and-protocol-amendments.
- The investigator prepares an internal budget for all tests, procedures, research personnel and patient costs. Once the PCRU Oversight Committee approves the protocol and budget, the clinical manager will assign research personnel to assist in the completion of the IRB application and the conduct of the study.

CFRI Publications Apr-June 2012