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## CFRI serves as research enterprise lynchpin

**L**e 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:

- Bindya 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.



Teeradache Viangteeravat

### 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.



C. Akunna Emeremni

## Renovation work continues

**L**e 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.

# PCRU Clinical Research Review and Approval Process

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 Neysa 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

- submit the clinical study agreement to the appropriate research administrator for review and signature.

## 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

1. Arevalo AR, Boston US, Goldberg SP, Becker JA, Knott-Craig CJ. Starnes procedure in a neonate with pulmonary atresia and intact ventricular septum. *Ann Thorac Surg.* 2012;93:1703-1704.
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4. Choudhri AF, Carr TM, 3rd, Ho CP, Stone JR, Gay SB, Lambert DL. Handheld device review of abdominal CT for the evaluation of acute appendicitis. *J Digit Imaging.* 2012;25:492-496.
5. Cignacco EL, Sellam G, Stoffel L, Gerull R, Nelle M, Anand KJ, Engberg S. Oral sucrose and "facilitated tucking" for repeated pain relief in preterms: a randomized controlled trial. *Pediatrics.* 2012;129:299-308.
6. Cohen H. Multiplanar CT for suspected pediatric pulmonary emboli (Commentary). *AAP Grand Rounds.* 2012;27:31.
7. Coopersmith CM, Wunsch H, Fink MP, Linde-Zwirble WT, Olsen KM, Sommers MS, Anand KJ, Tchorz KM, Angus DC, Deutschman CS. A comparison of critical care research funding and the financial burden of critical illness in the United States\*. *Crit Care Med.* 2012;40:1072-1079.
8. DeVincenzo JP. The promise, pitfalls and progress of RNA-interference-based antiviral therapy for respiratory viruses. *Antivir Ther.* 2012;17:213-225.
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11. Han X, Chesney RW. The role of taurine in renal disorders. *Amino Acids.* 2012; May 12. [Epub ahead of print].
12. Hare ME, Coday M, Williams NA, Richey PA, Tylavsky FA, Bush AJ. Methods and baseline characteristics of a randomized trial treating early childhood obesity: The Positive Lifestyles for Active Youngsters (Team PLAY) trial. *Contemp Clin Trials.* 2012;33:534-549.
13. Hastings MC, Afshan S, Sanders JT, Kane O, Eison TM, Lau KK, Moldoveanu Z, Julian BA, Novak J, Wyatt RJ. Serum galactose-deficient IgA1 level is not associated with proteinuria in children with IgA nephropathy. *Int J Nephrol.* 2012;315467. Epub 2012 Jun 17.
14. Jimenez-Truque N, Tedeschi S, Saye EJ, McKenna BD, Langdon W, Wright JP, Alsentzer A, Arnold S, Saville BR, Wang W, Thomsen I, Creech CB. Relationship between maternal and neonatal *Staphylococcus aureus* colonization. *Pediatrics.* 2012;129:e1252-1259.
15. Kiryluk K, Li Y, Sanna-Cherchi S, Rohanizadegan M, Suzuki H, Eitner F, Snyder HJ, Choi M, Hou P, Scolari F, Izzi C, Gigante M, Gesualdo L, Savoldi S, Amoroso A, Cusi D, Zamboli P, Julian BA, Novak J, Wyatt RJ, Mucha K, Perola M, Kristiansson K, Viktorin A, Magnusson PK, Thorleifsson G, Thorsteinsdottir U, Stefansson K, Boland A, Metzger M, Thibaudin L, Wanner C, Jager KJ, Goto S, Maixnerova D, Karnib HH, Nagy J, Panzer U, Xie J, Chen N, Tesar V, Narita I, Berthoux F, Floege J, Stengel B, Zhang H, Lifton RP, Gharavi AG. Geographic differences in genetic susceptibility to IgA nephropathy: GWAS replication study and geospatial risk analysis. *PLoS Genet.* 2012;8:e1002765.
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18. Ofir A, Hofmann K, Weindling E, Gildor T, Barker KS, Rogers PD, Kornitzer D. Role of a *Candida albicans* Nrm1/Whi5 homolog in cell cycle gene expression and DNA replication stress response. *Mol Microbiol.* 2012;84:778-794.
19. Pershad J, Waters TM. Use of tent for screening during H1N1 pandemic: impact on quality and cost of care. *Pediatr Emerg Care.* 2012;28:229-235.
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26. Wang DJ, Boltz DA, McElhaney J, McCullers JA, Webby RJ, Webster RG. No evidence of a link between influenza vaccines and Guillain-Barre syndrome-associated antiganglioside antibodies. *Influenza Other Respi Viruses.* 2012;6:159-166.
27. Wang GC, Dash P, McCullers JA, Doherty PC, Thomas PG. T cell receptor alphabeta diversity inversely correlates with pathogen-specific antibody levels in human cytomegalovirus infection. *Sci Transl Med.* 2012;4:128ra142.
28. Warner WC, Jr., Sawyer JR, Freeman BL, Chase A, Jaquith B. Screws versus hooks: implant cost and deformity correction in adolescent idiopathic scoliosis. *J Child Orthop.* 2012; Apr 23 [E-pub ahead of print]
29. Yohannan TM, Goldberg SP, Stamps JK, Mathis CA, Anthony Jr CL, Lasater OE, Knott-Craig CJ. Cardiac myxolipoma in a child: diagnosis and surgical management. *Congenit Heart Dis.* 2012.
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