We are very excited to welcome:

Rachel Dodd, our new research nurse in Transplant Services, who has replaced Tauri Harden.

Kathy Zusmanis, who has recently joined our team, and is everyone’s first point of contact for research proposal management. Thanks to her efforts, we are able to timely route submissions and proposals.

Michael Woodall and Rachel Holtzberg, senior Emory students, our research assistants for the

Featured Winter Research

Featured Industry Sponsored Study:

Zemplar Protocol (Part II)

Purpose: To determine the safety and efficacy of 3 mcg paricalcitol capsules in pediatric subjects with moderate to severe chronic kidney disease (CKD Stages 3 and 4).

Inclusion:
1. Patient is male or female from 10 to 16 years of age
2. Subject has CKD Stage 3 or 4 as determined by eGFR (15 to 59 mL/min/1.73 m2) at Screening.
3. Subject has 25-hydroxyvitamin D levels ≥ 30 ng/mL at Screening

Recruitment Timeline: Ongoing

Featured Registry Study:

PROMIS Nephrotic Syndrome

Purpose: To measure what patients are able to do and how they feel when they have active nephrotic syndrome and when they are in remission. Childhood onset nephritic syndrome is a condition which causes the kidneys to leak protein from the blood into the urine.

Inclusion:
1. Age between 8 and 17 years, inclusive
2. Subject able to speak and read English
3. Nephrotic syndrome defined as nephrotic range proteinuria (≥ 2+ urinalysis or urine protein/creatinine ratio >2 mg/mg)
4. Newly diagnosed with nephrotic syndrome with ≤ 2 weeks of corticosteroid therapy

Recruitment Timeline: Ongoing

News You Can Use

Resources for Clinical Research

Children’s Healthcare of Atlanta and its partners in research, Emory University and Georgia Tech, are pleased to announce the availability of new pilot project funds through the Pediatric Research Centers. The pilot award funds are designed to stimulate new research projects and build new collaborations in child health-related research areas. Each of the eight centers listed to the right has produced a center-specific RFA (Request for Application) to address major topics in pediatric health and disease.

We are teamed up with the Center for Transplant Immunology! For more information visit www.pedsresearch.com

Center for Clinical Outcomes Research & Public Health (CORPH)
Center for Cystic Fibrosis (CF) Research
Center for Endothelial Biology (CEB)
Center for Pediatric Healthcare Technology Innovation (CPHTI)
Children’s Center for Developmental Lung Biology (CC-DLB)
Children’s Center for Immunology & Vaccines (CCIV)
Children’s Center for Transplant Immunology & Immune Therapeutics (CTIITC)
Children’s Center for Cardiovascular Biology (CCCB)
Research Matters

**NIH is dropping the 2-day window for error correction effective January 25, 2011.**

This window has been available for a period of two days AFTER the stated deadline, and we have had it several times! Proposals will now need to be submitted via Grants.gov 2 days ahead of deadline in order to have time to correct any errors and hence PI’s will need to plan ahead accordingly. See [NIH NOT-OD-10-123](epeds newsletter, Sep 2010 edition)

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**Important Information for our Clinical Trials Investigators**

New requirements for those PIs involved in clinical trials have been established. **Specific training on “Key Concepts in Clinical Trial Research” are now required and must be completed by June 1, 2011.** All investigators on existing clinical trials will be required to complete 12 online training modules.

The modules can be found at Emory Learning Management System website: [www.emory.edu/elms-training](www.emory.edu/elms-training).

Login is your Emory NetID and password. Newly hired investigators or investigators new to clinical trials research will be required to complete all 12 modules prior to IRB approval to participate as a PI on a clinical trial. In addition to the 12 baseline modules, each investigator will be required to complete 12 hrs of update training modules prior to their biennial CITI training.

OCR, together with the IRB will identify and notify PIs who are required to complete the training. Compliance with the training will be monitored by the IRB.

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**Study Successes**

**Cystinosis Study**

Cystinosis is an inheritable disease marked by abnormal accumulation of the amino acid cystine in the lysosomes, which form crystals that damage cells. The crystals most significantly damage the kidneys. Current drug therapy for cystinosis includes Cystagon®, a pill that must be taken every 6 hours for the rest of the patient’s life. This study tested new time-delayed release capsules which may be taken every 12 hours.

Our research center at Emory was the world leader in recruitment for this study with 10 participants! Thanks to our collaboration with the Pediatric Research Center at Egelston Hospital and their wonderful nurses, we were able to schedule and see through over 200 visits (including countless EKGs) in just a few short months. We are currently in the extension phase of the study as we monitor our patients over the next six months.

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**New Current and Upcoming Spring Quarterly Protocols**

**Executive Function in Children with Hypertension**

The purpose of this study is to evaluate learning abilities, attention, and concentration in children and adolescent with high blood pressure. This study is open for participants age 10-18 years old with primary hypertension as defined by a casual SBP and/or DBP ≥ 95th percentile (confirmed by 24 hr ABPM).

**Open to enrollment!**

**Novartis Hypertension Study**

This double-blind 8 week study will evaluate dose response, efficacy and safety of aliskiren in children 6 - 17 years old with hypertension at low, mid and high weight-based doses. This study is being conducted to support monotherapy registration of aliskiren for the treatment of hypertension in children 6-17 years of age.

**Not open to enrollment yet!**

The success of any of our protocols depends on the support of all of our nurses and staff. Please take the time to review the particular research protocols highlighted in this issue and recommend any eligible patients to Margo Kamel, mkamel@emory.edu. Also, please feel free to make any suggestions that you feel will facilitate the conduct of any research project.

Thank you for all of your help!

Sincerely, Margo Kamel