# **Emory+Children's Pediatric Research Center**

A newsletter from the Center for Clinical and Translational Research



#### March 2015

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# Center Update: Cynthia Wetmore, MD, PhD

**Georgia**Institute

of **Tech**nology

Welcome to all and Happy Spring! We have many new "sprouts" to celebrate in the Center for Clinical and Translational Research. We have a fully functional Clinical Research Office at Scottish Rite (have you seen the flat screen with scrolling information on projects, people and opportunities?) and have celebrated our inaugural Research Grand Rounds presentation, given by Dr.

Ben Gold on March 16, 2015. There were over 50 people in the audience and it was the most well-attended Grand Rounds presentation at Scottish Rite this year.

We have issued a call for proposals for our second round of <u>Friends Grant funding</u> (deadline May 1, 2015) and also have <u>pilot grants available</u> through the CCTR and other Centers. Please mark your calendars for our annual Pediatric Research Conference on June 22, 2015 at the Emory Conference Center Hotel. We are planning poster sessions, keynote addresses and a technology demonstration complete with appetizers and beverages for "tech hour" to round out the day. <u>Prior registration is required</u>.

We have formed a Clinical Trials Advisory Committee to help guide our programming and help establish a responsive Clinical Research Office that will exist virtually (for now) and support all sites of our campus, including investigators at Georgia Tech. Please contact Kristen Herzegh (Kcoshau@emory.edu) if you would like to learn more about our programs or would like to serve on this Committee.

Please let us know your thoughts, interests and suggestions for future newsletter topics and also how things are going for you and your research. Our goal is to support and facilitate clinical research related to children's health and welcome your feedback.



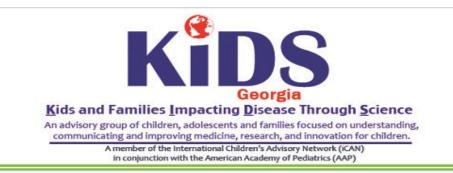
### Welcome: Amanda Cook Director of Clinical Research Services

The Center for Clinical and Translational Research is pleased to welcome Mrs. Amanda Cook to her new role as Director of Clinical Research Services. Amanda will provide support to the Emory -employed clinical research teams within the Department of Pediatrics. She will work closely with Children's Feasibility Analyst, the Grants Administration Team, and Clinical Research Man-

agement . In conjunction with these teams, Amanda will ensure that the DOP-employed CRCs and CRNs are compliant and aware of Children's policies.

In addition, Amanda will proactively troubleshoot operational or process issues as they arise, so as to facilitate timely initiation of new trials and ensure optimal enrollment. Collaborations with Dr. Wetmore will develop and articulate a shared vision and a comprehensive strategic plan, and to establish priorities for and evaluate progress and success of Clinical Research Services in support of the shared research mission and strategic objectives of The Pediatric Center.

Amanda's office is located on the 4th floor bridge of the Health Sciences and Research building. She can be reached at <u>amcook@emory.edu</u> or 404-727-5234.



What is KIDS? Kids and Families Impacting Disease Through Science (KIDS) is an advisory group of children, adolescents and families focused on understanding, communicating and improving medicine, research and innovation for children. KIDS is a collaboration between the American Academy of Pediatrics (AAP), Section on Advances in Therapeutics and Technology (SOATT), local AAP Chapters, children's hospitals, local schools and other partners.

At Children's, staff members help kids understand their care, whether through medical play with a Child Life Specialist or a conversation about science and health with another member of their team. It's all part of allowing kids to still be kids during treatment and giving them the chance to explore and grow along the way.

Now, the Emory+Children's Pediatric Research Center, along with several partners, is looking to take things one step further, helping kids become active participants in not only their own health, but in research studies that can affect other children.

The first Georgia chapter of Kids and Families Impacting Disease Through Science (KIDS), a collaboration between the American Academy of Pediatrics (AAP) and other partners, started in June 2014. KIDS chapters are made up of children ages 8-18—some who've been hospitalized or participated in clinical trials, others who are simply interested in science or medicine.

The kids discuss new protocols, new devices and new studies, while their parents can provide feedback on what makes a study work for their family.

When Stephanie Meisner, Clinical Research Manager and former PICU nurse, first heard about KIDS, she immediately thought of some of the children in her current trials, as well as her own kids. "I liked that they were asking kids about their opinions," she said. "Even simple questions like, 'what gets on your nerves about managing your care?"

Stephanie began working to establish a chapter last year, collaborating with Emory's Judson Miller, M.D., to gain approval from the Georgia AAP. The KIDS Georgia chapter's first meeting took place at the Georgia Tech design expo on new devices in the fall of 2014. Twenty-five kids got a VIP tour of the Invention Studio and expo, as well as a personal presentation from the student winners.

At the second meeting, held Saturday, Feb. 21, at Egleston, the ECMO team gave 40 kids a special look at their life-saving technology, demonstrating extracorporeal membrane oxygenation (ECMO) on a simulation baby. Georgia Tech's BME Healthreach Group also organized two hands-on activities, teaching the kids about the different components of blood and bones.

If you have patients or children who would also be interested in learning more about medicine and science and would like to join the KIDS Georgia chapter, contact:

# **Invention Studio**



Stephanie Meisner at

Stephanie.meisner@choa.org



## FRIENDS RESEARCH GRANTS

Eligibility - members of Children's Professional Staff who do not also have a compensated Emory faculty appointment.

Deadline: May 1, 2015 by 6pm

# TO LEARN MORE, AND APPLY, CLICK HERE

# **Biostatistical Support**

The Biostatics Core provides assistance with analytics and statistical methodology for the design and preparation of studies and grant proposals (such as open Friends Grant Call). Investigators are encouraged to engage the Core prior to submitting your proposal.

For more information, or to request an appointment, please email Dr. Courtney McCracken at courtney.mccracken@emory.edu

# **Dudley Moore Nursing and Allied Health Research Fund**

The Dudley Moore fund provides grant funding for research proposals that will enhance patient care.

Funding Limit-\$15,000

Application Deadline- Spring: May 1, 2015 Fall: October 2, 2015

*Eligibility*-all Children's nursing and allied health staff who provide services at one of Children's locations are eligible; Projects must have an impact on enhanced patient care, priority is given to projects that will provide evidence to change practice

For more information, please email <u>Linda.Riley@choa.org</u> or <u>click here</u>

## **CCTR PILOT GRANT CALL**

#### DUE APRIL 1, 2015

2015 Center for Clinical & Translational Research themes:

- Investigator-initiated trials
- Interventional studies in areas of genomics, biomarker development or validation
- Application of basic research advances for a "first in pediatrics" type of study
- Basic science projects that have the potential to translate into clinical trials within 2 years
- Studies with a potential for high impact

#### To learn more, and to apply, CLICK HERE

Hosted by

Inflammation in Pediatric Health: Improving care through innovation and technology

June 22, 2015 <u>Emory C</u>onference Center Hotel

(\*) MOREHOUSE



# Pediatric Research Center (PRC)

The Pediatric Research Center (PRC), located on the 2<sup>nd</sup> floor of Children's-Egleston campus, is the pediatric clinical interaction research site of the Atlanta Clinical and Translational Science Institute (ACTSI). The PRC staff and support services are availa-

ble to any Emory or Children's Investigator interested in implementing a protocol within the pediatric population. The PRC includes a 4 bed outpatient clinic, with overflow capabilities. In addition, we have a 4 bed inpatient research unit located in the 4-West area of Egleston campus. We have dedicated CITI-certified nursing & paramedic staff ready to assist you with your trial. Services range from basic vital signs, measurements, and phlebotomy to intensive PK studies, infusion of investigational drug products, and invasive procedures. Support services include research-specific resources such as the investigational pharmacy, bionutrition services, and a core research lab as well as all amenities offered to standard of care Children's patients. For more information, please visit us <u>http://www.pedsresearch.org/clinical-research/pediatric-research-center</u> or email inquiries to <u>PRC@choa.org</u>.

#### Things you may not know about the PRC:

• We assist with federal, investigator-initiated, AND industry protocols in the PRC.

• You don't have to be a doctor to have your protocol implemented with us. We'd love to help with nursing EBP or ancillary trials too!

- We are happy to service research protocols from Hughes Spalding, Scottish Rite, or specialty clinics at our site.
- We see patients newborn up to 21 years old, just like the hospital does.

Research protocols that are executed during standard of care inpatient visits sometimes require a little extra help. Consider using the PRC staff for that! We now have an hourly rate and are willing to travel to bedsides. Currently offered at Egleston Campus on a case-by-case basis. Contact Stephanie Meisner (<u>Stephanie.meisner@choa.org</u>) for details.

We are always willing to meet face-to-face to help you route your project through the ACTSI approval process.

# The PRC has been named a *Pfizer Pediatric Center of Excellence*. Only the second in the U.S., this distinction is in conjunction with the Emory Department of Pediatrics and Children's. Congratulations!



# **Research Coordinator Highlight: Saadia Khizer**

Saadia Khizer is lead research coordinator at Hughes Spalding and Scottish Rite. Originally from Pakistan, where Saadia obtained her medical degree, she moved to United States in 1994 with her family.

Saadia has been a key player in research at Hughes Spalding for almost six years. Throughout her time, she has helped with initiating a number of research projects. Currently at Hughes Spalding, she manages all research performed whether she is personally a part of study team or not. For every incoming study at Hughes Spalding, she meets with investigators and study team, reviews study protocols, and adheres to Children's research processes. She communicates with nurse managers to ensure patient care and flow is not interrupted and is responsible for routing the study through Hughes Spalding leadership for approvals. Since both Morehouse and Emory physicians are at Hughes Spalding, she has an equal interaction with both university systems. During her time at Hughes Spalding, she has worked on sickle cell clinical trials, CDC sponsored rotavirus vaccine studies, and NIH multicenter MRSA treatment Center study to name a few.

At Scottish Rite, she is lead research coordinator for Neurology. There are both federal and industry sponsored clinical trials and registries for this patient population. Many studies for Duchene muscular dystrophy, Becker Muscular dystrophy, epilepsy and neurofibromatosis are in pipeline. She has also initiated and updated the most comprehensive database for neurology patients at MDA clinic at Scottish Rite. This database has greatly helped in rolling in clinical trials for new drugs from pharmaceutical companies like Sarepta, Prosensa and Pfizer.

# Children's Feasibility Coordinator: Gigi Davis

Currently, it is a requirement that all Children's clinical studies involving human subjects with Children's billable items and services (i.e., billable items/procedures/services such as those with CPTs, EAPs, etc.) have a Coverage Analysis completed.

Gigi is responsible for the Coverage Analysis Process in the development of a clinical study budget. Coverage Analysis is an objective determination which entails a comprehensive analysis of clinical study related key documents such as protocol, budgets/payment schedules from the sponsor, informed consent and draft contracts. Utilizing these key study documents, Gigi will work with the PI and/or Study Coordinators to determine if billables are considered routine care and whether the associated costs are the financial responsibility of the sponsor or third party payers. The Coverage Analysis will help ensure compliance and ensure that research subjects will be correctly billed. It will also help assess the practicality of study participation before entering into a study agreement with a sponsor.

In addition, Gigi will provide an assessment of each clinical trial for financial and general feasibility. In the near future, Gigi will have access to Children's patient population data, which will allow her to provide researchers with data/patient population unique to Children's. This will aid in budget negotiations and whether a particular study is clinically and financially achievable.

Gigi's role as a clinical trial feasibility coordinator is to provide a valuable resource to researchers as they move through the process of considering and initiating a clinical trial.

To contact Gigi, please email gigi.davis@choa.org

# Sponsored Research Administrators

**Children's** —The grant administration team at Children's had developed a new tool to aid investigators, coordinators and other collaborative research partners in routing research studies for institutional review and approval at Children's. The checklist form outlines all required documentation and demystifies the process for all. The checklist can be found <u>here</u>.

To learn more about the Children's research administrators or for more information on how to utilize their services , please contact grantsadmin@choa.org or visit their page at <u>here</u>.

**Emory**—Emory Pediatric Research Administration Services (RAS) provides high quality, consistent service and compliance in all aspects of research administration. They offer one source for pre and post award research administration activities from highly knowledgeable staff. The team is strictly focuses on research administration. Intent to submit forms can be found <u>here</u>. To contact your RAS contact, <u>click here</u>.



# Scottish Rite Research Updates

# Save the Date: Research Grand Rounds: May 19th Courtney McCracken, PhD

"Leveraging Biostatistics Resources to Improve Pediatric Research"

# **Research Office Hours Update**

In order to best accommodate investigator needs, the research office will be staffed based on your appointment request. It request an appointment, please complete the brief intake form by clicking <u>HERE</u>