Pediatric Research Alliance

Spring Edition
April 2016

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* Coordinator News and Blog

Center Update: Cynthia Wetmore, MD, PhD

Happy Spring 2016! We hope this newsletter finds you well and enjoying the beautiful weather at this time of year.

People: CCTR continues to grow and add personnel and resources to support clinical research across our campuses. We have been fortunate to have recruited Kesley Tyson, MS, CCRP to our Center last fall as the manager of Start-up and Regulatory Affairs. Kesley brings a wealth of experience in clinical research having served as the Lead research coordinator for the Bleeding Disorders Clinic since 2013 and, prior to that, as a research coordinator at Boston Children's Hospital in the Department of Orthopedic Surgery. Kesley will be assisting investigators with study start-up, monitoring and compliance.

Another new recruit to CCTR is Bradley Hanberry, PhD, who was hired in December 2015 as the Director of the Molecular Clinical Trials Core Laboratory and Biorepository. Dr. Hanberry has training as a basic scientist in pharmaceutical and bio-medical sciences, as well as having most recently been employed as a Research Coordinator at iResearch Atlanta. He brings expertise in the design and conduct of correlative biology assays that will support our clinical studies. Dr. Hanberry has also helped with the transition of the Biorepository from CTID to CCTR and is working to expand our collection of disease-specific biological samples as well as those from healthy control patients.

With the help of Kristen Herzegh, we continue to build our expertise and support for the submission of Investigational New Drug applications. We are pleased to have supported Dr. Jacques Galipeau in the recent successful submission of an IND for the use of mesenchymal stromal cells to support haplo-identical bone marrow transplantation for sickle cell disease which is led by Dr. Beth Stenger in Aflac Cancer & Blood Disorders Center.

Places: In December 2015 we opened the newly-renovated ECC-RU with support from the ACTSI, Emory and Georgia Research Alliance. The space consists of 3 additional rooms for the conduct of clinical research. Two of these rooms have exam tables and one is a smaller room that is used for consultation/discussion. This clinical space is run by CCTR and available to all clinical investigators with IRB approved studies.

Events: We hosted a gathering for Emory and Children's clinical research coordinators last month to continue to support a unified approach to pediatric research across our campus. It was well attended with a crowd of 40. Enjoy a few pictures included below.

We also kicked off the first "PEARLS" (**P**ediatric **E**duc**A**tion **R**esearch **L**unch **S**eries) to provide continuing education and credit for research coordinators and nurses to support their ongoing professional growth and development. We will be hosting this series (including lunch) on the second Friday of every other month (April, June, August, October, December) and will rotate among locations throughout our campus.

Please feel free to send your thoughts, comments and suggestions – we appreciate your support and interest.

With best regards,

Cynthia Wetmore




Local Teens Take Home Peds 2040 Award

Jake Haygood and Hampton Woods, both high school freshman, won the distinct honor of "Most Popular Vote" at this year's Peds 2040 conference. Their winning project, in their words:

"We have devised a system in which patients who are undergoing emergency treatment, or who have a preexisting conditions can wear an easily identifiable RFID wrist band. This device is passive and does not require the use of a battery. The wrist band can physically store medical data on it such as date of birth, medications given, conditions, etc. When the patient arrives at a healthcare facility their wristband can be scanned, and medical data can be readily available for medical personnel to view. The data can then be uploaded to a medical charting system such as Epic..

Hampton & Jake at Peds 2040

RFID stands for radio frequency identification. RFID chips are used in a wide variety of industries and applications including corporate badges and access systems. Each chip emits a unique identification number and some can even store data. The RFID technology that we will be using in our products is passive (powered by electromagnetic waves emitted from a scanner), very light weight, and inexpensive."

Both Jake and Hampton attend Mount Paran Christian School in Kennesaw. They are members of the robotics team 7373 and serve on the iCAN Georgia chapter board.

Follow Haygood & Woods Co.
Twitter: @Haygoodandwoods and Instgram:HaygoodandWoodsCO

Biorepository Subsidy

The Biorepository Core offers clinical sample processing and storage services for investigators conducting basic, epidemiologic, translational and clinical research related to improving child health. The core supports investigator-initiated, center-based and disease-based research studies.

Investigators interested in using the CCTR Biorepository may apply for a subsidy of the labor portion of the currently published rates. Investigators may apply for this subsidy through two categories:

Category 1: Unfunded investigators who wish to collect samples to generate data for child health-related extramural grant applications.

Category 2: Investigators who agree to collect an additional purple-top tube (minimum 1 mL), and/or urine or stool sample for donation to the biobank, with acknowledgement that the donation may not be possible for every patient depending on the weight or clinical condition of the patient.

For more information, please contact:
Dr. Brad Hanberry bradley.hanberry@emory.edu

Happenings

* **4/19- Scottish Rite Research Grand Rounds**
Scottish Rite hospital—Main Auditorium (7:30am)
"Neurofibromatosis type 1"
David S. Wolf, MD, PhD

* **4/22- CCTR/CORPH Seminar**
Egleston Classroom 5 (12:00pm)
"A Smoke-Free Homes Research Program: Mixing Quantitative and Qualitative Methods"
Michelle Kegler DrPH, MPH

* **5/17- Scottish Rite Research Grand Rounds**
Scottish Rite hospital—Main Auditorium (7:30am)
"Genetic Risk Factors for Late Effects in Pediatric Cancer Survivors: a Focus on Hypothyroidism"
David Siegel, MD, MPH

* **6/10- Pediatric EducAtion Research Lunch Series (PEARLS)**
Egleston Classrooms 5-7 (12:00pm)

* **6/14– Clinical Trials Advisory Council (CTAC)**
Interested in learning more or joining? Email Kcoshau@emory.edu

* **5/6—Dudley Moore applications due**
Dudley Moore Nursing and Allied Health Research Fund

Director of Clinical Research Services: Amanda Cook

Recently, the new and improved pedsresearch.org website was launched! This site is a collaborative effort that incorporates research cores, centers and resources across the Pediatric Research Alliance. Along with a great new look, we have added many new features. Here is an area I would like to highlight:

- **Research Coordinator Resources** – Focuses on tools and information for research coordinators and nurses. Includes announcements, news articles and upcoming meetings.
- **Dedicated Clinical Research Facilities** – Details the PRC, ECC-RU, and IDS.
- **Regulatory and Compliance** – Offers an overview and links to offices involved with research regulatory and compliance.
- **Electronic Research Systems** – Always wondered what REDCap is or who can give you access to ELMS? This page provides links and descriptions to the various websites, databases and systems used for research.
- **Institution Fact Sheets and Rates** – A quick snapshot of info sponsors are always asking for, like IRB meeting schedule, DUNS number, and congressional district.
- **New Investigator Resources** – Links to policies and training specific to Investigators.
- **Training and Credentialing** – Outlines everything you need to know about training and credentialing at Emory and CHOA.

Please let me know if there are other resources you would like to see!

Clinical Research Resources

(http://www.pedsresearch.org/research/resources/clinical-research-resources/)

2016 Pediatric Research Conference

Register Today: www.pedsresearch.org

June 21st—5:00pm - Georgia Aquarium

- **Cocktails, dinner, keynote lecture by Raymond F. Schinazi, PhD, DSc**

June 22nd—8:00am - Georgia Aquarium

- **Keynote presentations**
- **Presentations by faculty and selected abstract authors**
- **Scientific poster sessions**
- **Technology demonstrations**
- **Networking**
- **Social hour**

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SOUTHEASTERN PEDIATRIC RESEARCH INNOVATION CONFERENCE

Start-up & Compliance Coordinator: Kesley D. Tyson

Kesley D. Tyson, MS, CCRP, is the start-up and compliance coordinator to the Center for Clinical and Translational Research in the Department of Pediatrics at Emory University where she provides consulting services in all aspects of clinical research to investigators, provides data and safety monitoring for investigator initiated drug and device studies, and oversees research staff educational development initiatives. She also provides group and one-on-one training in study start-up activities, regulatory, and project management topics.

Prior to moving to Emory in 2015, she was a lead research coordinator at Children's Healthcare of Atlanta, Aflac Cancer and Blood Disorders Center where she provided oversight for all aspects of clinical research in the Hemostasis and Thrombosis Program. Prior to Children's Healthcare of Atlanta, she was a lead research coordinator for several years with Boston Children's Hospital in the department of orthopedic surgery in the division of sports medicine where she served as the primary point of contact for research operations. Along with her experience, she has also acquired a Master's of Science degree in Regulatory Affairs for Drugs, Biologics, and Medical Devices from Northeastern University in Boston, MA and a Bachelor's of Science degree in Health Sciences from the University of Alabama at Birmingham.

Responsibilities within CCTR:

- Research compliance and start-up consulting
- Research and Data Safety Monitoring
- Research Coordinator Educational Support and Resources
- Regulatory and general oversight for the Emory Children's Center Research Unit (ECC-RU)
- **P**ediatric **E**duc**A**tion **R**esearch **L**unch **S**eries (**P.E.A.R.L.S.**)

Research Coordinator Resources

Kesley's Coordinator's Corner

April's Blog Entry: **Learning Protocols**

You can't read every protocol and have them memorized in a single day…or even a month. Here is a brief practical approach to learning your research protocol.

Don't: Don't stress yourself out trying to learn 54 protocols in one day.

Do: Print all of the schedule of events (SOE) tables and the visit details page(s) from each of your protocols. Review those first. Study those small subtitles under the tables and learn what should happen at each visit. In my opinion, these are the most important sections of the protocol to a coordinator. Make checklists about what should occur at each visit. Take the checklist with you when you conduct a visit. It ensures that you will not miss anything that you're supposed to do. Creating the checklists from the schedule of events (SOE) and visit descriptions helps you learn the study a lot faster. From the checklist you created, make your source documents. These are the forms that you will initially collect all of the data you need for your case report form (CRF). By creating your own sources, it familiarizes you even more with the protocol. So, to recap, the quick and painless way to learn your protocols are to:

- Print/review the schedule of events and visit descriptions
- Create a checklist for each task required at each visit
- Create the source documents for the visits

You will need to eventually learn the protocol, but when transitioning into a new position as a coordinator or having to learn multiple studies at a time, this is by far the least painful process I have experienced thus far. It's also a good idea to take a manila folder with you to the visit that contains a list of frequently asked questions, the SOE, and visit descriptions in case the PI has questions. The study synopsis and sponsor contact information are also nice to have handy. The synopsis is also short and sweet and usually includes weight requirements and blood volumes as well as inclusion/exclusion criteria. No one will judge you for reading your notes. Do you have any tricks you use to learn your protocols? Please feel free to email comments and suggestions to cctr@emory.edu.

Reminders

* Complete the patient pre-registration form for visits that will generate a CHOA billable. The form must be completed at least a day prior to the research visit or on the same day as consenting.
* Complete the patient tracker after each visit.
* Enter newly consented trial subjects into the Emory Research Management System (ERMS).