

Pediatric Research Alliance



Center for Clinical & Translational Research Update—Fall 2016

As we move into the holiday season, I find it easy to be thankful for the many accomplishments we have seen within our pediatric clinical and translational research community. The density of this issue certainly speaks to that. Thank you to all who drive and support this research. It is truly a collaborative endeavor.

The Scottish Rite Research Office recently celebrated its second anniversary. Thank you to those who attended our celebratory morning mingle. As always, we welcome the opportunity to discuss your research interests and goals. We are also pleased to share that Scottish Rite will continue to host quarterly Research Grand Rounds. If you are interested in presenting, or would like to suggest a topic, email Kristen Herzegh at kcoshau@emory.edu.

The Emory Children's Center Research Unit will celebrate its first anniversary next month. Please join us for lunch on [December 12th](#) to celebrate, find out what we've learned so far and discuss how we can continue to support your clinical research needs.

In August, we hosted Dr. Benjamin Wilfond, Director of Seattle Children's Center for Pediatric Bioethics. Dr. Wilfond's presentation "Research on medical practices - Public attitudes for research consent" proved thought provoking for our pediatrics investigators, their study teams and others throughout the university. I encourage you all to read more about this subject by [clicking here](#).

Last, but certainly not least, please join me in extending a warm congratulations Dr. Brad Hanberry (Director, Biorepository Core) and his wife Brittney. They welcomed a healthy baby girl, Ella Rae, on November 18th.

As always, please send us your thoughts and suggestions. We appreciate your feedback as we strive to support and facilitate your clinical research needs. We look forward to continued collaboration and success in 2017!

With best regards,
Cynthia Wetmore



Gabapentin Premedication for Pediatric Anterior Cruciate Ligament Reconstruction: Randomized Control Trial

David Nusz, M.D. Principal Investigator, Margaret Gettis DNP, CPNP Co-Investigator

Anterior Cruciate Ligament Reconstruction is a common surgical procedure for adolescents often associated with significant postoperative pain. To date, few research studies have assessed pain management strategies in the pediatric ACL population. Current methods to reduce ACL pain include regional nerve blocks and use of opioid or non-steroidal anti-inflammatory analgesia. Although effective in adults, use of gabapentin for pediatric ACL pain relief has not been well studied. Gabapentin is hypothesized to provide a low cost and effective intervention to reduce adolescent postoperative pain and opioid use after ACL reconstruction. **Continued on page 5.**



Left to Right- Jane Chen PharmD, Investigational Pharmacist; Margaret Gettis DNP David Nusz MD, Allison Musick PharmD; Pharmacy Team Lead.



Director, Clinical Research Services: Amanda Cook

Industry Clinical Trial Status Report

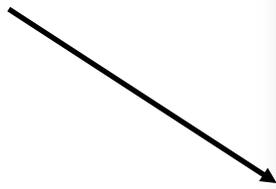
Weekly, I upload a status report of all industry sponsored studies for the DOP.

To access the report:

1. Visit the Research Administration page on [pedsresearch.org](http://www.pedsresearch.org):

<http://www.pedsresearch.org/research/resources/research-administration>

2. Click the highlighted link



Research Administration

Research Administration provides the infrastructure for pre- and post-award management of sponsored research projects. This includes proposal submission, budget preparation, routing documents for appropriate internal approvals, and ongoing fiscal management over the duration of the award.

The process varies and depends on many different factors: your institution affiliation, type of research conducted and location where research activities will occur.

Click below to see Your Research Pre-award Pathway:

- [CHOA PI: All Research Types](#)
- [Emory PI: Human Subject Research](#)
- [Emory PI: Animal Research](#)
- [Emory PI: Wet/Bench Laboratory Research](#)
- [Emory PI: Human Subject + Wet/Bench Laboratory Research](#)
- [Emory PI: Human Subject + Animal Research](#)

GRADY, MOREHOUSE AND GEORGIA TECH

INDUSTRY CLINICAL TRIALS PRE-AWARD STATUS REPORT

[Click here](#) for a weekly pre-award status report for industry sponsored clinical trials.

At a quick glance, you can see how your study is progressing through the pre-award process – IRB, budgets, contracts and awards. There is also contact information for who is responsible for each step in the process, in case you have any questions.

DOP Industry Clinical Trial Status Report: October 23, 2016

Contact Information for questions:

| | | | |
|---|--|--------------------------------|--|
| CHOA Coverage Analysis: | stcr@choa.org | Sponsor Contract Negotiations: | amc@emory.edu |
| CHOA Budget Development, non-Affix studies: | amc@choa.org | IRB, non-Affix studies: | your study team |
| CHOA Budget Development, Affix studies: | aflex@choa.org | IRB, Affix studies: | aflex@choa.org |
| Emory Budget Development: | amc@emory.edu | Emory NDA: | amc@emory.edu |
| Sponsor Budget Negotiations: | amc@emory.edu | CHOA Subcontract: | amc@choa.org |

| PI Last Name | PI First Name | Name of Sponsor | Date Instart to Submit Form Completed | EPDS# | Emory IRB # | CHOA Coverage Analysis Status | CHOA Budget Development Status | Emory Budget Development Status | Sponsor Budget Negotiations Status | Sponsor Contract Negotiations Status | IRB Status | Emory NDA Status | CHOA Subcontract Status |
|--------------|---------------|---------------------|---------------------------------------|-------|-------------|-------------------------------|--------------------------------|---------------------------------|------------------------------------|---|--|---|-------------------------|
| Anderson | Evan | Novartis | 3/18/2016 | 37541 | IRB0009888 | N/A | N/A | Completed 7/28/2016 | Completed 7/28/2016 | Start follow up to sponsor 8/24/2016 | Approved 8/11/2016 | | N/A |
| Anderson | Evan | NovImmune | 7/15/2016 | 38234 | IRB0009154 | N/A | N/A | Completed 10/19/2016 | Sponsor reviewing 10/19/2016 | Start negotiations to sponsor 8/20/2016 | Assigned to 10/24/2016 Completed Pending | | N/A |
| Brown | Robert Clark | AdvaCentra | 5/10/2016 | 37208 | IRB00087670 | | Completed 6/15/2016 | Completed 6/30/2016 | Completed 9/15/2016 | Completed 10/5/2016 | Approved 6/10/2016 | Received 10/11/2016 | Requested 10/11/16 |
| Cash | Thomas | United Therapeutics | 8/18/2016 | 38481 | IRB0009200 | | Pending some process 9/28/2016 | | | Negotiations Started 8/8/2016 | Pending | | |
| Chakraborty | Rana | Novartis | 5/18/2016 | 37382 | IRB00090162 | Completed 8/24/2016 | Completed 7/13/2016 | Completed 8/30/2016 | Revised changes with PI 10/11/2016 | Completed 8/15/2016 | IRB sent to CHOAs for review 8/24/2016 | Done. Requested by IRB Staff 10/20/2016 | |
| Chakraborty | Rana | Novartis | 6/15/2016 | 38288 | IRB0008827 | N/A | N/A | Completed 8/4/2016 | Revision sent to sponsor 8/27/2016 | | Approved 8/18/16 | | N/A |
| Cherani | Nishi | Prolecta Bioscience | 4/28/2016 | 38470 | IRB00091189 | Completed 8/25/2016 | Completed 6/30/2016 | Completed 9/15/2016 | Completed 9/15/2016 | Pending IRB approval 8/27/2016 | Assigned to 11/2/2016 Completed Pending | | |

Data Source: PDSVL, IRB, EPDS
Created by: amc@emory.edu

Emory Business Process Improvement Scholar

Congratulations, Amanda, on your successful completion of the Emory Business Process Improvement (BPI) Scholars Program: Gamma Cohort, Class of September 2016.

BPI Scholars is a one-year professional development program in which high-performing, early and mid-career Emory staff learn and develop project management, communication, analytical, and leadership skills.

Amanda's project was titled "Improving the Pediatric Clinical Research Pre-award Experience for Faculty: creating a proactive and systematic process for navigating the path from study development to patient enrollment."



What's happening in the ECC-RU: Joint Associated Mechanical Sounds (JAMS)

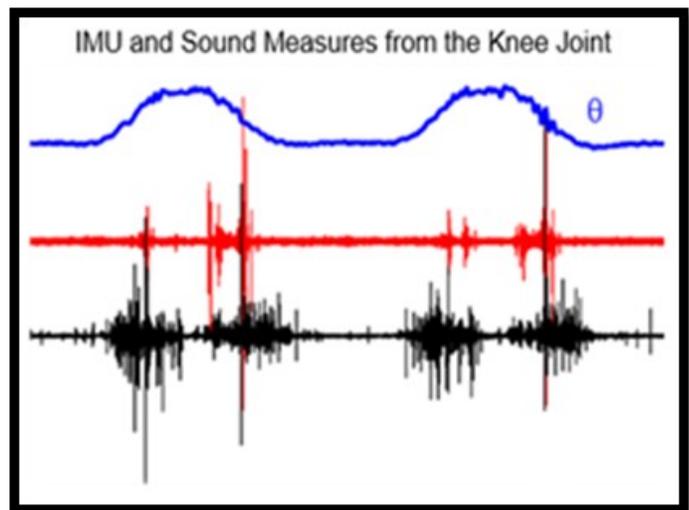
Emory, Georgia Tech and Children's Healthcare of Atlanta are using the ECC-RU (Emory Children's Center Research Unit) to collaborate on an innovative study to change how we manage pediatric arthritis patients.

Juvenile Idiopathic Arthritis (JIA), an autoimmune disease of the joints, is one of the most common chronic illness of children. JIA is nearly as common as juvenile diabetes, meaning that it affects more children than sickle cell anemia, cystic fibrosis, hemophilia and the muscular dystrophies combined.

Fortunately, JIA is treatable with early intra-articular steroid injections and biologic medications. However, these treatments have several side-effects ranging from GI upset all the way to potentially increasing the risk of cancer. It is with that in mind that the need for ongoing monitoring, and personalized treatment regimens becomes clear.

Currently, we rely on a combination of imaging, physical exam, lab tests, symptoms and clinician's judgement to monitor JIA. There is not a specific biomarker used to easily monitor the disease progression. The goal of our research is to discover a new biomarker for monitoring joint health. In order to do so, we are listening to the joints. We have all heard our joints crack and pop - our project is discovering the meaning behind those noises. Particularly, we are recording the sounds emitted by patients' joints and correlating that with their clinical scenario.

For the study, a customized, wearable sensing hardware was designed specifically for pediatric patients using commercially available, off-the-shelf (COTS) microphones, sensors, and electronics. The use of COTS will greatly accelerate the process of hardware development, while reducing cost, and will allow for rapid data collection.



The hardware consists of small, high-quality microphones (both piezoelectric contact and electret microphones) and accelerometers connected via flexible wires to recording equipment and a PC (or digital recorder). Example measurements from a knee joint are shown in the figure. The top plot (blue line) represents the angle of the knee from full flexion to full extension. The next two plots (red and black) are the sounds we record. This data was obtained with existing sensing hardware at the Inan Research Lab and is analogous to our development plans for this study. These microphones and sensors will be attached, temporarily, near various joints on the surface of the skin with COTS adhesives and wearable textile wraps.

Ultimately, we plan to use these sounds in two ways: to easily monitor JIA and to inform a feedback-controlled, personalized treatment schedule.

For more information:

- *Click here to find about the ECC-RU: [Click here](#)*
- *Meet the investigators and study team on page 6*



Lori Ponder placing sensors on patient.

SoCRA's 25th Annual Conference

Emory University and Children's Healthcare of Atlanta were in attendance at SoCRA's 25th annual conference in Montreal, Canada. The collaborative groups presented 3 posters at the meeting.

["An Electronic Clinical Research Study Management System"](#)

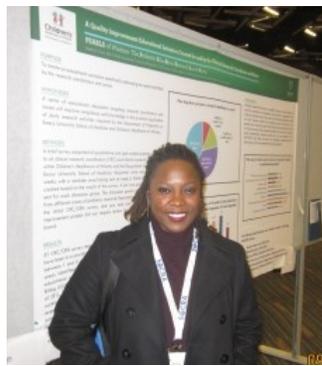
Kesley D. Tyson, M.S., C.C.R.P.; Cedric L. Truss, M.S.H.I.; Lasandra Patterson, C.C.R.P.

["A Quality Improvement Educational Initiative Created for and by the Clinical Research Coordinator and Nurse"](#)

Kesley D. Tyson, M.S., C.C.R.P.; Amanda M. Cook; Terrell Faircloth, C.C.R.C.; Rebecca Cleeton, M.P.H., C.C.R.P.; Brooke Hartwell, R.N., B.S.N.; and Liezl de la Cruz, C.C.R.C.

["A Multi-Institutional Clinical Research Training and Credentialing Tracking Database"](#)

Kesley D. Tyson, M.S., C.C.R.P.; Amanda M. Cook; Bridget Strong, M.B.A., C.C.R.P.; and Terrell Faircloth, C.C.R.C

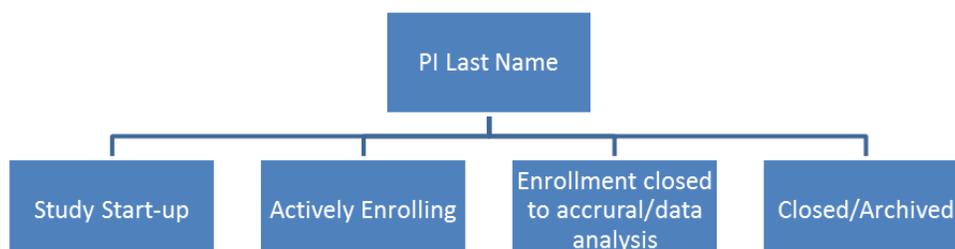


Kesley's Corner: Get organized!

Here are a few tips to help you get your team research shared drive organized.

- If you have multiple investigators, organize the folders by their last name. There are sure to be fewer PI's than there are studies. This helps to limit the amount of folders you have to click through to find studies. It also helps you learn who your PIs are and which studies they are working on.
- Once you have the folders organized and labeled with the PI's last name, each folder should include the following folders within it: "Study Start-up", "Actively Enrolling", "Enrollment closed to accrual/data analysis", and "Closed/Archived". Most studies will fall into these categories.
- The studies can then be labeled with whatever short name you have assigned it and placed into the appropriate folder.

A little organization goes a long way and being able to find your study information is half of the battle.



Gabapentin Trial - continued from page 1

Led by Drs. Nusz and Gettis, a pilot study was proposed and approved by Children's IRB with funding from the Friends Foundation. The double blind RCT study of adolescents (12-18yrs) examines the efficacy of gabapentin to reduce postoperative pain after ACL reconstruction compared to placebo (N=100). Twenty four patients have been recruited to date. Phone calls at 24 and 48 hours postop and completion of a pain diary during the first three days are used to assess pain, functional mobility, and side effects. Length of PACU/hospital stay, and unexpected hospital admissions also are examined.

The study's specific aim is to determine if one preoperative dose of gabapentin (15mg/kg (up to 600mg) will reduce pain and opioid use postoperatively for 3 days after ACL surgery. Surgeon variability has been minimized by limiting study eligibility to adolescent ACL patients of one experienced pediatric surgeon, Dr. Michael Busch. This study will (1) assess gabapentin's relief and opioid sparing effect; (2) describe patient symptoms and function/mobility in the early postoperative period; and (3) assess aspects of the postoperative course (length of stay, hospital readmission). The results of this pilot will provide the basis for a larger funded randomized clinical trial.

The study is an example of multi-disciplinary collaboration between Children's Anesthesiology Department, Children's Orthopaedics of Atlanta, as well as Children's Center for Pain Relief, Pharmacy and Nursing Research Departments. It addresses an important problem arising from clinical practice and provides an opportunity to make a contribution to scientific knowledge related to reduction of pediatric postoperative pain.

Dr. Ravi Patel "Causes and Timing of Death in Extremely Premature Infants from 2000 through 2011"

Current Atlanta Clinical & Translational Science Institute (ACTSI) [KL2 Mentored Clinical and Translational Research Scholar](#) and ACTSI Master of Science in Clinical Research (MSCR) graduate, **Ravi Mangal Patel, MD, MSc** is the first author of a paper entitled *Causes and Timing of Death in Extremely Premature Infants from 2000 through 2011* in the [New England Journal of Medicine \(NEJM\)](#). Patel graduated with a Master of Science in Clinical Research (MSCR) in May 2014. "I want to thank the Emory MSCR and KL2 program. What I learned has been invaluable, and I'm sure this played a large role in this paper as well as those of countless other students," said Patel, assistant professor of pediatrics at Emory University School of Medicine and Children's Healthcare of Atlanta.

In a large, national study of extremely premature infants, Patel and his colleagues found that death rates decreased from 2000 to 2011. An analysis of specific causes found that deaths attributed to immaturity or pulmonary causes and complicated by infection or central nervous system injury all decreased; however, deaths attributed to necrotizing enterocolitis (intestinal complication resulting from prematurity) increased. The research team prospectively analyzed data from 6,075 deaths among 22,248 live births, with gestational

ages of 22 to 28 weeks, approximately 12 to 18 weeks before their expected due date. The infants were born in hospitals within the 25-center Neonatal Research Network, supported by the Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH.

Read More at the [Emory News Center](#).



Ravi Mangal Patel, MD, MSc, at Grady Memorial Hospital NICU

Funding Call—Emory URC & ACTSI

Proposals exploring all aspects of clinical and translational biomedical research, including development of biostatistical methodology, bioethics, and assessment of new technologies will be considered. Potential applicants are strongly encouraged to contact the [ACTSI](#) office to discuss whether their proposed research project is consistent with the clinical translational goals of this support mechanism. The main review criteria are the fundamental merit of the proposal and the qualifications of the applicant to perform the proposed work. Other criteria also considered in the initial review and subsequent funding decisions are detailed in the general call for URC proposals. Applications will be evaluated for scientific merit by the URC Biological Sciences Subcommittee. Meritorious proposals will be evaluated for funding by a joint council of URC and ACTSI leadership.

For more information on the proposal, [click here](#).

Meet the JAMS Team - continued from page 3

CO-PRINCIPAL INVESTIGATORS:

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CO-INVESTIGATORS:

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STUDY TEAM:

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Division of Pediatric Rheumatology

Lai Hin Kimi Chan
Pralhad Lab Research Specialist
Emory University Bachelor of Science '16

Andrew Wiens, PhD Student
Electrical & Computer Engineering PhD Program
Georgia Tech, Technology Square Research Building



JAMS team: (L to R) Caitlin Teague, Lori Ponder, Daniel Whittingslow, Kimi Chan, Dr. Omer Inan, Dr. Sampath Prahalad, Dr. Patricia Vega-Fernandez