

Human Research Protection Program (HRPP) Newsletter

Spring 2014

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1. Welcoming New Leadership

Research at Children's is growing by leaps and bounds and we are fortunate to have the talent and leadership to meet the demands of a research portfolio with top ten ranking from the NIH. Please join us in welcoming the following new leaders to the research administration team here at Children's:

Farah Chapes recently transitioned into the role of VP, Research and Academic Administration. Previously Chapes served with the Children's Government Affairs team leading the state & federal Government/Community Affairs efforts for the Marcus Autism Center, as well as, Federal Legislative initiatives for Children's Healthcare of Atlanta system. In her new role, Chapes will partner with Paul Spearman, M.D., Chief Research Officer to oversee the research and teaching programs Children's funds in collaboration with its academic partners, Emory University School of Medicine, Morehouse University School of Medicine and Georgia Institute of Technology.

Kim LaBoone recently joined Children's as the Finance Director for Academic Administration. In her new role Kim has financial responsibility for Children's research and teaching programs, support of the Children's Pediatric Research Trust, and collaborations with our academic partners on financial matters. Kim is a certified public accountant and has significant grants and A-133 experience as the chief financial officer for the Cobb/Douglas Community Health Services Board. She also has over twenty-five years of experience in the healthcare industry with her tenures at Ernst & Young, KPMG, and more recently as the Director of Financial Services for Saint Joseph's Health System. Kim will work very closely with Farah Chapes and Kris Rogers.

Shanta Laurie is the new Manager with the Office of Sponsored Programs. Shanta recently served as Senior Grants Financial Coordinator with the Office of Grants Accounting. Shanta has extensive preaward research administration experience and will oversee the process of applying for funds, reviewing and accepting agreements and contracts and the set-up of grant activity accounts at Children's.

Shakeeta Nicholson was recently named the new Manager of the Office of Grants Accounting. Shakeeta has been with Children's for approximately four years, most recently as Senior Grants Financial Coordinator supporting the AFLAC Cancer and Blood Disorders Center (AFLAC). Shakeeta brings a wealth of knowledge through her experience with AFLAC.

2. What's In a Name- The "New" Office of Research Administration

The office formerly known as Grants Administration has a new name...The Office of Research Administration (ORA). Although the name has changed you can expect the same great service supporting research across Children's. *The Office of Research Administration is your first point of contact for help with new external research applications.* To learn more about the Office of Research Administration click here.

Congratulations to Lori Brown on her recent promotion to Sponsored Research Administrator, Sr. Lori is the primary research administrator for Scottish Rite but works on many studies active across Children's.

3. Updates for Research Coordinators- Conducting Research at CHOA

Proposal Routing Checklist

The Office of Research Administration released a new tool designed to aid coordinators and other collaborative research partners in routing research studies for institutional review and approval at Children's. The form outlines all required documentation and demystifies the process for all. The checklist can be found here.

SOCRA Exam at Egleston

<u>Saadia Khizer</u> has arranged for the SOCRA exam to take place at Egleston in October. The SOCRA Exam will be held at Egleston, Classroom 8 & 9, on Oct. 31st 2014 from 10 am to 1 pm. The registration deadline is September 19th, 2014. This exam provides you certification as a Certified Clinical Research Professionals (CCRP) in the clinical research community. If you have any questions please contact Saadia Khizer, Lead Research Coordinator, Hughes Spaulding.

Congratulations

Senior Research Nurse Cheryl Stone recently obtained the status of Certified Clinical Research Professional (CCRP). Cheryl is a seasoned research coordinator and her THAPCA study was recognized as the highest enrolling site for two year running (2012-2014). The THAPCA study is covered 24/7 by a team including coordinators from both the PICU and the CICU.

4. Policy updates from the IRB at Children's

Protocol Summary

The IRB is now requiring a Protocol Summary for all multi-site, full board (greater than minimal risk) studies. The template can be found on the IRB website and is called Protocol Summary Guidelines. The protocol summary should describe operations specific to the Children's study site (such as standard of care at Children's, the consent process and measures to ensure confidentiality of data) and provide IRB members with a synopsis of the proposed research that helps to address the criteria for approval as outlined in the federal regulations. Please be advised that applicable studies will not be processed without an appropriate protocol summary. Contact the IRB with questions about the new requirement.

Policy Highlight

Policy Highlight: 1.64 Oral Interpretation for Limited English Speaking Persons and Written Translation of Consent Forms for Research Children's has policies and procedures in place to accommodate the enrollment of non-English speaking subjects. Remember that if you encounter non-English speaking subjects unexpectedly, you can work with the IRB to enroll the subject using a short form consent and following procedures approved by the IRB and identified in the regulations.

5. Updates from the Office of Grants Accounting

Research Billing

Children's is currently updating processes for research patient billing. The first step in this process includes completion of the Research Visit Pre-Registration Form. This form is found on www.choa.org, click on Research at the top of the page then click on Research Visit Pre-Registration link on the menu to the right. You can also use this link http://www.choa.org/Pediatric-Research/Research-Visit-Pre-Registration.

Effective Immediately, please make sure to complete this form for all research visits that include a Children's billable, including procedures (technical) fees or physician (professional) fees. This must be completed at every visit associated with your clinical research study. You should complete this form at the time of consent and before the end of that business day for all new patients entering a clinical research study that includes billables. For subsequent research visits, the form should be completed in advance of the scheduled visit and no later than the time of visit. Completion of this form is mandatory.

Research Billing...continued

You should continue to complete patient trackers and forward to OGA via email/fax (oga@choa.org or 404-785-9470). As a reminder, both technical and professional activities should be included on your tracker.

Patient Care Quotes/Pricing

Patent care request or research pricing inquiries should be sent to oga@choa.org. Please contact OGA for research pricing for both Egleston and Scottish Rite.

NEW OGA invoicing process

Effective immediately please send your invoice requests to OGAinvoices@choa.org. this would include the ancillary departments requesting invoices to OGA for internal billing, as well as external entities sending invoices to the CHOA Office of Grants Accounting for payment. The new address should be used for invoicing for all studies across all Children's campuses.

6. Children's Investments in Research Infrastructure Leverage for Climb to #5 in NIH Funding

Children's primary academic partner, the Emory Department of Pediatrics, has achieved No. 5 in the 2013 National Institutes of Health (NIH) rankings for pediatrics, exceeding a joint goal to reach the top 10 by 2018. Recently funded NIH projects include those at the Marcus Autism Center and the Aflac Cancer and Blood Disorders Center. This achievement is no small feat and Children's investment in the research infrastructure to support this growth takes place across the Children's enterprise. Since the release of the strategic plan outlining the path to achieving the top ten ranking in 2007 Children's:

- nearly quadrupled clinical and non-clinical staff supporting the research enterprise at Children's (pharmacy, coordinators, research lab, finance, legal affairs, academic administrations etc..)
- supported the construction of the new state of the art <u>Health Sciences Center Research Building</u> at Emory University
- launched the <u>Pediatric Research Center</u> in partnership with the ACTSI to provide the inpatient and outpatient facilities available for investigators engaged in pediatric clinical research
- developed the Marcus Autism Center into a nationally recognized <u>center of excellence</u> for the provision of coordinated and comprehensive services for children and adolescents with developmental disabilities
- <u>committed over \$75 million</u> to establish seven pediatric research centers of excellence
- codified research partnerships with The Emory and Georgia Tech to increase funding and collaboration for pediatric translational research
- invested significant time and resources to support re-implementation of the Lawson Grants
 Management system for more accessible award management, tracking and reporting

The examples above only represent a fraction of the effort and investment Children's continues to put forth to support the dynamic pediatric research agenda of the Emory+Children's Pediatric Research Center. As we continue to grow in our ability to undertake life changing pediatric research, we look forward to continuing our climb towards research excellence and closer partnerships with our supporters and collaborators.

About the HRPP Newsletter

This newsletter has been created by members of the academic administration and clinical research at Children's Healthcare of Atlanta. It offers news-worthy topics, helpful regulatory tips, updates to policies, and guidelines for others involved in clinical research. Submit materials for the next edition here.

Office of Research Administration
Office of Sponsored Programs
Office of Grants
Accounting

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New Address: 1687 Tullie Circle, Atlanta, GA 30329

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