Pediatric Institute Transition – FAQs Related to Research

Main contact: Nadine Spring

General Mailbox: PedsClinicalResearch@emory.edu

Q: What is the Pediatric Institute?

A: The Emory and Children's Pediatric Institute is an affiliation that represents an investment on behalf of both institutions to ensure a long-term and sustainable future. With our faculty and mission at the forefront, the Institute's goal is to improve the lives of children in Georgia and beyond. The Pediatric Institute is not a grant or gift accepting institution.

Q: Can I route my grant through the Pediatric Institute?

A: No. You can route your grants through either Emory or Children's. Further details are below.

Q. How do I describe the Pediatric Institute in the facilities, resources, and environment section of my grant application?

A: You should not mention or describe the Pediatric Institute in the grant application. You should continue to describe the environment at Emory, Children's and any other location of the research. See this link for boilerplate you may use for this purpose-
http://www.pedsresearch.org/uploads/blog/doc/InstitutionalEnvironment-Boilerplate.docx

Q. How should I describe my relationship with the Pediatric Institute in my biosketch?

A. You should not include a reference to the Pediatric Institute on your biosketch. The institute does not change your affiliation related to grant submissions. Emory faculty members will continue to list Emory University as the academic employer.

Q. Is there any part of the grant application that will describe or mention the Pediatric Institute?

A. There may be instances where a brief explanation of the Pediatric Institute will be required in the budget justification. Emory OSP and the RAS will provide guidance and input as needed.

Q. How should I list my affiliation with the Pediatric Institute on my manuscript?

A. The Pediatric Institute is an inward facing entity. Please do not list it on grant applications and manuscripts. Instead, you should continue to use the separate institute affiliations including Emory University Department of Pediatrics and/or Children's Healthcare of Atlanta. You should continue to describe the environment at Emory, Children's and any other location of the research. See this link for boilerplate you may use for this
purposehttp://www.pedsresearch.org/uploads/blog/doc/InstitutionalEnvironment-Boilerplate.docx

Q: What has changed?

A: There are some changes to the way some research projects are routed through Research Administration at Emory and CHOA. Pediatric Institute employees with an industry sponsored clinical trial or a Children's Oncology Group (COG) funded study should route these studies through Children's rather than Emory. This change eliminates the duplicate effort in the previous method resulting in more efficient processing.

Q: When does the transition start?

A: The Pediatric Institute launched on September 1, 2018. However, on June 1, 2018, Children's began to take responsibility for certain clinical trial contracting activities and IRB oversight. The transition period allowed time to negotiate the agreement with the sponsor in advance of the Pediatric Institute launch date of September 1, 2018. Now that the Pediatric Institute launch is complete, all new approaches are in effect.

Q: Whom does this change affect?

A: This change affects Children's clinicians who also have an Emory academic appointment. It affects which entity (Children's or Emory) manages your award. It also affects how you certify your effort. Effort related to industry sponsored clinical trials or a Children's Oncology Group (COG) funded study are now certified through Children's. All other effort certification will continue to be managed through the Emory system.

Q: Which studies do I need to submit to CHOA?

A: The following should be routed to and are managed by Children's:

- Industry Sponsored clinical trials (Non-investigator initiated) taking place at CHOA facilities.
    - If your industry sponsored clinical trial uses and Emory research coordinator, the study should still route to CHOA, but you will need a sub-contract or preferably a service agreement to cover the Emory research coordinator's time.
- Children's Oncology Group (COG) funded studies.

Q: What studies should I submit to Emory/Pediatric RAS?

A: The following should be routed to and are managed by Emory/Pediatric RAS:

- Investigator initiated clinical trials that are supported by industry, provided the Emory faculty PI holds the IND or IDE. For more details about the submission process for these studies, contact Margaret Huber.
- Industry sponsored clinical trials taking place at non-CHOA locations such as Emory Midtown, Ponce Clinic, Grady, or leased Emory space.
- Federally funded research (i.e. NIH funded studies).
- Research funded by foundations and other sponsoring agencies.

Q: From which IRB do I need to seek approval?

A: You should submit your study to either Children's or Emory's IRB based on the routing pathway as stated above. In some cases, a study will need to be submitted to an external IRB. In addition:

- If your study involves both adults and children, you should submit it to Emory. A subcontract would be executed for the Children's services.

- If your study involves a chart review using only Children's medical records, you should submit it to Children's IRB.
- If your study is a chart review that includes interviews or surveys with Children's patients and their caregivers you should submit it to Children's IRB.

Contact us if you have questions or need further clarification.

Q: What do I need to do?

A: Be sure to submit your studies to the appropriate institution. We understand change can be confusing and we are here to address your concerns and questions. Please reach out to Nadine Spring with any questions.

Q: How do I submit my studies?

A: If your new study needs to be submitted to Children's, please submit it here.

If your new study needs to be submitted to Emory, please submit it here.

Q: How does this change impact my research studies?

A: These changes are to enhance our efficiency in clinical research. We anticipate that these changes will result in faster award processing and shorter times from submission to enrollment.

Q: Whom do I contact?

A: We look forward to working together under the Pediatric Institute. For questions, concerns, or comments, feel free to contact:

CHOA	**Emory**
Stephanie Meisner Director, Clinical Research E: stephanie.meisner@choa.org P: 404-785-6453	**Nadine Spring** Director, Clinical Research Services E: nadine.spring@emory.edu P: 404-727-5234
Sarah Marie Huban Director, Research Administration E: sarahmarie.huban@choa.org P: 404-785-7477	**Chloe Shay** Interim Director, Research Administration Services (RAS) E: chloe.shay@emory.edu P: 404-712-1683
	Liz McCarty Executive Admin & Vice Chair for Administration E: mmccar2@emory.edu P: 404-712-8226

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Additional Children's research contacts are as follows:

Children's Research Administration supports Children's cost centers, service lines and other strategic research focus areas by partnering with research investigators, research coordinators, and the Office of Sponsored Programs (OSP) and Grants Accounting for proposal submission, award negotiation, award management and close-out. Research Administration is the liaison between the cost centers/service lines and Office of Sponsored Programs and Grants Accounting.
General Mailbox: GrantsAdmin@choa.org Manager: Chee-Chee Manghram

The Children's Office of Sponsored Programs provides guidance and assistance in the process of applying for funds, reviewing and accepting agreements and contracts and setting up grant activity accounts once an award is made.
General Mailbox: osp@choa.org Manager: Tanya Blackwell

The Children's Institutional Review Board (IRB) is a committee that helps protect the rights and welfare of human subjects in research.
General Mailbox: irb@choa.org Manager: Sarah Marie Huban

Children's Research Compliance performs assessments to improve study practices, prevents research non-compliance and misconduct, provides education and informs researchers about regulations, policies and State laws.
Manager: Emily Smotherman

Additional Emory research contacts are as follows:

Office for Clinical Research (OCR)
General Mailbox: OCR@emory.edu

The **OCR Education and Outreach** team hosts Research Matters quarterly and provides mandatory and other clinical research training for Emory investigators, research nurses, and clinical research coordinators (CRC).
Contact: Bridget Strong at bstrong@emory.edu or (404) 778-2975.

The **OCR Pre-Award** team reviews Emory clinical trials and clinical research with EHC and Grady (excluding Pediatrics) billable items and services (CPT-driven) for Medicare billing compliance. They develop a Prospective Reimbursement Analysis (PRA) for these studies to clearly identify which study-related items and services can be billed to third party payor according to CMS regulations. They also develop and negotiate financially viable study budgets for Emory non-federal clinical trials (excluding Pediatrics) to cover all costs identified in the protocol, informed consent document, clinical trials agreement and sponsor's budget.

Contact: Pam Terry at pgterry@emory.edu or (404) 778-2973.

The **OCR Clinical Research Support Services** team facilitates pre-award approvals for Emory industry clinical trials and just in time for federally funded clinical trials (excluding Pediatrics) across Office of Research Administration departments, providing quarterly performance metrics by department.
Contact: Sherry Coleman at scole23@emory.edu or (404) 727-4371.

The **OCR Clinical Trials.gov Service Center** handles ClinicalTrials.gov inquiries, registration, updates, and results reporting for Emory-sponsored, investigator-initiated research, facilitating compliance with FDA regulations, and NIH and ICMJE requirements.
Contact: Jennifer Prozonic at jprozon@emory.edu or (404) 778-3840

The **OCR Data Integration and Integrity** team supports patient safety and research billing compliance by activating Emory clinical trials in the Emory Research Management System (ERMS) and the Emory Electronic Medical Record (EeMR), and uploading study documents to EeMR including the Clinical Research Key Points, Investigational Drug Information Sheet, and PRA. Once the CRC enters the subject in ERMS, OCR flags the subject in EeMR as participating in a clinical trial to place all charges on 100% bill hold and uploads the signed informed consent document.
Contact: Vickie Swafford at vswaffo@emory.edu or (404) 778-4521

The **OCR Invoicing** team invoices the sponsor for all Emory industry sponsored clinical trials and other clinical trials/research (excluding Pediatrics) if the sponsor requires an invoice for payment of CPT driven items and services. For these studies, OCR performs invoicing to the sponsor, accounts receivable, accounts payable, and monthly reporting to the PI and study team.
Contact: OCR_Invoicing@emory.edu.

The Emory Office of Sponsored Programs handles non-industry contracts, and awards for federal grants, foundation grants, corporate grants (to formal grant programs), and government contracts.
Contact: Holly Sommers

The Emory Office of Technology Transfer (OTT) handles agreements with industry partners.
Contacts: Cale Lennon and Tammie Bain

The Emory Institutional Review Board is a team that ensures the protection of human subjects in research.
Contact: Rebecca Rousselle