



## Pediatric EducAtion Research Lunch Series (PEARLS)

Ancillary Services in Clinical Research
December 13, 2019

## Services Available at Emory

Courier from CAP to HSRB

• ECC-RU

• PEARLS

Sponsored Accounts

CCTR Co-Directors



## Specimen Courier from CAP to HSRB

Three hour weekday service from CAP to HSRB (non-urgent samples)

Log samples that are left at CAP

Online forms of documentation

Date	Time	Name	Sample Location (circle)
			Refrigerator or Freezer

-----To Be Filled Out By Courier Connection ONLY------

Sample Pickup	
Date	
Time	
Courier Initials	

Sample Drop-off	
Date	
Time	
Courier Initials	



#### Children's Clinical and Translational Discovery Core



The Children's Clinical and Translational Discovery Core offers laboratory and technical assistance to investigators conducting basic science, epidemiologic, translational, and clinical research. Our mission is to support and compliment the research efforts of investigators by providing laboratory research services, technical assistance, and access to biological samples that represent a variety of diagnoses and healthy volunteers.

#### **Biorepository**



Access to a variety of human biological specimens from both healthy control participants and patients with a variety of diagnoses.

- Emory University IRB approved Protocol, Consent, and Assent
- > Biospecimen Collection Services



#### **Correlative Biology Studies**

Support and advice on the conduct of clinical trials from initial study design and planning through the implementation and interpretation of molecular assays of drug targets and genomic correlates of disease.

This includes, but is not limited to:

- > Biological Sample Analysis
  - Cell-Based Assays
    - > Custom Experimental Design

#### **Clinical Trials Support**

Clinical sample processing and storage services for their subsequent use in hypothesis-driven clinical research.

- > Study Design Consulting
- > Sample Collection Kit Building
- ➤ Biospecimen Processing
- ➤ Biospecimen Storage
- Sample Distribution



#### **Key Contacts and Location**

- Core Director: Christopher C. Porter, MD chris.porter@emory.edu
- Laboratory Director: Brad Hanberry, PhD bradley.hanberry@emory.edu

Emory Health Sciences Research Building (HSRB)

2nd Floor, Rm E264

## Emory Children's Center – Research Unit (ECC-RU)

- First floor of the Emory Children's Center. Badge access is needed
- Research staff workroom, storage room, phlebotomy chair, two exam rooms, and a consult room

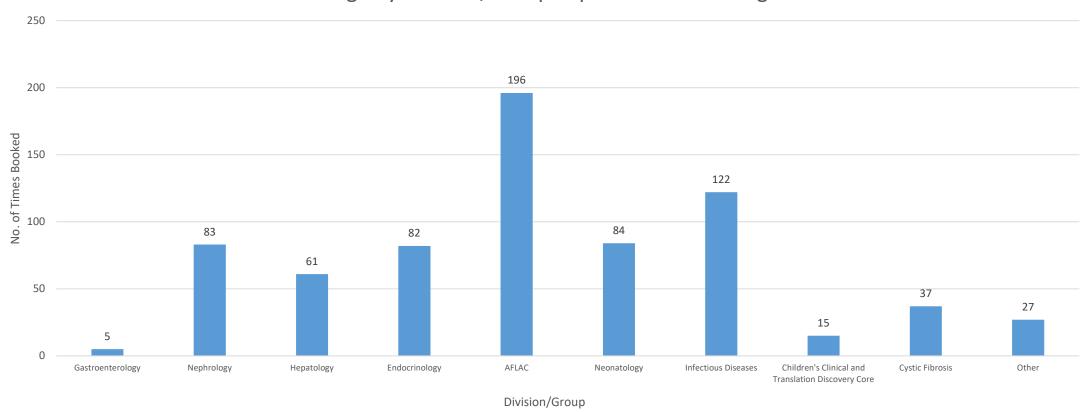
Basic clinical supplies are supplied, but teams are responsible for

providing anything further



## ECC-RU Usage

ECC-RU Usage by Division/Group September 2018- August 2019



## Emory Children's Center – Research Unit (ECC-RU)

• \*\*\*Due to space constraints, study monitors are sometimes in the research unit.

 Use the self-service online scheduling system to request rooms for a research visit

- Part time phlebotomist is available for research studies
  - Do not ask the transplant or infusion teams for assistance with phlebotomy

#### **PEARLS**

Monthly, 2<sup>nd</sup> Friday of the month at noon with lunch provided

Remember to RSVP two days prior to the event

 Created specifically for CRCs/CRNs working in Pediatrics a CHOA

Get involved – help to identify and coordinate speakers



## **Emory Sponsored Accounts**

For CHOA employees who need access to Emory's systems

- Emory Learning Management System (ELMS)
- Remember your passwords

Annual renewals



## CCTR Co-Directors – October 1, 2019

 Claudia Morris, MD - Professor of Pediatrics & Emergency Medicine and Research Director for the Division of Pediatric Emergency Medicine has been involved in clinical and translational research for over 2 decades



 Miriam Vos, MD, MSPH - Professor in the Division of GI, Hepatology and Nutrition and Director of Graduate Studies for the Nutrition & Health Sciences Program in the Laney Graduate School



PEARLS Presentation in January



#### Research in Radiology

#### Jack Goldberg, MS

**Research Coordinator** 

**Department of Radiology** 

#### **Radiology Services**

- Imaging at SR and EG
  - General Diagnostics (also at CAP)
  - MRI
  - CT
  - Ultrasound
  - Nuclear Medicine
  - Interventional Radiology

- Grant Pricing
- Feasibility Forms
- Imaging Transfer

#### **Start-Up Process**

- Feasibility Forms Phantom/Qualification scans
  - Sometimes required by Sponsors
  - Send directly to Jack
- Research Protocol Review Form (RPRF)
  - All studies with a radiology component should have there protocol reviewed by Radiology.
  - This ensures we can accommodate your study and prepared when your first patient arrives in our department.
  - Submit form to Jack Goldberg
    - Include a final protocol and imaging manuals
    - Find form at Careforce → Departments → Radiology → Radiology Research
- Department Approval Forms (DAF)
  - Contains information for:
    - Initiation Fees
    - Maintenance Fees
    - Technical Fees
    - Professional Fees

#### Fee Schedule - What It Covers

#### Study Initiation (\$750)

- Review protocol
- Prepare budget
- Protocol training
- Feasibility forms
- Qualification scans
- Build sequences onto scanners

#### Study Maintenance (\$50/m)

- Maintain study materials
- Phantom and QC scans
- Data Transfer Forms
- Transfer of scans to sponsor
- De-identified disks
- Reading guidelines for Radiologists

<u>Technical Fees</u> – cost of performing the scan <u>Professional fees</u> – cost of reading the scan

#### Department Approval Form (DAF) - Radiology

Initiation Fee	■ Waived ■ \$750 one-time charge				
Maintenance Fees	Not Applicable Waived \$50/month when services are usedpatientsscans each =possible months				
Procedure Name	CPT	Egleston Technical Fee	Interpretation Fee	Scottish Rite Technical Fee	Scottish Rite Interpretation Fee

List name and CPT code for each scan or procedures:

### Research Protocol Review Form (RPRF)

	General	
1	At which CHOA locations will the radiology procedures be performed?	☐ EG ☐ SR ☐ WB ☐ TC
2	What is the target enrollment number for the CHOA site?	
3	Provide an age range of your target population.	
4	Is a CHOA Radiologist a co-investigator on this study?	YES NO
4a	If yes, provide the name(s) of the radiologist(s).	
5	Does the Sponsor supply an Imaging Manual or a document with imaging instructions that exists separate from the protocol?  Note: Please confirm with Sponsor. Provide a copy with this completed form. If a manual is supplied AFTER the review, a new review will be required and may change the outcome of the first review.	YES NO
6	Does the sponsor require or suggest Radiology complete training specific to your protocol?  Note: Please confirm with Sponsor. If yes, please ask Sponsor to email an outline of the training requirements to the radiology coordinator.	☐ YES ☐ NO
7	Does your Sponsor require any Phantom or QA scans performed at the initiation or during the duration of the study?  Note: Please confirm with Sponsor.	YES NO
8	Will sedation be used on all or some of the patients enrolled in this study?  Note: This includes sedation ordered for research or as clinically indicated.	Yes, as clinically indicated Yes, IRB approved/pending No sedation
9	What modalities will be used during the research study? For each modality marked, complete the corresponding sections below.  MRI: MRI, MRA/MRV, Cardiac MRI Nuclear Medicine: PET/CT, PET, MIBD, DXA, Bone Scan, Liver SPECT Interventional Radiology: Liver Biopsy, Fluoroscopy  If you require tumor imaging and specific scans are unknown at the start of the study, select each modality that may be used.	X-Ray MRI CT Nuclear Medicine Ultrasound Interventional Rad.
10	How will data be transferred from Radiology to Sponsor?  Ex. de-identified disk, sFTP, online upload, Rad report printed from EPIC, etc.	
10a	If online uploading is required, who will be the one uploading the data?	
10b	If data is being uploaded, what website will each scan be uploaded to?  Ex. MRI to Resonance Health, DEXA to Bioclinica, etc.	
11	Will you need a waiver of a clinical read on any scans performed in this study?	YES NO
11a	If yes, list which scans should not be read by CHOA Radiology.	
11b	If yes, is there a Central Reviewer who will be reading the images?	YES NO
11c	If yes, when will the Central Reviewers read the images (i.e., 2 days, 2 years)?	
11d	If yes, will the Central Reviewers let CHOA know if there are any incidental findings?	YES NO

### **RPRF – Modality Specific**

	Magnetic Resonance Imaging (MRI)				
1	What pages in the protocol discuss MRI?				
	What MRI procedures are requested?				
	List out individual orders.				
	MRI Brain without contrast				
2	MRI spine with and without contrast				
	MR Spectroscopy of extremity				
	If you require Tumor Imaging and specific scans are unknown at study start-				
	up, enter "Tumor Imaging."	26			
	How many times are the patients scanned throughout the study?	Min:			
3	Provide minimum number of individual scans required for a single patient.	Max:			
	If maximum number of scans varies from patient to patient depending on cycles, subgroups, etc., mark as such.	Varies from patient to patient			
4	Does the study require a morning or early afternoon scan?	YES NO			
4a	If yes, explain why it is required.	TES NO			
та	Is an MRI required at the screening visit (or first visit of the study)?				
_	Note: The wait list for an MRI is two-three weeks. Please be sure to allow				
5	enough time between patient enrollment and screening visit to accommodate	YES NO			
	the busy MRI schedule.				
6	Do you require Radiology to complete Data Transfer Forms (DTF) or Research	□ YESM □ NO			
0	Forms for each patient scan?	I IES INO			
	Does the protocol request the reading Radiologist to provide certain	□ YESM □ NO			
7	measurements or information in the radiology report?	Waiver Requested			
	If no, Radiology assumes we will perform our SOC reading protocols.				
7a	If yes, describe reading requirements.				
8	Any additional comments concerning scan(s)?				
	Radiology Use Only				
1	Is there an imaging manual for MRI?	YES NO			
2	Does the Sponsor require Phantom/QC Scans?	YES NO Initial			
		Ouarterly <sup>M</sup>			
2a	If yes, at what interval?	Monthly <sup>M</sup>			
La	ii yes, at what interval:	AnnuallyM			
		Other:			
3	Will Radiology perform a clinical read?	□ YES □ NO			
3a	If no, who approved the waiver?				
4	Will the study team need a de-identified disk or data transfer?	☐ YES <sup>M</sup> ☐ NO			
5	Is a specific scanner required?	YES NO			
5a	If yes, which one?				
6	Do the requested procedures match our SOC imaging protocols?	YES NO			
ба	EG Radiology Review:				
бb	SR Radiology Review:				
7	Will radiology perform specific reading requirements?	YESM NO			
7a	EG Radiology Review:				
7b	SR Radiology Review:				
8	Additional comments:				

#### RPRF – Order Specific Language

Below is the information that should be inserted by the ordering physician(s) when the order is placed. Information goes into the comments section of the order form. This information allows radiology to know this is a research scan and what procedures to perform. It also allows radiology to prepare properly thus limiting any disruptions in our clinical workflow.

Radiology Order Form Comments Section		
X-Ray		
MRI		
CT		
Nuclear Medicine		
Ultrasound		
Interventional Rad.		

#### **Processes During Study**

- Notify radiology of NOA
  - We need to know when enrollment will start
- Order research scans the same way you would order a clinical exam (EPIC or Paper form)
- Include the research language in the comments section of the order form
  - See RPRF results (ex. Research PTC: see imaging manual. Perform on Prisma)
- If your study is a non-SOC exam, email radiology about upcoming visits
  - This helps us prepare for more complicated studies
- If you need a specific date/time, email Victoria Allen
- Send Radiology updated protocols and imaging manuals
- Billing to a research sponsor: submit patient trackers. Be sure to include technical and professional fees

#### Tips/FAQ/Frequently Seen Issues

- Non-SOC vs. SOC radiology exams
  - It's not just about frequency or who pays. It's also about the kinds of images requested.
- Poor communications
  - No Imaging Manuals provided or notice of radiology required training
- No notice of enrollment
  - Many of your non-SOC exams are built onto our scanners. We don't build them until we know enrollment is about to start.
- Poor description of procedures
  - A Brain MRI is not a enough of a description. Is contrast requested?
  - Fluoroscopy is not a enough of a description. Where on the body do you need it?
- Always include study name in the subject line of an email.
  - I oversee 120+ studies. I don't remember which study is yours by your name alone.

#### **Contact Info**

- Jack Goldberg, MS
  - Jack.Goldberg@choa.org
  - Work: 404-785-2527
- Office Locations
  - EG: Ground Floor Radiology Administration office
  - SR: Radiology Department Team Work Room office

#### **Questions?**



# CARDIOVASCULAR IWAGING RESEARCH CORE (CIRC)





Pediatric Research Alliance

## OUR MISSION

- Increase quality of data collection for imaging research protocols
- Provide an environment that is protected from clinical activities
- Allow imaging modalities to be utilized for additional studies in non-traditional settings
- Increase scientific productivity





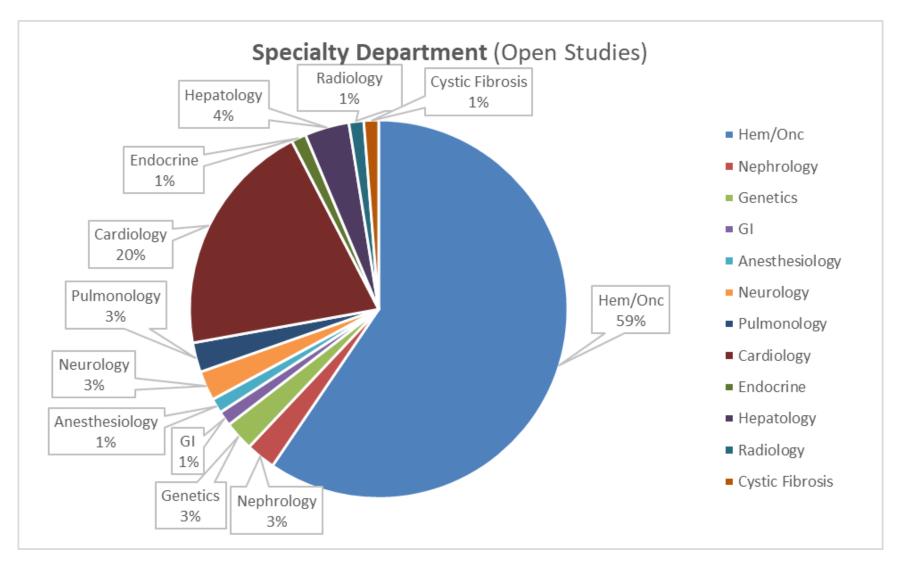
## WHAT IS AN IWAGING CORE LAB?

- A "core" facility is a shared resource, containing capabilities (technical, equipment, knowledge) that can be used by multiple users and is applicable to multiple studies.
- Key characteristics
  - Defined space
  - Central focus
  - Specific user group
- We are one of three pediatric core imaging labs in the nation recognized by the American Society of Echocardiography (ASE).
  - Children's Healthcare of Atlanta
  - Cincinnati Children's Hospital Medical Center
  - Children's Hospital of Wisconsin





## CUSTOMER BASE





## SERVICES OFFERED

#### **Technical**

#### **Echocardiograms**

- Complete & Limited Non-Congenital
- Complete & Limited Congenital
- Flow Doppler
- 3-D Imaging
- Strain and tissue Doppler functional Imaging
- Vascular/ Carotid Assessment

#### Stress Echocardiograms

- Upright Bicycle
- VO<sub>2</sub> Analysis

**Exercise Stress testing** 

Electrocardiograms





## SERVICES OFFERED CONT.

#### **Data Analysis**

#### **Administrative**

Cardiac MRI (logistical & analysis)

Non-Invasive Imaging Protocol Development

Consultative Expertise (Cardiology, Sonography & Research)

**Research Imaging Software** 

Post-processing capabilities

Dedicated Research Exam room

Image Transfer and Upload





## WHAT WE DO

- Develop study protocols
- Monitor sonographer training and image quality for adherence
- De-identify and transfer studies for analysis to Vendor-Neutral platform
- Assess analysis data for outliers
- Monitor and manage IRB requirements for imaging physicians and sonographers
- Reconcile activity trackers and invoices
- Prepare study budgets to include appropriate CPT codes and charge structure.





## OUR CONTRIBUTIONS

- Abstracts and Podium presentations:
  - **CHOP Cardiology**
  - American Society of Echocardiography Scientific Sessions
  - Southeastern Pediatric Research Conference
  - Society of Cardiovascular Magnetic Resonance
  - American Society of Pediatric Hematology/Oncology COG
  - **American Academy of Pediatrics**
  - **American Heart Association**
  - American College of Cardiology
- Workgroups and collaborations
  - **ACC-ACPC** Quality network Metrics
  - Society of Pediatric Echocardiography Sonographer Collaboration
  - PHN-Echo Z-score study
  - COG DVD Registry Long-term survivorship (428 ++ studies)





#### NON INVASIVE CARDIOLOGY REQUEST FORM

Children's Healthcare of Atlanta The Heart Center CIRC **EglestonCampus** 

1405 Clifton Road, N.E. Atlanta, GA 30322-1101 Office (404)785-6476 Fax(404) 785-1277

Patient Name:	_
DOB:	
Diagnosis:	
MRN:	
Account/HAR#:	

Study NameLocation SREG		
Parent/Guardian's Name:	Phone:CellWork:	
Address:	City:State: Zip:	
Guarantor Name: Guara		
Guarantor Phone: Relations	hip to Patient:	
Insurance/Medicaid Plan: Poli		
*Please note: Outpatients that require prior authorization must hav	• • —	
Authorization #: CPT:		
ECHOCARDIOGRAMS _Echo Complete (Congenital)	ELECTROCARDIOGRAMS _ Electrocardiogram	
Diagnostic questions: Each individual procedure code order	_ Vascular Exam (RESEARCH ONLY)	
Special requests or instructions? Sedation:YesNo		
Inform CIRC office if pt is late or rescheduled before appoint	ment time so appropriate accommodations can be made	
	ointment to be scheduled and confirmed	
Ordering Physician's Signature/Date (REQUIRED):		
Print MD Name:	Coordinator Name	
Practice Name:		
	Coordinator Phone	
Procedure Date & Time	-	
Office Use Only		
DATE AND TIME OF APPOINTMENT:	SCHEDULED BY:	

## SCHEDULING

#### Scheduling with CIRC Services:

- Please give us at least 2 business days to schedule your appointment
- Fill out the form completely and legibly





Amy Park, MPH, Research Coordinator

Deanna Hill, CCRP. Research Coordinator

Joan Lipinski, MHS, RDCS, FASE, Manager

Dr. Ritu Sachdeva, MD, Medical Director

Sassan Hashemi, MD, Imaging Processing Scientist



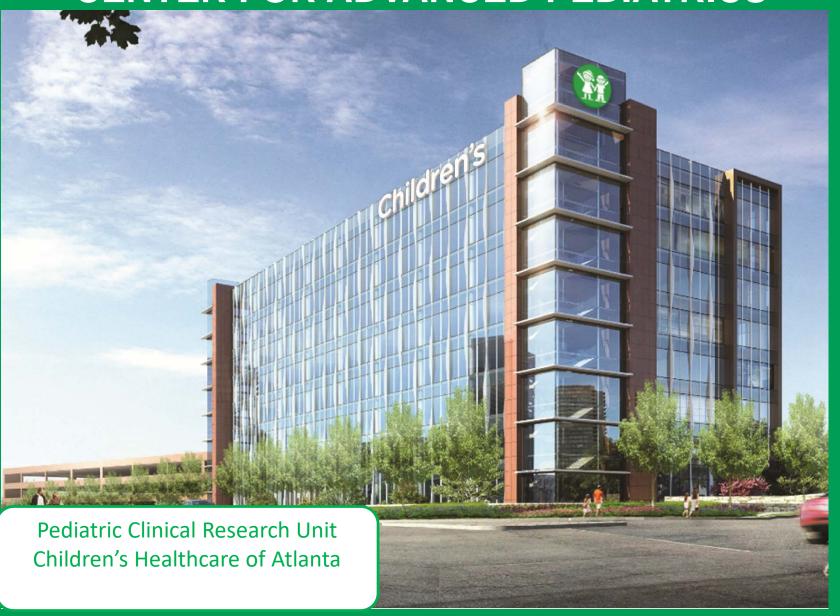
# Pediatric Research Unit at Center for Advanced Pediatrics

Cheryl Stone, RN, CCRP
Lead Research Nurse
Children's Healthcare of Atlanta
Pediatric Clinical Research Unit
Center for Advanced Pediatrics





#### **CENTER FOR ADVANCED PEDIATRICS**

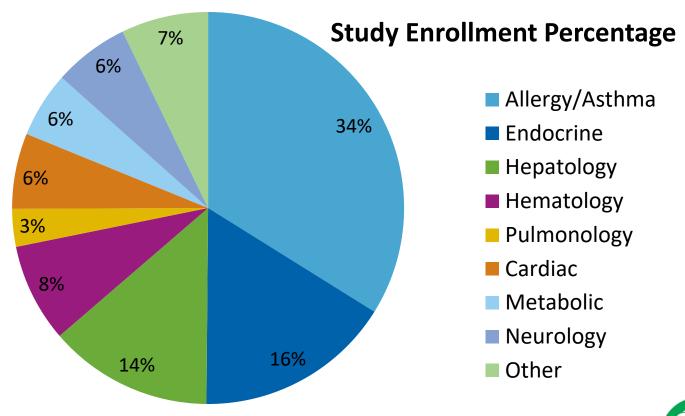


## Research in the Center for Advanced Pediatrics

- 7 Highly skilled, PALS certified staff
- 4,237 sq/ft of Clinical Space
- 6 dedicated exam rooms
- Intake Room
- Consult room
- 8 dedicated computer work spaces for Coordinators
- 2 Docking Stations

- Central Lab for clinical lab resulting
- CHOA Research Lab for processing and shipping
- Radiology Services on 1<sup>st</sup> floor
- Parking garage with 1120 spaces
- Virtual in-patient rooms at Egleston
- 672 sq/ft Investigational Drug Pharmacy within the Unit

#### Pediatric Research Unit Studies by Specialty





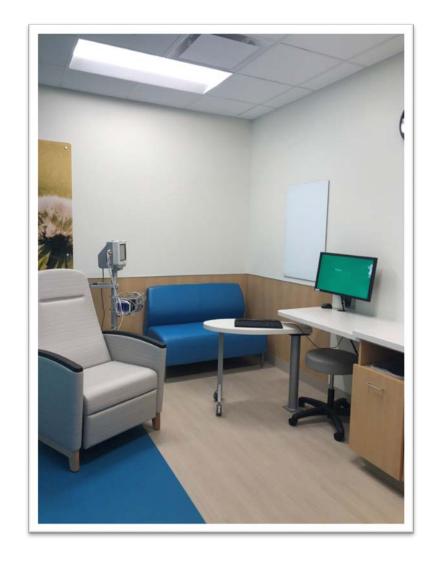


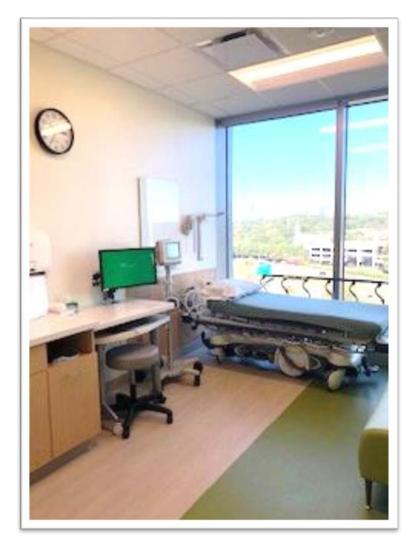
# **Outpatient Pediatric Research Center**

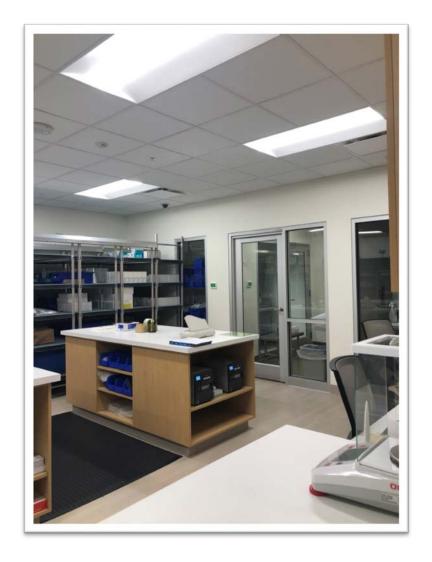




# **Patient Rooms at CAP**







# **Pharmacy at CAP**

# Services Provided by Research Staff

- Protocol Review
- Conduct Study Round Tables
- EPIC order development
- CR-Assist Study Build
- CR-Assist Coordinator Training
- Patient Scheduling
- Carry out all aspects of protocol

## **Other Services Provided**

- Phlebotomy Services
- Perform ECGs in PRU
- Room Utilization Only Option
  - X-rays available in CAP
- Protocol training for In-Patient staff



# How do I get my study in PRU?



# **First Steps**

Email Study Protocol to Grants Administration.

This allows Research Administration to assess for feasibility, begin the CHOA budget and department routing needs.

 Department Approval Form (DAF) and budget request forwarded to Pediatric Research Unit.

This begins the process for the PRU. A thorough review of protocol is conducted and budget provided. A signed DAF and budget will be sent to OGA.



# **Scientific Advisory Committee (SAC) Submission This starts the ball rolling for PRU staff**

Georgia CTSA protocol submission information: http://georgiactsa.org/discovery/protocol-submission.html

Click the link to file SAC application in Emory Redcap https://is.gd/SACapplication



You will need the below items to upload into REDCap during the SAC application:

- Copy of Protocol/Research Plan
- Emory IRB letter of approval (if available, can route still if IRB pending)
- IRB-approved consent forms. If you do not have the IRB-approved consent, a draft version will be accepted.
- PI Biosketch if new team
- DRAFT Day to Day Order Sets (see below for template information).

## **Round Table Meeting**

- Request to schedule a Roundtable Meeting with Clinical Research Unit after SAC approval letter received & draft orders turned in.
- Roundtable meeting day/times are typically Tuesdays thru Thursdays, Noon-1pm. Other day/times are available.
- WebEX will be an option for those partners that are not able to attend the Round Table in person.
- Those invited to attend the Round Table are to include the following: PI, Sub-I, Coordinator, Lead or Backup Coordinators, Pharmacy, Research Lab, CIRC, Technology team, Finance team



## What to Expect During and After Round Table Meeting

#### **During Round Table**

- Study overview given by PI
- Checklist reviewed (IRB approval, SAC approval, credentialing at CHOA completed, etc.)
- Each order set reviewed in detail to ensure protocol compliance and accuracy

#### **After Round Table**

- All edits and changes to order sets finalized
- PI will verify order sets for accuracy
- Order sets are sent to EPIC team for build
- Order sets go LIVE in EPIC
- PRU team builds the study visits in CR-ASSIST
- PRU team provides training for Coordinators for CR-ASSIST

## **Order Sets**

- Submit draft order sets to the Clinical Research Unit at above email addresses for edits
- Draft order sets are due 2 weeks prior to roundtable meeting. Use CHOA PRU Day to Day Order Set Template found here: http://georgiactsa.org/discovery/protocolsubmission.html
- Order sets should be in a 'close to final' state requiring only minor modifications and additions when they are submitted to the PRU staff

## **Final Step**

The final step that MUST take place before we can schedule patients in the

Pediatric Research Unit ......

#### YOU MUST HAVE A

**CHOA** 

**NOTICE OF AWARD (NOA)** 



For questions regarding Clinical Research
Cheryl Stone, RN, CCRP
Lead Research Nurse
Clinical Research Center
Children's Healthcare of Atlanta
404-785-6454
Cheryll.stone@choa.org







## **Laboratory and Pathology Clinical Research Core**

**Clinical Research Processing** 

### **Services**

- Sample Processing and Shipping of:
  - Plasma and Serum
  - PBMCs
  - Urine
  - Stool
  - Tissue
- Monitored freezers and short term storage
- Clinical Research Pricing for Local (In-House) and Central Laboratory testing
- Research Pathology service pricing
  - Slides
  - Tissue

	General Services				
Level 1	No Processing (<15 min)				
	Aliquot, store, ship				
Level 2	Routine Processing (<30 min)				
	Single spin, aliquot, store, batch, ship				
Level3	Moderate Complexity Processing				
	(<60 min)				
	Mononuclear Separation (Ficoll), aliquot,				
	store and batch ship; multiple spins or				
	other processing that requires < 60				
	minutes				
Level 4	High Complexity Processing (>60 min)				
	TBD by research lab team member on				
	case by case basis				

## Coverage

- Provide services at CAP, Egleston, and Scottish Rite
- Operating Hours: M-F 8:00 am 4:30 pm
- After hours, weekend and holiday processing is available upon request.
- Weekly schedule sent every Friday

Clinical Research Processing Schedule 12/2/2019 – 12/6/2019							
	2	3	4	5	6		
	Monday	Tuesday	Wednesday	Thursday	Friday		
САР	*	Cali	Cali	*	*		
SRH	Edgar	Danielle	Danielle	Danielle	Danielle		
ЕСН	Danielle	Christeen / Edgar	Christeen	Christeen / Edgar	Christeen / Edgar		

## **Study Start-Up Checklist**

- Approved Lab DAF
- ☐ Laboratory Budget
- NOA
- ☐ Kits and Study Supplies
- ☐ Lab Manual and Processing Instructions

## **Questions?**

- Contacts:
  - ECH Processing: 404-785-1930
  - SRH Processing: 404-785-1176
  - CAP Processing: 404-785-5437 Ext 17315
  - labresearchcoordinator@choa.org
  - pathvendormailbox@choa.org