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
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 complement 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

**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

**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

**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
www.pedsresearch.org
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

Division/Group

- Gastroenterology
- Nephrology
- Hepatology
- Endocrinology
- AFLAC
- Neonatology
- Infectious Diseases
- Children's Clinical and Translation Discovery Core
- Cystic Fibrosis
- Other

No. of Times Booked

- Gastroenterology: 5
- Nephrology: 83
- Hepatology: 61
- Endocrinology: 82
- AFLAC: 196
- Neonatology: 84
- Infectious Diseases: 122
- Children's Clinical and Translation Discovery Core: 15
- Cystic Fibrosis: 37
- Other: 27
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, 2nd 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 at 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

**Technical Fees** – cost of performing the scan
**Professional fees** – cost of reading the scan
<table>
<thead>
<tr>
<th>Procedure Name</th>
<th>CPT</th>
<th>Egleston Technical Fee</th>
<th>Interpretation Fee</th>
<th>Scottish Rite Technical Fee</th>
<th>Scottish Rite Interpretation Fee</th>
</tr>
</thead>
</table>

List name and CPT code for each scan or procedures:
## Research Protocol Review Form (RPRF)

| General |
|------------------|------------------|
| 1. At which CHOA location 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? | YES | NO |
| Note: Please confirm with Sponsor. Provide a copy with this completed form. If a manual is supplied AFTER this review, a new review will be required and may change the outcomes of the first review. | |
| 6. Does the sponsor require or suggest Radiology complete training specific to your protocol? | YES | NO |
| Note: Please confirm with Sponsor. If yes, please ask Sponsor to email an outline of the training requirements to the radiology coordinator. | |
| 7. Does your Sponsor require any Phantom or QA scans performed at the initiation or during the duration of the study? | YES | NO |
| Note: Please confirm with Sponsor. | |
| 8. Will sedation be used on all or some of the patients enrolled in this study? | Yes, as clinically indicated | Yes, IRB approved/pending | No sedation |
| Note: This includes sedation ordered for research or as clinically indicated. | |
| 9. What modalities will be used during the research study? For each modality marked, complete the corresponding sections below: | X-Ray | MRI | CT | Nuclear Medicine | Ultrasound | Interventional Rad. |
| MRI, MRI, MRA, MRE, Cardiac MRI | | | | | | |
| Nuclear Medicine: PET/CT, PET, MIBG, DNA, 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. | | | | | | |
| 10. How will data be transferred from Radiology to Sponsor? | |
| Ex: de-identified disk, FTP, 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 Radiology Health, DEXA to Hologic, 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 |
# Magnetic Resonance Imaging (MRI)

<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>What MRI procedures are requested?</td>
<td></td>
</tr>
<tr>
<td>MR Brain without contrast</td>
<td></td>
</tr>
<tr>
<td>MRI spine with and without contrast</td>
<td></td>
</tr>
<tr>
<td>MR Spectroscopy of extremity</td>
<td></td>
</tr>
<tr>
<td>If you require Tumor Imaging and specific scans are unknown at study start-up, enter &quot;Tumor Imaging&quot;</td>
<td></td>
</tr>
<tr>
<td>How many times are the patients scanned throughout the study?</td>
<td>Max:</td>
</tr>
<tr>
<td>Provide minimum number of individual scans required for a single patient.</td>
<td></td>
</tr>
<tr>
<td>If maximum number of scans varies from patient to patient depending on cycles, phenotypes, etc. mark as such.</td>
<td></td>
</tr>
<tr>
<td>Does the study require a morning or early afternoon scan?</td>
<td>YES NO</td>
</tr>
<tr>
<td>Does an MRI required at the screening visit (or first visit of the study)?</td>
<td></td>
</tr>
<tr>
<td>Note: The wait list for an MRI is two-three weeks. Please be sure to allow enough time between patient enrollment and screening visit to accommodate the busy MRI schedule.</td>
<td>YES NO</td>
</tr>
<tr>
<td>Do you require Radiology to complete Data Transfer Forms (DTF) or Research Forms for each patient scan?</td>
<td>YES NO</td>
</tr>
<tr>
<td>Does the protocol request the reading Radiologist to provide certain measurements or information in the radiology report?</td>
<td>YES NO</td>
</tr>
<tr>
<td>Radiology assumes we will perform our SOC reading protocols.</td>
<td>Waive Requested</td>
</tr>
<tr>
<td>If yes, describe reading requirements.</td>
<td></td>
</tr>
<tr>
<td>Any additional comments concerning scan(s)?</td>
<td></td>
</tr>
</tbody>
</table>

## Radiology Use Only

<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is there an imager manual for MRI?</td>
<td>YES NO</td>
</tr>
<tr>
<td>Does the Sponsor require Phantom QC Scans?</td>
<td>YES NO</td>
</tr>
<tr>
<td>If yes, at what interval?</td>
<td>Initial</td>
</tr>
<tr>
<td>Quarterly</td>
<td>Monthly</td>
</tr>
<tr>
<td>Annually</td>
<td>Other</td>
</tr>
<tr>
<td>Will Radiology perform a clinical read?</td>
<td>YES NO</td>
</tr>
<tr>
<td>If no, who approved the waiver?</td>
<td></td>
</tr>
<tr>
<td>Will the study team need a de-identified disk or data transfer?</td>
<td>YES NO</td>
</tr>
<tr>
<td>Is a specific scanner required?</td>
<td>YES NO</td>
</tr>
<tr>
<td>If yes, which one?</td>
<td></td>
</tr>
<tr>
<td>Do the requested procedures match our SOC imaging protocols?</td>
<td>YES NO</td>
</tr>
<tr>
<td>EG Radiology Review:</td>
<td></td>
</tr>
<tr>
<td>SR Radiology Review:</td>
<td></td>
</tr>
<tr>
<td>Will radiology perform specific reading requirements?</td>
<td>YES NO</td>
</tr>
<tr>
<td>EG Radiology Review:</td>
<td></td>
</tr>
<tr>
<td>SR Radiology Review:</td>
<td></td>
</tr>
<tr>
<td>Additional comments:</td>
<td></td>
</tr>
</tbody>
</table>
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.

<table>
<thead>
<tr>
<th>Radiology Order Form Comments Section</th>
</tr>
</thead>
<tbody>
<tr>
<td>X-Ray</td>
</tr>
<tr>
<td>MRI</td>
</tr>
<tr>
<td>CT</td>
</tr>
<tr>
<td>Nuclear Medicine</td>
</tr>
<tr>
<td>Ultrasound</td>
</tr>
<tr>
<td>Interventional Rad.</td>
</tr>
</tbody>
</table>
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?
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 IMAGING 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

Specialty Department (Open Studies)

- Hem/Onc: 59%
- Cardiology: 20%
- Pulmonology: 3%
- Neurology: 3%
- Anesthesiology: 1%
- GI: 1%
- Genetics: 3%
- Nephrology: 3%
- Radiology: 1%
- Cystic Fibrosis: 1%

Colors:
- Hem/Onc
- Nephrology
- Genetics
- GI
- Anesthesiology
- Neurology
- Pulmonology
- Cardiology
- Hepatology
- Radiology
- Cystic Fibrosis
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\textsubscript{2} 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)
Please give us at least 2 business days to schedule your appointment.

Fill out the form completely and legibly.
THANK YOU

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
Pediatric Clinical Research Unit
Children’s Healthcare of Atlanta
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 1st 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

Study Enrollment Percentage

- Allergy/Asthma: 34%
- Endocrine: 6%
- Hepatology: 6%
- Hematology: 8%
- Pulmonology: 3%
- Cardiac: 7%
- Metabolic: 14%
- Neurology: 16%
- Other: 3%

Children’s Healthcare of Atlanta
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

<table>
<thead>
<tr>
<th>During Round Table</th>
<th>After Round Table</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Study overview given by PI</td>
<td>• All edits and changes to order sets finalized</td>
</tr>
<tr>
<td>• Checklist reviewed (IRB approval, SAC approval, credentialing at CHOA completed, etc.)</td>
<td>• PI will verify order sets for accuracy</td>
</tr>
<tr>
<td>• Each order set reviewed in detail to ensure protocol compliance and accuracy</td>
<td>• Order sets are sent to EPIC team for build</td>
</tr>
<tr>
<td></td>
<td>• Order sets go LIVE in EPIC</td>
</tr>
<tr>
<td></td>
<td>• PRU team builds the study visits in CR-ASSIST</td>
</tr>
<tr>
<td></td>
<td>• PRU team provides training for Coordinators for CR-ASSIST</td>
</tr>
</tbody>
</table>
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/protocol-submission.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

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
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

<table>
<thead>
<tr>
<th>Clinical Research Processing Schedule</th>
<th>12/2/2019 – 12/6/2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 3 4 5 6</td>
<td>Monday Tuesday Wednesday Thursday Friday</td>
</tr>
<tr>
<td>CAP</td>
<td></td>
</tr>
<tr>
<td>SRH</td>
<td>Edgar</td>
</tr>
<tr>
<td>ECH</td>
<td>Danielle</td>
</tr>
</tbody>
</table>
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