Department of Clinical Research Kristine Rogers Director & Research Integrity Officer TEL: 404-785-1215 FAX: 404-785-9470	Children's® Healthcare of Atlanta	**Investigational Drug Service Pharmacy** Jim Rhodes, Research Pharmacist **Clinical Research Laboratory** Diana Worthington-White, Manager **Pediatric Research Center** Stephanie Meisner, Manager

Investigational Drug Service Outpatient and Clinic Medication, Clinical Research Laboratory and Pediatric Research Center Guidelines

Hours of Operation

- **Laboratory and PRC:** 8am to 5pm Monday-Friday.
  - Laboratory samples that require same day processing must be received no later than 5:00pm. If same day shipping is required, samples must be in the lab by 4:00pm.
- **Pharmacy** – 8am to 4:30pm Monday-Friday
  - **Note:** We provide service for studies on the Egleston, Scottish Rite, and Hughes Spalding campuses and may not always be available in the Egleston IDS Pharmacy. It is very important to plan ahead.
- Before hours, after hours or weekend and holiday services may be considered upon request based on staff availability and will require prior notification. **For laboratory**, additional fees may be imposed on those studies requiring after hours/weekend processing.

Scheduling

- **Laboratory**: All time sensitive lab sample processing must be approved at least 48 hours in advance.
  - Unscheduled patients with same day, time sensitive lab processing require a minimum of 2-hour notice directly to lab personnel.
- **Pharmacy**: Advanced notification for scheduled patient visits will be provided to the pharmacy as soon as the patient visit has been scheduled.

- **PRC**: Visits must be scheduled in CR Assist by **at least 48 hours in advance** of the visit.
  - Cancellations or changes to appointment time/schedule must be made **at least 24 hours in advance.**
  - Inability to cancel within the 24 hours advance notice will require direct notification to PRC staff via email (michelle.popler@choa.org or Jessica.heyer@choa.org) or phone call to Stephanie Meisner, Manager (404-785-6453).

Late Arrivals / No Shows

- **Laboratory** subjects must arrive within 60 minutes of scheduled appointment time. Late Arrivals will be accommodated within the hours stated above if staff is available. Any patient who arrives late and whose processing requirements will subsequently extend past 5:00 pm should be rescheduled.
- **Pharmacy** must be notified of late arrivals/no shows in a timely manner (within 20 minutes) to minimize disruptions to the IDS pharmacy workflow and to allow on-time patients to receive meds as scheduled
- **PRC** subjects must arrive within 60 minutes of scheduled appointment time; *schedule accordingly*. PRC **must be notified of late arrivals within 30 minutes of their scheduled time** to minimize disruptions in PRC workflow and to allow on-time patients to receive care as scheduled. Late Arrivals will be accommodated within the hours stated above if space is available and acuity allows. Any patient who arrives late and whose appointment will subsequently extend past 5:30 pm should be rescheduled.
- **Ancillary Services** such as CIRC, EKG's, should be notified of cancellations as well.

Research Coordinator/PI Responsibilities

- It is the responsibility of the PI and/or research coordinator to accompany each patient during each visit. The PI or co-I(s) should attend the initial subject visit for all studies with multiple study visits. **Study orders must be signed prior to the initiation of care** and delivered to the PRC before or with the arrival of the patient.
- All lab and pharmacy services ***must be confirmed*** with respective areas prior to patient appointment. All lab tubes, equipment, etc. must be delivered by the coordinator to PRC prior to patient appointment or with the patient arrival unless arrangements have been made directly with affected services.
- Children's IRB Authorization Agreement (IAA) must be in place on all Emory IRB approved trials and a copy of the approval emailed to PRC staff prior to scheduling first subject. IAA's can be found on Careforce Connection: http://careforceconnection/Departments/ClinicalResearch/InstitutionalReviewBoard/SitePages/Forms%20And%20Instructions.aspx or you can email PRC@choa.org and request one.
- It is the responsibility of the PI and/or research coordinator to properly route their project through Children's OSP and Grants Management Departments. Emory projects requiring use of ANY Children's ancillary services (professional fees, lab, pharmacy, EKG's, etc.) **must have a Children's subcontract in place with a Children's Notice of Award before any subjects can be seen.**

Adult Subjects

- The PRC will service research subjects from **Newborn up to 21 years of age**.
- Please refer to **Children's Patient Care Policies and Procedures, Admission Policy 3.16**: "The only patients who may be admitted at Children's beyond their 21st birthday (18th at Hughes Spalding) are those in need of services not offered elsewhere in the state of Georgia, those receiving ongoing cancer treatment and/or in the process of serial or staged surgical procedures. The admitting physician must notify the campus specific Medical Director (or his/her designee) Monday through Friday during normal business hours or the Medical

Administrator on call during evenings, nights, and weekend, to seek approval for these patients prior to initiation of treatment. **Requests for exceptions to this policy will be handled by the campus medical director in consultation with the Chief Medical Officer."**

- To request Adult visits in the Outpatient PRC, please email PRC@choa.org and request the "*Request for Adult Subject Visits in Children's Outpatient Research Center*" form. This form should be completed by the Principal Investigator and submitted to Stephanie Meisner, RN, BSN, CCRP-Clinical Research Manager (Stephanie.Meisner@choa.org) **prior** to finalization of protocol, grant submission, IRB submission, or contract negotiation.
- Adult subject visit approvals will be handled on a case-by-case basis based on the request form and must be approved by the PRC Manager, PRC Medical Director, Director of Clinical Research, and Egleston Campus Medical Director.

In Case of Emergency

- PRC will initiate appropriate emergency medical interventions according to **Children's Patient Care Policies and Procedures, Rapid Response Systems-Within the Hospital Policy 2.37:** "Response to the Deteriorating patient through clinician actions includes, but is not limited to, calling the physician, activating Rapid Response, and activating Code Blue."
- The Principal Investigator will be notified as soon as possible and will be responsible for care and orders. If emergency involves Anaphylaxis reaction, the PRC Anaphylaxis Protocol will be initiated including administration of appropriate medications according to **Children's Research Center Clinical Practice Guideline, Adverse/Anaphylactic Drug Reactions Guideline 3.7.**
- Patient/Subject will be transported to appropriate area for further management per PI order.

Contacts

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PRC

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