Guidelines for Conducting Research in the Emory Children's Center Research Unit (ECC-RU)

Responsible Officials: Miriam Vos, MD, MSPH
Administering Division/Department: Administration, Department of Pediatrics
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Policy Sections:

I. Overview:

The purpose of this policy, in keeping with Emory University's comprehensive approach to research integrity, is to assist principal investigators in further protecting human subjects who participate in a research protocol being conducted in the Emory Children's Center Research Unit (ECC-RU).

The ECC-RU is an Emory University space dedicated to research-only subject visits for Institutional Review Board (IRB) approved studies. There are two exam rooms, one consult, a phlebotomy chair, a staff workroom, and a storage room. The consult room can also be used as an exam room. The phlebotomy chair can be reserved for phlebotomy-only research visits.

II. Applicability:

This policy applies to principal investigators and research staff who utilize the Emory Children's Center Research Unit as a study site for their IRB approved human subjects research protocols.

The policy describes the following areas:

- Location
- Hours of Operation
- Appointments
- Training and Compliance
- Principal investigator and Research Staff Responsibilities
- Equipment
- Procedures
- Emergency Plan

III. Policy Details

Location
Emory Children's Center
2015 Uppergate Drive Atlanta, GA 30322

1st Floor, Rooms: 164, 170, 172, and 173

Hours of Operation
Monday-Friday; 8am-5pm; other hours and days may be considered upon request and will require prior approval from the Center for Clinical and Translational Research (CCTR).

IRB Approvals
Use of the ECC-RU is for IRB approved protocols only. ECC-RU personnel will request a copy of your IRB approval letter.

SAC Application
Study teams are required to submit any new studies being conducted in the ECCRU for initial review and approval via the SAC Application page.

a. The ECCRU is currently available at no cost to study teams. Therefore, the Georgia CTSA Clinical Research Centers (GCRC) Service Center Fee Schedule is not applicable at this time.

b. Please include **Emory Children's Center (ECC)** under the following category on the application: *What GCRC location(s) will you be utilizing to conduct your Study?*

c. Under **GCRC Services Needed** please select: *Space Only*

Appointments
Use and visits must be scheduled utilizing the online scheduling system located at: https://eccru.acuityscheduling.com/. There is an eight-hour maximum scheduling window. If more time is required, please contact ECC-RU@emory.edu for authorization. All appointments are to be scheduled/canceled/rescheduled by research staff only. Research staff is responsible for relaying appointment information to the appropriate parties.

a) Cancel/Reschedule Appointments
• To cancel/reschedule an appointment, click on the "view appointment details" link in your appointment confirmation email. You will be directed to the appointment conformation page where there will be options to reschedule the appointment to another date/time, or cancel the appointment completely.

• If you delete or lose your confirmation email, you can request the link by contacting ECC-RU@emory.edu .

b) Late Arrivals/No Shows

• If your research participant is more than 30 minutes late for their scheduled appointment, they will need to be rescheduled for a later time-slot via the online scheduling system.
• If the research staff is late for a scheduled appointment, they should notify the subject and the front desk.

c) Room reservations
• ECCRU users have approval to access and use room(s) that they have reserved in Acuity. Accessing rooms that have not been properly reserved is unauthorized and not permitted.
• Research teams that need to set up study equipment/supplies should do so during their scheduled time slot. Staff should refrain from setting up study items prior to the start of the scheduled visit. If additional time is needed, study teams should reserve a longer time slot in Acuity to accommodate the additional time.

Training and Compliance
Research staff members must complete all training and compliance requirements applicable to their job descriptions. Staff members should only perform activities and procedures for which they have verifiable training and or credentialing.

Audits
The Center of Clinical and Translational Research will conduct audits of clinical studies conducted in the ECC-Research Unit to ensure compliance with Emory's institutional guidelines and provide oversight as needed.

If a clinical trial conducted within the ECCRU is selected for an FDA inspection, whether for-cause or not-for-cause, the study team must notify the ECCRU leadership team immediately upon receiving the notification. Please email Sarah Marie Huban at ssmit37@emory.edu or Mary Mungai at mmungai@emory.edu.

Principal Investigator and Research Staff Responsibilities

The Principal Investigator (PI) is ultimately responsible for the conduct of the study. Specific responsibilities include the following:
• Obtain IRB approval before initiating any protocol specific activities in the ECCRU.
• Provide IRB approval letter to the ECC-RU.
• Obtain informed consent and or assent before initiating any study-related activities.
• Ensure that signed copies of informed consent concerning research that involves medical treatment are placed in the participant’s clinical records and research records, unless otherwise required by an IRB or rules/regulations governing medical records.
• Accompany research subjects into the research unit for each visit.
• Provide study supplies to conduct your study visits.
• Clean the exam room at the completion of each visit.

Equipment

Do not use the equipment located in the transplant or infusion units, as these are not considered part of the ECC-RU. For assistance regarding the equipment, please contact ECC- RU@emory.edu

Procedures

Research staff must provide all study supplies for study visits including supplies for venipuncture. It is the responsibility of the PI to ensure proper training and credentialing has been completed for each member of the research team.

Allowable in University Buildings	Allowable in University Buildings with Modifications	Clinically Provisioned Space Only (Appropriate for the Research Activity)
• Finger Stick • Healthy Subject Physical Exam • Indirect Calorimetry • Language Intervention • Medical Review • Neurocognitive Testing • Neurological Exam • Nutritional Counseling • Oral Swabbing Or Saliva Collection • Patient Record Review • Recording vital signs • Research Subject Interview • Survey / Questionnaire Administration • Ultrasound	• Biopsies • Blood Draw / Blood Test • Blood Processing / Storage • Drug Injection Or Infusion • EEG • EKG/ECG • Handling Biohazard Substances / Biological Substances • Imaging involving radiation exposure • Intravenous Injection • Psychologically Stressful Test • Noninvasive Vascular Function Testing • Parenteral or Oral Drug Administration (Where Direct Observation Is *Not* Required For Safety) • Physical Exam (Requiring	• Epidural Drug Infusion • Implanted Medical Devices (Invasive Or Requires Monitoring For Adverse Outcomes, e.g. FDA Class III) • Invasive Vascular Function Testing (High Risk Subjects) • Parenteral or Oral Drug Administration (Where Direct Observation *Is* Required For Safety) • Studies Involving Radiation Exposure • Treadmill Testing (High Risk)

	Handling of Biohazardous Equipment) • Six Minute Walk Testing • Treadmill Testing (Low or Moderate Risk) • Urine Collection, Testing, And Disposal • Vaccinations	

Drug Administration
Drug administration must be conducted by an appropriate, credentialed staff and must be verifiable. It is the principal investigator's responsibility to ensure compliance.

Emergency Plan
The following procedures should be followed in the event of an emergency:

- Call 911
- Notify the closest clinic staff member
- After the incident has resolved, please send an email to ECC-RU@emory.edu describing the event and conclusion

An Automatic External Defibrillator (AED) is located in the first floor of the Emory Children's Center in the vestibule between rooms 150A and 150B.

A fire extinguisher is located in the hallway of the ECC-RU.

For moderate to high-risk studies, an Emergency Plan must be established and submitted to ECCRU manager for review.

Storage
Study supplies are not to be stored in the exam rooms. Research study supplies may be stored in the storage room between rooms 169 and 173 in the research unit. If you store research supplies, please label them with your name, contact information, and study duration. Lockers are provided for research staff to place personal belongings when conducting study visits. Please empty the lockers of your personal items at the end of your visit to accommodate other staff members.

IV. Phlebotomy Services

The Department of Pediatrics (DOP) does not offer phlebotomy services. When a research participant needs blood drawn for the purposes of a research study one option is to have a qualified member of the study team collect the sample. If you would like to have a member of your team complete the Emory phlebotomy training, please reach out to Sarah Marie Huban (ssmit37@emory.edu).

V. Frequently Asked Questions

What is the ECC-RU?
The ECC-RU is an Emory University space dedicated to research only subject visits for IRB approved studies. There are two exam rooms, one consult room (which can also be used as an exam room), a storage area, staff workroom, and a phlebotomy chair. The rooms are available for Pediatric Institute members and their study staff.

When can I use for phlebotomy chair?
You can book the phlebotomy chair for phlebotomy-only visits. If you need to consent the subject, conduct an interview, etc., please book one of the private exam rooms.

Where are you located?
Emory Children's Center
2015 Uppergate Drive Atlanta, GA 30322
1st Floor, Rooms: 164, 170, 172, and 173

What times are the rooms available?
Monday-Friday; 8am-5pm; other hours and days may be considered upon request and will require prior approval from CCTR.

How are appointments scheduled?
ECC-RU has a dedicated online scheduling system: https://eccru.acuityscheduling.com/
Rooms may be booked from 30 minutes up to 8 hours.

How will patients check-in?
A research team member will need to meet all patients in the lobby of the Emory Children's Center and escort them to the scheduled room.

How do you get access to the unit?
Badge access is needed to enter the suite. You can request badge access by completing the form located on pedsresearch.org. If you have any questions concerning the submission process, please reach out to Mary Mungai at mmungai@emory.edu .

Clinic rooms are unlocked during regular office hours. You will need prior approval to access the rooms after normal business hours and instructions on obtaining a key to unlock your reserved room will be sent to you.

Will there be a charge for using the space?
There is no charge for the space at this time. In the future, we may have a fee for industry sponsored trials.

Will there be supplies available in the rooms?
The rooms will have gloves, paper for exam tables, sharps containers, handwashing soap, hand sanitizer, and sanitizing wipes. The study teams will need to provide any other needed supplies.

What procedures are allowed in the ECC-RU?
You may perform research activities under the purview of your approved and verifiable credentials.

Who cleans the rooms after a visit?
Each team is responsible for cleaning the rooms after their visit. Sanitizing wipes will be provided. Exam rooms also have brushes and dustpans.

VI. Contact Information

ECC-RU Phone: 404-727-4888

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