

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

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Administering Division/Department: Administration, Department of Pediatrics

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Policy Sections:

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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 Sarah Marie Huban at ssmit37@emory.edu for authorization. All appointments are to be scheduled/canceled/rescheduled by research staff only. Research staff are 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 confirmation 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 Sarah Marie Huban at ssmit37@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.

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.

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 leadership.
- 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 [Sarah Marie Huban at ssmit37@emory.edu](mailto:ssmit37@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 <i>Not</i> Required For Safety) • Physical Exam (Requiring Handling of Biohazardous Equipment) • Six Minute Walk Testing • Treadmill Testing (Low or Moderate Risk)	• 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) •

	• Urine Collection, Testing, And Disposal • Vaccinations • Studies involving ill participants	
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Studies that enroll ill participants (i.e., active respiratory symptoms or involve highly transmissible diseases):

- Must be conducted in Rooms D or E (outside the unit);
- Participants must be met at the door and provided a mask;
- Participants must be escorted directly to Room D or E (no waiting);
- After the visit, the room must be cleaned:
 - Clean from high to low, clean to dirty. Start by dusting high, less-touched surfaces and working your way down to the floor.
 - Work from the cleanest areas toward the dirtiest to avoid cross-contamination.
 - Vigorously clean high-touch areas such as doorknobs, light switches, chairs. Focus on the patient zone, including exam table, armrests and medical equipment
 - Wipe down surfaces, use hospital grade, EPA-registered disinfectant and a fresh, clean cloth to wipe down all surfaces.
 - Allow for dwell time: Read the product label and let the disinfectant remain wet on the surface for the specified dwell time to ensure it kills all pathogens.
 - Clean medical equipment: Disinfect all reusable medical equipment used on the patient, such as stethoscopes and blood pressure cuffs, following the manufacturer's instructions.
 - Remove PPE and perform hand hygiene: Carefully remove your PPE inside the room to avoid contamination. Dispose of single-use items in the designated waste receptacle and wash your hands thoroughly.
 - Final inspection: Ensure all surfaces have been cleaned and disinfected

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

I) **POLICY**

ECC-RU uses the local emergency medical system to provide appropriate care to research volunteers in the event of an emergency. Types of emergencies include but are not limited to seizures, parent event, chest pain, vasovagal/syncopal episodes or allergic reaction/anaphylaxis.

II) **SCOPE**

This SOP describes steps to take in a medical emergency occurring in the designated research rooms on the first floor of the ECC-RU. It applies to all research participants and legal guardians/accompanying visitors at the ECC for a research visit.

III) **PROCEDURE**

a. Emergency Preparedness: A medical emergency may occur at the ECC-RU if a research volunteer has a life threatening or adverse reaction to a study product. Examples of life-threatening adverse reactions are anaphylaxis and cardiopulmonary arrest. Below are general guidelines for research teams to follow:

1. The study investigator responsible for overseeing the study protocol should be present on-site during all vaccinations and/or medication administrations. Additionally, all research staff members involved with patient care should be trained in Basic Life Support (BLS), which includes proficiency in the use of an Automated External Defibrillator (AED).
2. In case of an emergency, the study principal investigator, co-investigators, or designated responder are responsible for overseeing the emergency management of the participant and directing other personnel to obtain necessary assistance or supplies. After-hours the PIs or CO-Is becomes the designated responder.
3. Portable office emergency medication, equipment, and emergency supplies are kept in the clinic. An emergency cart and AED are located in the staff workroom (room 164). Contact the IDS Pharmacy for any questions at 404-712-7485 related to the supplies in the emergency kit.
4. EMS response time to ECC-RU is approximately 20 minutes. In case of an emergency, valet services when available, are located at the ECC building front entrance, and can assist EMS providers in directing them to the patient's location.

The following procedures should be followed IN THE EVENT OF AN EMERGENCY:

-Call 911

-Notify the closest research staff member

-Take care of the patient first, contact your study investigator/designated responder as soon as possible and request on-site assistance.

- **-Contact ECCRU management team**

-After the incident has been resolved, please send an email to Sarah Marie Huban at ssmit37@emory.edu describing the event and follow-up.

Automatic External Defibrillators (AEDs) are located in the following locations:

- The staff workroom within the research unit in room 164.

- The first floor of the Emory Children's Center in the vestibule between rooms 150A and 150B.

Emergency supplies are located in the purple cart inside the staff workroom. To access the supplies you will need to unlock the cart. You can unlock the cart by accessing the key located on the side of the cart OR by using code shown below:







Waterloo
Healthcare Medical Carts

PUSHBUTTON LOCKING INSTRUCTIONS

Your Simplex Cabinet Lock is presently set with a combination of:
First push #2 and #4 together, and then #3.

Make a habit of turning the knob LEFT (counter-clockwise) before pushing the combination. Should anyone have attempted an improper combination, this action clears off such an attempt and reactivates the buttons.

TO OPEN:

- 1) Turn the PUSHBUTTON knob LEFT (counter-clockwise) to activate all buttons
- 2) Push proper buttons in present order for the combination
- 3) Turn PUSHBUTTON knob RIGHT (clockwise) to open

TO LOCK:

- 1) Be sure the drawers of the cart are fully closed (you may feel a click when you push the drawer in fully). Drawers that are not fully closed will make it so the cart will not lock properly
- 2) Turn PUSHBUTTON knob LEFT (counter-clockwise) until it stops. Ensure that the pushbutton lock knob is in the locked position

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 ECC-RU 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

Phlebotomy services are available to support clinical research teams requiring assistance with blood draws within the ECC-RU. If you or your research team would like to request a phlebotomist for a blood draw(s) during your research visit, please

complete the form located on pedsresearch.org at least 24hours prior to your visit to ensure service. There is a \$25 fee associated with each participant, in accordance with the Emory research services fee schedule.

If you prefer to have a qualified member of your study team collect the sample, and would like to request 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 outside 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 Sarah Marie Huban at sarah.marie.huban@emory.edu.

Clinic rooms are unlocked during regular office hours.

If you need to access a clinic room(s) after normal business hours, you will need prior approval. This includes any visits that occur before 8:00am or after 5:00pm Monday -

Friday or anytime on Saturday or Sunday. You can request approval by completing the form located on pedsresearch.org. Please note that all after-hours visits must have at least two staff present on-site (ECC or HSRB). Additionally, if you plan to administer an investigational product after hours, you must have a provider-level Investigator or Co-Investigator and one other study staff member present on site (ECC or HSRB). Once your request is approved, 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

Sarah Marie Huban

Director, Clinical Research

Phone: 404-727-5234

Email: ssmit37@emory.edu

Liz McCarty

Executive Administrator & Vice Chair for Administration

Phone: 404-712-8226

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