

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

Responsible Officials: Clinton Joiner, MD, PhD

Administering Division/Department: Administration, Department of Pediatrics

Effective Date: February 1, 2019

Policy Sections:

- I. Overview
- II. Applicability
- III. Policy Details
- IV. Phlebotomy Services
- V. Frequently Asked Questions
- VI. Contact information

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 protocol.

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.

Appointments

Use and visits must be scheduled utilizing the online scheduling system located at: <https://eccru.acuityscheduling.com/>. There is a two 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 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 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 notify the subject, the front desk, and the phlebotomist, if phlebotomy services were requested.

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.

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 ECC-RU.
- 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.

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.

Storage

Study supplies are not to be stored in the exam rooms. Research study supplies may be stored in the storage room located 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 completion of your visit in an

effort to accommodate other staff members.

IV. Phlebotomy Services

The Department of Pediatrics (DOP) offers phlebotomy services that are available by request for IRB-approved studies. 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. The other option is to use our part-time phlebotomist, Monique Savage.

Contact Info for Monique Savage

Cell: 773-960-4849 (preferred method of contact)

Email: monique.l.savage@emory.edu

Personal Email: msavagem3k@gmail.com

Process to Utilize Phlebotomy Services

1. Reserve your time and room in the ECC-RU using the [Acuity Scheduling System](#).
2. If you need to utilize the DOP's research phlebotomy services, be sure to check off "ECC-RU Phlebotomy Services Requested" **AND** indicate the specific time the phlebotomist will be needed. For instance, you may have booked the room from 9am to noon, but will need the phlebotomist at 10:30am.
3. Send Monique Savage an Outlook Calendar Invitation with the specific time that she will be needed to her [Emory email account](#). This should be done at least 48 hours prior to the appointment.
4. Monique Savage has agreed to respond to the calendar invitations within 24 hours.
5. In the event that the research participant cancels or reschedules, the CRC should notify Monique Savage ASAP. Text message is her preferred method of contact for these notifications.
6. In the event that Monique Savage has communicated she is unavailable, cancels or does not show up for an appointment and you are not able to reschedule your participant, first inform Nadine Spring, then pursue the back-up research phlebotomy services outlined below. Please note, however, that this option is only to be used in rare situations.

Back-Up Research Phlebotomy Services:

*Note: This should **not** be your first method for scheduling research phlebotomy. Please only use this option if Monique Savage has indicated she is unavailable, cancels, or does not show up and if you are unable to schedule the participant at an alternate time. Inform [Nadine Spring](#) when this happens. Please give at least 24 hours' notice, and provide your own tubes and labels.*

Primary Contact

Kathy Stephens

kasteph@emory.edu

404-712-8552

Secondary Contact

Felicia Glover

Felicia.glover@emory.edu

404-727-4056

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 DOP faculty and their team members.

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 2 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.

Where are the keys located?

Badge access is needed to enter the suite. Reach out to Nadine Spring for access. Team leads are responsible for sharing the exam room keys amongst their team members.

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

ECC-RU Email: ECC-RU@emory.edu

Nadine H. Spring, MPH, MS, CCRC

Director, Clinical Research Services

Phone: 404-727-5234

Email: nadine.spring@emory.edu

Liz McCarty

Executive Administrator & Vice Chair for Administration

Phone: 404-712-8226

Email: mmccar2@emory.edu

Clinton Joiner, MD, PhD

Vice Chair for Research

Phone: 404-727-5813

Email: clinton.joiner@emory.edu