EXECUTIVE SUMMARY

Clinical Research Orientation and Training for Clinical Research at Emory University

Introduction

The purpose of this document is to provide details of the clinical research training programs at Emory University for clinical research staff (i.e., Investigators, Research Fellows, Research Nurses, Research Coordinators, Key Personnel, etc.). Review mandated policy by the Clinical Trials Operations Committee (CT Ops).

Clinical research staff training is based on the number of years at Emory and clinical research experience. Staff who see patients in any Emory Healthcare facility or need access to the Epic medical record system will require credentialing from the Office of Nursing Verification/EHC Credentialing. *Please see the diagrams below.*

Staff Level	Learning Track Level	New Hire, Emory Rehire, Emory Promotion	Clinical Research Experience	Orientation	Training
Green	0	New	0 years	Yes	In-House Remote 1 Remote 2 Self-Pace In-Field Exam
Blue	1	New	1+ years	Yes	Remote 1 Remote 2 Self-Pace In-Field Exam
Intermediate A	2	Varies	2-5 years	Yes	Remote 2 Self-Pace In-Field Exam
Intermediate B	3	Varies	5-10 years	Yes	Remote 2 Self-Pace Exam
Advanced	4	Varies	10+ years	Yes	Exam Only

New Hire = a new employee hired in a clinical research role at Emory.

Emory Rehire = a former employee rehired in a clinical research role at Emory.

Promotion = an existing employee advanced to a new clinical research role at Emory within any department. If the role is within the same job category, please ensure your RedCap eCREST is modified with the new role. OCR will contact you for any questions.

EHC Credentialing	Tier	Phlebotomy	CPR Needed	Research Badge Wait Time
No patient contact	1	No	No	1-7 days
Direct patient contact	2	No	Yes	14-30 days
Direct patient w/additional competencies (H&P, vitals, EKG, etc.)	3	Yes	Yes	30-60 days

Pending Application? Attend monthly Credentialing Office Hours every 2nd and 4th Wednesdays via Zoom. For questions, contact research.credentialing@emoryhealthcare.orgor 404.712.0510.

SCOPE

Clinical research staff who conduct or coordinate an NIH-definition of a clinical trial (PDF) must follow the program schedule to obtain a certificate of completion and to be listed on an IRB-approved research study. **This schedule provides a 1-week onboarding process that should be factored into the new hire's training plan.**

Clinical Research Orientation (CRO)

Clinical Research Orientation is required for *all new hires, rehires, or promotions* (excluding investigators that receive orientation from their respective department) at Emory University and Emory Healthcare conducting or coordinating an NIH-definition of a clinical trial (PDF) to receive details and knowledge about available resources, training, and Emory Healthcare Credentialing.

Staff are notified via various ways – HR Welcome Letter, your Manager/Supervisor, or from the Office for Clinical Research. For more information about clinical research orientation, please contact us at OCR@Emory.edu.

Orientation is the 1st Monday of each month from 8:30 am – 1:00 pm EST. Dates are available in Emory Learning Management System (Brainer) > search "Clinical Research Orientation."

Clinical Research Training

In-House Training

The **In-house training (on-campus)** is an 8-hour course to provide **green** staff-level new hires with basic clinical research concepts. The course provides an introductory overview aimed at everyone involved in clinical research. It focuses on why and how clinical research is carried out, the spectrum of clinical research, and the research process by highlighting scientific methods, study design, protocol preparation, and much more.

In-house training is the 1st Tuesday of each month for **green** staff from 8:30 am – 5:00 pm EST on Emory University Main Campus, 1599 Clifton Road, Atlanta, GA 30322. Details are sent to students after Orientation.

Remote (1)

The **Remote (1) training** is a 4-hour course to provide **green** and **blue** staff-level new hires/rehires/promotions with an introduction to clinical research at Emory University. Staff will learn the clinical operations at Emory, including the roles and responsibilities of each party involved in clinical research. Before seeing a subject or working on a study, the course will include steps necessary for Emory's submission and approval process, including the project, proposal, contract, and budget.

Remote (1) training is the 1st Wednesday of each month for both **green** and **blue** staff level new hires via online Zoom. Details are provided to students after Orientation.

Remote (2)

The **Remote (2) training** is a 4-hour course to provide both **green** and **blue** staff-level hires/rehires/promotions with introduction to clinical research at Emory University. Staff will continue from **Remote (1) training** to learn what steps are necessary after a study has received award approval, and to prepare the site for subject enrollment, recruitment, study coordination, documentation, monitoring, close-out, and much more.

Remote (2) training is the 1st Thursday of each month for both **green** and **blue** staff level new hires via online Zoom. Details are provided to students after Orientation.

Self – Pace Learning

The **Self-pace learning** consists of several modules on specific topics to further enhance your knowledge about clinical research at Emory University. Below is a catalog table of those modules. *Please see the table of eLearning modules below.*

Self-Pace Modules

Pre-requisites (https://about.citiprogram.org/)

- CITI Biomedical and/or Biomedical Refresher
- CITI CRC (Clinical Research Coordinator)
- CITI Good Clinical Practice & ICH
- CITI Health Privacy and Information Security

eLearning Modules (https://emory.brainier.com/#/login)

**Note: You will only see these modules after staff-level tracked assignments, usually beginning the Friday of the 1-week onboarding process.*

1. Ancillary Departments
   a. Emory Medical Laboratory – EML
   b. Investigational Drug Services – IDS
   c. Radiology Services
2. Compliance
   a. Audit and Inspections
   b. Conflicts of Interest
   c. CT.gov Compliance & Reporting
   d. Research Misconduct
3. Institutional Review Board (IRB)
   a. Emory Informed Consent Form (ICF)
   b. Emory IRB Submission
   c. Reportable New Information (RNI)
4. Medical Devices
5. Research Administration Offices for Clinical Research
   a. Environmental Health & Safety Office (EHSO)
   b. Office of Sponsored Programs (OSP)
   c. Research Administrative Services (RAS)
   d. Research Grants and Contracts (RGC) – Award Setup
   e. Research Grants and Contracts (RGC) – Award Closeout
6. Software
   a. Epic Medical Records at Emory Healthcare
   b. OnCore Clinical Trials Management System (CTMS)
7. Study Maintenance
   a. Documentation
   b. Standard Operating Procedures (SOPs)

Self-pace training modules are completed in Brainer and students will receive an email on how to register and complete the modules during the 1-week onboarding after Orientation. However, the self-paced training modules must be complete in order to take the **examination**.

Examination

The **Green** and **Blue** staff levels must complete an **examination** to assess knowledge of the topics in the clinical research training program. The exam is open-booked and delivered via SurveyMonkey after **Self-paced training.** If the role of the student is to conduct and/or coordinate clinical research activities and it is their primary job responsibility, they must pass with an **80% or higher**. Remediation is provided to students who do not pass the examination to address areas of weakness. *For more information, please see the table below of exam content percentages and Clinical Research Training - Course Failure Policy.*

Percentage of Exam Content

Percentage of Exam	Category	Departments or Content
30%	Stakeholders (Sponsor, PI/Study Team)	Definitions, Roles and Responsibilities, including expectations.
35%	Regulatory	Study start-up and closeout, Essential document submission, UP/AE/SAE, Consent process,
15%	Documentation/Compliance	Drug and Device accountability, SOPs, Source Documents, and PI Record Keeping.
10%	Audit and Monitoring	CAPA, Trust Line and Research Misconduct
10%	CITI Review	Belmont Report, FDA 152 Form

Once a student has completed the 1-week onboarding plan and passed the **examination**, a **certificate of completion** will be provided to students who score 80% or higher on the examination. Students are to upload the certificate in their RedCap eCREST record and provide it to the IRB to engage in clinical research activities and be added to the IRB application as part of the study team.

In-Field Training

The **In-Field training** at Emory University is completed by the Office of Clinical Trials Audits and Compliance department (CTAC). CTAC will contact students who have completed the 1-week onboarding plan **six to eight weeks** afterward to assess needs and provide additional tools used in the clinical research environment for study maintenance, documentation, and monitoring. A list of the clinical trial resources can be found here.

CTAC also helps Emory researchers implement studies with compliance and efficiency, which will lead to reliable and accurate data to contribute to science. For assistance, contact ctcompliance@emory.edu or visit their website.

Refreshers (Continuing Education)

The **Refresher (renewal)** training is continuous education as clinical research changes due to new guidance, policies, or procedures. Refreshers are to be renewed every **three years** when you are to renew your CITI training.

Refresher Modules

Renewals (https://about.citiprogram.org/)

- CITI Biomedical Refresher
- CITI CRC (Clinical Research Coordinator)
- CITI Good Clinical Practice & ICH

Renewal eLearning Modules (https://emory.brainier.com/#/login)
**Note: Upload renewal certificates in your RedCap eCREST record.*

- A total of 3.0 C Electives from GaCTSA – https://twd.ce.emorynursingexperience.com/
- For Winship staff only – can use the **Clinical Research Staff Annual Certificate** of Completion.

If you have never completed a RedCap eCREST profile, please contact OCR@Emory.edu.

COMPLIANCE

The Office for Clinical Research (OCR) & Emory Healthcare (EHC) Credentialing Office will assess each students training and credentialing record at Emory University for compliance. Non-compliance of the policies/mandates will be reviewed by the Institutional Review Board (IRB) and Office of Research Integrity and Compliance (ORIC).

Any questions? Contact the Office for Clinical Research (OCR) at OCR@Emory.edu or 404.778.4960.