

Clinical Research Orientation and Training for Emory University

Clinical research **orientation and baseline training** are required for all new hires/rehires/promotions conducting or coordinating [clinical research studies](#) (i.e., observational, qualitative, socio-behavioral, and clinical trials) at Emory University. Training will also include monthly sessions or reviews in Months 1, 3, 6, and 12 for monitored continuous learning, as well as annual reviews for existing staff. New *Investigators* who are magnet-designated®, Clinical Research Nurses, Clinical Research Coordinators, or [Other Key Personnel](#) are assigned their learning curriculum at the [Clinical Research Orientation](#). CME/CEU/Nursing [credits](#) are issued for several courses and organizations. *Review the table below and page 2 for affiliated sites, including Winship Cancer Institute CTO Staff.*

Emory University's [IRB](#) will verify that all clinical research staff have completed the CITI courses in [Insight](#), which are prerequisites to the baseline training. Emory's [ECRO](#) will conduct quarterly reviews of baseline training participation and, every September, a yearly review of non-compliance for existing staff. Non-compliance will be reported to the relevant compliance agencies. To minimize study disruptions, ensure that staff complete the necessary training tailored to their roles. ECRO [CRSS Team](#) can provide “refreshers” to you and your staff, update training information, and records. Any extra-departmental training will be considered supplemental.

Emory Healthcare (EHC) **research credentialing** is required for Emory University clinical research staff who have direct contact with subjects in an [EHC facility](#) and/or will need access to patient medical records in [Epic](#) for EHC subjects, including remote staff who need access to patients’ medical records. **Direct contact** includes transporting patients, collecting specimens, obtaining vital signs, taking measurements, performing ECGs, and performing phlebotomy, among other tasks. For information, contact Elizabeth Botheroyd at elizabeth.botheroyd@emoryhealthcare.org. View the EHC [Application Instructions, v8.2025](#), and the EHC Non-Emory Healthcare Staff Credentialing [policy](#). *Note: New hires must have CPR certification at the time of hire and before Clinical Research Orientation.

If you are a student or a staff member observing or shadowing an Investigator, please contact OCR@Emory.edu.

Role	Type of Study	Biomedical Focus CITI ¹	CRC CITI ⁴	GCP-ICH CITI ²	Health Privacy & Information Security CITI	SHB CITI ¹	Clinical Research Orientation Brainer	Clinical Research Baseline Training Brainer	eDisclose eDisclose ³	EHSO BioRaft ⁵	OnCore, Insight and EPIC Brainer ⁶ EpicU ⁶
Investigators (PI, Co-I, or Sub-I)	Investigators working on NIH-defined clinical trials, including FDA-regulated clinical trials.	X		X	X		Attend your department or SOM		X	X	X
	Investigators working on an NIH-supported clinical trial that is <u>not</u> FDA-regulated.	X (or SHB CITI)		X	X	X (or Biomed CITI)	Attend your department or SOM		X	X	X
	Investigators working on a clinical research study that is neither FDA-regulated nor NIH-funded.	X (or SHB CITI)			X	X (or Biomed CITI)	Attend your department or SOM Orientation .		X	X	X
	Investigators who are magnet-designated® working on studies per NIH definition.	X (or SHB CITI)	X	X	X	X (or Biomed CITI)	X	X	X	X	X
Clinical Research Nurses, Coordinators, Research, Pharmacists, and Other Key Personnel	Clinical research staff working on NIH-defined clinical trials, including FDA-regulated clinical trials.	X	X	X	X		X (if new to Emory, Rehire, or Promotion)	X	X	X	X
	Clinical research staff working on an NIH-supported clinical trial that is <u>not</u> FDA-regulated.	X (or SHB CITI)	X	X	X	X (or Biomed CITI)	X (if new to Emory, Rehire, or Promotion)	X	X	X	X
	Clinical research staff working on a clinical research study that is neither FDA-regulated nor NIH-funded.	X (or SHB CITI)			X	X (or Biomed CITI)	X (if new to Emory, Rehire, or Promotion)	X	X	X	X If billables or OCR invoiced

¹ The Biomedical Refresher includes three additional Emory-specific modules (Emory Institutional & Regulatory Information, Audit Findings, and Ethical Issues in Clinical Research). Renewal every three years in CITI.

² CITI Group 5: GCP & ICH courses are for clinical research staff working on [NIH-definition of a clinical trial](#) (which includes FDA-regulated studies) clinical trials. Renewal is every three years in CITI.

³ The eDisclose, previously eCOI, training is for faculty and staff to disclose financial interests and request approval for external activities. Please visit COI's [eDisclose SharePoint site](#).

⁴ The CITI CRC (Clinical Research Coordinator) course is for experienced and non-experienced clinical research nurses, coordinators, and other key personnel who function as coordinators. It is renewed every three years in CITI.

⁵ Bloodborne Pathogens (BBP) for Research training is required annually for those working on protocols that involve human bloodborne pathogens (including Grady campus or buildings (e.g., Ponce Clinic). Additional training in biosafety and laboratory may be required from [EHSO](#). The EHSO—Shipping and Transport of Biological Materials and Refrigerants (Dry Ice) training course is available at [CITI](#).

⁶ **OnCore CTMS training** is provided by your department's OnCore Superuser; **Insight training** is for Proposals and IRB submission. **Epic training** is for clinical research staff who need access to the medical records. View system training resources & information [here](#).

All new hires/rehires/promotions who conduct or coordinate clinical research studies with an Emory investigator may be subject to additional training at Emory. **Please review the chart below.**

Note: Emory Clinical Research Orientation is not required for non-Emory staff but will be essential to understand how research is conducted at Emory. We will work with your site's Training Manager to address your training needs.

Role	Emory Affiliated Sites	Emory Biomedical/SHB <u>CITI</u> 1 (see pg.1)	Emory CRC <u>CITI</u>	Emory GCP-ICH <u>CITI</u> 2 (see pg.1)	Emory CITI Health Privacy and Information Security <u>CITI</u>	Emory Clinical Research Orientation & Baseline Training	OnCore, Insight and EPIC <u>Braine</u> ⁶ <u>EpicU</u> ⁶
Clinical Research Nurses, Coordinators, Research Pharmacists, or Key Personnel	Atlanta Veterans Administration Medical Center (AVAMC) New hires must work with Tedra Ricks at 404-321-6111 ext.206190 in the credentialing office. For IRB application submissions , visit https://www.va.gov/atlanta-health-care/research/ .	Atlanta VA CITI Biomedical/SHB is Equivalent to Emory . AVAMC staff must affiliate with Emory and complete three additional modules or SHB, if needed, as a part of the pre-req for CRO/CRT.	Atlanta VA CITI does not offer the CITI CRC course and Not Equivalent to Emory . AVAMC staff must complete if they work with an Emory PI at an Emory site, as a part of the pre-req for CRO/CRT.	Atlanta VA CITI GCP-ICH Equivalent to Emory . AVAMC staff must affiliate with Emory and complete three additional modules or SHB, if needed, as a part of the pre-req for CRO/CRT.	Atlanta VA CITI Health Privacy and Information Security is Equivalent to Emory . AVAMC staff entering data in OnCore CTMS or accessing the Epic medical record system must submit proof of completion for system access.	Emory CRO/CRT is Not Equivalent to AVAMC Research Training. It is mandatory and specific to Emory's processes. If an AVAMC staff works for an Emory PI using their Emory appointment, they must complete this training.	OnCore CTMS, Insight, and Epic training is Not Equivalent to any AVAMC Training. AVAMC staff who see subjects at an Emory facility must undergo OnCore training with their Superuser and complete Emory Epic training to access the medical record system.
	Children's Healthcare of Atlanta (CHOA) New hires must contact Research Education Manager Jennifer Shipp for training and sponsored accounts at researcheducation@choa.org or 404.785.3535. For IRB application submissions , visit https://www.choa.org/research/institutional-review-board .	Children's CITI Biomedical/SHB is Equivalent to Emory .	Children's does not offer the CITI CRC course for those who function as coordinators. Not Equivalent to Emory . Children's staff must complete if they work with an Emory PI at an Emory site, as a part of the pre-req for CRO/CRT.	Children's CITI GCP-ICH is Equivalent to Emory .	CITI Health Privacy and Information Security is different for each institution Equivalent to Emory . Children's staff must complete if you enter data in OnCore CTMS or access the Epic medical record system.	Emory CRO/CRT is Not Equivalent to CHOA's Research Training. It is mandatory and specific to Emory's processes. If a Children's staff works for an Emory PI using their Emory appointment, they must complete this training. Work with Jennifer Shipp.	OnCore CTMS, Insight, and Epic training is Not equivalent to CHOA's Velos CTMS. Children's staff must complete OnCore training with their Superuser if they enter data in Emory OnCore CTMS, and complete Emory Epic training to access the medical record system.
	Grady Health System (GHS) New hires must contact Associate Director of Research Programs Naquia Mitchell at mailto:EGResearch@emory.edu or 404-727-9365. For IRB/ROC application submissions , visit https://www.gradyhealth.org/office-of-research-administration/#services .	Grady staff employed by Emory must be complete Emory CITI Biomedical or SHB.	Grady staff employed by Emory must be complete Emory CITI CRC module if they function as a coordinator	Grady staff employed by Emory must be complete Emory CITI GCP-ICH module.	Grady staff employed by Emory must be complete Emory CITI Health Privacy and Information Security if they enter data in OnCore CTMS or access the Epic medical record system.	Grady staff employed by Emory must be complete Emory CRO/CRT course in addition to any training offered by Grady. Work with Naquia Mitchell.	OnCore CTMS, Insight, and Epic training is Not Equivalent to any Grady Training. Grady staff who see subjects at an Emory facility must undergo OnCore training with their Superuser and complete Emory Epic training to access the medical record system.
Winship CTO Staff	Winship Cancer Institute (WCI) New hires must contact Senior Program Associate Ashlea Moore at Amoor30@emory.edu or 404-727-0942. Note: The Winship Regulatory team handles IRB submissions.	Winship CTO staff employed by Emory must be complete Emory CITI Biomedical or SHB.	Winship CTO staff employed by Emory must be complete Emory CITI CRC module if they function as a coordinator.	Winship CTO staff employed by Emory must be complete Emory CITI GCP-ICH module.	Winship CTO staff employed by Emory must be complete Emory CITI Health Privacy and Information Security if they enter data in OnCore CTMS or access the Epic medical record system.	Winship CTO staff employed by Emory must be complete Emory CRO/CRT course and any training offered by Winship for onboarding. Work with Ashlea Moore.	Winship CTO staff employed by Emory must be complete OnCore and Epic training with their TEO team and if they enter data in OnCore CTMS or access the Emory medical record system. Insight Training is completed by Winship's Regulatory Team.

CITI = Collaborative Institutional Training Initiative
 CTMS = Clinical Trials Management System
 CRC = Clinical Research Coordinator
 CRO/CRT = Clinical Research Orientation & Clinical Research Training
 eCOI = Electronic Conflict of Interest
 EHSO = Environmental, Health & Safety Office
 ELMS = Emory Learning Management System

FDA = Food & Drug Administration
 GCP & ICH = Good Clinical Practice & International Conference of Harmonization
 HIPAA = Health Insurance Portability & Accountability Act
 IRB = Institutional Review Board
 NIH = National Institutes of Health
 ROC = Research Oversight Committee
 SHB = Social Health & Behavioral
 SOM = School of Medicine