

Clinical Research Orientation and Training for Emory Staff on NIH-defined Clinical Trials

Training supports the quality of clinical trials, the protection of research participants, and the generalizability of study results. Orientation and baseline training is **required** for all staff new to Emory or new to clinical research for studies that meet the [NIH-definition of a clinical trial](#) (which includes FDA-regulated studies) at Emory. CME/CEU/Nursing [credits](#) are issued for several courses and organizations.

Orientation and core course completion will be **required before participation** in any research study. If coursework is not completed by the submission of a new study or an amendment (e.g., adding personnel), the IRB will remove the staff from the study, and a hard stop will be imposed by the IRB. They will not be allowed to participate until the coursework is completed by showing a certificate of completion. Any additional departmental training will be considered supplemental. *See page 2 for requirements at Emory affiliated sites (AVAMC, CHOA, and Grady).*

Emory Healthcare (EHC) **credentialing is required for Emory clinical research staff** who have direct contact with subjects in an EHC facility and/or will need access to patient medical records for EHC subjects, including remote staff who need access to patient’s medical records. Direct contact is defined as transporting patients, collecting specimens, obtaining vital signs, obtaining measurements, performing ECGs, phlebotomy, etc.). *Investigators* who are magnet-designated®, *Clinical Research Nurses*, *Clinical Research Coordinators*, or *Other key personnel* are to contact the EHC Research Credentialing Office, at research.credentialing@emoryhealthcare.org or 404.712.0510. Please review the [Clinical Research Role Matrix](#) to understand your roles and responsibilities.

Note: For anyone observing or shadowing an investigator, clinical research nurse, or clinical research coordinator, please contact OCR@Emory.edu for guidance.

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 ELMS	Clinical Research Training per Tracks (Will be assigned at Orientation)	eDisclose eDisclose ³	EHSO BioRaft ⁵	OnCore CTMS ELMS
Investigators (PI, Co-I, or Sub-I)	Investigators working on an FDA-regulated clinical trial.	X		X	X		Attend SOM Orientation		X	X	X If no CRC is on the team
	Investigators working on a NIH-supported clinical trial that is <u>not</u> FDA-regulated.	X (or SHB CITI)		X	X	X (or Biomed CITI)	Attend SOM Orientation		X	X	X If no CRC is on the team
	Investigators working on a clinical trial that is neither FDA-regulated or NIH-funded.	X (or SHB CITI)			X	X (or Biomed CITI)	Attend SOM Orientation		X	X	X If no CRC is on the team
	Investigators who are magnet-designated® working on studies per the NIH definition.	X (or SHB CITI)	X	X	X	X (or Biomed CITI)	X	X	X	X	X
Clinical Research Nurses, Coordinators, Research Pharmacists, or Key Personnel	Experienced clinical research nurses or coordinators working on an FDA-regulated clinical trial.	X	X	X	X		X (if new to Emory, Rehire, or Promotion)	X (Training track will be assigned)	X	X	X
	Experienced clinical research nurses or coordinators working on a 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 (Training track will be assigned)	X	X	X
	Experienced clinical research nurses or coordinators working on a clinical trial that is neither FDA-regulated or NIH-funded.	X (or SHB CITI)			X	X (or Biomed CITI)	X (if new to Emory, Rehire, or Promotion)	X (Training track will be assigned)	X	X	X If billables or OCR invoiced
	Clinical research nurses or coordinators with less than 5 years of clinical research experience working on an FDA-regulated clinical trial.	X	X	X	X		X (if new to Emory, Rehire, or Promotion)	X (Training track will be assigned)	X	X	X
	Clinical research nurses or coordinators with less than 5 years of clinical research experience working on a 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 (Training track will be assigned)	X	X	X
	Clinical research nurses or coordinators with less than 5 years of clinical research experience working on a clinical trial that is neither FDA-regulated or NIH-funded.	X (or SHB CITI)				X (or Biomed CITI)	X (if new to Emory, Rehire, or Promotion)	X (Training track will be assigned)	X	X	X If billables or OCR invoiced

¹ The Biomedical Refresher includes 3 additional Emory-specific modules (Emory Institutional & Regulatory Information, Audit Findings, and Ethical Issues in Clinical Research). Renewal every 3 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 3 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 both experienced & non-experienced clinical research nurses, coordinators, and other key personnel functioning in the role of a coordinator. Renewal every 3 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 for biosafety and laboratory may be required from [EHSO](#). The EHSO - Shipping and Transport of Biological Materials and Refrigerants (Dry Ice)” training course is available in [CITI](#).

Staff at a non-Emory or an Emory affiliated site conducting or coordinating on studies that meet the [NIH-definition of a clinical trial](#) with an Emory investigator may be subject to additional training at Emory.

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 CITI ¹ (see pg.1)	Emory CRC CITI	Emory GCP-ICH CITI ² (see pg.1)	Emory CITI Health Privacy and Information Security CITI	Emory Clinical Research Training per Tracks (Will be assigned per your Site Training Manager)	Emory OnCore CTMS ELMS
Clinical Research Nurses, Coordinators, Research Pharmacists, or Key Personnel	Atlanta Veterans Administration Medical Center (AVAMC): <ul style="list-style-type: none"> 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/. 	Equivalent to Emory. Must affiliate with Emory CITI Biomedical to complete 3 additional modules or SHB if needed.	Not equivalent. Must complete if staff member is working with an Emory PI at an Emory and non-Emory site.	Not equivalent. Must affiliate with Emory CITI GCP-ICH to complete 3 additional modules or SHB if needed.	Not equivalent. Must complete if you will be entering data in OnCore CTMS or accessing Epic medical record system.	Not equivalent. Must complete if staff member is working with an Emory PI at an Emory and non-Emory site.	Not equivalent. Must complete if you will be entering data in OnCore CTMS or accessing Epic medical record system.
	Children's Healthcare of Atlanta (CHOA): <ul style="list-style-type: none"> New hires must contact Research Educator Dana Terrell Faircloth for training and sponsored accounts at dana.faircloth@choa.org or 404.785.3535. For IRB application submissions, visit https://www.choa.org/research/institutional-review-board. 	Equivalent to Emory. Must affiliate with Emory CITI Biomedical to complete 3 additional modules or SHB if needed.	Not equivalent. Must complete if staff member is working with an Emory PI at an Emory site.	Not equivalent. Must complete if you will be working with an Emory PI.	Not equivalent. Must complete if you will be entering data in OnCore CTMS or accessing Epic medical record system.	Not equivalent. Must complete if staff member is working with an Emory PI at an Emory site.	Not equivalent. Must complete if you will be entering data in OnCore CTMS or accessing Epic medical record system.
	Grady Health System (GHS): <ul style="list-style-type: none"> New hires must contact Associate Director of Research Programs, Naquia Mitchell at naquia.mitchell@emory.edu or 404-727-9365. For IRB/ROC application submissions, visit https://www.gradyhealth.org/office-of-research-administration/#services. 	Must complete. Emory CITI Biomedical or SHB.	Must complete. Emory CITI CRC module.	Must complete. Emory CITI GCP-ICH module.	Must complete. Must complete if you will be entering data in OnCore CTMS or accessing Epic medical record system.	Not equivalent. Must complete if staff member is working with an Emory PI at an Emory site.	Not equivalent. Must complete if you will be entering data in OnCore CTMS or accessing Epic medical record system.

CITI = Collaborative Institutional Training Initiative
 CTMS = Clinical Trials Management System
 CRC = Clinical Research Coordinator
 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