

## 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 are **required** for all staff on clinical research studies that meet the [NIH definition](#) (which includes FDA-regulated studies) at Emory. CME/CEU/Nursing [credits](#) are issued for several courses and organizations.

Before participating in any research study, orientation and core course completion will be required. If core course completion is not completed, the Emory IRB will remove the staff from the study and impose a hard stop. They will not be allowed to participate until the core course is completed by showing a certificate of completion and uploading it in Emory RedCap eCREST. 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 patients' medical records. Direct contact is defined as transporting patients, collecting specimens, obtaining vital signs, obtaining measurements, performing ECGs, phlebotomy, etc.). For information, contact the EHC Research Credentialing Office at [research.credentialing@emoryhealthcare.org](mailto:research.credentialing@emoryhealthcare.org) or 404.712.0510. Review the [Clinical Research Role Matrix](#) to understand your roles and responsibilities. For pending applications, view [EHC Credentialing Support Help](#).

The core course completions and EHC Credentialing are for *Investigators* who are magnet-designated®, Clinical Research Nurses, Clinical Research Coordinators, or [Other Key Personnel](#) and assigned at [Clinical Research Orientation](#). View the [Executive Summary](#). If you observe or shadow an Investigator, please contact [OCR@Emory.edu](mailto:OCR@Emory.edu) for guidance.

Role	Type of Study	Biomedical Focus <a href="#">CITI</a> <sup>1</sup>	CRC <a href="#">CITI</a> <sup>4</sup>	GCP-ICH <a href="#">CITI</a> <sup>2</sup>	Health Privacy & Information Security <a href="#">CITI</a>	SHB <a href="#">CITI</a> <sup>1</sup>	Clinical Research Orientation Brainer	Clinical Research Training per Tracks (Will be assigned at Orientation)	eDisclose <a href="#">eDisclose</a> <sup>3</sup>	EHSO <a href="#">BioRaft</a> <sup>5</sup>	OnCore CTMS Brainer
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 <a href="#">SOM Orientation</a> .		X	X	X If no CRC is on the team
	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 <a href="#">SOM Orientation</a> .		X	X	X If no CRC is on the team
	Investigators working on a clinical trial that is neither FDA-regulated nor NIH-funded.	X (or SHB CITI)			X	X (or Biomed CITI)	Attend your department or <a href="#">SOM Orientation</a> .		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 (Training track will be assigned)	X	X	X
Clinical Research Nurses, Coordinators, Research, Pharmacists, or Other Key	Clinical research staff working on an NIH-defined clinical trials, including 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 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 (Training track will be assigned)	X	X	X
	Clinical research staff working on a clinical trial 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 (Training track will be assigned)	X	X	X If billables or OCR invoiced

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> 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](#).

<sup>4</sup> 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.

<sup>5</sup> 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 <u>CITI 1</u> (see pg.1)	Emory CRC <u>CITI</u>	Emory GCP-ICH <u>CITI 2</u> (see pg.1)	Emory CITI Health Privacy and Information Security <u>CITI</u>	Emory Clinical Research Orientation & Training per Tracks <u>(Will be assigned per your Site Training Manager)</u>	Emory OnCore CTMS <u>Brainer</u>
Clinical Research Nurses, Coordinators, Research Pharmacists, or Key Personnel	<b>Atlanta Veterans Administration Medical Center (AVAMC):</b>  New hires must work with Tedra Ricks at 404-321-6111 ext.206190 in the credentialing office. <ul style="list-style-type: none"> <li>For IRB application submissions, visit <a href="https://www.va.gov/atlanta-health-care/research/">https://www.va.gov/atlanta-health-care/research/</a>.</li> </ul>	CITI Biomedical/SHB is <b>Equivalent to Emory.</b> Must affiliate with Emory CITI Biomedical to complete 3 additional modules or SHB if needed.	CITI CRC course is <b>Not Equivalent to Emory.</b> Must complete if staff member is working with an Emory PI at an Emory and non-Emory site.	Emory GCP-ICH <b>Not Equivalent to Emory.</b> Must affiliate with Emory CITI GCP-ICH to complete 3 additional modules or SHB if needed.	Emory CITI Health Privacy and Information Security <b>Not Equivalent to Emory.</b> Must complete if you enter data in OnCore CTMS or access the Epic medical record system	Emory Clinical Research Training <b>Not Equivalent to Emory.</b> Must complete if staff member is working with an Emory PI at an Emory and non-Emory site.	Emory OnCore CTMS <b>Not equivalent to Emory.</b> Must complete if you will be entering data in OnCore CTMS or accessing Epic medical record system.
	<b>Children's Healthcare of Atlanta (CHOA):</b>  New hires must contact Research Educator Jennifer Shipp for training and sponsored accounts at <a href="mailto:jennifer.shipp@choa.org">jennifer.shipp@choa.org</a> or 404.785.3535. <ul style="list-style-type: none"> <li>For IRB application submissions, visit <a href="https://www.choa.org/research/institutional-review-board">https://www.choa.org/research/institutional-review-board</a>.</li> </ul>	CITI Biomedical/SHB is <b>Equivalent to Emory.</b> Must affiliate with Emory CITI Biomedical will complete 3 additional modules or SHB if needed.	CITI CRC course is <b>Not Equivalent to Emory.</b> Must complete if a staff member works with an Emory PI at an Emory and non-Emory site.	Emory GCP-ICH <b>Not Equivalent to Emory.</b> Must affiliate with Emory CITI GCP-ICH will complete 3 additional modules or SHB if needed.	Emory CITI Health Privacy and Information Security <b>Not Equivalent to Emory.</b> Must complete if you enter data in OnCore CTMS or access the Epic medical record system.	Emory Clinical Research Training <b>Not Equivalent to Emory.</b> Must complete if a staff member works with an Emory PI at an Emory and non-Emory site.	Emory OnCore CTMS <b>Not equivalent to Emory.</b> Must complete if you enter data in OnCore CTMS or access the Epic medical record system.
	<b>Grady Health System (GHS):</b>  New hires must contact Associate Director of Research Programs, Naquia Mitchell, at <a href="mailto:naquia.mitchell@emory.edu">naquia.mitchell@emory.edu</a> or 404-727-9365. <ul style="list-style-type: none"> <li>For IRB/ROC application submissions, visit <a href="https://www.gradyhealth.org/office-of-research-administration/#services">https://www.gradyhealth.org/office-of-research-administration/#services</a>.</li> </ul>	Emory CITI Biomedical or SHB <b>must be completed</b> by Grady staff.	Emory CITI CRC module <b>must be completed</b> by Grady staff.	Emory CITI GCP-ICH module <b>must be completed</b> by Grady staff.	Emory CITI Health Privacy and Information Security <b>must be completed by</b> Grady staff if you enter data in OnCore CTMS or accessing Epic medical record system.	Emory Clinical Research Training <b>Not equivalent to Emory.</b> Must complete if a staff member works with an Emory PI at an Emory site.	Emory OnCore CTMS <b>Not equivalent to Emory.</b> Must complete if you enter data in OnCore CTMS or access the 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