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



Page 1 of 2

Training supports the quality of clinical trials, the protection of research participants, and the generalizability of study results. At Emory, orientation and baseline training are required for all staff on clinical research studies that meet the [NIH definition](https://grants.nih.gov/policy/clinical-trials/definition.htm) (which includes FDA-regulated studies). CME/CEU/Nursing [credits](http://ocr.emory.edu/training/Continuing%20Credits.html) are issued for several courses and organizations.

Before participating in any research study, orientation and completion of the core course will be required. If the core course 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 they show a certificate of completion and upload 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 patient’s 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 or 404.712.0510. Review the [Clinical Research Role Matrix](https://ocr.emory.edu/_includes/documents/ehc-clinical-research-role-matrix3.xlsx) to understand your roles and responsibilities. For pending applications, view [EHC Credentialing Support Help](https://www.ocr.emory.edu/_includes/documents/ehc-credentialing_research_office_hours_flyer_fy231.docx).

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](https://www.ocr.emory.edu/resources/training/orientation.html). If you observe or shadow an Investigator, please contact OCR@Emory.edu for guidance.

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| **Role** | **Type of Study** | **Biomedical Focus** [CITI](https://about.citiprogram.org/en/homepage/) 1 | **CRC** [CITI](https://about.citiprogram.org/en/homepage/)4 | **GCP-ICH** [CITI](https://about.citiprogram.org/en/homepage/) 2 | **Health Privacy & Information Security** [CITI](https://about.citiprogram.org/en/homepage/)  | **SHB** [CITI](https://about.citiprogram.org/en/homepage/) 1 | **Clinical Research Orientation** [Brainer](https://emory.brainier.com/#/login) | **Clinical Research Training per Tracks** (Will be assigned at Orientation)  | **eDisclose** [eDisclose3](https://emory.sharepoint.com/sites/eDisclose/SitePages/Training.aspx) | **EHSO** [BioRaft](https://emory.bioraft.com/)5 | **OnCore CTMS** and EPIC [Brainer](https://emory.brainier.com/#/login) |
| 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 Orientation](https://med.emory.edu/about/faculty/faculty-development/career-development/new-faculty-orientation-and-resources/index.html). |  | X | X | XIf no CRC is on the team  |
| Investigators working on an NIH-supported clinical trial that is *not* FDA-regulated. | X(or SHB CITI) |  | X | X | X(or Biomed CITI) |  Attend your department or [SOM Orientation](https://med.emory.edu/about/faculty/faculty-development/career-development/new-faculty-orientation-and-resources/index.html). |  | 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 [SOM Orientation](https://med.emory.edu/about/faculty/faculty-development/career-development/new-faculty-orientation-and-resources/index.html). |  | 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(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 Personnel | 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 not 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 | XIf 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](https://grants.nih.gov/policy/clinical-trials/definition.htm) (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](https://emory.sharepoint.com/sites/eDisclose/SitePages/Training.aspx).

4 The  [CITI](https://about.citiprogram.org/) CRC (Clinical Research Coordinator) course is for both experienced & non-experienced clinical research nurses, coordinators, and other key personnel functioning as a coordinator. Renewal 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 for biosafety and laboratory may be required

 from [EHSO](https://www.ehso.emory.edu/training/courses.html). The EHSO - Shipping and Transport of Biological Materials and Refrigerants (Dry Ice)” training course is available in [CITI](https://about.citiprogram.org/).

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V15, 4/19/24
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Staff at an Emory-affiliated site conducting or coordinating studies that meet the [NIH-definition of a clinical trial](https://grants.nih.gov/policy/clinical-trials/definition.htm) with an Emory investigator may be subject to additional training at Emory.



Page 2 of 2

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| **Role** | **Emory Affiliated Sites** | **Emory Biomedical/SHB**[CITI](https://about.citiprogram.org/en/homepage/) 1 (see pg.1) | **Emory CRC** [CITI](https://about.citiprogram.org/en/homepage/) | **Emory GCP-ICH** [CITI](https://about.citiprogram.org/en/homepage/) 2 (see pg.1) | **Emory CITI****Health Privacy and** **Information Security** [CITI](https://about.citiprogram.org/en/homepage/)  | **Emory Clinical Research Orientation & Training** **per Tracks**  |  **Emory OnCore CTMS and EPIC**[Brainer](https://emory.brainier.com/#/login) |
| 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/.](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 completeif 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 training is **Not Equivalent** to any AVAMC CTMS Training.  If an AVAMC staff works for an Emory PI using their Emory appointment, they must complete this training if they enter data in OnCore CTMS or access the Emory Epic medical record system. |
| **Children’s Healthcare of Atlanta (CHOA)** **New hires** must contact Research Education Manager Jennifer Shippfor training and sponsored accounts at researchheducation@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. Thus, it is**Not Equivalent to Emory.** Children’s staff must completeif 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 CTMStraining is **Not equivalent** to CHOA’s Velos CTMS**.**Children’s staff must complete if they enter data in OnCore CTMS or access the Emory Epic 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. |  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 Securityif 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.  | Grady staff employed by Emory**must be complete** OnCore CTMStraining if they enter data in OnCore CTMS or access the Emory Epic medical record system.Grady’s Epic is **Not equivalent** to Emory’s Epic.  |

***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.*

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

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

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