**INTRODUCTION**
This executive summary provides details of the clinical research orientation and baseline training programs at Emory University for clinical research staff (i.e., Investigators, Research Fellows, Research Nurses, Research Coordinators, Key Personnel, etc.). Orientation and training details are viewable on the OCR webpage > Orientation. View the Clinical Research [Training](https://ocr.emory.edu/guidelines/guidelines.html) Requirements for Emory and Emory Affiliates, as outlined by the Clinical Trials Operations Committee (CT Ops), which outlines all required training.

Clinical research orientation and baseline are required for all new hires, rehires, and promotions conducting or coordinating clinical research studies (i.e., observational, qualitative, socio-behavioral, and clinical trials) at Emory University. However, staff who see patients in any Emory Healthcare (EHC) facility or need Epic medical record system access will require EHC credentialing. **CLINICAL RESEARCH ORIENTATION:** **GETTING STARTED (4-6 hours In-Person orientation)**Clinical research at Emory University involves observational, qualitative, qualitative, socio-behavioral, and clinical trial studies. Emory clinical research staff must attend a clinical research orientation to learn about and understand the key stakeholders, university policies and procedures in clinical research, roles and responsibilities, and the training track assignment based on categories of their roles and functions based on tasks, type of human research, and years of experience using both [ACRP](https://acrpnet.org/competency-domains-clinical-research-professionals) and [SOCRA](https://www.google.com/url?sa=t&source=web&rct=j&opi=89978449&url=https://www.socra.org/assets/SOCRA-Educational-Key-Competencies-Graphics.pdf&ved=2ahUKEwjMuOS0vq2KAxVWMNAFHVjrBr8QFnoECBgQAQ&usg=AOvVaw3Wc5BrRUYNEOKU0Yn2cbEY) competency domains for Clinical Research Professionals. *See the figure below.*

**Month 2 Check-In**

**All staff must complete.**

One-Year Review of Training and Support

 **BASELINE SITE TRAINING**: **CLINICAL RESEARCH AT EMORY (8 hours In-Person training)**
Baseline site training ensures you are knowledgeable and skilled enough to be on an Emory IRB-approved application based on your role at an Emory site that includes:

1. Clinical Research Types
2. Emory Clinical Research Workflow Process, both Pre & Post Award
	1. Funding Types: Federal, Industry, Internal, or Unfunded
3. Protocol review
4. Research Misconduct
5. IRB and Ethical Considerations
	1. Informed Consent review
6. Recruitment Strategies
7. Data Management
8. Resources- OCR Website (Guidelines/Policies/Forms/Training/Links/Reports)
9. Additional eLearning modules: Ancillary Departments, IRB, Medical Devices (optional), ClinicalTrials.Gov, Compliance, Study Maintenance, and Site Monitoring Visits

After baseline site training, new hires/rehires/promotions will be monitored for a year of continuous learning and improvement to measure key performance indicators (KPIs) of benefits and risks. The time points are Month 1, Month 2, Month 3, Month 6, and Month 12. Existing staff will be monitored annually. Staff will be categorized, and training assignments will be provided at CRO.

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| **Clinical Research Training (CRT) Category Assignment and Competency Domain for CR Professionals** |
| **Categories**  | **Competency Domains** |
| General Researcher - Non-CT | **Pre-Req** (Emory CITI Biomedical/SHB, Health Privacy Information & Security/HIPAA, CITI Clinical Research Coordinator (CRC) |
| Non-Subject Facing: <5 years, Observational Study  | **1-Scientific Concepts & Research Design** |
| Non-Subject Facing: >5 years, Observational Study  | **2-Ethical, Participant Safety, Considerations** |
| Non-Subject Facing: <5 years, Clinical Trial Study  | **3-Medicines, Development, & Regulation** |
| Non-Subject Facing: >5 years, Clinical Trial Study  | **4-GCP** |
| Non-Subject Facing: <5 years, Basic Science Study  | **5-Study & Site Mx** |
| Non-Subject Facing: >5 years, Basic Science Study  | **6-Data Mx & Informatics** |
| Subject Facing: <5 years, Observational Study  | **7-Leadership & Professionalism** |
| Subject Facing: >5 years, Observational Study  | **8-Communication & Teamwork** |
| Subject Facing: <5 years, Clinical Trials Study  |  |
| Subject Facing: >5 years, Clinical Trials Study  |  |
|  |  |
| ***Reference:***  |  |
| Competency Domains for the Clinical Research Professional |  |
| [Sonstein, S.A., Seltzer, J., Li, R., Jones, C.T., Silva, H., Daemen, E. (2014, June). Moving from compliance to competency: A harmonized core competency framework for the clinical research professional (PDF - 259KB). Clinical Researcher. 28(3); 17-23.](https://mrctcenter.org/clinical-trial-competency/wp-content/uploads/sites/5/2019/02/2014_6_harvard_mrct_clinical_researcher_publication_competency_framework.pdf) |

**MONTH 1:** **STUDY VISIT AND DOCUMENTATION** **(2 hours online via Zoom)**
Month 1 training is a more in-depth review of the study visit and documentation. New hires/rehires/promotions will learn the following:

1. Site Initiation Visits
2. Study Visit Preparation
	1. Ancillary Departments: EML, RAD, IDS, Device Department
3. Documentation
	1. SAE/AE/UP/Deviations
	2. Source Docs
	3. Case Report Forms (CRFs)
	4. eRegs Redcap
	5. Anonymization/Redaction
4. Systems Used for Documentation at Emory University
	1. OnCore CTMS
	2. Epic HER
	3. Redcap
	4. Insight
	5. Others
5. Study Monitoring
	1. CAPA

**MONTH 2:** **CHECK-IN ONLY (Office Hours)**Month 2 is a quality check of your 60 days of employment. New hires/rehires/promotions will be asked the following:

1. Have you completed your OnCore training with your department's OnCore Superuser?
2. Have you been contacted by CTAC for a review?
3. Have you received EHC credentialing?
4. Have you completed EHC Epic training?
5. Have you completed Insight training, if applicable?
6. Does your study document in RedCap?

**MONTH 3:** **FINANCIAL MANAGEMENT AND RESEARCH BILLING (2-3 hours online via Zoom)**
Month 3 training is a workshop designed to help the study teams understand research billing and its importance in clinical research for compliance. The workshop will include the following topics that new hires/rehires/promotions will learn:

1. Review of the Pre & Post Process related to research billing
	1. Pre-Award Budget
	2. Pre-Award Coverage Analysis (CA), if applicable
	3. Award Approval – what does the Clinical Trial Agreement (CTA) say?
2. Study Visit Tracking
	1. EDC vs OnCore
3. Invoicing
	1. What is needed?
	2. What is invoiced?
	3. Summary of Transactions (SOTs)
4. Finances
	1. Clinical Trials Billing Department (CTBD) – Biller Review
		1. What is documented and charged to the research grant account?
		2. Investigational Drug Services charges
		3. Emory Healthcare charges
	2. Research Administrative Services (RAS)
		1. Are you being notified by RAS of your grant accounts?
		2. Are there any discrepancies?
	3. Research Grants & Contracts (RGC)
		1. Have they invoiced for any of your studies?
		2. Are any of your studies ready for closeout? Who has been notified?
	4. Emory Finance Department – Controller’s Office
		1. Have you been audited? What did it say?

**MONTH 6: STUDY CLOSEOUT & RECORD RETENTION** **(1-2 hours online via Zoom)**Month 6 discusses the end process of a clinical research study. New hires/rehires/promotions will learn the following:

1. Review of a Study Closeout Letter
	1. Were the appropriate departments at Emory notified?
2. Review of the Emory Record Retention policy
	1. What is the requirement? For Emory? For the Sponsor per the CTA?
3. Invoicing and Available Funds
	1. Are the funds available for record retention?
4. Storage
	1. How will they be stored? Off-site? In-House? Electronic?
	2. Database Lock?

**Month 12: YEARLY REVIEW (1-2 hours online via Zoom)**
Month 12 is a yearly assessment to see how you have progressed in your role at Emory University. New hires/rehires/promotions will review the following:

1. Review of the Clinical Research Roadmap from Baseline Site Training
2. Is additional training needed?
	1. [GaCTSA Training and Workforce](https://georgiactsa.org/training/index.html) Development modules
3. Career Pathway
	1. Career Elements
	2. Available certifications for your role
4. Provide Emory CRO/CRT Checklist Training Log

**ANNUAL REVIEW**: **CHECK-REVIEW ONLY (Total of 5 credits; Annually)**
Annual review is for existing staff hired before the current year. Existing staff will update training records in eCREST by completing 1 of the following:

1. A total of 3 credit hours of [GaCTSA Training and Workforce](https://georgiactsa.org/training/index.html) Development modules
2. A current [ACRP](https://acrpnet.org/certification)/[SOCRA](https://www.socra.org/certification/certification-program/program-overview/) certification.
3. A total of 3 credit hours from a clinical research conference, i.e., WCG-[MAGI](https://www.wcgclinical.com/events/), [ACRP](https://2025.acrpnet.org/events), or [SOCRA](https://www.socra.org/annual-conference/2025/2025-annual-conference-information/).
4. A total of 3 credit hours from a clinical research professional development course on clinical research topics only (not just clinical), such as:
	1. [American Nurses Association Continuing Education](https://www.nursingworld.org/continuing-education/)
	2. [Emory Clinical Cardiovascular Research Institute](https://eccri.emory.edu/education/index.html)
	3. Emory [SOM Live Courses](http://med.emory.edu/cme/CMETracker/)
	4. Emory [SON Events](https://www.nursing.emory.edu/pages/events-calendar)
	5. Emory [SON Experience and Nursing Education](https://www.nursing.emory.edu/emory-nursing-experience)
	6. [Medscape CME & Education](https://www.medscape.org/)
	7. [NIH Training Opportunities](https://www.nih.gov/research-training/training-opportunities)
	8. [RSPH Continuing Education](https://sph.emory.edu/departments/gh/continuing-ed/index.html)
	9. [WCG](https://www.wcgclinical.com/events/) MAGI Clinical Research
	10. [Winship Cancer Institute CE](https://winshipcancer.emory.edu/education-and-training/continuing-education/index.php)

Existing staff will also update training records in eCREST by completing 2 of the following within that current year, as these sessions are provided frequently throughout the year:

1. OCR [Research Matters](https://ocr.emory.edu/resources/training/research-matters.html) educational seminar
2. [Winship Clinical Trials Office](https://winshipcancer.emory.edu/clinical-trials/clinical-trials-office/index.php) Annual Training for Clinical Staff (*contact Ashlea Moore, Sr. Program Manager,* *amoor30@emory.edu**)*

**MANAGERS/SUPERVISORS**OCR supports departments by ensuring their staff are oriented to Emory University's policies and guidelines for human subject research. Please be sure the staff follows the training schedule listed above. The Orientation schedule can be found on the OCR’s [webpage](https://ocr.emory.edu/resources/training/orientation.html). Managers/supervisors can use the [Onboarding Checklist](https://ocr.emory.edu/_includes/documents/clinical-research-welcome-checklist-v61.docx) to validate training for a standard training review.
***\*Starting in 2025, managers of new hires will receive a quarterly assessment report and an annual competency maturity score to assess their current level of capability and progress within their specific job role.***

**DISABILITY**OCR and the Emory Department of Accessibility Services (DAS), part of the Office of Institutional Equity and Compliance, assist qualified students, faculty, and staff with obtaining various services and ensuring that all matters of equal access, reasonable accommodation, and compliance are adequately addressed. If you need accommodations, please provide details to the course instructor, complete the Employee Accommodation Request Form,and provide any supporting documentation.

**COMPLIANCE**OCR and Emory Healthcare (EHC) Credentialing Office will assess each student's training and credentialing record at Emory University for compliance. The Institutional Review Board (IRB) and Office of Research Integrity and Compliance (ORIC) will review non-compliance with the policies/mandates**.**

Emory University's [IRB](https://irb.emory.edu/) will verify that all clinical research staff have completed the CITI courses, which are prerequisites to the baseline training. The [OCR](https://ocr.emory.edu/resources/training/orientation.html) will conduct quarterly reviews of baseline training participation. Non-compliance will be reported to the relevant compliance agencies. To reduce study disruptions, ensure staff complete the necessary training based on their roles. Any extra-departmental training will be considered supplemental.

**Any questions?** Contact the Office for Clinical Research (OCR) at OCR@Emory.edu or 404.778.4960. *All data is captured in an electronic training track system called eCREST (Emory Collaborative Research Training), established in 2016 and used for review between Emory, Emory affiliates, and Emory Clinical Trials Audit & Compliance.*