V15, 10/29, 2025
Developed by the ECRO CRSS Team

EXECUTIVE SUMMARY

Clinical Research Orientation and Training

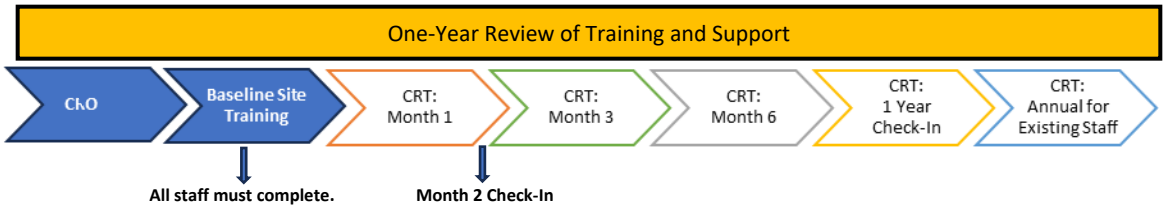
INTRODUCTION

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 ECRO's webpage > Orientation. View the Clinical Research Training 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 who conduct or coordinate 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 require access to the Epic medical record system must be EHC credentialed.

CLINICAL RESEARCH ORIENTATION (CRO): (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 and SOCRA competency domains for Clinical Research Professionals. *See the figure below.*



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
    a. Funding Types: Federal, Industry, Internal, or Unfunded
3. Protocol review
4. Research Misconduct
5. IRB and Ethical Considerations
    a. Informed Consent review
6. Recruitment Strategies
7. Data Management
8. Resources- ECRO/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 to measure continuous learning and improvement, focusing on key performance indicators (KPIs) related to 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 the CRO.

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.

MONTH 1: STUDY VISIT AND DOCUMENTATION **(3.5 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
    a. Ancillary Departments: EML, RAD, IDS, Device Department
3. Documentation
    a. SAE/AE/UP/Deviations
    b. Source Docs
    c. Case Report Forms (CRFs)
    d. eRegs Redcap
    e. Anonymization/Redaction
4. Systems Used for Documentation at Emory University

a. OnCore CTMS
b. Epic HER
c. Redcap
d. Insight
e. Others

5. Study Monitoring
    a. 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 study teams understand research billing and its importance in clinical research for compliance purposes. 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
    a. Pre-Award Budget
    b. Pre-Award Coverage Analysis (CA), if applicable
    c. Award Approval – what does the Clinical Trial Agreement (CTA) say?
2. Study Visit Tracking
    a. EDC vs OnCore
3. Invoicing
    a. What is needed?
    b. What is invoiced?
    c. Summary of Transactions (SOTs)
4. Finances
    a. Clinical Trials Billing Department (CTBD) – Biller Review
        i. What is documented and charged to the research grant account?
        ii. Investigational Drug Services charges
        iii. Emory Healthcare charges
    b. Research Administrative Services (RAS)
        i. Are you being notified by RAS of your grant accounts?
        ii. Are there any discrepancies?
    c. Research Grants & Contracts (RGC)
        i. Have they invoiced for any of your studies?
        ii. Are any of your studies ready for closeout? Who has been notified?
    d. Emory Finance Department – Controller's Office

i. Have you been audited? What did it say?

MONTH 6: STUDY CLOSEOUT & RECORD RETENTION (eLearning in Articulate)
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
    a. Were the appropriate departments at Emory notified?
2. Review of the Emory Record Retention policy
    a. What is the requirement? For Emory? For the Sponsor per the CTA?
3. Invoicing and Available Funds
    a. Are the funds available for record retention?
4. Storage
    a. How will they be stored? Off-site? In-House? Electronic?
    b. 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 + Assessment Quiz
2. Review and Update Emory CRO/CRT Checklist Training Log
3. Is additional training needed?
4. Career Pathways
    a. Career Elements
    b. Available certifications for your role
5. Requirements needed for Annual Review

ANNUAL REVIEW: (Total of 8 credits; Annually)
An annual review is for existing staff hired before the current year. Existing staff will update training records in eCREST by completing the following:

REQUIRED 3 HOURS: Enter the **current** **CITI Training date** and upload the necessary certificate of completion.

- CITI Good Clinical Practice (GCP) and ICH
- CITI Biomedical Refresher and/or Social Behavior
- CITI CRC Module

2 HOURS REQUIRED FROM EITHER OF THE OPTIONS BELOW: Enter the **current** date and upload a **document/certificate** of attendance or completion.

- ECRO/OCR Research Matters educational seminar
- Winship Clinical Trials Office Annual Training for Clinical Staff (*contact Ashlea Moore, Sr. Program Manager, amoor30@emory.edu*)

3 HOURS REQUIRED FROM EITHER OF THE OPTIONS BELOW: Enter the **current** date and upload a **document/certificate** of attendance or completion.

- A total of 3 credit hours of GaCTSA Training and Workforce Development modules
- A current ACRP/SOCRA certification.
- A total of 3 credit hours from a clinical research conference, i.e., WCG-MAGI, ACRP, or SOCRA.
- A total of 3 credit hours from a clinical research professional development course on clinical research topics only (not just clinical), such as:
    a. American Nurses Association Continuing Education
    b. Emory Clinical Cardiovascular Research Institute
    c. Emory SOM Live Courses
    d. Emory SON Events
    e. Emory SON Experience and Nursing Education
    f. Medscape CME & Education
    g. NIH Training Opportunities
    h. RSPH Continuing Education
    i. WCG MAGI Clinical Research
    j. Winship Cancer Institute CE

***Automatic reminders are sent from eCREST RedCap 365 days from your initial baseline training date, but a manual review is conducted in September every year for non-compliance. Notifications will be sent to staff whose training records require updating. Also, to ensure staff are up to date with their training records, the ECRO CRSS Team may initiate a compliance check and provide a departmental training session for compliance updates. These sessions can also count as "refreshers" for you and your staff.**

Regarding the new changes for 2025, per the December 24, 2024, ECRO/CTO Listserv notification of the latest changes, managers of new hires/rehires/newly promoted staff 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.

MANAGERS/SUPERVISORS

ECRO 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 ECRO/OCR's webpage. Managers or supervisors can use the Onboarding Checklist to validate training for a standard training review.

PROMOTIONS/EXPERIENCED STAFF

Staff promoted to new roles may or may not be required to attend CRO/CRT again. If the role is within the same department with the same title (e.g., CRC I at Neurology to CRC I at Winship), the staff member does not need to attend, provided they have complied with their training records.

Experienced staff (i.e., those with more than 5 years of experience in clinical research) are required to complete both CRO and CRT if their training records do not reflect compliance. If the staff member's training records comply, he/she may be exempted. Contact the Emory Clinical Research Office (ECRO) at ocr@emory.edu for more information.

STUDENTS/VOLUNTEERS

Students may participate in Emory clinical research studies as paid staff/interns or receive college credits for their learning experience. Unpaid or volunteer students can only participate in an observational role as part of their learning experience.

Due to the stratified learning model above, we understand that students may not be able to attend all sessions, and accommodations can be made on a case-by-case basis. Otherwise, we can provide an excused letter for your professor for that time, as the clinical research orientation and training are required for all Emory staff participating in clinical research studies and activities.

DISABILITY

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

COMPLIANCE

ECRO 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 the Office of Research Integrity and Compliance (ORIC) will review instances of non-compliance with policies/mandates**.**

Emory University's IRB will verify that all clinical research staff have completed the CITI courses, which are prerequisites to the baseline training. The ECRO will conduct quarterly reviews of CRO, CRT, and Annual Review training. 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. Any extra-departmental training will be considered supplemental to the required training.

Any questions? Contact the Emory Clinical Research (ECRO) at OCR@Emory.edu or 404.778.4960.

All data is captured in an electronic training tracking system called eCREST (Emory Collaborative Research Training), established in 2016, and used for reviewing among Emory, Emory affiliates, and Emory Clinical Trials Audit & Compliance.