COURSE FAILURE POLICY

Clinical Research Orientation and Training

The Clinical Research Orientation and Training course is **required** for *all new hires, rehires, and those who have been promoted in a new clinical research role* (excluding investigators that receive an orientation from their respective department) at Emory University and Emory Healthcare conducting or coordinating an NIH definition of a clinical trial (view both the Executive Summary to understand the training process flow and the Emory Required Training for Investigators and Coordinators policy). The course is designed in several parts to provide a basic framework of the roles and responsibilities to equip clinical research coordinators, research nurses, fellows, and residents with the tools to succeed at Emory. A post-examination is provided to assess knowledge of the following topic areas below and students whose primary job responsibility must pass with an 80% or higher.

Percentage of Exam Content

Percentage of Exam	Category	Departments or Content
30%	Stakeholders (Sponsor, PI/Study Team)	Definitions, Roles and Responsibilities, including expectations.
35%	Regulatory	Study start-up and closeout, Essential document submission, UP/AE/SAE, Consent process,
15%	Documentation/Compliance	Drug and Device accountability, SOPs, Source Documents, and PI Record Keeping.
10%	Audit and Monitoring	CAPA, Trust Line and Research Misconduct
10%	CITI Review	Belmont Report, FDA 152 Form

Examination Attempts:

1. **1st attempt** – completes open book and self-pace exam and fails the post-examination. *The student will need to reschedule a date & time to remediate and re-take the exam.*

2. **2nd attempt** – after 1st attempt and fail again, must re-take course per their learning track and re-take the exam. *The student will need to re-register for an upcoming course date to complete and re-take the exam.*

3. **3rd and final attempt** – areas of weakness will be discussed with the supervisor and the employee. *Discussion with the supervisor on next steps to consider other employment or reassignment of duties. Involvement of HR may be needed at this point.*

Notes: If the employee states clinical research study coordination is not their primary job responsibility, they must get that in writing and validate with supervisor. If the employee is a student, they must review the Students in SOM Labs/Research policies to adhere to specific guidelines.

Refreshers: Clinical Research Training

Training is to be renewed every 3 years when renew your CITI trainings. You will complete the following to refresh as continuing education: 1) CITI Biomedical Refresher, 2) CITI Health Privacy and Information Security, 3) CITI CRC module, and 4) A total of 3.0 CEUs elective modules from Georgia CTSA at https://twd.ce.emorynursingexperience.com/. The elective modules can be any module of your liking. A certificate of completion for each refresher must be uploaded in your eCREST profile.

If you have never completed an eCREST profile, please contact OCR@Emory.edu.

Approved by Clinical Trials Operations Committee
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