

COURSE FAILURE POLICY

Clinical Research Training (Part 1) Course

The Clinical Research Training – Part 1 (formerly *Virtual Training and Credentialing for Clinical Research Staff/2-Day Classroom: Intro to CR*) course is baseline training **required** for all staff new to Emory or new to clinical research for studies that meet the [NIH-definition of a clinical trial](#) (which includes FDA-regulated studies). The course is designed in two 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 Clinical Research Training – Part 1 and fails the post-examination.
The student will need to reschedule a date & time to remediate and re-take the post-examination. Remediation and the re-take do not happen on the same day.
2. **2nd attempt** – after 1st attempt and fail again, must re-take the course.
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 the supervisor and the employee.
Discussion with 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 in writing and validate with supervisor.

Students must review the [Students in SOM Labs/Research](#) policies to adhere to specific guidelines.