Course Failure Policy for the Virtual Training and Credentialing for Clinical Research Staff Course

The Introduction to Clinical Research at Emory 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 to provide a basic framework of the roles and responsibilities to equip clinical research coordinators, research nurses, fellows, and residents with the tools to be successful in their job roles at Emory. The course is virtual, instructor-led, and students participate in course discussions and activities. 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.

- Stakeholders (Sponsor; PI/study team; Departments: RAS, IRB, OCR, OTT, IDS, COI; facilities/collaborators): 30% of the exam.
- IRB (consent, submissions, role, ads, UP/SAE/AE, Study Close Out, Reportable Events, Closure Reports): 35% of the exam.
- Documentation/Compliance (Drug Accountability, Definitions, SOP, Source Documents, PI Record Keeping): 15% of the exam.
- Audits/Office of Research Integrity Compliance (CAPA, Trust Line/Misconduct): 10% of the exam.
- CITI (Belmont Report, FDA Form 1572): 10% of the exam.

Examination Attempts:

1st attempt – completes course, pre-requisites, & fails test.
The student will need to work with the course instructor to reschedule a date & time to re-take the post-examination. Remediation doesn’t happen on the same day.

2nd attempt – re-review study materials & re-take the test.
The student will need to re-take the course and the post-examination.

3rd attempt – discuss areas of weakness with supervisor & employee involving Human Resources & performance counseling then re-takes the full classroom course & test.
If the student fails after the 3rd attempt, discussion with supervisor to consider other employment or reassignment of duties.

Note: If the employee states clinical research study coordination is not their primary job responsibility, they must get in writing and validate with supervisor.

Approved by Clinical Trials Operations Committee v2,2.1.22