



EMORY
UNIVERSITY
SCHOOL OF
MEDICINE

Date: May 23, 2016

To: Clinical Chairs, School of Nursing, School of Public Health, EHC Nursing

From: Dr. Jeffrey L. Lennox, M.D., Associate Dean of Clinical Research

A handwritten signature in black ink, appearing to read "J. Lennox", with a long horizontal flourish extending to the right.

Subject: Revised Training Requirements for Investigators and Research Coordinators
Conducting FDA-regulated Clinical Trials at Emory

We need to continue the training requirement to ensure investigators are aware of their responsibilities in the conduct of a clinical trial, and have adequate training to enhance those responsibilities. We understand the difficulties with accessing and completing the training within the eLMS (Emory Learning Management System), and the need for a more user-friendly system. Effective June 1, 2016, we will move the on-line modules from the eLMS to the CITI (Collaborative Institutional Training Initiative) environment. Other process improvements include: 1) Limiting the mandatory training to those conducting FDA-regulated clinical trials at Emory to reduce the burden on those performing social and behavioral research, and 2) Extending Continuing education to every three years to harmonize with the VA, CHOA, and IRB.

- The initial on-line training modules for investigators will be accomplished through the CITI *Good Clinical Practice* (GCP) course with three additional modules customized for Emory. This will be beneficial as the CTSA and NIH are planning to require GCP training for all CTSA and NIH funded studies in the future--placing Emory ahead of the game and eliminating redundant training.
- We will continue to offer the 2-day classroom course for clinical research coordinators new to Emory or new to research, and will offer on-line modules through the CITI *Clinical Research Coordinator* course (with three additional Emory-specific modules) for experienced coordinators with prior GCP training.
- To date, there have been 1,533 investigators and 1,107 coordinators who have taken these baseline courses. They will be grandfathered in with the revised training requirements and only required to take the continuing education within three years of the date of their baseline clinical trials training (investigators completed the *Key Concepts in Clinical Research* course and coordinators completed the *Introduction to Clinical Research* course).
- The continuing education requirement will incorporate three additional Emory-specific clinical trials modules into the existing CITI Biomedical Refresher course. Therefore, it will not be necessary to have the faculty and research teams take an additional training course to meet their continuing education requirements.