



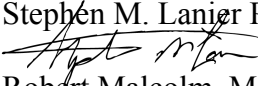
Office of the Associate
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EFFECTIVE NOVEMBER 1, 2008

Date: September 8, 2008

To: All Investigators and staff involved in the conduct or oversight of Human Research and Clinical Investigation

From: Stephen M. Lanier Ph.D., Associate Provost for Research at MUSC

Robert Malcolm, M.D., Director of the Office of Research Integrity

Re: Continuing education requirements - MIAMI CITI COURSE REFRESHER
MODULE 101

Colleagues:

As you probably know, we are seeking accreditation of our Human Research Protection Program through the Association for the Accreditation of Human Research Protection Programs (AAHRPP).

This is now the gold standard for such accreditation and we are submitting joint applications with the Ralph A. Johnson VA Medical Center, for which we serve as the affiliate Institutional Review Board. MUSC submitted their application August 31, 2008 with a site visit of the external review team to be scheduled in early 2009.

Having worked on this application for almost one year, we can assure you that it is an important step for MUSC and will enhance our process and procedures across many aspects of our operation benefiting all involved.

There will be some changes in the operational policy going forward in accordance with AAHRPP standards. We will be communicating such changes via email and postings on the MUSC Research web site.

Our internal review process identified a need for continuing education for those involved in human research at MUSC to ensure compliance at nationally accepted standards.

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After reviewing several mechanisms for such continuing education, we have selected the MIAMI CITI COURSE REFRESHER MODULE 101. There is no charge to the investigator for this training.

The AAHRPP accreditation process involves enhancement of our current policies and extends beyond immediate operation of the IRB to many other aspects of our university under the umbrella of a broader Human Research Protection Program

We have also collected the policies and procedures already in place for the MUSC Institutional Review Boards and organized them with more detailed information and updated guidelines in a HRPP Guide, that we hope will facilitate protocol development, submission and review while enhancing all aspects of our HRPP. This will soon be posted on the MUSC research web site.

Thank you very much for your commitment to our programs and for all that you do for the Medical University.

WHO MUST COMPLETE THE CONTINUING EDUCATION REQUIREMENT?

All individuals that completed the initial 17 basic modules focused on biomedical research provided through the Miami Collaborative Institutional Training Initiative or CITI and are involved in human research studies (<http://www6.miami.edu/citireg/>).

Individuals with a VA appointment are ALREADY required to complete similar continuing education modules at the CITI site on an ANNUAL basis and this will, of course, satisfy the requirement from the MUSC Office of Research Integrity for continuing education in Human Research Protection.

WHEN MUST I COMPLETE THE CONTINUING EDUCATION REQUIREMENT?

The MIAMI CITI COURSE REFRESHER MODULE 101 must be completed every three years following initial completion of the training modules already required at the initiation of human research at MUSC and the Ralph A. Johnson VA Medical Center.

To facilitate this process, individuals involved in human research are required to complete the MIAMI CITI COURSE REFRESHER MODULE 101 upon submission of the annual continuation review process for HR protocols BEGINNING NO LATER THAN NOVEMBER 1, 2008. **This refresher module should take you one hour or less to complete.**

The CITI site will guide you to the appropriate module for continuing education and record the completion just as it does for our current CITI training module.

If you have any questions, comments or suggestions, please contact Donna Heartley, Business Manager, Office of Research Integrity (792-9865, heartley@musc.edu) or Lynn M. Veatch,

Ph.D., Special Projects to the APR (792-3247, veatchlm@musc.edu).