

IMPORTANT!

TO: All Faculty Members, Researchers and Research Team Members Utilizing an EVMS or an EVMS-approved IRB

FROM: William J. Wasilenko, Ph.D., Associate Dean for Research

DATE: January 24, 2007

RE: IRB Education Requirements for 2007

In our continuing efforts to assure the protection of human research subjects and assist researchers, EVMS is requiring annual refresher education for faculty/staff who conduct research with human subjects. Education programs are a proactive step being taken nationally at the majority of medical schools to provide researchers with the latest regulatory requirements and procedures for protecting research subjects.

Accordingly, all investigators and their research team members who engage in human subjects research **must complete between March 1, 2007 - June 30, 2007** one of the human subjects protections education requirements outlined below. Education is mandatory and required for IRB approval of all new protocols and all active protocols. Your past 2006 education will only be valid until June 30, 2007. Your new 2007 training will be valid until June 30, 2008. The following education options are available to facilitate completion of this requirement:

Annual Refresher Education Programs

1. *For research team members who already have documentation of human subjects protections training/education on file with the Office of Research, any one of the following options would meet the requirement for refresher education:*
 - a. Attendance at an approximately two hour educational workshop on **Thursday March 22** in the Brickhouse Auditorium with registration and lunch starting at 11:30 am and the program commencing at noon. The featured speaker is **Doc Muhlbaier, Ph.D. from Duke University**. His talk is titled “**Data and Specimen Repositories: How to Manage and be HIPAA Compliant**”. This will also include a question and answer session on HIPAA as it applies to human subjects research so bring your questions. To attend, please e-mail Nicole Priest at priestnl2@evms.edu. Please include your name, department, phone number and e-mail address (for confirmation purposes); **or**
 - b. Completion of the web-based “CITI **Refresher** Course in the Protections of Human Research Subjects” provided by the University of Miami. This program,

in which EVMS participates, is entirely online. To achieve certification, you must complete all the required modules, as well as any optional modules that may be of interest to you, and achieve a combined test score of 80% or higher. The modules are pre-selected depending upon whether your area of research is biomedical or social sciences/behavioral. You do not have to complete all of the modules in a single session. This training option can be accessed at: www.citiprogram.org. You may take the refresher course again if you selected this option for your 2006 refresher education; **or**

c. Watching a video of the March 10, 2006 OHRP seminar and take the quiz. You must score 80% or higher to pass the quiz and receive credit for this education option. The link to this education option is: http://info.evms.edu/Research_html/IRB/IRB_Refresher_index.htm. The link is available on the EVMS intranet only; **or**

d. Attendance at a human subjects protections education/training program provided by a professional society or training firm, documented by a certificate of completion dated in early 2007.

2. *For research team members who may be new to EVMS or have no documentation of education/training on file in the Office of Research, the following human subjects protections education requirements must be completed:*

a. Completion of the web-based “CITI **Basic** Course in the Protections of Human Research Subjects” provided by the University of Miami. This program, in which EVMS participates, is entirely online. To achieve certification, you must complete all modules and achieve a combined test score of 80% or higher. The modules are pre-selected depending upon whether your area of research is biomedical or social sciences/behavioral. You do not have to complete all of the modules in a single session. This training can be accessed at www.citiprogram.org.

Additional Optional Training

Completion of HIPAA for Research Training. This optional training may be accomplished by:

- Taking the “**For Whose Eyes Only?**” EVMS HIPAA research training program located on Blackboard. This option is for persons who are on campus. The accompanying quiz must be completed with a score of 80% or higher for training to be documented; **or**
- Reading the NIH website “Protecting Personal Health Information in Research: Understanding the Privacy Rule” at http://privacyruleandresearch.nih.gov/pr_02.asp. This option requires a

signed statement from the investigative team member that he or she has read and understood the material presented on the website. This statement should be sent to Research Compliance at EVMS to be included in your education/training record.

Who is a research team member? You are a research team member if you are working on any part of a research project that requires IRB review. All persons, including residents, students, coordinators, and data management, are considered team members if their effort contributes to a study.

We thank you for your cooperation in strengthening our research program involving human subjects.

Please contact the Office of Research (Thomas Abbott or Kari Bos) for any questions or for more information.