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: February 11, 2013

RE: Human Subjects Research Training/Education Requirements

The purpose of this memo is to announce to all current Research Team Members involved in Human Subjects Research on an EVMS-approved Institutional Review Board (IRB) protocol, that Refresher Training is now due for all who previously completed refresher or initial training in 2011.

A summary of education requirements for individuals engaged in human subjects research is provided below. This education is mandatory and required for IRB approval of all new protocols and all active protocols.

Refresher Education Programs

Refresher education is required to be completed every two years. As noted below, new investigators are required to complete the Basic CITI training course before commencing a research project involving human subjects.

Current investigators who completed either the Basic CITI course or Refresher education/training will need to complete *refresher* education/training within two years of completing that education/training as outlined below.

Refresher Education:

For research team members who already have documentation of human subjects protections training/education on file with the Office of Research, the requirement for refresher education is:

a. 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 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 previous refresher education; or

- b. Evidence of completion of a comparable CITI Refresher Course from another institution. Please contact the Office of Research for information and questions about these comparable courses and training programs; **or**
- c. Attendance at a human subjects protections education/training program provided by a professional society or training firm, documented by a certificate of completion.

<u>Initial Education Program for New Investigators and Research Team</u> Members:

For investigators and 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 prior to engaging in human subjects research:

- 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.
- Evidence of completion of a comparable CITI Basic Course from another institution within the past two years. Please contact the Office of Research for information and questions about these comparable courses and training programs.

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.

These education programs are part of our continuing efforts to assure the protection of human research subjects and assist researchers. 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 conducting research involving human subjects.

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

Please contact the Office of Research at 446-8480 (Thomas Abbott abbottts@evms.edu or Kari Bos boske@evms.edu) for any questions or for more information.