



UNIVERSITY of  
MASSACHUSETTS  
BOSTON  
100 Morrissey Blvd.  
Boston, MA 02125-3393

Office of the Vice Chancellor  
for Academic Affairs and Provost  
617.287.5600  
Fax: 617.287.5616

September 5, 2007

**MEMORANDUM TO:** University Community

**FROM:** Paul J. Fonteyn, Provost and  
Senior Vice Chancellor for Academic Affairs

**SUBJECT:** Required Training for Research with Human Subjects

The university's Institutional Review Board (IRB) must review all research and research-related activity proposed by any member of the UMass Boston community that involves human subjects in any way. This requirement is based upon our assurance given to the federal Department of Health and Human Services that UMass Boston researchers—faculty members, students, administrators, staff members—are aware of and follow all federal rules and regulations concerning the protection of human subjects in research as contained in the Code of Federal Regulations, Title 45, Part 46 (45 CFR 46).

Failure to follow the policies and procedures governing research with human subjects can lead not only to serious penalties for the individual violator, but also to serious sanctions against the entire university, including substantial fines, the suspension of federal funds—including federal student financial aid funds—and, in the most serious cases, debarment of all researchers at the university from seeking extramural support for sponsored research. All new applications, modification requests, annual reviews, continuation requests, and completion of activities reports for research with human subjects must be submitted to the university's IRB for their review and action. Studies that have completed the recruitment of human subjects and are now in the data analysis phase must also seek annual review. Any adverse event in research with human subjects must be reported immediately to the IRB, to be followed by a written report and supporting documentation. All IRB forms and instructions can be found on the Office of Research and Sponsored Programs website at the Internet URL <http://www.umb.edu/research/orsp>, select the "Compliance" option.

Since November 1, 2004, all PIs and co-investigators have been required to provide evidence of their understanding of the federal rules and regulations, as well as the UMass Boston policies and procedures, concerning research with human subjects before the IRB will consider the approval of new submissions, modifications, or continuation requests for research with human subjects. In addition, the release of university funds, whether from external or internal sponsors, that support a PI's or co-investigator's research with human subjects requires similar evidence. For

students engaged in research with human subjects, both the student and his or her faculty or staff sponsor must provide the required evidence.

UMass Boston has contracted with the University of Miami to provide online training through the Collaborative IRB Training Initiative (CITI) free for members of the university community on issues related to the protection of human subjects in research. The CITI modules span a variety of areas including the assessment of risk, informed consent, and research involving special populations such as children or prisoners. The required modules can be completed in more than one sitting at the researcher's convenience. At the completion of the training, UMass Boston is notified that the training has been completed and the researcher's name is added to a dynamic database monitored by the university's IRB administrator, Lauren Shniderman.

To register for the CITI training, log on to <http://www.citiprogram.org> and click on the red link to "Register for the CITI course." Select "University of Massachusetts Boston" from the "All Others" drop down list and submit. You will then be asked to select a username and password. Follow the registration prompts until you reach the main menu, select the "Basic Course," and begin the training. If you have questions concerning UMass Boston policy and procedures relating to research with human subjects, or questions concerning the CITI training and how to register for the training, please call or send a message to Kristen Kenny at 617-287-5374 or [kristen.kenny@umb.edu](mailto:kristen.kenny@umb.edu).

Thank you for your continuing assistance in ensuring that UMass Boston meets its obligations in this vital compliance area.

cc: J. Keith Motley, Chancellor  
Mary Ellen Colten, Chair, Institutional Review Board