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DATE: August 31, 2009

TO: University Community

FROM: Winston Langley, Provost and 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 all UMass Boston faculty members, students, administrators and 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 <http://www.umb.edu/research/orsp/compliance/irbforms.html>.

All PIs and co-investigators are required to provide evidence of their understanding of federal rules and regulations, as well as 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 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 free online training on issues related to the protection of human subjects in research for members of the university community through the Collaborative IRB Training Initiative (CITI). The CITI modules span a variety of areas including assessment of risk, informed consent, and research involving special populations such as children or prisoners. All UMass Boston researchers engaged in research with human subjects are required to complete the CITI training course. 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, Kristen Kenny. The process for accessing the CITI training course appears below.

All UMass Boston researchers engaged in research with human subjects are required to complete the CITI refresher training course, specifically the social/behavioral research modules, every three (3) years. For students engaged in research with human subjects, both the student and their faculty or staff sponsor must provide the required evidence of completing the CITI refresher course. You will be notified by Kristen Kenny via e-mail when you will need to complete this one-hour refresher course. The process for accessing the CITI refresher training course appears below.

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

Process for completing the CITI training course:

1. Visit the CITI website at <http://www.citiprogram.org>
2. To register click the red link “Register Here” then select “University of Massachusetts Boston” from the “Participating Institutions” drop down list.
3. You will then be asked to select a username and password.
4. Follow the registration prompts until you reach the main menu, select the “Basic Course,” and begin the training.
5. 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.

Process for completing the CITI refresher training course:

1. Visit the CITI website at <http://www.citiprogram.org>
2. Log-on to the website by entering your username and password*→You will be directed to the main Learner menu→Section One: review and confirm your profile information→Section Two: institutional header, see Human Research Curriculum→Click on "Grade Book" to display all refresher social/behavioral course modules.
3. Complete the refresher training course by reading the module text and taking the quizzes.
4. Review/complete the instructions on the institutional (or last) module. The institutional module must be completed before the results of your quizzes can be forwarded to the CITI Program.
5. You have now completed the human subject protection continuing education requirements.

*If you cannot remember your username and/or password, both pieces of information are stored on a CITI database. So you can request this information through the CITI Program website.

cc: J. Keith Motley, Chancellor
Zong-Guo Xia, Vice Provost for Research and Strategic Initiatives
Paul Nestor, IRB Chair