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MEMORANDUM FOR: University Community

FROM: ~~Emily~~ McDermott,
Interim Provost and Vice Chancellor for Academic Affairs

SUBJECT: Research with Human Subjects

The university's Human Research Protection Program (HRPP) is committed to protecting the rights and welfare of human subjects. The UMass Boston Institutional Review Board (IRB) must review all human research proposed by any member of the UMass Boston community. This requirement is based upon our assurance given to the U.S. Department of Health and Human Services that the university follows the ethical principles of the Belmont Report for all human research as well as the legal requirements of the Code of Federal Regulations, Title 45, Part 46 for human research conducted or supported by any U.S. federal department or agency adopting the "Common Rule."

Investigator Responsibilities

In conducting human research, all investigators and research staff are required to follow the requirements listed in the **INVESTIGATOR MANUAL (HRP-103)**. Investigators cannot commence research until IRB approval and any other required prior approvals (e.g., biosafety approval; departments or divisions that require approval of the use of their resources) are in place. Investigators are also responsible for ongoing requirements in the conduct of approved research that include, in summary:

- obtaining and documenting informed consent of subjects or subjects' legally authorized representatives prior to the subjects' participation in the research, unless these requirements have been waived by the IRB;
- obtaining prior approval from the IRB for any modifications of the previously approved research, including modifications to the informed consent process and document;
- ensuring that requests for continuing review and notification of study completion (final report) are submitted to the IRB;
- promptly reporting to the IRB any unanticipated problems involving risks to subjects or others and/or reports of serious or continuing noncompliance with the regulations or the requirements or determinations of the IRB.

Investigators are obligated to ensure that all members of the research staff engaged in human research are qualified and provide evidence of their understanding of the federal rules and regulations as well as of the UMass Boston policies and procedures concerning 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 advisor should provide the required evidence.

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 suspension and termination of research, 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.

How to determine if your activity is "Research with Human Subjects"

Activities that are not human research do not require IRB review. If there is uncertainty about whether a proposed activity meets the regulatory definitions of "research" with "human subjects" visit the Office of Research and Sponsored Programs (ORSP) website for a step-by-step process tool to determine if your activity needs IRB review: **Do I Need IRB Review?**

Training

UMass Boston has contracted with the Collaborative Institutional Training Initiative (CITI) Program to provide online human research training. All UMass Boston investigators and research staff who are engaged in research with human subjects are required to complete the appropriate CITI training course every three (3) years and have a valid CITI completion certificate as confirmation prior to conducting any research. The CITI modules span a variety of areas including the assessment of risk, informed consent, and research involving vulnerable populations such as children or prisoners. The required modules can be completed in more than one sitting at the researcher's convenience. Previous coursework from another institution that is not commensurate with UMass Boston requirements will not be accepted. In some cases, previous coursework will transfer after the researcher completes steps in CITI to add affiliation with University of Massachusetts Boston.

For step-by-step CITI training requirements and instructions, visit the ORSP website at: https://www.umb.edu/orsp/research_committees/irb/required_training

IRB Forms and Templates

IRB application forms and the protocol template have recently been updated to improve readability, eliminate redundancies and unnecessary sections, and to make them more in line with best practices. Applicants are encouraged to use the updated forms, although the old forms will be accepted by the IRB until the transition to **Kuali**, a fully electronic IRB submission system, in 2021. New tools (checklists and worksheets) are also available to help investigators with developing and conducting IRB protocols. All IRB forms and instructions can be found on the Office of Research and Sponsored Programs (ORSP) Web site at: https://www.umb.edu/orsp/research_committees/irb

Contacts

For questions concerning the UMass Boston IRB, human research protections or human research training, contact Sharon Wang, Senior IRB Administrator, at 617.287.5374 or sharon.wang@umb.edu or irb@umb.edu.

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

cc: Katherine Newman, Interim Chancellor
Bala Sundaram, Vice Provost for Research and Dean of Graduate Studies
Matthew L. Meyer, Associate Vice Provost for Research and Director of ORSP
Paul Nestor, Chair, Institutional Review Board
Sharon Wang, Senior IRB Administrator