Policy and Procedures on Human Subjects in Research

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Approved by _____

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Date_____

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LeadingAge Policy and Procedures for Research with Human Subjects

Introduction

LeadingAge is committed to research engaging older adults and conducts research designed to help our nation address the challenges and seize the opportunities associated with a growing older population. This work is being carried out by The LeadingAge LTSS Center @UMass Boston.

LeadingAge is committed to protecting and the rights and welfare of human subjects. Because of the Center's affiliation with UMass Boston all research with human subjects proposed by any member of LeadingAge community must be reviewed by the UMass Boston Institutional Review Board (IRB), except when research can be reviewed by an IRB at a research site. The IRB approval 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."

The funding portfolio at LeadingAge is comprised of federally funded awards (grants and contracts), non-federal awards (grants and contracts), and agreements with technology and other companies. All research projects funded by above sources or unfunded are subject to IRB review.

Investigator Responsibilities

Investigators cannot commence research until IRB approval and any other required prior approvals (e.g., departments 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

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regulations as well as of the LeadingAge's policies and procedures concerning research with human subjects. For students engaged in research with human subjects, both the student and his or her 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 LeadingAge, 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 LeadingAge LTSS Center @UMass Boston from seeking extramural support for sponsored research.

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

Activities that are not human research (e.g., scholarly and journalistic activities such as oral history, journalism, biography, literary criticism, legal research, and historical scholarship; educational activities such as class projects not intended for use outside of the course; quality improvement limited in application to the project's immediate setting; case reports) 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 UMass Boston Office of Research and Sponsored Programs (ORSP) website (https://www.umb.edu/orsp/research_committees/irb/do_you_need_review) 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 The LeadingAge LTSS Center @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 UMass Boston ORSP website at:
https://www.umb.edu/orsp/research_committees/irb/required_training

Compliance Management

All LTSS Center @UMass Boston researchers should contact the LeadingAge's Human Subjects Protection Officer (HSPO) before initiating any research involving human subjects. The HSPO

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will guide the researcher through the application process at UMass Boston, including determining if the research involves human subjects. The HSPO will also ensure and document that all staff have up-to-date and appropriate IRB training via CITI. With support of the IRB Secretary, the HSPO will also keep files of all IRB approved studies, including applications and approvals, and ensure that renewals whenever appropriate are submitted to the IRB to maintain an active status for all studies.

Contacts

The HSPO, Verena R. Cimarolli can be contacted at vcimarolli@leadingage.org or 202-508-9411 and the IRB Secretary, Alexandra Hennessa can be contacted at ahennessa@leadingage.org or 202-508-1210.

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

All IRB forms and instructions can be found on UMass Boston's Office of Research and Sponsored Programs (ORSP) Web site at: https://www.umb.edu/orsp/research_committees/irb

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