UMASS GLOBAL INSTITUTIONAL REVIEW BOARD

Guidelines for Course-Related Student Research Projects

A. Introduction

The UMASS GLOBAL Institutional Review Board (IRB) recognizes it may be difficult at times to distinguish between research projects that require IRB review and those which are designed to provide an experience in research methodology and learning course materials.

All faculty, staff and students at UMASS GLOBAL conducting research involving human subjects as defined in 45 CFR 46.102 must submit their research protocol to an Institutional Review Board (IRB) for review and approval prior to commencing the project. In order to assist investigators in deciding whether a planned activity constitutes research involving human subjects, the following federal definitions of research and human subject are provided:

- *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
- *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains:

    1. Data through intervention or interaction with the individual, or
    2. Identifiable private information

B. Thesis and Dissertation Projects

Students who conduct research under the above definitions for their thesis or dissertation must submit an application to the IRB for review and approval prior to commencing the project. The IRB also must be consulted when the project is begun in a formal academic course, but intended to contribute to a thesis or dissertation, and when students plan to submit the work for professional publication or presentation regardless of the connection to a formal thesis or dissertation process.

C. Class Work Assignments

These types of assignments are usually not intended to (or are not likely to) contribute to generalizable knowledge. They would not be considered "research" if they are projects being conducted for educational purposes and use in the UMASS GLOBAL class *only*.

If a student and/or instructor is uncertain whether or not a project will produce findings worthy of publication or dissemination outside of the immediate classroom environment, the student and/or instructor should submit the project for IRB review when the intent of the project becomes the conduct of research (i.e., to contribute to generalizable knowledge), as opposed to the intent of instructing students in research methodology. For example:

1. If a student's goal, when undertaking a course-related project, is to produce findings that will contribute to generalizable knowledge then that student should submit the project to the IRB for review prior to commencing the research.

2. If a student has no intent of contributing to generalizable knowledge at the beginning of a project but generates information that could later be developed into a research project, that student must then submit the project in accordance with the criteria of a project exempt from review or other categories of research, as appropriate.

D. Projects with Public Use Data Sets or De-identified Data
§46.101 (b) Research exempt from review. Category (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
Certain projects involving the use of existing, public or de-identified data sets may qualify as exempt from review under Exempt Category (4) as presented above. In order for the IRB to make that determination, the investigator generally must submit an application to the IRB for review.
Any data source should be considered as potentially requiring IRB review, regardless of its public nature because of rapidly changing expectations and regulations regarding both privacy and research review. Students and faculty should consult the IRB in the early planning phases of research involving public use data sets to make sure of the appropriate IRB oversight expectations.

E. Submission to the IRB
1. Completion of a IRB application for student research projects that require IRB review (i.e., "research" as defined by CFR 46.102) should be submitted to the IRB on the appropriate application, with the student listed as the principal investigator and the instructor signing as the faculty sponsor. Faculty members serving as sponsors are responsible for assisting the student in preparing the IRB application and protocol for IRB review and for the supervision of the student's research.
Course research projects involving human subjects, designed to contribute to generalizable knowledge, where the entire class is conducting a project(s) centered on the same research question, should be submitted to the IRB on the appropriate course related research application, with the instructor listed as the principal investigator and the students listed as co-investigators.

2. Timelines for processing a IRB application
It is recommended that requests for exempt or expedited review be submitted to the IRB three weeks before the research is to begin. Research projects requiring full board review should be submitted to the IRB at least one month before the research is to begin in order to allow sufficient time for the review process. (*These timelines are only recommendations. Protocols may be processed more quickly if the IRB does not require revisions or additional information.)*
Since course projects are often conducted in a short timeframe, it is advisable to limit the scope of course-related research activities to those that qualify for exempt or expedited review in order to avoid the longer IRB processing time generally needed for projects that require full board review. It is strongly advised that course related projects requiring IRB review be conducted over more than one semester due to the IRB review and approval process timelines.
Please notify the IRB to the course timeframe for completing course- related research by attaching a completed Application for Course-Related Research Involving Human Participants. The IRB will conduct reviews for course-related projects as quickly as possible.

F. Questions
Instructors and/or students who have questions about IRB review of course-related projects are encouraged to contact the IRB Chair at **IRB@UMASS GLOBAL.edu.**