BOARD OF HIGHER EDUCATION

REQUEST FOR COMMITTEE AND BOARD ACTION

COMMITTEE: Assessment and Accountability **NO**.: AAC 08-15

COMMITTEE DATE: April 17, 2008

BOARD DATE: April 25, 2008

MOVED: The Board hereby approves the application of the **University of Massachusetts** Worcester to award the **Master of Science in Clinical Investigation**.

Upon graduating the first class for this program, the University of Massachusetts Worcester shall submit to the Board a status report addressing its success in reaching program goals as stated in the application and in areas of enrollment, curriculum, faculty, resources, and program effectiveness.

Authority: Massachusetts General Laws Chapter 15A, Section 9(b).

Contact: Aundrea Kelley, Associate Vice Chancellor for Academic Policy

BOARD OF HIGHER EDUCATION

April 2008

University of Massachusetts Worcester
Master of Science in Clinical Investigation

INTENT AND MISSION

The University of Massachusetts Worcester (UMW) has submitted a proposal to offer a Master of Science in Clinical Investigation at the Worcester Medical School campus (UMMS). The purpose of this proposed program is to provide graduates with the skills necessary to successfully design, conduct, and analyze the results of clinical investigations at the individual and population-wide level, as well as design and analyze the results of studies on the molecular pathophysiology of disease. This program is structured to ground students in the principles of clinical investigation, while providing a flexible multidisciplinary focus that allows tailoring of the curriculum to the needs and interests of young researchers who aspire to become successful independent clinical investigators.

The University's mission is to provide an affordable and accessible education of high quality and to conduct programs of research and public service that advance knowledge and improve the lives of the people of the Commonwealth, the nation, and the world. The President's office reviewed the preliminary proposal and authorized the development of the final proposal in December 2007. It was approved by the University's Board of Trustees Committee on Academic and Student Affairs on February 25, 2008, and by the Board of Trustees on March 19, 2008. The Letter of Intent was circulated on March 3, 2008.

NEED AND DEMAND

The proposed program has been designed to address growing national concerns over the shortage of trained clinical investigators. The National Institutes of Health (NIH) has recognized growing barriers between clinical and basic research and has initiated a broad, re-engineering effort to catalyze development of a new discipline – Clinical and Translational Science. In response, the University's recently established the Center for Clinical and Translational Sciences at the UMMS. Secondary goals of the proposed program are to develop a sustained pipeline of well-trained clinical researchers and future faculty members for purposes of growing the clinical and translational research enterprise at the UMMS.

The proposed program seeks to place the UMMS at the forefront of the new National Institutes of Health (NIH) goals for clinical and translational research. The UMMS is the

recipient of an NIH planning grant to develop a Clinical and Translational Science Award (CTSA) application. To qualify for receipt of a CTSA, faculty at the UMMS must develop an innovative, advanced degree program that will nurture a cadre of well-trained multi-disciplinary investigators and research teams. The proposed program is the University's response to this challenge.

ACADEMIC AND RELATED MATTERS

Admission Requirements

The proposed program is primarily intended for individuals already trained in the medical sciences, as well as others with relevant scientific backgrounds and experiences who desire further training in research design and methodology. Individuals accepted into the clinical investigation training program will represent a wide variety of backgrounds and disciplines with different levels of undergraduate and postgraduate training. Applicants admitted to the program are expected to demonstrate a high degree of motivation and commitment to a career in patient-oriented clinical investigation.

Projected Enrollments

Three to five students are expected to enroll initially into the proposed program. The number is expected to double during the second and third year and then to stabilize with between seven to ten students each year thereafter. An equal number of students who wish to obtain a Certificate of Advanced Study in Clinical Investigation are expected to enroll each year, as well, increasing the initial cohorts to six to ten, with eventual enrollment of a total of 15 to 20 students per year. To incentivize the recruitment of physicians into clinical research, UMMS faculty, staff and physicians will receive a tuition waiver for this advanced degree.

Curriculum (Appendix A)

A significant portion of the Master's in Clinical Investigation curriculum derives from ongoing courses currently provided by the CPHR program of the Graduate School of Biomedical Science (GSBS). The Master's Degree Program in Clinical Investigation offers the option of two tracks for focused trainee concentration. One track will have a focus on population-based clinical research, while the other track will have as its focus bench-to-bedside translational research. These concentration tracks will allow students to enhance their knowledge base, based on their current interests and career objectives. For completion of the master of science degree, a total of 36 credits are required, and a publishable master's thesis must also be completed. In addition to the master of science degree, the University will also offer a 24-credit Certificate of Advanced Study in Clinical Investigation to interested health care professionals. This latter program is designed for those who do not wish to obtain an additional degree but desire to acquire advanced skills in clinical research and investigation.

RESOURCES

Faculty and Staff

Teaching faculty will comprise existing members of the Graduate School of Biomedical Science, all of whom are Medical School faculty. The Clinical Investigation program, when mature, will require the recruitment of additional faculty in the disciplines of epidemiology, biostatistics, and biomedical informatics. The University is committed to these recruitments.

Facilities and Infrastructure

This new program will be administered and housed under the auspices of the GSBS at the UMMS. The GSBS (established in 1977) comprises four divisions – Basic and Biomedical Sciences (BBS), Biomedical Engineering (BME), Clinical and Population Health Research (CPHR) and the MD/Ph.D. program. The GSBS has an integrated and flexible infrastructure for program and faculty development, curriculum development, student recruitment, student orientation/matriculation, course registration and student tracking.

Field and Clinical Resources

The research component of each master's track student will be directly supported by the research funds of the sponsoring faculty mentor. All students will be funded by the Center for Clinical and Translational Sciences at the appropriate Post-Graduate Year (PGY) level.

FISCAL (Appendix B)

A three-year budget is attached in Appendix B.

EVALUATION

The program was reviewed by Drs. Richard A. Galbraith, M.D., Ph.D., F.R.C.P., Dean. College of Medicine, University of Vermont; and Timothy P. Flanigan, M.D., Ph.D., Professor of Medicine, Brown University. Overall, the reviewers expressed strong support for the program with a few minor recommendations, including detailed development of appropriate assessments tools for on-line coursework, the expansion of on-line course offerings for the certificate program, and clarification of some course descriptions. The campus has responded appropriately to each suggestion offered by the reviewers.

STAFF ANALYSIS AND RECOMMENDATION

The staff has thoroughly reviewed all documentation submitted by UMW and external reviewers. Staff recommendation is for approval of the Master of Science in Clinical Investigation.

Upon graduating the first class for this program, UMW shall submit to the Board a status reports addressing its success in reaching program goals, as stated in the application and in the areas of enrollment, curriculum, faculty resources, and program effectiveness.

Appendix A: Curriculum

Core Courses

MCI 601	Introduction to biostatistics in clinical research – 3 credits
MCI 605	Introduction to clinical epidemiology – 3 credits
MCI 610	Design of observational studies and clinical trials – 3 credits
MCI 615	Biomedical informatics (3 course credits) – 3 credits
MCI 620	Scientific writing and oral presentation – 3 credits
MCI 625	Ethical, legal and social implications of clinical investigation – 2 credits
MCI 630	Intermediate biostatistics in clinical research – 3 credits
MCI 635	Topics in molecular medicine – 2 credits
MCI 640	Team science concepts – 2 credits

Population and Clinical Health Sciences Research Track

MCI 701	Cardiovascular epidemiology – 2 credits
MCI 705	Cancer epidemiology – 2 credits
MCI 710	Pharmacoepidemiology – 2 credits
MCI 715	Molecular epidemiology– 2 credits
MCI 720	Geriatric epidemiology – 2 credits
MCI 725	Health services research– 2 credits
MCI 730	Survival analysis – 2 credits
MCI 735	Regression techniques – 2 credits

Translational Sciences Research Track

MCI 740	Advanced therapeutics technologies – 2 credits
MCI 745	Drug development I (discovery – preclinical) – 2 credits
MCI 750	Drug development II (first in humans) – 2 credits
MCI 755	Genomics (gene expression/microarra