Clinical and Translational Science

Degree Offered
Master of Science
Also offered - Graduate Certificate in Clinical and Translational Science

Program Description
The Master of Science in Clinical and Translational Science Program offers a broad curriculum that will meet the diverse needs of trainees. The program will be built on seven core courses that emphasize approaches to research design and analysis, provide opportunities for networking and collaboration, and introduce translational research concepts. Additional courses will be offered in three broad areas of emphasis from which the students can choose.

Fields of Research
Epidemiology and Outcomes Research
Courses offered will closely correspond to the once existing Master of Science in Epidemiology Program. The courses focus on training individuals who will conduct population-based and clinical outcomes research.

Translational Research
Courses will emphasize “Bench to Bedside” research. The courses will focus on training individuals who wish to bridge the research gap between basic and clinical research (e.g. drug development, genetics research, use of animal models). Trainees are expected to include both basic scientists who wish to take their work toward clinical application and clinical scientists who wish to investigate the science underlying clinical observations with the goal of developing new understandings or treatments.

Commercial Development of Drugs, Biologics, Devices and Diagnostics
Courses emphasize the commercialization and regulatory compliance for various classes of therapeutics and diagnostics. This area of emphasis utilizes some existing courses offered in the Healthcare Technologies Program and Bioinformatics programs.

Program Degree Requirements
Thirty (30) credits are required for graduation. Several areas of concentration are provided that are intended to accommodate students with different backgrounds and professional interests. However, each student will have an individualized educational program composed of core courses required of all students (12 credits), elective courses selected as appropriate for the student’s interest (12 credits), and a
Master’s thesis project completed under the mentorship of a three-member multidisciplinary faculty mentoring committee (6 credits).

**Required Courses**

**20220 Clinical Statistics I.** 3 credits.

**20221 Clinical Statistics II.** 3 credits

**10222B Ethics and Integrity in Science.** 1 credit. (See listing within Bioethics Program.)

**14212B Ethics of Technology Utilization.** 1 credit. (See listing within Bioethics Program.)

**20100 Introduction to Clinical and Translational Science.** 1 credit.

This course provides an overview of the rationale, process and methodologies of clinical and translational research. The scope of the course is broad and includes basic science discovery, animal studies, drug and device preclinical and clinical development, outcomes research, and epidemiology. The course will utilize case studies that illustrate translational research and will be interactive in format. Instructors will be drawn from both basic science and clinical departments.

**20150 Introduction to Epidemiology (Clinical Epidemiology I).** 2-3 credits.

The course provides: 1) an overview of epidemiologic concepts; 2) an introduction to the approaches and techniques that are used to measure and monitor health status in populations; 3) an introduction to study designs to assess disease prevention and intervention; and 4) an introduction to clinical research study designs that elucidate causative factors for disease.

**20261 Clinical Trial Design.** 1 credit.

This course is intended to introduce students to clinical trials methodology and to assist those who wish to evaluate and interpret published reports of trials. This course is focused on the design and development phases of the clinical trials, recruitment techniques, data collection and data quality issues, assessment of adverse effects, participant adherence, data monitoring, sample size requirements, techniques of survival analysis, reporting and interpretation of results, and multi-site studies.

**20299 Master’s Thesis.** 0.5 - 6 credits.

A total of 6 Master’s Thesis credits is required for program completion. All students will complete a master’s thesis describing a translational or clinical research project in which he or she participated in both the design and execution. The Committee will be comprised of a thesis mentor and two additional faculty members (one of whom is a biostatistician). The Committee will approve the project in advance,
will provide guidance and supervision of the project, and will critique and, if appropriate, approve the thesis.

**20301 Graduate Seminar.** 0.5 credit.
The two-year seminar series is designed to provide students with opportunities to learn about the clinical outcomes, epidemiologic, and clinical translational research that is being conducted at the Medical College and its partnering institutions. It provides opportunities for students to network with experienced investigators and provides a forum in which to share and discuss research ideas. In attending the seminars, students have the opportunity to identify topics for their own research, research collaborators, and appropriate research mentors. Students are also introduced to a number of novel research study designs and institutional research resources. The seminar is structured so that the presenter provides an overview of his/her research with emphasis on the research question, the study design, research ethics, ways to solve barriers to conducting research, and research findings that result in further research ideas. The sessions are interactive, and time is allotted for discussion following the formal presentation. The seminar is attended by a variety of individuals including graduate students who are taking the course for credit, graduate students who attend without credit, faculty from diverse backgrounds, research staff and individuals from outside the institution. All students are required to present at least one seminar related to their own research.

**20295 Reading and Research.** .5 to 3 credits.

**20285 Independent Study.** .5 to 3 credits
Self-directed study course for students enrolled in the Master of Science Program in Clinical and Translational Science. Involves completion of advisor-guided project. Advisors must be identified by student and approved by the MS in Clinical and Translational Science Program. Course may be completed for .5 to 3 credits each semester. Student's time investment includes regular meetings with course advisor, completion of pertinent program paperwork required for the course, assigned readings and other research-related projects as agreed upon by the student and advisor (subject to approval by the program director).

**Elective Courses (Non-Concentration Specific Electives for CTS Program Students)**

**20103 Patient Safety & Safety Science** 1 credit
The purpose and goal of this course is to present both fundamentals and advanced principles of Patient Safety and Safety Science. Dominant myths will be explored and debunked. Topics to be covered will include: The scope of the patient safety problem, the relationship
between safety and quality, tools in investigating and improving safety, the role of culture, systems, critical and creative thinking, leadership, high reliability organizations, and resiliency. This course is recommended for individuals who have an interest in understanding and improving patient safety, regardless of whether they are a clinician.

20106 Introduction to Community Engagement—Module 1; Constructs in Community Engagement and Community Engagement in Research. 1 credit

This course is the first of up to three sections that serve as an introduction to the concepts, theories, and principles in community engagement (CE) and community engagement in research (CEnR), with an emphasis on community/academic partnerships. It will examine the methods and strategies of CEnR including partnership development, capacity building, and ethical. Prerequisites: None.

20107 Introduction to Community Engagement - Module 2; Strategies and Methods within Community Engagement in Research. 1 credit.

This course is the second of up to three sections that serve as an introduction to the concepts, theories, and principles in community engagement (CE) and community engagement in research (CEnR), with an emphasis on community/academic partnerships. It will examine the strategies and methods of CEnR including funding, health disparities, capacity building, project planning and communication. Prerequisite: Completion of Introduction to Community Engagement 20106.

20108 Introduction to Community Engagement, Module 3: Translational Research and Community Engagement. 1 credit.

This course is the third and final part of up to three sections that serve as an introduction to the concepts, theories, and principles in community engagement (CE) and community engagement in research (CEnR), with an emphasis on community/academic partnerships. It will examine the relationship between CEnR and other forms of research, information systems and development of research questions. In addition, the course will study cases, evaluation and discuss the future of CEnR. Prerequisites: Completion of Introduction to Community Engagement Course 20106 and 20107.

20140 Leadership in Academic Health Care I. 1 credit

Communication & Leadership.

This course is part of a seminar series specifically directed towards fellows and other health professionals planning to enter careers in academic medicine, especially those with a primary care focus (such as Family & Community Medicine, General Internal Medicine and General Pediatrics). There are no prerequisites. The series is organized into
four, one-credit offerings. This seminar is the first of the four-part series.

**20141 Leadership in Academic Health Care II.** 1 credit. 
*Organizations & Change.*  
Continuation of Leadership in Academic Health Care I. This module focuses on the roles of academic health centers, organizational behavior and strategies for promoting change.

**20142 Leadership in Academic Health Care III.** 1 credit. 
*Leadership & Personal Effectiveness.*  
Continuation of Leadership in Academic Health Care I. This module focuses on general leadership issues, time management and academic roles, building effective teams and problem-solving strategies.

**20143 Leadership in Academic Health Care IV.** 1 credit. 
*Academic Advancement.*  
Continuation of Leadership in Academic Health Care I. This module focuses on identifying one’s own leadership style, characteristics of productive research environments, promotion and tenure, interviewing and negotiating skills.

**20242 Models of Disease and Drug Discovery.** 1 credit.  
This course covers the concepts involved in developing disease models in the laboratory and using these model systems to identify candidate drugs that will eventually be developed for therapy in the clinic. Topics covered include current stem cell culture and animal models used to study human diseases, computational screening approaches for designing and identifying small molecules in drug discovery, and the steps involved in taking a drug from the bench to the clinic. Specifically, models for human disease ranging from stem cells to small animal (zebrafish) to large animal (sheep) for biomedical research will be discussed. Course material will cover techniques for drug screening, platforms developed by companies and academics to screen drugs and steps involved in the drug discovery process. It is anticipated that advantages and disadvantages of each model system will be discussed followed by the practical aspects of designing screens for small molecules using these model systems. At the end of the course, each student is expected to prepare a report that will outline the logical progression of identifying a small molecule against a target of student’s interest, and to make it a commercial drug for clinical use.

**20253 Methods in Grant Preparations.** 1 credit.  
The purpose and goal of this course is to present advanced principles of National Institutes of Health (NIH) Grant preparation. Topics to covered will include: Writing with a purpose and intent; writing statements of innovation and significance; research design; and translational research. The course will also address how to succinctly state overall and specific hypotheses and specific aims with affirmation
and relevance. The course will suggest specific writing styles with the intent of clearly stating the importance of the specific aims and bringing them to fruition and purpose. Special attention will be placed on how to write in a manner which presents proposal aims in an important and timely manner. The course will stress writing styles which relate distinct importance and purpose in a manner which relates novelty in the experimental design. Most of the course will cover the 12-page RO1 application. However, some time will also be devoted to other specific types of awards (i.e., mentored K awards, training grants, and programmatic initiatives). This course is recommended for individuals who have already located funding resources and are currently working on one or more grant proposals.

**20255 Clinical Research Methods Workshop. 1 credit.**
This course is intended to teach clinical fellows and junior faculty an approach to designing epidemiologic research studies. This course is designed to allow students to learn the principles of clinical epidemiology by applying those principles to the development of a protocol document that they are expected to complete in the two-month time period of the course. It is generally not suitable for those whose research will involve only animal or basic laboratory research. Specific topics addressed in the course include: asking a research question, defining study subjects and measurements, study designs, sample-size calculations, ethical considerations, data management, and writing study protocols.

**20263 Meta Analysis. 1 credit.**
This course is designed to provide learners with the tools to critically appraise and independently conduct studies using meta-analytic methods. The specific course objectives are to (1) identify the strengths and weaknesses of meta-analysis and when the method is appropriate; (2) utilize the steps of meta-analysis, including question definition, literature review, data abstraction, analysis and publication; and (3) identify the theory and statistical methods of meta-analysis including fixed and random effects models, tests of heterogeneity, publication bias, file drawer tests, and sensitivity analysis.

**Elective Courses (Concentration in Epidemiology and Outcomes Research)**

**20256 Research Methods in Epidemiology (Clinical Epidemiology II. 3 credits.**
This course covers the fundamental concepts of types of study designs, data collection methods and data analyses in epidemiology. Cohort and case-control study designs will be presented in depth with a review of the methods used to address bias and confounding in the context of these designs. Recent developments in methods for
Elective Courses (Concentration in Translational Research)
20240 Translational Genetics. 2 credits.
The primary goal of this course is to teach students how to develop a research program utilizing the molecular genetics toolbox to ask genetic questions in the clinical setting. To this end, students will be provided with background in molecular genetics strategies and study designs as well as an understanding of common genetics questions emanating from the clinic so that they will be better able to make connections between bench and bedside. In addition, they will be challenged to think creatively and through a translational focus during course-long case studies and group projects.

Elective Courses (Concentration in Commercial Development of Drugs, Biologics, Devices and Diagnostics)
14211 Biomedical Technology Standards and Regulations. 2 credits. (See listing within Healthcare Technologies Management Program.)
20242 Models of Disease and Drug Discovery. 1 credit. - (Animals Models of Disease?)
This course covers the concepts involved in developing disease models in the laboratory and using these model systems to identify candidate drugs that will eventually be developed for therapy in the clinic. Topics covered include current stem cell culture and animal models used to study human diseases, computational screening approaches for designing and identifying small molecules in drug discovery, and the steps involved in taking a drug from the bench to the clinic. Specifically, models for human disease ranging from stem cells to small animal (zebrafish) to large animal (sheep) for biomedical research will be discussed. Course material will cover techniques for drug screening, platforms developed by companies and academics to screen drugs and steps involved in the drug discovery process. It is anticipated that advantages and disadvantages of each model system will be discussed followed by the practical aspects of designing screens for small molecules using these model systems. At the end of the 9 weeks duration of the course, each student is expected to prepare a report that will outline the logical progression of identifying a small molecule against a target of student’s interest, and to make it a commercial drug for clinical use.
20250 Fundamentals of Intellectual Property. 1 credit.
This course surveys the principles of intellectual property (IP) and how IP is generated and leveraged to promote the development of new drugs, diagnostic tests, and medical devices. Students will examine
various ways IP is codified and protected through the use of patents and copyrights. Students will also become familiar with the various agreements that impact on IP rights in the context of clinical and translational research. These agreements include confidentiality agreements, clinical trial and sponsored research agreements, collaborative research and development agreements (CRADAs), consulting agreements, material transfer agreements, and license agreements.

**Elective MCW Healthcare Technologies Courses for Clinical and Translational Science Program**  
(See listings within *Healthcare Technologies Management Program.* )

- **14212 Ethics of Technology Utilization.** 1 credit.
- **HCTM 6500* Product Development of Medical Devices.** 2 credits.
- **14298 Seminars in Drug and Device Development.** 2 credits (1 per semester).
  * Indicates Marquette University course number. All Marquette University courses require an off-campus registration course procedure.
- **ENTP 6110* New Venture Formation.** 1-3 credits.
- **MANA 6100* Organizational Behavior.** 3 credits.
- **HCTM 200* Survey of Biomedical Engineering Technology.** 3 credits.
- **HEAL 6840* Environment of Healthcare Delivery.** 2 credits.
- **HCTM 6200* Biomedical Technology Assessment.** 3 credits.
- **ENTP 6115* Growth Strategies for Entrepreneurial Companies.** 3 credits.
- **ENTP 6180* Entrepreneurial Finance.** 3 credits.
- **FINA 6100* Financial Management.** 3 credits.
- **ACCO 6000* Accounting Foundations.** 2 credits.
- **ACCO 6100* Managerial Accounting.** 3 credits.
- **MARK 6100* Marketing Management.** 3 credits.