Institute for Clinical and Translational Research
AT EINSTEIN AND MONTEFIORE
Building Bridges in the Bronx and Beyond

Einstein Montefiore Institute for Clinical and Translational Research

Clinical Research Training Program

MS in Clinical Research Methods

Catalog 2025

1300 Morris Park Avenue
Jack & Pearl Resnick Campus
Harold & Muriel Block Building 5th Floor
Bronx, NY 10461

EINSTEIN
Albert Einstein College of Medicine
Montefiore

Contents

About This Catalog

This online catalog describes the master's degree program in clinical research methods, which has been offered by the Clinical Research Training Program (CRTP) of the Albert Einstein College of Medicine since 1998. The degree is awarded as an affirmation that the Scholar has acquired the fundamental knowledge and skills required to conduct clinical research. This ability is achieved by completing a prescribed curriculum and a period of research supervised by the Scholar's mentor, the Director, and the Associate Directors of the CRTP. The Academic Policies of the CRTP and a description of the course of study are detailed below. In addition to the guidelines presented within this document, Scholars are expected to meet the standards of professional behavior expected of all members of the College of Medicine.

Educational Mission of the Clinical Research Training Program

The Clinical Research Training Program is an intensive two-year program designed for those pursuing a career in investigator-initiated, hypothesis-driven clinical research, and is offered through the Institute for Clinical and Translational Research (ICTR) at Einstein and Montefiore.

Founded in 2007, the ICTR promotes the collaboration between Albert Einstein College of Medicine and Montefiore Medical Center. The ICTR is a member of the nationwide Clinical and Translational Science Awards (CTSA) consortium, funded by the National Center for Advancing Translational Sciences (NCATS) of the National Institutes of Health (NIH). The CTSA is designed to break down barriers that inhibit cross-disciplinary, bidirectional research from the laboratory to the clinic and back again. The CTSA Consortium aims to improve human health by transforming the research and training environment to enhance the efficiency and quality of clinical and translational research.

Accreditation

Einstein is fully accredited by The Middle States Commission on Higher Education (MSCHE), 3624 Market Street, Philadelphia, PA 19104, 1-267-284-5000. MSCHE is one of six regional accrediting agencies in the United States, each of which accredits institutions of higher education within a specific geographic region. Middle States is recognized by the U.S. Department of Education, enabling eligibility to participate in federal student financial aid programs (e.g., federal loans, grants, and work-study) administered by the U.S. Department of Education.

The MS in Clinical Research Methods is registered with the New York State Education Department under program code 21439, HEGIS code 0419.00. Einstein holds an Absolute Charter from the State of New York to award the MD, PhD, and MS degrees.

Governance of the Clinical Research Training Program

The CRTP, sponsored by Albert Einstein College of Medicine under the leadership and advocacy of Dean Yaron Tomer is an educational program which operates under the auspices of the Einstein- Montefiore Institute of Clinical Translational Research (ICTR) which is supported by the Clinical and Translational Science Award (CTSA) of which Marla Keller, MD is the Principal Investigator. Direct oversight is provided by Aileen McGinn, PhD, Director of the CRTP.

The CRTP benefits from guidance of the ICTR External Advisory Committee (EAC), which comprises a group of nationally known leaders in academic medicine, research, and research education.

The committees listed below are responsible for assuring the quality of the academic program, uniform implementation of CRTP policies, and fair treatment for the students and faculty of the CRTP.

The CRTP Executive Committee

Oversight of curriculum, mentoring, research activities and Scholar progress is provided by an Executive Committee, which meets monthly.

Aileen P McGinn, PhD
Professor, Department of Epidemiology and Population Health
Director, Clinical Research Training Program

Jacqueline Achkar, MD MS FIDSA
Professor, Department of Medicine (Infectious Disease) and Microbiology & Immunology
Associate Director for Bench to Bedside Translational Research - CRTP

Johanna Daily, MD
Professor, Department of Medicine (Infectious Disease) and Microbiology & Immunology
Associate Director for Mentoring and Career Development - CRTP

Dean Hosgood, PhD
Professor, Department of Epidemiology and Population Health
Associate Director for Population and Clinical Sciences Research - CRTP

David Lounsbury, PhD
Associate Professor, Department of Epidemiology and Population Health and Family & Social Medicine
Associate Director for Patient Centered & Outcomes Research - CRTP

Melissa Fazzari, PhD
Associate Professor, Department of Epidemiology and Population Health and Family
Statistical Advisor-CRTP

The CRTP Admissions Committee

All members of the Executive Committee serve on the Admissions Committee in addition to members selected by the Program Director. The Admissions Committee is responsible for making all admissions decisions. Members review the candidates' qualifications, interview candidates and are responsible for making all admissions decisions.

The CRTP Program Administration

Aileen P McGinn, PhD
Director, Clinical Research Training Program
Professor, Department of Epidemiology and Population Health

Nancy Marte
Educational Program Manager

General contact: crtp@einsteinmed.edu

Admissions

The Albert Einstein College of Medicine is committed to a policy of equal opportunity and non-discrimination and encourages applications from qualified students regardless of race, color, religion, national origin, sex, age, handicap, marital status, or sexual orientation within the meaning of applicable law.

An applicant for enrollment in the CRTP should hold a doctoral degree (MD or PhD) or a degree from an allied health profession including dentistry or nursing. Alternatively, MD/MS applications are accepted from students who are currently matriculated in the Albert Einstein College of Medicine.

Eligibility Criteria

- An academic affiliation with Albert Einstein College of Medicine prior to matriculation into the CRTP
- The program considers MD's, PhD's, sub-specialty fellows, medical students and faculty members of Einstein and Montefiore
- Albert Einstein College of Medicine's medical students have the option to apply as a CRTP MD/MS
- Faculty and Fellows must hold an appointment at Einstein or an affiliated institution for the two years enrolled in the CRTP
- Strong interest in, and aptitude for, clinical research
- Scholars must have 80% protected time during the first summer and 50% protected time for the duration of the program. This protected time includes course work and research time.
- A firm written commitment from the trainee's department (Chair, Division Head, or Fellowship Director) that all necessary resources will be made to the Trainee. This includes confirmation of the protected time with demonstrable reductions in clinical, teaching, and administrative responsibilities, as needed, space, and a computer
- Identification of a research project and a mentor

Application Process

All application materials must be submitted through the online application portal as of January 1st but no later than March 1st (including requests for all supporting letters) for consideration in the class that commences the following July. The online application system allows for the uploading of the following required materials:

Applicant Information Form

A Personal Statement that describes the applicant's career goals and explains why they believe this training program will help them achieve those goals. Not to exceed one page single-spaced using 12- point font

A Research Plan that contains a brief description of the applicant's study question and approach. Not to exceed two pages single-spaced using 12-point font.

A Full Curriculum Vitae

Supporting Letters: *The following letters will be solicited and submitted by their author through the online application system:*

Mentor(s) Letter: Each applicant will need to provide an email address for at least one individual who will serve as their mentor during the CRTP. This individual will be asked to submit a letter through the online application system, which will contain a mentoring plan, a description of the research environment they will provide the applicant, a research timeline and how they will advocate for the applicant to receive adequate time for research. The mentor will also be asked to submit their NIH biosketch and a list of former trainees (if applicable). If the scholar will have co-mentors, one mentor may submit a letter on behalf of the mentoring team.

Letters of Reference: Each applicant needs to provide email addresses for one (1) individual (who is different from proposed mentor(s)) who can provide a letter addressing their potential for a career in clinical research.

Letter Guaranteeing Protected Time (Faculty and Fellows only): Each applicant must provide an email address for the appropriate individual who can guarantee their protected time while in the CRTP. This letter may come from a Fellowship Director, Department Chair or Division Head. In instances where this letter is signed by more than one individual, please designate only one-point person for submission of this letter. The individual selected will be asked to submit a letter which includes their support of the applicant's participation in the Clinical Research Training Program and their guarantee that the applicant has the required protected time during the two years that they are enrolled in the program in which to attend classes, complete homework, prepare for examinations, conduct research, and develop and defend a thesis.

The letter should specifically acknowledge the following:

- The first summer requires 80% protected time (i.e., no more than 8 hours per week should be committed to non-CRTP activities). Classes are held four days a week for six weeks (i.e., Monday-Thursday 9:00-12:50 and occasional afternoon sessions). NB: During the first summer the pace of the program is particularly intense. Additionally, there is a take home exam due approximately 2 weeks after the last summer class
- After the first summer, Scholars require 50% protected time (i.e. absolutely no more than 20 hours per week should be committed to non-CRTP activities). Required classes, and most electives, for the remainder of the two-year program are held on Tuesdays & Thursdays from 9:00-12:50
- The trainee must have appropriate space to pursue their studies and perform research and have access to a computer capable of running up-to-date statistical and data management graphics software
- That this individual will serve as a liaison between the trainee, the trainee's mentor, and the director of the training program if the need should arise

Interviews: Each applicant is interviewed by the Director of the CRTP and one or two additional members of the Admissions Committee. Applications will be held over to subsequent years only at the discretion of the Director.

Affirmation of Good Academic Standing (Medical Students only): After submission of the online application the Dean of Students will be contacted to provide affirmation that medical school applicants are in good academic standing.

Official Transcript (Faculty and Fellows only): In addition to the online application, *Faculty and Fellows only* will need to have an official transcript directly from their doctoral degree institution sent to:

Clinical Research Training Program Albert Einstein College of Medicine Jack and Pearl Resnick Campus
1300 Morris Park Avenue, Block Building Bronx, NY 10461
Phone: 718-430-4008 Fax: 718-430-2521

Questions about the application process can be addressed to the Educational Program Manager:
Nancy Marte, nancy.marte@einsteinmed.edu Phone: 718-430-4008

General Policies

The CRTP adheres to all Policies and Procedures endorsed by the Albert Einstein College of Medicine, including but not limited to the Computer Policy and Policy on Non-Discrimination, Affirmative Action & Sexual Harassment.

Matriculation

The CRTP operates on the semester system. The curriculum schedule is available through the CRTP web site: https://einsteinmed.edu/centers/ictr/education/clinical-research-training-program/

First year Scholars of the MS program advance into the second-year contingent upon successful completion of all first-year courses and approval of the thesis proposal. There will be clear deadlines for submission of thesis abstracts and proposals.

Protected Time

Scholars must have a minimum of 50% protected time during their matriculation in the CRTP, except for the intensive introductory summer course, which is a coordinated curriculum of epidemiology, biostatistics, data analysis, developing a research question and team science, requiring a minimum of 80% protected time.

Mentored Research

Trainees will have identified a mentor and a research project prior to the initiation of training. The program can assist the Scholar with identifying mentors. The CRTP is an institutionally supported program, seeking to enhance the academic environment in clinical research through training and career development activities. The program requires the active involvement of the mentor, and the support of the Scholar's department. Effective communication among the Scholar, the mentor, the department, and the CRTP is critical to ensuring the Scholar's success. Toward that end, the CRTP will communicate with the appropriate individuals supervising the Scholar, as necessary, in the event of academic difficulties or scientific or professional misconduct. A Scholar's unsatisfactory progress in the CRTP may lead to changes in their research, mentor, clinical obligations, or other aspects of the Scholar's professional activities, as deemed necessary through consultations between the Program Director and the Scholar's supervisors. The goal of such consultations would be to enhance the likelihood for the Scholar's successful completion of the CRTP.

Credit Requirements

The didactic program meets or exceeds the state mandated 30 credit hour requirement over 2 years. The course work consists of credit for the CRTP required core courses, elective coursework, and the Master's thesis. Current curriculum and course descriptions are available in this document and on the CRTP web site.

Credit Hour Calculations

Credit Hour Definition for Courses: One (1) credit hour is earned for fifteen (15) 1-hour (of 50 minutes each) sessions of lecture or classroom instruction, with the expectation of two (2) additional hours of outside study or reaching for each class session.
Credit Hour Definition for Full-Time Research: One (1) credit hour is earned for each forty-five (45) 1-hour session of academic activity. Forty-five hours of academic activity yields one (1) credit hour.

Attendance/Absenteeism/Leaves of Absence

In general, CRTP classes are scheduled during all months of the calendar year except for June and January, during which time there are no classes. The CRTP adheres to the academic calendar of the School of Medicine. *(Please note: Scholars who choose an elective offered by Sue Golding Graduate Division or any other institution should check the start date of those courses.)*

Attendance for all scheduled classes is expected of all Scholars. No more than one missed class per course is permissible. The CRTP Executive Committee reserves the right to enforce this rule considering individual circumstances. Scholars are required to make-up any missed course work in the event of a legitimate class absence. Clinical obligations, vacations, conferences, or other meetings are ***not*** legitimate excuses for missed classes. In some instances, allowances will be considered in the event of documented illness of up to 2 weeks' duration. If such an occurrence arises it is the Scholar's responsibility to contact the Program leadership and discuss the feasibility of successful completion of course work.

Leaves of absence are adjudicated on a case-by-case basis by the Executive Committee. Any extended leave of absence (e.g., due to illness, pregnancy, etc.) for greater than two weeks' duration will only be granted with the approval of the Director and must be in writing on official CRTP letterhead. A one-year extension may be granted in order for a Scholar to successfully complete required coursework. In the event a Scholar needs a prolonged leave of absence, an additional year extension may be granted. Scholars who complete requirements within the two-year extension will graduate without prejudice.

Unexplained absences are viewed negatively and may result in termination of enrollment in the CRTP.

Withdrawal

Scholars in good standing who are unable to return at the beginning of any semester or who find it necessary to discontinue their participation in the CRTP for any reason during the academic year, may be granted withdrawal from CRTP by the Director in writing on official CRTP letterhead.

Non-matriculated Scholars

Non-matriculated enrollment in electives are permitted as space allows. Prior approval must be obtained from the Program Director and the course leader. If approved, the Scholar is responsible for supplying documentation that all prerequisites are met. Successful completion of a course will be recorded by the CRTP office.

Policy on Scientific Conduct

The following definition from the College's Policy on Scientific Misconduct will be used to evaluate whether a Scholar's research activities constitute "scientific misconduct".

"Scientific misconduct includes fabrication, falsification, plagiarism or other practices that seriously deviate from those commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest differences in interpretation or judgments of data."

Instances of suspected scientific misconduct involving research by Scholars will be considered in accordance with the Policy on Scientific Misconduct of the Albert Einstein College of Medicine. Instances of professional misconduct by Scholars that do not fall within the guidelines of scientific misconduct will be considered in accord with the Policy on Professional Conduct presented below. The Executive Committee will have primary responsibility for determining the appropriate venue for investigation of alleged misconduct and seeing that the allegations are thoroughly and fairly investigated.

Policy on Professional Conduct

The CRTP requires at all times the highest standards of professional conduct. Professional misconduct includes, but is not limited to, plagiarism or cheating in academic courses offered by the CRTP and by the Medical School, fabrication or falsification of academic work or data, intentionally damaging or interfering in the academic activities of other members of the College of Medicine or assisting others in any of these acts and the failure to meet generally accepted standards of personal integrity and professional conduct. Inappropriate or disruptive behavior toward colleagues, faculty, or other College staff may constitute professional misconduct.

Ignorance of the standards of professional conduct will not excuse a student from responsibility for their actions. Plagiarism or cheating will result in dismissal from the CRTP. References are available in the library to help Scholars evaluate the ethical implications of their actions.

Syllabus

The CRTP program enrolls up to 16 Scholars each year. Each Scholar is required to have a mentor, a research project, and protected time for the full two years of the program. The program focus is on developing clinical research methodological skills. All matriculates start in July with the Clinical Research-Intensive Course with classes meeting Monday through Thursday from 9:00am-12:50pm. For the remainder of the program, required classes are held on Tuesdays and Thursdays, 9:00am – 12:50pm. Most, but not all, electives are also scheduled on Tuesdays and Thursdays, 9:00am-12:50pm. There are no CRTP classes during the months of January and June or on Jewish Holidays. Registration for all courses, including electives, should be done through the CRTP office.

For Faculty and Fellows (non-MD/MS scholars)

In addition to the introductory material covered in the summer intensive course, the core curriculum includes intermediate courses in epidemiology and biostatistics with a data analysis component, research ethics, works-in-progress, an overview of translational science research methodologies, an intensive grant writing workshop which culminates in a mock study section, professional development seminars, and elective course offerings. The program culminates with a written thesis, which is an original hypothesis-driven first -author manuscript suitable for publication.

In total, non-MD/MS scholars are required to take 47.5 credits (inclusive of 16 thesis credits) plus a minimum of 5 elective credits for a total of 52.5 credits.

For MD/MS Scholars

The five-year MD/MS track is designed for medical students interested in learning clinical research methods. Students must have completed their clerkship year before enrolling in this program. Students apply to the program during the **third (clerkship) year** of medical school. Accepted students will take a gap-year off from medical school to participate in Einstein's Clinical Research Training Program (CRTP) courses while working on clinical research activities under a faculty mentor. Medical Students in the CRTP are required to devote the entire gap year plus Blocks 1-4 of their senior year to the CRTP curriculum. During the remainder of their senior year in medical school CRTP MD/MS students have the option of doing a senior research fellowship or spend time during allotted SP months in their senior year of medical school for completion of their papers or completing electives.

In addition to the introductory material covered in the summer intensive course, the core curriculum for the MD/MS scholars includes intermediate courses in epidemiology and biostatistics with a data analysis component, research ethics, an overview of translational science research methodologies, and a manuscript writing course series in which the MD/MS scholars write an original, first-author research manuscript. This is in addition to the thesis manuscript, which is also an original hypothesis-driven first -author manuscript suitable for publication. Thus, MD/MS scholars write two first-author original clinical research papers which are suitable for publication.

In total MD/MS scholars are required to take 41.5 credits (inclusive of 16 thesis credits) plus a minimum of 4 elective credits for a total of 45.5 credits. They are exempt from taking Professional Development Seminars, Grant Writing I & II and Works-in-Progress I & II. However, they are required to present their research during both the first spring semester and the second fall semester during a mutually convenient time in the works-in-progress courses. Time-permitting, they are encouraged to attend other seminars and work-in-progress sessions.

Medical students pay only four years of medical school tuition for the five-year program (no additional tuition for the Master's degree), and fellowship stipends may be available. Candidates who complete the CRTP successfully will receive both the MD degree and MS in Clinical Research Methods at graduation.

Clinical Research Training Program Schedule

First Summer	First Fall	First Spring	Second Summer	Second Fall	Second Spring
Clinical Research Intensive (7.0 credits)	Multivariable Regression (5.5 credits)	Translational Science Research Methodologies (3.0 credits)	Research Ethics (2 credits)	*Grant Writing II (3.0 credits) **Manuscript Writing II (3.0 credits)	*Professional Development Seminars (2.0 credits)
	Epidemiologic Research Methods (3.0 credits)	*Works in Progress I (2.0 credits)	*Grant Writing I (2.0 credits) **Manuscript Writing I (2.0 credits)	*Works in Progress II (2.0 credits)	
	Thesis Research (2.0 Credits)	Thesis Research (4.0 Credits)	Thesis Research (2.0 Credits)	Thesis Research (4.0 Credits)	Thesis Research (4.0 Credits)
		Electives†		Electives†	Electives†

All courses required except as noted:
*Required for non-MD/MS Scholars
**Required for MD/MS scholars
†Electives: non-MD/MS scholars are required to complete a minimum of 5 elective credits; MD/MS scholars are required to complete a minimum of 4 elective credits

List of Courses (by semester)

Summer Semester – First Year

CLRM 5840 Clinical Research Intensive (7.0 credits)

This is an intensive introduction to clinical research which provides the fundamental concepts of epidemiology and biostatistics that will provide the foundation for more advanced work in these areas. Additionally, students will learn how to critically evaluate the clinical research literature, understand how to develop a research question, and use statistical software to complete basic data management and statistical analyses.

Fall Semester - First Year

CLRM 5860 Multivariable Regression (5.5 credits)

Multivariable Regression builds on the knowledge of univariate and bivariate analyses that were learned in the Clinical Research-Intensive course and introduces concepts related to multivariable model building for multiple linear regression, logistic regression, and survival analysis. Both the lecture and the data analysis portions will focus on multiple regression model building, interpretation, and diagnostic tests, assessing for interaction, and statistical adjustment for confounding.

CLRM 5820 Epidemiologic Research Methods (3.0 credits)

This course focuses on the analytical issues of epidemiological studies: biases, confounding, interaction, statistical methods used in case-control and cohort studies, and sample size/statistical power. The in-class exercises will reinforce these concepts. Students are expected to know the basic design issues of retrospective and prospective studies as well as clinical trials from Clinical Research-Intensive Course.

CLRM 5881 Thesis Research Credits (2.0 credits)

Spring Semester - First Year

CLRM 5846 Translational Science Research Methodologies (3.0 credits)

This course is designed to provide a broad exposure to research methodologies across the translational research spectrum. Speakers have been selected based on their outstanding reputation for the area of research they are speaking on and include both senior level faculty at Einstein/Montefiore as well as outside speakers from various Universities across the country. These seminars provide a unique opportunity to meet and hear from experts you may not have access to otherwise.

CLRM 5841 Works in Progress I (2.0 credits)

This is the first of two courses designed to enable the students to obtain feedback from their peers about challenging issues with their research. Scholars are often working on specific aims, feasibility issues or rudimentary analyses. These sessions are also opportunities to practice presenting research. Mentors are invited and CRTP leadership attends. MD/MS scholars are not required to take this course but are highly encouraged to enroll in it if their schedule allows; however, it does not contribute to their elective credit requirement.

CLRM 5881 Thesis Research Credits (4.0 credits)

Summer Semester - Second Year

CLRM 6870 Research Ethics (2.0 credits)

The objective of this course is to enable the participants to recognize ethical issues in research with human subjects and to conduct an analysis of problematic situations using ethical principles. This course covers the main issues confronting researchers and members of IRBs: informed consent, risk-benefit analysis, collection of biological samples and bio-banking, undue inducements, research integrity, multinational research, public health research, and protections for vulnerable populations in research.

CLRM 6842 Manuscript Writing I (2.0 credits)

For MD/MS scholars only
This course is the first of a two-course sequence designed for MD/MS scholars in the CRTP to guide them in preparing a mentor-guided first –author hypothesis driven research paper based on their own analysis. This paper can be based on a secondary dataset which addresses the student and mentor's research focus or can derive from data collected as part of the student thesis research.
Students attend seminars and have progress meetings with the course director and their mentors at regular intervals in the summer and continue working on their paper while meeting regularly with their mentor and the course director through the fall semester. NOTE: This clinical research paper is distinct from the thesis.

CLRM 6844 Grant Writing I (2.0 credits)

MD/MS scholars are not permitted to take this course
The grant-writing course is designed for fellows and faculty in the CRTP to guide them in an intensive experience designed to impart the skills necessary to produce a proposal for NIH (K-career development), which starts in the summer and continues in the Fall Semester. The summer course consists of lectures which are dispersed during the six-week summer semester and include an overview of the NIH system, scientific writing for grants and papers and constructing specific aims.
Also, during the summer, Scholars will begin meeting in small, assigned groups with an assigned leader during which time they will produce sections of grants. The critical function of the small group is to obtain detailed feedback from the leader and group members on each scholar's evolving grant. During the Fall semester Scholars will continue meeting in their small groups with the goal of submitting a finished proposal by mid-November. The fall semester culminates in a mock NIH-style study section.

CLRM 5881 Thesis Research Credits (2.0 credits)

Fall Semester - Second Year

CLRM 6843 Manuscript Writing II (3.0 credits)

For MD/MS scholars only
This is a continuation of the summer course where MD/MS scholars complete a mentor-guided first- author hypothesis driven research paper based on their own analysis. NOTE: This clinical research paper is distinct from the thesis.

CLRM 6845 Grant Writing II (3.0 credits)

MD/MS scholars are not permitted to take this course.
This is a continuation of Grant Writing I where Scholars continue working in small groups to obtain detailed feedback from group leaders and members on evolving grant work. Students produce a grant application and participate in an NIH style Mock Study Section at the culmination of this course.

CLRM 6841 Works in Progress II (2.0 credits)

A continuation of Works in Progress I, in this second session, the Scholar's research work should be farther along, but issues may remain. The student's presentation can include an aim, hypothesis, approach, analytic plan with possibly a preliminary analysis, and a discussion of the results. Mentors are invited and CRTP leadership attends presentations by students preparing them for the final thesis presentation at the time of graduation. MD/MS scholars are not required to take this course but are highly encouraged to enroll in it if their schedule allows; however, it does not contribute to their elective credit requirement.

CLRM 5881 Thesis Research Credits (4.0 credits)

Spring Semester - Second Year

CLRM 6890 Professional Development Seminars (2.0 credits)

MD/MS scholars are not permitted to take this course
This course is a series of seminars from leadership at Einstein-Montefiore, and other noted individuals, on various topics of professional development. Topics vary from year to year and range from learning how to effectively network and how to best negotiate for an academic faculty research position to planning for academic promotion.

CLRM 5881 Thesis Research Credits (4.0 credits)

Electives (Fall and Spring Semesters)

MD/MS scholars in the CRTP take at least four elective credits throughout the two years of the program; however, they are usually completed during the first four semesters of the CRTP before they go back into their 4th year of medical school. CRTP scholars who are not medical students need to earn a minimum of 5 elective credits throughout the two years of the program. Possible elective credit can be earned via the following:

- A directed study, with approval from the CRTP Executive Committee
- Any of the following electives offered through the CRTP

CLRM 5822 Molecular Epidemiology (2.0 credits) **Outside normal class hours

This course focuses on the design, methodological and analytical issues of molecular epidemiological studies: design strategies, strengthens, limitations, sample collection and processing, and biomarkers measurements and quality control considerations. The in-class exercises and homework will reinforce these concepts. Students are expected to be proficient in designing, conducting, and interpreting retrospective and prospective studies as introduced in Epidemiologic Research Methods. Offered in Fall Semester.

CLRM 5821 Advanced Epidemiologic Research (2.0 credits)

This course will introduce advanced topics in epidemiology with the primary goal of expanding knowledge of evolving methodological issues for epidemiological studies and causality inference. Topics such as more efficient study designs (e.g., nested case-controls, case-cohort, case-crossover) in epidemiological studies, causal diagrams and causal inference, propensity score and instrumental variable analysis to address confounding and bias will be covered. At the end of this course students will have a better understanding of various epidemiological methods used in clinical and epidemiological studies. Offered in Spring Semester.

CLRM 5861 Design and Analysis of Longitudinal Data Studies (2.0 credits)

This course presents modern approaches to the analysis of longitudinal data. Topics include design of longitudinal studies, generalized linear models for correlated data (including generalized estimating equations, generalized linear mixed effects model), computational issues and methods for fitting models, and missing data issues. STATA statistical software will be used in the data analysis component of this course where the students will learn how analyze and interpret linear models for repeated measure for continuous and discrete data. Offered in Spring Semester.

CLRM 6895 Intro to Implementation Science (1.0 credits)

Introduction to Implementation Science will present scholars with an overarching overview of fundamental concepts and emerging topics within the field of implementation research. The course will present key concepts such as adapting evidence-based interventions, understanding determinants of implementation, designing implementation strategies, selecting pragmatic designs, organizing measures, and dissemination approaches. The concepts, tools and skills presented will support scholars that are focused on addressing the clinical Know-Do Gap, translating evidence-based interventions into real-world clinical practice. Scholars will utilize this course to produce key sections of developing/future grants utilizing implementation science methodologies.

CLRM 5848 Stakeholder Engaged Methods Part I (1.0 credits) & Part II (2.0 credits)

Robust methods in stakeholder engaged research (SER) can lead to discovery of new practices, programs and policies that improve health systems performance. It serves to align clinical and translational research priorities with those of patients and their care givers by improving the relevance of research questions, increasing the transparency of research activities, and accelerating the dissemination and adoption of evidence-based practices. SER can also be leveraged to establish and sustain partnerships, coalitions, and other collaborative structures that support organizational and community change initiatives. This course is organized in two parts. In part one, scholars receive an introduction to methods for conducting effective SER (Fall, 1 credit). In part two, scholars will work with the course leader to conduct a SER activity of their choice, to gain hands-on SER experience (Spring, 2 credits). Part one is prerequisite to part two. Part two is optional.

CLRM 5850 Bench to Bedside in Clinical Practice and Translational Science (1.0)

This course will introduce standard and new laboratory approaches that are used in clinical practice to screen, diagnose and characterize diseases in Medicine across all disciplines. The course will start by introducing some basic concepts in immunology, genetics, and human host responses at large and how these can be used in clinical practice and research. It will then be followed by introducing a range of the most frequently used bench tools and technologies in clinical practice and translational Medicine.

CLRM 5852 Real World Data for Clinical and Translational Research (1.0)

This elective course equips learners with the knowledge and practical skills required to work effectively with routinely collected healthcare data, known as Real World Data (RWD), to generate Real World Evidence (RWE). These skills are essential for clinical and translational researchers aiming to leverage RWD to improve treatments and clinical care processes. The course covers foundational concepts, including medical vocabularies, data models, computable phenotyping, and study design principles. Learners will explore advanced topics such as causal inference, algorithmic bias, and natural language processing. Hands-on exercises will develop proficiency in data science tools (e.g., SQL, R), cohort construction, and working with external data repositories. Participants will also learn to integrate a data science plan into grant proposals, fostering their ability to conduct independent research using RWD. This course prepares clinical investigators to navigate the complexities of real-world data and translate it into actionable evidence for improving health outcomes.

CLRM 5880 Directed Study (various credits)

Under special circumstances, scholars in need of a course in a translational research methodology that is not currently provided in the CRTP curriculum may arrange for a directed study. Approval is granted on an individual basis by the CRTP Executive Committee and is a limited privilege. To be considered, the scholar must submit in writing the need for a directed study, how it will benefit them in the current or future research, identify an appropriate faculty sponsor and a proposed syllabus.

Master's Thesis

To qualify for the M.S. degree in Clinical Research Methods from the Albert Einstein College of Medicine, each Scholar must complete a Master's Thesis. Satisfactory completion of the thesis requires a thesis submitted with approval of the student's mentor and will undergo a review process outlined below.

Goals of the Thesis

The Thesis is the capstone of the CRTP and the M.S. degree. The Clinical Research Training Program is designed to combine didactic classroom learning with a hands-on, mentored research experience; the Thesis is the culmination of that experience. By successfully defending the Thesis, each Scholar is expected to demonstrate mastery of the knowledge and skills required to conduct clinical research.

Thesis Format

The thesis is required to be in the style of a manuscript that is suitable for publication in a peer-reviewed journal. The thesis must include an original analysis of data conducted or overseen by the Scholar of either newly collected, existing from a parent study, or from secondary sources, which addresses a clearly stated and justified hypotheses. A review paper is not acceptable, except for a meta-analysis using appropriate statistical techniques. The manuscript must be written by the Scholar, who must be the **first** author with the primary responsibility for its content in accordance with standard practice of biomedical journals. The analysis and the preparation of the manuscript must take place while the Scholar is enrolled in the CRTP and must not represent work that has been done prior to CRTP enrollment. A major peer-reviewed journal must be identified by the Scholar and approved by the CRTP; the thesis must conform to that journal's manuscript requirements. While it is not required that the manuscript actually be submitted to a journal before consideration as a Master's Thesis, it is hoped that all such Thesis will ultimately be submitted for publication.

General Requirements

1. The Thesis must represent the Scholar's own work. While clinical research is by its nature collaborative, the Scholar must be the leader of the research team. The Scholar's contribution must be that of the first author with the primary responsibility for its content in accordance with standard practice of biomedical journals.
2. The Thesis project must involve data collection or an original analysis of existing data.
3. The Thesis project must have a hypothesis, i.e., use appropriate epidemiologic design for the question and must include comparison groups. (Please note: Phase I drug studies are not acceptable).
4. The Thesis must be a clinical research project, as defined by the NIH Director's Panel on Clinical Research.

Clinical Research is research with human subjects that is:

- Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. It includes mechanisms of human disease,

therapeutic interventions, clinical trials, and development of new technologies.
- Epidemiological and behavioral studies.
- Outcomes research and health services research. Studies falling under 45 CFR part 46.101(b) (4) (Exemption 4) are not considered clinical research by this definition.

Procedures

The Thesis process will be overseen by the CRTP Director, Aileen McGinn, PhD.

The Thesis Proposal

Thesis Proposals are due by **February 1** of the first year. Required components are:

- Title
- Specific Aims
- Preliminary Data/Analysis, if available (not required)
- Description of the project*
- Mentor's name and signature
- Specific peer-reviewed journal whose format will be used
- A proposed timetable (for data collection and draft submission)

*The project description should indicate what research question will be addressed and should identify at least one testable hypothesis. A brief (1-2 paragraphs) background should focus on justifying the importance of the research. It should indicate a sampling or subject recruitment strategy; a basic study design; an analytic strategy; and a sample size calculation or power analysis. The project description should be no more than 2-3 pages (double-spaced).
Changes in thesis topic after submission of the thesis proposal must be made in writing and approved by the Scholar's mentor and CRTP Executive Committee.

Mentoring Team

Every Scholar is admitted to the CRTP with an identified Mentor(s). Very often as their research progresses the Scholar finds that he or she requires additional expertise. In fact, it is unusual for a clinical research project to progress without the help and advice of several faculty members with a variety of relevant specialized knowledge. An example of this would be a Scholar with a Mentor who may be highly knowledgeable about the disease the Scholar is studying and a very strong advocate for the Scholar's career development but whose research is translational or basic science. The Scholar may need a Co- Mentor with epidemiologic or health services research methodological skills that are more closely aligned with the Scholar's thesis or research interest. Sometimes the CRTP provides expertise such that a Scholar does not feel the need for additional Mentoring. Often there is a group of faculty members that work together in a research program, such as a biostatistician, epidemiologist, and physician- scientist, all of whom may provide Mentoring to the Scholar. It is increasingly common, though not required, that Scholars have Mentoring Teams.

Statistical Consultations

All Scholars are required to obtain statistical consultation twice during the development of the Thesis as detailed below. Formal consultation can be provided by Dr. Melissa Fazzari. To arrange a statistical consultation with Dr. Fazzari email her directly (Melissa.Fazzari@einsteinmed.edu) indicating you would like to discuss your CRTP thesis project. Scholars must provide 2 examples of papers that discuss their topic and proposed design.

If a Scholar has another statistician involved in the project, that person can serve as the statistical consultant with the approval of the CRTP leadership.

Fall Year 1: Each Scholar will meet individually with Dr. Melissa Fazzari or other approved consultant to review their hypothesis, methodology, sample size estimate, and statistical analysis plan. This will be useful in the development of the Thesis Proposal.

Fall Year 2: Each Scholar is required to have an individual follow-up meeting with Dr. Melissa Fazzari or another approved consultant to go over the interim analysis of the thesis project.

Thesis Grading Process

Thesis grading is pass/fail and is reviewed in a manner similar to a peer-reviewed journal submission. Two reviewers, selected by the CRTP, will critique each thesis and a consensus decision will be made as to whether the submission is accepted as is ("Pass"), needs minor revisions or needs major revisions (and re-evaluation for determination of grade). Written critiques will be provided to the candidate.

Thesis Presentations

Each Scholar is required to present her/his thesis work during a series of seminars held in May of the second year. Scholars will have 30 minutes allotted: a 15-minute presentation, followed by 15 minutes of discussion. They are also required to submit on or before the day of their thesis presentation a poster version of the thesis as a PowerPoint slide

M.S. "with distinction"

The candidate will be eligible for an "MS with Distinction" if a manuscript is submitted to a journal prior to graduation and is accepted for publication within the next 12 months.

For Scholars who are first author on original manuscripts which are based on analyses from multicenter or other studies that require final approval of a Study's Executive Committee as the last step prior to submission to a journal for peer review are eligible for an MS "with distinction" if 1) the manuscript was submitted to the Executive Committee or equivalent prior to CRTP graduation and 2) the paper was accepted for publication within 12 months of CRTP graduation. If one of these criteria is met, the candidate will be considered for the award of an MS "with Distinction."

The decision will be made by the CRTP Executive Committee and will consider the thesis (including publishing journal) and the candidate's academic performance throughout the CRTP.

Guidelines for Grading CRTP Research and Thesis

Final Objective: The CRTP Scholar should be able to utilize theoretical and practical aspects of learning to design, execute and present the results of hypothesis-driven clinical research consistent with the mission of CRTP: "to identify, educate, and mentor clinician scientists for productive careers in clinical research."

Enabling Objectives: The CRTP Scholar should complete a scholarly thesis, which will lead to further research activity in accordance with the following principles:

1. **Hypothesis**
   a. What is/are the specific questions to be answered?
   b. What population will be studied?
   c. What is the setting, e.g., academic hospital-based, outpatient-based, community-based?
   d. What final population will the findings be applicable?
2. **Study Design**
   a. What will be the nature of the study, e.g., randomized controlled clinical study, case control study, cross-sectional study, other?
   b. What will constitute the control group/s?
   c. Are inclusion and exclusion criteria clearly defined?
   d. How will the potential for sample selection bias be minimized?
   e. Are primary and secondary end-points justified and clearly defined?
   f. Will the study have sufficient sample size for adequate statistical power?
3. **Data collection**
   a. Has the reliability and reproducibility of observations been assured?
   b. Are data collection methods appropriate with adequate sensitivity and specificity to analyze study end-points?
4. **Data analysis**
   a. Are data internally consistent, i.e., do the numbers add up, are subgroups reconciled, are data tables correct?
   b. Are charts and tables utilized appropriately? Are data amenable to statistical analysis? Have relevant statistical methods been correctly applied? Have statistical methods used clearly identified for individual data sets?
   c. How reliable is the statistical significance of data? Have additional statistical methods been applied or comparisons made to verify whether differences hold up?
   d. Does data analysis include consideration of the sensitivity and specificity of the findings?
   e. Does data analysis consider the possibility of confounding variables, including incompatibilities between control and experimental groups?

5. **Data interpretation and conclusions**
    a. Are conclusions justified by the data analysis? Has the hypothesis been adequately tested?
    b. Are findings discussed appropriately and placed in proper context with the existing literature?
    c. What are the limitations and weaknesses of the study? What further questions will be appropriate to address? How will the studies guide or lead to future clinical research of the scholar?
6. **Objective evaluation of research**
    a. Evaluation of the specific areas indicated above will be appropriate for determining the quality of research and whether the goals of thesis work have been met.
    b. The completed thesis should provide insights into the overall breadth and depth of the scholar's knowledge in clinical research.

Timetable for Thesis

Year One:

September	• Start/Continue meeting regularly with mentor(s) • Continue to define and develop research project • Obtain and use reference software • Begin literature search on selected research topic
October – January	• Arrange the first statistical consultation with Dr. Melissa Fazzari by sending her an email (Melissa.fazzari@einsteinmed.edu) • IRB submission should be underway • For scholars using secondary datasets from multicenter studies, concept sheets and other required forms should be submitted in order to obtain data
February – June	• February 1: Submission deadline for thesis proposal • Works-In-Progress Presentation, go over with mentor in advance • Work on thesis (Introduction & Methods can be written in advance of final results) • Obtain dataset for those who are using secondary datasets • IRB approval should be complete, and data collection ongoing • Works-in-Progress Presentation, go over with mentor in advance

Year Two:

July	• First draft of thesis should be submitted for comments to mentor and co-mentors
August – December	• Second statistical consult should be arranged in the fall • Works-in Progress
January	• Penultimate draft of thesis complete
February	• February 1: Thesis abstract submitted
March	• March 1: Final thesis submission • Review/grading process begins
April-May	• Thesis decisions distributed first week of April • Thesis revisions, if indicated, due by first week of May • Thesis presentations

Student Evaluation and Academic Standards

Scholars are expected to familiarize themselves and to comply with the rules of conduct, academic regulations, and established practices of the Albert Einstein College of Medicine and the CRTP. The admission of a Scholar, his/her continuation in any program of the College, the receipt of academic credits, graduation, and the conferring of any degree are entirely subject to the disciplinary powers of the CRTP and the College and to the Scholar's maintenance of high standards of ethical and Scholarly conduct. The Director, on the recommendation of the CRTP Executive Committee, may dismiss Scholars who are considered to be unfit for matriculation in the CRTP or for infringement of these policies and standards.

- Course examinations: Course examinations are a part of the evaluation process for most courses.
- Course grades: Scholars enrolled for credit and attending the entire course, will receive a Grade of Pass (P) or Fail (F). No credit is granted for courses with a grade of Fail. Scholars who fail a course may ask to be re-examined at the discretion of the Executive Committee.
- Master's Thesis: The Thesis is the capstone project of the CRTP, and its successful completion earns the Master's candidate credit toward the degree.

Official Transcript

Course and grade records will be maintained for every student in the form of a permanent transcript in accordance with the policies described in the Student Evaluation and Academic Standards section, above. The College has formulated its Student Record Policy to guarantee the rights of privacy and access as provided by the **Family Education Rights and Privacy Act of 1974**. This policy applies to all Scholars. Copies of the Student Record Policy are available in the CRTP office. Scholars who wish to review their records may do so on written request to the Director of the CRTP. Requests for transcripts should be made online at: https://www.einsteinmed.edu/alumni/resources/

Visiting (International) students sponsored by Yeshiva University may request a transcript online at http://www.yu.edu/transcript.

This online catalog supersedes all previous Catalogs and academic regulations and is binding on all students. It was prepared on the basis of the best information available at the time of publication. The Albert Einstein College of Medicine (referred to as 'Einstein') reserves the right to change tuition, fees, course offerings, regulations, and admission and graduation requirements at any time without prior notice. Changes are effective immediately, unless explicitly specified to the contrary.