



Albert Einstein College of Medicine

Montefiore

Einstein-Montefiore Institute for Clinical and Translational Research

Clinical Research Training Program

MS in Clinical Research Methods

Catalog 2016

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

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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 Director 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

The Albert Einstein College of Medicine is affiliated with Yeshiva University which is licensed by the New York State Education Department to award the Master of Science in Clinical Research Methods to students successfully completing the CRTP. Accreditation of the degree programs offered through the Albert Einstein College of Medicine is provided by both the Middle States Association of Colleges and Schools and the American Association of Medical Colleges.

Governance of the Clinical Research Training Program

The CRTP, sponsored by Albert Einstein College of Medicine under the leadership and advocacy of Dean Allen Spiegel, 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 Harry Shamoon, MD is the Principal Investigator. Direct oversight is provided by Paul Marantz, MD, MPH, Associate Dean for Clinical Research Education and Founder of the Einstein CRTP, and 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

Associate Professor, Department of Epidemiology and Population Health
CRTP Director

Hillel Cohen, DrPH

Professor, Department of Epidemiology & Population Health
Associate Director for Curriculum

Johanna Daily, MD

Associate Professor, Department of Medicine (Infectious Disease); Department of Microbiology & Immunology
Associate Director for Mentoring and Career Development

Elina Jerschow, MD, MS

Assistant Professor, Department of Medicine (Allergy & Immunology)
Recent Graduate Representative

Frederick Kaskel, MD, PhD

Professor, Department of Pediatrics (Nephrology)
Associate Director for Thesis Support & Evaluation

Paul R. Marantz, MD, MPH

Professor, Departments of Epidemiology & Population Health; Medicine
Associate Dean for Clinical Research Education

Ellie Schoenbaum, MD

Professor, Department of Epidemiology & Population Health; Medicine; and Ob-Gyn & Women's Health
Director of Medical Student Education

The CRTP Admissions Committee

All members of the Executive Committee serve on the Admissions Committee in addition to members selected by the Program Director. Members of the Admissions Committee 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

Associate Professor, Department of Epidemiology and Population Health

Paul Marantz, MD, MPH

Associate Dean for Clinical Research Education

Professor, Departments of Epidemiology & Population Health; Medicine

Nancy Marte

Educational Program Manager

Claude Abner

Administrative Assistant

General contact: crtp@einstein.yu.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, disability, 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 MDs, PhDs, sub-specialty fellows, medical, or graduate students and faculty members of Einstein and Montefiore
- Albert Einstein College of Medicine's medical students have the option to apply to the CRTP MD/MS Track; see further details in the section below
- 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

MD/MS Track

The five-year MD/MS track is designed for medical students interested in learning clinical research methods. Students must have completed their clerkship year in order to attend this program. Students apply to the program during the **third (clerkship) year** of medical school. Accepted students will take a year off to participate in Einstein's Clinical Research Training Program (CRTP) courses while working on clinical research activities under a faculty mentor. There are additional programmatic elements that are required during the second year of the CRTP which medical students complete during their senior year of medical school.

Medical students in the CRTP are exempt from taking the second year CRTP Clinical Research Seminars I & II courses. In place of these courses, they are required to take three Selective/Elective credits. Medical students return to their senior medical school year but will complete CRTP required manuscripts during this time. There is a Grant/Manuscript Writing Course in the second summer of the program in which medical students write an original, first-author research manuscript. This is in addition to the thesis manuscript. Often, they will do a senior research fellowship or spend time during allotted (2) SP months for this purpose. All students complete a minimum of 30 credits to earn the M.S. in Clinical Research Methods.

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 are available. Candidates who complete this dual degree program successfully will receive both the M.D. degree and the M.S. in Clinical Research Methods at graduation.

Application Process

All application materials must be submitted by **March 1** (including all requests for letters) through the online application portal for consideration in the class that commences the following July.

Applications are accepted via our online application system. This system allows the uploading of the following required materials:

Applicant Information Form, which is accessible via the appropriate online application link

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 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 that 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).

Letters of Reference: Each applicant needs to provide email addresses for two (2) individuals who can provide letters 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 the following:

- Their support of the applicant's participation in the Clinical Research Training Program
- 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 9:00-12:30 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). Classes for the remainder of the two-year program are held on Tuesdays & Thursdays from 9:00-12:30
- 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 an Admissions Committee Member, the Associate Director and the Director of the CRTP. 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: 718-430-2080 Fax: 718-430-2521

Questions about the application process can be addressed to:

Aileen McGinn PhD, Director aileen.mcgin@einstein.yu.edu Phone 718-430-3740

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 will be available through the CRTP web site: <http://www.einstein.yu.edu/centers/ictr/ret/clinical-research-training-program/curriculum/>

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, with the exception of the introductory summer course, which is a coordinated curriculum of epidemiology, biostatistics, data analysis and specific aims requiring 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(s), and the Master's thesis.

Current curriculum and course descriptions are available through the CRTP office and web site.

Status

Scholars are expected to maintain full-time status. Scholars must maintain continuous registration in the CRTP program until graduation. Full time status is defined by registration and attendance in all prescribed courses for each scholar's class year. Failure to maintain enrollment status can have both academic and financial consequences.

Attendance/Absenteeism/Leaves of Absence

In general, CRTP classes are scheduled during all months of the calendar year with the exception of 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, Ferkauf School of Psychology or any other institution should check the start date of those courses.)*

Attendance for all scheduled classes is expected of all Scholars, including research seminars, works-in-progress, and thesis presentations. No more than one missed class per course is permissible. The CRTP Executive Committee reserves the right to enforce this rule taking into account 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.

Non-matriculated Scholars

Non-matriculated enrollment in one or more courses is discouraged. On very rare occasion a non-matriculated individual may take an individual CRTP course. This Scholar must obtain permission 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 Scholars participate in the core curriculum as a group throughout the two years. Matriculates start July 1 with the “clinical research-intensive course” with classes meeting Monday through Thursday from 9:00am-12:30pm. For the remainder of the program, classes are held on Tuesdays and Thursdays, 9:00am – 12:30pm. There are no classes during the months of January and June. The core curriculum includes sequential courses in epidemiology, biostatistics with a STATA analysis lab and a program in research ethics. Works-in-progress sessions occur during both years. The second year of the program includes an intensive grant writing workshop which culminates in a mock study section. There are also seminars focusing on research methods and leadership skills. The program culminates with a written thesis, which is an original hypothesis-driven, first-author manuscript suitable for publication.

All students are expected to complete coursework sequentially, without interruption (i.e. no semesters off). Courses are designed to build upon one another. As such, individual courses or subjects may not be taken outside full enrollment in the degree program.

Registration for all courses, including electives, should be done through the CRTP office.

Clinical Research Training Program Schedule					Class of 2019
First Summer-	First Fall	First Spring	Second Summer	Second Fall	Second Spring
Clinical Research Intensive Epidemiology I Biostatistics I Data Analysis I Specific Aims I Clinical Research Resource Sessions	Multivariable Regression	Advanced Topics in Biostatistics with Data Analysis	Grant/Manuscript Writing I	Grant/Manuscript Writing II	Thesis Credits
	Epidemiologic Research Methods	Works in Progress I	Research Ethics I & II	Works in Progress II	
		Advanced Topics in Epidemiology			
		Clinical Research Seminars I & II*			
CRTP ELECTIVES (various credits) <i>Electives may be taken in any semester</i>					
Thesis Work (Written Thesis submitted by March 1 of Year 2)					

*These may count as elective credit for those in the MD/MS Program

*This graphic has been changed to reflect minor changes to the curriculum as noted below in the List of Courses by asterisks**

List of Courses (by semester)

Summer Semester – First Year

Clinical Research Intensive

This summer course is an intensive four-module course consisting of: Epidemiology
Biostatistics Data Analysis
Specific Aims & Clinical Research Resource Sessions

Fall Semester - First Year

Multivariable Regression (5.25 credits)

**replaces Biostatistics II with Data Analysis Lab (3 credits) and Biostatistics III with Data Analysis Lab (3 credits). The new course is a blending of the two prior courses*

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 data analysis portions will focus on multiple regression model building, interpretation, diagnostic testing, assessing for interaction and statistical adjustment for confounding.

Epidemiologic Research Methods (2 credits)

**previously named Epidemiology II*

This course focuses on the analytical issues of epidemiological studies: biases, confounding, interaction, statistical methods used in case-control and longitudinal studies, and sample size/statistical power. The homework will reinforce these concepts. Students are expected to know the basic design issues of cross-sectional, case-control and prospective studies as well as clinical trials from Epidemiology I.

Spring Semester - First Year

Advanced Topics in Biostatistics with Data Analysis Lab (2 credits)

**previously offered in Summer Semester of second year*

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 continuous and discrete data.

Advanced Topics in Epidemiology (1 credit)

This course aims to introduce advanced concepts and topics in epidemiology with the primary goal of expanding knowledge and understanding of evolving methods in this field. Topics will include discussion about causation and causal inference, efficient study designs (e.g. nested case-controls, case-cohort) in biomarker/molecular epidemiological studies; biomarkers of exposure and disease in epidemiological studies, different types of confounding and biases and methods to address them including causal diagrams and propensity score analysis. The course will also address misclassification and methods to assess reliability and reproducibility of exposure/outcomes measures in epidemiologic studies. At the end of the course students will have a better understanding of epidemiologic methods and their application in different clinical and epidemiological studies.

Works in Progress Seminars (1 credit)

The first of two seminars focused on students' research to prepare for the final theses presentation at the time of graduation. These sessions are designed to enable the Scholar 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 the research. Mentors are invited and CRTP leadership attends.

Summer Semester - Second Year

Grant/Manuscript Writing I (1 credit)

For Faculty/Fellows — Grant Writing I

The grant-writing course is an intensive experience designed to impart the skills necessary to produce a proposal for NIH (K-career development or R-investigator initiated), which starts in the summer and continues in the Fall Semester (Grant/Manuscript Writing II 2 credits). 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.

For Medical Students — Clinical Research Manuscript I

Medical students in the CRTP write two first-author original clinical research papers (hypothesis-driven) which are suitable for publication. The first original clinical research paper is the culmination of Grant/Manuscript Writing I (Summer) and II (Fall) and is due mid-November when the Scholars in the grant-writing course submit their grants. This clinical research paper is distinct from the thesis, which is the second original clinical research paper.

Research Ethics I & II (2 credit)

**Previously offered in separate semesters, now combined into one course*

This seminar examines the ethical, legal and public policy issues surrounding the use of human subjects in biomedical research. You do not need a medical or science background to take this course.

Fall Semester - Second Year

Grant/Manuscript Writing II (2 credit)

For Faculty/Fellows — Grant Writing II

This is a continuation of the summer course 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.

For Medical Students — Clinical Research Manuscript II

This is a continuation of the summer course where students are working on a clinical research paper. This clinical research paper is distinct from the thesis, which is the second original clinical research paper.

Works in Progress II (1 credit)

A continuation of Works in Progress Seminar, 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.

Spring Semester - Second Year***Clinical Research Seminars I & II (3.5 credits)***

**previously offered later in the curriculum*

This course is an exciting compilation of research seminars focused on various areas of clinical research. 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. Seminars that address leadership skills are also provided.

CRTP Selectives/Electives (various credits)

Medical students in the CRTP take three elective/selective credits in place of the second year Clinical Research Seminar courses. Selective/Elective credits may be taken at any time during the two years of the program allowing medical students the flexibility to fulfill their medical school requirements while completing the Master's program.

CRTP scholars who are not medical students only need one elective credit, but have the option to enroll in additional electives with the director's approval. Possible elective credit can be earned via the following:

- Any selective from the CRTP - note that some courses require prior approval from instructor), OR
- An elective offered through Einstein's Graduate School
- An elective outside of Einstein with approval from the CRTP Executive Committee

There are three CRTP Selectives:

Cost-Effectiveness & Decision Analysis

This tutorial in cost-effectiveness and decision analysis will provide the learner with hands-on experience in designing and implementing a cost-effectiveness study based on an actual project (pending, active, or completed) that the learner is involved in. The learner will meet with the instructor periodically (via Skype and e-mail) and we will, together, identify the data needs for the analysis, explore sources for obtaining those data from the literature or methods for gathering the data during the project (or both), and construct an actual or mock analysis. Techniques taught include structuring and evaluating decision trees, Markov and other state-transition processes, micro-costing, macro-costing, discounting and other adjustments to the value of value streams over time, application and extrapolation of results of clinical and observational studies. At the end of the course, the learner will have carried out a decision or cost-effectiveness analysis on his or her own data. The results should be suitable for publication.

Human Genetics

This course will consist of lectures covering a broad range of topics in human genetics. It will begin with a discussion of the human genome and the clinical and basic science applications that emerged from the human genome initiative. This will be followed by a review of the regulation of gene expression, focusing on basic molecular biology, evolutionary considerations and clinical implications. Then, a series of lectures will be given covering chromosomal disorders, Mendelian disorders, complex traits genetics, and the strategies used to identify disease-causing genes (genome wide association studies [GWAS], exome and whole genome sequencing, and CNV discovery). This will be followed by lectures on cancer genetics and epigenetics. Finally, clinical applications of genomic research with respect to pharmacogenomics and personalized medicine will be discussed. By the end of the course, students will be able to intelligently read and interpret molecular and genetic findings related to their areas of interest.

The Design and Analysis of Health Outcome/Effectiveness Studies

In designing outcomes/effectiveness studies, this elective has two objectives: (1) to extend knowledge and understanding of research design options that are alternatives to, or enhance or extend RCT, Cohort, and Case Control study designs, and (2) to introduce you to select statistical techniques that are related to these design alternatives.

The course begins with an overview of “effectiveness” research, and the concept of risk adjustment. The literature used in this course is multidisciplinary, borrowing from the behavioral sciences, the emerging disciplines of prevention science, public health, clinical research, health services research and comparative effectiveness. To better understand the statistical techniques being discussed, Scholars will be provided with a, or can use their own, data set. Scholars will be expected to present, and write up, their analysis.

Master’s Thesis (3 credits)

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. 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 by the Scholar, either newly collected, existing from a parent study, or from secondary sources, that is conducted by the Scholar 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 Theses will ultimately be submitted for publication.

General Requirements

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.

The Thesis project must involve data collection or an original analysis of existing data.

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).

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 **December 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 (item #2 above) 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. 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. Yungtai Lo. (Yungtai.Lo@einstein.yu.edu) 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. Yungtai Lo 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. Yungtai Lo 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 generally 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.

Timetable for Thesis

Year One:

September	<ul style="list-style-type: none"> Start meeting regularly with mentor(s) Continue to define and develop research project Obtain & use reference software Begin literature search on selected research topic
October – November	<ul style="list-style-type: none"> Arrange the first statistical consultation with Dr. Yungtai Lo by sending him an email (yungtai.lo@einstein.yu.edu)
December	<ul style="list-style-type: none"> December 1: Submission deadline for thesis proposal 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	<ul style="list-style-type: none"> Works-In-Progress Presentation, go over with mentor in advance
March – June	<ul style="list-style-type: none"> 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

Year Two:

July	<ul style="list-style-type: none"> July 1: First draft of Thesis should be submitted for comments to mentor and co-mentors
September-October	<ul style="list-style-type: none"> Second Biostatistical consult should be arranged in the fall Penultimate draft of thesis complete
December	<ul style="list-style-type: none"> Works-in Progress
February	<ul style="list-style-type: none"> February 1: Thesis abstract submitted
March	<ul style="list-style-type: none"> March 1: Final thesis submission Review/grading process begins
April	<ul style="list-style-type: none"> Thesis decisions distributed first week of April Thesis revisions, if indicated, due by end of April
May	<ul style="list-style-type: none"> Thesis presentations Graduation luncheon

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 is consistent with policies of Yeshiva University and 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:

<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](#) ("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.