Clinical Research Training Program

Academic Policies, Procedures, & Guidelines

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The Master's degree offered by the Clinical Research Training Program (CRTP) of the Albert Einstein College of Medicine 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 and the Director of the CRTP. The Academic Policies of the CRTP 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.

Section 1
Organization 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 for Clinical and 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, Director of the CRTP.

The CRTP benefits from guidance of the ICTR External Advisory Committee which is comprised of a group of nationally known leaders in academic medicine, research, and research education. The ICTR Scientific Advisory Review Committee (SARC) oversees policies and progress of the CRTP.

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.

The CRTP Admissions Committee
All members of the Executive Committee serve on the Admissions Committee in addition to members selected by the Program Director. Membership includes past graduates of the CRTP. Admissions Committee is responsible for making all admissions decisions. Members review the candidates’ qualifications and conduct personal interviews.
Section 2
Supervising Faculty and Staff

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

Catherine Yankou, MPH
Educational Program Manager

Nancy Marte
Administrative Assistant

CRTP Executive Committee

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Associate Professor, Department of Epidemiology and Population Health
Director, Clinical Research Training Program

Jacqueline M Achkar, MD, MSc
Associate Professor, Department of Medicine (Infectious Diseases)
Associate Professor, Department of Microbiology & Immunology
CRTP Associate Director of Bench to Bedside Translational Research

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

Frederick Kaskel, MD, PhD
Professor, Department of Pediatrics (Nephrology)
Associate Director for Thesis Support & Evaluation

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

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

Paul R. Marantz, MD, MPH
Professor, Departments of Epidemiology & Population Health; Medicine (CRTP Founder)
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
Section 3
Accreditation

The Albert Einstein College of Medicine is accredited by the New York State Education Department to award the Master of Science in Clinical Research Methods to students successfully completing the CRTP. As a degree-granting program under its accredited parent institution the Albert Einstein College of Medicine, the CRTP adheres to all Policies and Procedures endorsed by that institution, including but not limited to the Computer Policy and Policy on Non-Discrimination, Affirmative Action & Sexual Harassment.

Section 4
Admission to the Clinical Research Training Program

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. Applications for admission to the CRTP, along with details of the application procedure, are accessible online at: [http://www.einstein.yu.edu/centers/ictr/crtp/application-eligibility/](http://www.einstein.yu.edu/centers/ictr/crtp/application-eligibility/).

The application form, research plan, personal statement, applicant’s CV and contact information for proposed mentor(s)’s, the individual who can guarantee the applicants time and two individuals who can provide a letter of support (other than mentor or guarantor) need to be entered on the online application portal by March 1st to guarantee consideration for matriculation in July of same year. Additionally, official transcripts from the applicant’s doctoral degree granting institution need to be requested and sent to:

Clinical Research Training Program
Albert Einstein College of Medicine
Jack and Pearl Resnick Campus
1300 Morris Park Avenue, Block 5th Floor
Bronx, N.Y. 10461

Transfer students are generally not accepted to the CRTP. In the rare event that there is a transfer student, it is at the discretion of the CRTP Executive Committee how many credits and which credits can be transferred.

Each applicant is interviewed by one or two Admissions Committee Members, and the Director of the CRTP. Additionally medical students must be in good academic standing as per the Office of Student Affairs. Applications will be held over to subsequent years only at the discretion of the Director.
Section 5
General Policies

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/crtp/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 and 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.

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.

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 reading for each class session.

Credit Hour Definition for Laboratory Rotation and 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 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 or Ferkauf School of Psychology 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 Director and discuss the feasibility of successful completion of course work.

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. Such instances are adjudicated on a case by case basis by the Executive Committee and may necessitate a one-year extension in order to successfully complete all required coursework. Additionally, in the event a Scholar needs a prolonged leave of absence prior to completing the requirements of the Masters degree, a two-year extension may be obtained from the Director in writing on official CRTP letterhead in which to complete the required coursework or the thesis. 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 a withdrawal from CRTP by the Director in writing on official CRTP letterhead.

Non-matriculated scholars
Auditing and non-matriculated enrollment in one or more courses is discouraged. On very rare occasion a non-matriculated individual may take an individual CRTP course for credit. 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.

Section 6
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. Thesis requirements, policies, and procedures are described in detail in Section 11.

Section 7
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 Section 6. 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: https://www.yu.edu/transcript.

Section 8
Policy on Scientific Conduct

The College of Medicine expects that all members of the academic community will display the highest personal integrity and conduct themselves according to accepted ethical standards in every aspect of their professional lives. Dishonesty in the academic arena can neither be accepted nor ignored by scholars and faculty of the College and it is their joint responsibility to see that high standards of conduct are upheld.

The following definition of "misconduct in science" from the College's Policy on 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",

will be used to evaluate whether a scholar's research activities constitute scientific misconduct. 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 in Section 9. 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.

**Section 9
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 exonerate a student from responsibility for their actions. Plagiarism or cheating will normally result in dismissal from the CRTP. References are available in the library to help scholars evaluate the ethical implications of their actions.

**Section 10
Role of Mentors and Supervisors (Chair, Division Head, Fellowship Director)**

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 (as described in Section 6) or scientific or professional misconduct (as described in Sections 8 and 9). A scholar’s unsatisfactory progress in the CRTP may lead to changes in her/his research, mentor, clinical obligations, or other aspects of the Scholar’s professional activities, as deemed necessary through consultations between the CRTP 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.
Section 11
Thesis Requirements, Procedures, and Timetable

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 do clinical research.

Thesis Format
A manuscript suitable for submission for publication in a peer-reviewed journal is required. Such a manuscript must include an original analysis of data conducted by the scholar, either newly collected, existing from a parent study, or from secondary sources addressing 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
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:
   1. 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
- development of new technologies

2. Epidemiological and behavioral studies.
3. 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 Aileen McGinn, PhD, Director of the CRTP.

**The Thesis Proposal**
Thesis Proposals are due by **December 1** of the first year. Required components are:

1. Title;
2. Specific Aims;
3. Preliminary Data/Analysis, if available (not required);
4. Description of the project*;
5. Mentor’s name and signature;
6. Specific peer-reviewed journal whose format will be used; and
7. A proposed timetable (for data collection and draft submission).

*The project description (item #4 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 at least one 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. To arrange a statistical consultation with Dr. Lo email him directly (Yungtai.Lo@einstein.yu.edu) indicating you would like to discuss your CRTP thesis project. Also, bring 2 examples of papers that discuss your 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.

**Fall Year 1:** Each Scholar will meet individually with Dr. Yungtai Lo or another approved consultant to review your 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 your thesis and a consensus decision will be made as to whether your 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. You are also required to submit on or before the day of your thesis presentation a poster version of your 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**
- Start meeting regularly with mentor(s)
- Continue to define and develop research project
- Obtain & use reference software
- Begin literature search on your research topic

**October – November**
- Arrange the first statistical consultation with Dr. Yungtai Lo by sending him an email (yungtai.lo@einstein.yu.edu)

**December**
- 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**
- Works-In-Progress Presentation, go over with mentor in advance

**March – June**
- 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**
- July 1: First draft of Thesis should be submitted for comments to mentor and co-mentors

**September-October**
- Second statistical consult should be arranged in the fall
- Penultimate draft of thesis complete

**December**
- Works-in Progress

**February**
- February 1: Thesis abstract submitted

**March**
- March 1: Final thesis submission.
- Review/grading process begins

**April**
- Thesis decisions distributed first week of April
- Thesis revisions, if indicated, due by end of April

**May**
- Thesis presentations.
- Graduation luncheon
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.

The College 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.

Regulations in the current online catalog supersede those in all previous catalogs and are binding on all students.