# TABLE OF CONTENTS

Welcome..................................................................................................................................... 3  
Program Administration............................................................................................................. 4  
Faculty........................................................................................................................................ 5  
Chapter 1: Mount Sinai Clinical Research Education Program Introduction......................... 7  
  1. Program Policies and Guidelines.................................................................................... 8  
  2. Mission Statement.......................................................................................................... 8  
  3. Specific Goals................................................................................................................. 9  
  4. Statement of Values......................................................................................................... 9  
  5. Responsible Conduct in Research.................................................................................. 9  
  6. Program Competencies................................................................................................. 10  
Chapter 2: Program Eligibility and Application Process.......................................................... 15  
  1. Eligibility...................................................................................................................... 15  
  2. Application Process....................................................................................................... 15  
Chapter 3: Registration Process for Courses, Electives and Independent Study......................... 17  
  1. Course Registration and Enrollment............................................................................. 17  
  2. Independent Study........................................................................................................ 17  
  3. Electives offered in other programs or at other institutions.......................................... 18  
Chapter 4: Satisfactory Progress, Academic Probation and Academic Advisory Program...... 19  
  1. PhD in Clinical Research Satisfactory Progress Policy................................................ 19  
  2. MSCR and CRTP Satisfactory Progress Policy............................................................... 19  
  3. Academic Advisory Program........................................................................................ 19  
Chapter 5: Graduation Procedures and Degree Conferral......................................................... 20  
  1. Overview of Graduation Procedures............................................................................. 20  
  2. Graduation Application Form....................................................................................... 20  
  3. Other requirements preceding conferral of degree....................................................... 21  
Chapter 6: Degree Requirements (CRTP, MSCR, & PhD in Clinical Research)..................... 21  
  1. Overview of General Requirements.............................................................................. 21  
  2. Master of Science in Clinical Research (MSCR).......................................................... 21  
  3. Dual MD/MSCR Student/ PORTAL Program.............................................................. 24  
  4. PhD in Clinical Research.............................................................................................. 27  
Chapter 7: Clinical Research Education Program Forms........................................................... 37
Welcome

Welcome to Mount Sinai Graduate School of Biomedical Sciences’ Clinical Research Education Programs, including a 1) Clinical Research Training Program (CRTP; 2) Master of Science in Clinical Research (MSCR); and 3) PhD in Clinical Research, and congratulations on choosing to pursue one of these important courses of study. You will be joining other students in our Program from diverse backgrounds who are making a difference in the health of individuals and communities at large. In response to student evaluations, we have curriculum mapped the fundamental coursework on clinical research methodology and introduced a new course on computational tools in clinical research to better address the needs of our students and to enhance knowledge of informational resources and tools of utility in clinical investigation. The Clinical Research Education Program makes full use of its truly unique setting. It is housed in one of the most prestigious academic medical centers in the world and located between two socioeconomic extremes: the Upper East Side of Manhattan and East Harlem. The opportunities for learning in this environment and for pursuing a range of arenas in clinical/translational research are truly endless. We look forward to mentoring you and helping you find and hone your own interests, methodologic approaches and critical thinking skills as you embark on becoming an outstanding clinical investigator.

Wishing you much success in the Program and beyond,

Janice Gabrilove, MD
Director, Clinical Research Education Programs (CRTP, MSCR & PhD)
The James F. Holland Professor of Medicine & Oncological Sciences
Icahn School of Medicine at Mount Sinai School
Mount Sinai Graduate School of Biomedical Sciences

N.B. Out of respect for our environment and doing whatever we can to reduce our carbon footprint, the Clinical Research Education Programs will not routinely print copies of the Student Handbook. We would like our students to refer to it online whenever possible. We will always be sure to notify you by email of substantive changes to the information contained herein.

Disclaimer This handbook is meant to guide potential and current students in the Clinical Research Education Programs of Mount Sinai Graduate School of Biomedical Sciences. The Program reserves the right to make amendments to the contents without notice. The content of this handbook is not intended to be nor should it be regarded as a contract between the Program and any student or other person.
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CHAPTER 1: THE MOUNT SINAI CLINICAL RESEARCH EDUCATION PROGRAM
POLICIES, GUIDELINES, MISSION STATEMENT

INTRODUCTION

The Clinical/Translational Research Training Programs (CLR programs) of The Mount Sinai Graduate School of Biomedical Sciences are designed to foster the development of future leaders in patient oriented research. These training opportunities are intended to encourage the development of critical thinking necessary to conduct innovative hypothesis driven, independent and collaborative clinical/translational scientific research, in an effort to improve patient care and the wellbeing of society. In particular, we hope to enhance the research opportunities of clinical scientists as well as enhance the ability of basic scientists to better position themselves to translate the promise of their respective discoveries into the clinical arena, in a meaningful way with significant impact.

A rigorous curricular foundation designed to promote an in depth understanding of research methodologies and processes essential to translating the promise of scientific discovery into solving problems of disease is central to these educational initiatives, and forms the basis of our Certificate Program, Masters of Science in Clinical Research, and a new Ph.D. in Clinical Research.

The Clinical Research Training Program (CRTP) is an introductory, 1 year, part-time certificate version of the MSCR program which includes the core coursework without a Masters Thesis requirement or 2nd year research seminars and journal club.

The Masters of Science in Clinical Research (MSCR) is a 2 year program that provides an exceptional educational experience to outstanding health professionals, such as clinical / post-doctoral fellows, junior faculty, veterinarians, nurse Ph.D.s, allied health professionals, and other trainees (M.D., M.D./Ph.D., and 'basic science' Ph.D. students) with the knowledge, skills, and experience to successfully launch clinical and/or translational research-intensive careers. The MSCR has two main components: 1) graduate courses including biostatistics, epidemiology, research design, data analysis, informatics, bioethics and grant writing; and 2) a mentored clinical research project leading to a Masters thesis. The program is designed to be completed in 2 years. However, coursework can be taken over a longer period of time.

The Ph.D. in Clinical Research is designed for those outstanding candidates who are health professionals that desire a more intense educational experience to prepare them for a career in clinical or translational research. The program provides a strong didactic foundation combined with a mentored clinical research experience leading to a doctoral degree in Clinical Research.

Four tracks/training areas are offered within the MSCR and Ph.D. in Clinical Research Programs:

1) Translational Research: Bench to Bedside
2) Clinical Trials Research
3) Population, Outcomes and Implementation Research
4) Molecular Epidemiology
Within the context of these specific tracks, students may choose to develop an area of concentration or focus, developing specific expertise in:

- General Clinical Research
- Health Services Research & Health Policy Research
- Behavioral Research & Cognitive Tools
- Biostatistics: Quantitative and Qualitative Methods
- Epidemiology: Basic, Molecular and Clinical
- Informatics & Bioinformatics
- Outcomes Research
- Ethics
- Genomics & Personalized Medicine
- Drug Development
- Clinical Trials Research
- Translational Science

These areas of special focus build upon strengths reflective of the Icahn School of Medicine at Mount Sinai, Graduate School of Biomedical Sciences, and Mount Sinai’s Institutes and Departments.

Having trained over 100 outstanding candidates for successful careers in clinical/translational research, these various programs prepare individuals to be active facilitators in “Team Science” designed to solve problems of disease and facilitate the growth of individuals who will conduct well conceived and relevant clinical/translational research that leads to improved health and health care.

1. PROGRAM POLICIES AND GUIDELINES

The Clinical Research Education Program adheres to guidelines set forth by the Icahn School of Medicine at Mount Sinai, Graduate School of Biomedical Sciences, and Human Resources policies regarding fair and ethical dealings to ensure non-discrimination, harassment-free and equal opportunities with respect to education, research, patient services and employment. The Program adheres to all institutional policies on affirmative action, alcohol and drugs, HIV/AIDS non-discrimination, acts of sexual and other forms of harassment and unacceptable behaviors, retaliation, family and medical leave, rules of conduct, student behavior, and faculty, staff, and student relations. These policies are described in the Graduate School of Biomedical Sciences Student Handbook.

Please be sure to review the Graduate School of Biomedical Sciences Student Handbook for important information about academic policies, the registrar’s office, financial support, and student services. In some cases, there may also be additional guidelines that are specific to a student’s program of study in the Clinical Research Education Program Handbook. All students are required to familiarize themselves with the information contained within the Clinical Research Education Program Student Handbook and in the Graduate School of Biomedical Sciences Student Handbook.

2. MISSION STATEMENT

The mission of the Clinical Research Education Program is to 1) provide rigorous academic training and mentorship in patient-oriented clinical and translational research to outstanding
candidates from the health professions; 2) stimulate the acquisition of specific research skills and methodologies, the development of critical thinking skills; and 3) conduct better translational research that is relevant and leads to improved health and health care.

3. SPECIFIC GOALS

1. Enhance appreciation for the spectrum and promise of clinical/translational research
2. Foster knowledge regarding basic principles fundamental to the conduct of clinical research
3. Promote the ability to develop and refine a good research question
4. Encourage the development of an efficient, effective & ethical study design
5. Highlight the importance of mentorship

4. STATEMENT OF VALUES OF MOUNT SINAI CLINICAL RESEARCH EDUCATION PROGRAM

Statement of Values
The Clinical Research Education Program, of Icahn School of Medicine at Mount Sinai and Graduate School of Biomedical Sciences, is dedicated to improving the health of individuals and communities. The Program is based on the following core values:

**Sound Science:** We value the use of the scientific method to solve problems of disease and improve the health of individuals and the society at large.

**Community:** We value joint program-community participation in identifying and improving the health status of communities by enabling them to identify and address their unique public health problems.

**Diversity:** We value the recognition of the cultural context of individuals and populations and work to educate clinical investigators with the cultural competencies necessary to understand and respect diverse populations.

**Social Justice:** We value fostering and advocating for policies that reduce or eliminate health disparities.

**Teamwork:** We value working with others through cooperation and collaboration using interdisciplinary, multidisciplinary and trans-disciplinary teams in education and research.

**Professionalism & Responsible Conduct:** The Clinical Research Education Program Adheres to the Medical Educator code of conduct and the (medicinal & graduate) Code of Conduct outlined in the Icahn School of Medicine of Mount Sinai Medical Student Handbook, which applies to all students at Icahn School of Medicine at Mount Sinai and Mount Sinai Graduate School of Biomedical Sciences.

5. RESPONSIBLE CONDUCT IN RESEARCH

Requirements for Coursework on Responsible Conduct in Research (RCR)
The requirement by NIH, for investigators to have "face to face" training in Responsible Conduct of Research (RCR) can currently be met by means of: 1) enrolling and completing the entire 8 hour RCR course directed by Charles Mobbs or can be fulfilled by a combination of opportunities totaling 8 hours in which one can receive such instruction including:
1. Charles Mobbs' course (1-2 select sessions (Each session counts as 2 hours)
2. CLR0016 (counts as 2 hours of face time)
3. CLR0017, 0018, and 0019 (participation in all 3 courses counts as 2 hours of face time)
4. CLR0700 (counts as 2 hours of face time)

All of the CLR courses utilize case based discussions as does the Charles Mobbs’ course, strongly encouraged by NIH.

Although it currently does not satisfy the NIH requirements, we will include whether a student has or has not completed the Collaborative Institutional Training Initiative (CITI) course in: Basic Courses in the Protection of Human Research Subjects.

- Biomedical Focus (Investigators/Research Staff)
- Good Clinical Practice (GCP)

Please refer to your program checklist to ensure that you have met the RCR requirement.

6. PROGRAM COMPETENCIES

The Clinical Research Education Program supports the advancement of integrated and interdisciplinary education, training, and career development in Clinical and Translational Science. NCRR, in collaboration with the CTSA Education and Career Development Key Function Committee, formed the Education Core Competency Work Group to define the training standards for core competencies in clinical and translational research. The work group’s final recommendations for core competencies include 14 thematic areas that should shape the training experiences of junior investigators by defining the skills, attributes, and knowledge that can be shared across multidisciplinary teams of clinician-scientist. The Clinical Research Education Program has recently adopted these program competencies for all students.

The Program uses these thematic competencies to guide overall program learning objectives, overall curriculum development, and course specific learning objectives. Students will be expected to achieve proficiency in these thematic areas in the course of class work, the, seminars, journal club, independent study and through the Master’s Thesis and/or PhD dissertation. Attainment of these respective competencies will be assessed through the satisfactory completion of course work.

Core Competencies in Clinical and Translational Research Core Thematic Areas Competencies are outlined as follows:

I. CLINICAL AND TRANSLATIONAL RESEARCH QUESTIONS

- Identify basic and preclinical studies that are potential testable clinical research hypotheses.
- Identify research observations that could be the bases of large clinical trials.
- Define the data that formulate research hypotheses.
- Derive translational questions from clinical research data.
- Prepare the background and significance sections of a research proposal.
- Critique clinical and translational research questions using data-based literature searches.
- Extract information from the scientific literature that yields scientific insight for research innovation.
II. LITERATURE CRITIQUE

- Conduct a comprehensive and systematic search of the literature using informatics techniques.
- Summarize evidence from the literature on a clinical problem.
- Describe the mechanism of a clinical problem reviewed in a manuscript.
- Use evidence as the basis of the critique and interpretation of results of published studies.
- Identify potential sources of bias and variations in published studies.
- Interpret published literature in a causal framework.
- Identify gaps in knowledge within a research problem.

III. STUDY DESIGN

- Formulate a well-defined clinical or translational research question to be studied in human or animal models.
- Propose study designs for addressing a clinical or translational research question.
- Assess the strengths and weaknesses of possible study designs for a given clinical or translational research question.
- Design a research study protocol.
- Identify a target population for a clinical or translational research project.
- Identify measures to be applied to a clinical or translational research project.
- Design a research data analysis plan.
- Determine resources needed to implement a clinical or translational research plan.
- Prepare an application to an IRB.

IV. RESEARCH IMPLEMENTATION

- Compare the feasibility, efficiency, and ability to derive unbiased inferences from different clinical and translational research study designs.
- Assess threats to internal validity in any planned or completed clinical or translational study, including selection bias, misclassification, and confounding.
- Incorporate regulatory precepts into the design of any clinical or translational study.
- Integrate elements of translational research into given study designs that could provide the bases for future research, such as the collection of Biomedical specimens nested studies and the development of community-based interventions.

V. SOURCES OF ERROR

- Describe the concepts and implications of reliability and validity of study measurements.
- Evaluate the reliability and validity of measures.
- Assess threats to study validity (bias) including problems with sampling, recruitment, randomization, and comparability of study groups.
- Differentiate between the analytic problems that can be addressed with standard methods and those requiring input from biostatisticians and other scientific experts.
- Implement quality assurance systems with control procedures for data intake, management, and monitoring for different study designs.
- Assess data sources and data quality to answer specific clinical or translational research questions.
- Implement quality assurance and control procedures for different study designs and analysis.
VI. STATISTICAL APPROACHES

- Describe the role that biostatistics serves in biomedical and public health research.
- Describe the basic principles and practical importance of random variation, systematic error, sampling error, measurement error, hypothesis testing, type I and type II errors, and confidence limits.
- Scrutinize the assumptions behind different statistical methods and their corresponding limitations.
- Generate simple descriptive and inferential statistics that fit the study design chosen and answer research question.
- Compute sample size, power, and precision for comparisons of two independent samples with respect to continuous and binary outcomes.
- Describe the uses of meta-analytic methods.
- Defend the significance of data and safety monitoring plans.
- Collaborate with biostatisticians in the design, conduct, and analyses of clinical and translational research.
- Evaluate computer output containing the results of statistical procedures and graphics.
- Explain the uses, importance, and limitations of early stopping rules in clinical trials.

VII. BIOMEDICAL INFORMATICS

- Describe trends and best practices in informatics for the organization of biomedical and health information.
- Develop protocols utilizing management of information using computer technology.
- Describe the effects of technology on medical research, education, and patient care.
- Describe the essential functions of the electronic health record (EHR) and the barriers to its use.
- Explain the role that health information technology standards have on the interoperability of clinical systems, including health IT messaging.
- Access patient information using quality checks via electronic health record systems.
- Retrieve medical knowledge through literature searches using advanced electronic techniques.
- Discuss the role of bioinformatics in the study design and analyses of high dimensional data in areas, such as genotypic and phenotypic genomics.
- Collaborate with bioinformatics specialists in the design, development, and implementation of research projects.

VIII. RESPONSIBLE CONDUCT OF RESEARCH

VIII.a. Clinical Research Ethics Competencies

- Summarize the history of research abuses and the rationale for creating codes, regulations, and systems for protecting participants in clinical research that requires community input.
- Critique a clinical or translational research proposal for risks to human subjects.
- Explain the special issues that arise in research with vulnerable participants and the need for additional safeguards.
- Determine the need for a risk-benefit ratio that is in balance with the outcomes in clinical and translational research.
• Describe the elements of voluntary informed consent, including increasing knowledge about research, avoiding undue influence or coercion, and assuring the decision-making capacity of participants.
• Assure the need for privacy protection throughout all phases of a study.
• Assure the need for fairness in recruiting participants and in distributing the benefits and burdens of clinical research.
• Adhere to IRB application procedures.
• Explain how the structural arrangement of science and the research industry may influence the behavior of scientists and the production of scientific knowledge.

VIII.b. Responsible Conduct of Research Competencies
• Apply the main rules, guidelines, codes, and professional standards for the conduct of clinical and translational research.
• Adhere to the procedures to report unprofessional behavior by colleagues who engage in misconduct in research.
• Implement procedures for the identification, prevention, and management of financial, intellectual, and employment conflicts of interests.
• Apply the rules and professional standards that govern the data collection, sharing, and protection throughout all phases of clinical and translational research.
• Apply elements of voluntary informed consent, of fostering understanding of information about clinical research, and for avoiding undue influence or coercion, and taking into consideration the decision-making capacity of participants.
• Explain the need for privacy protection and best practices for protecting privacy throughout all phases of a study.
• Explain the need for fairness in recruiting participants and in distributing the benefits and burdens of clinical research.
• Explain the function of the IRB.

IX. SCIENTIFIC COMMUNICATION
• Communicate clinical and translational research findings to different groups of individuals, including colleagues, students, the lay public, and the media.
• Translate the implications of clinical and translational research findings for clinical practice, advocacy, and governmental groups.
• Write summaries of scientific information for use in the development of clinical health care policy.
• Translate clinical and translational research findings into national health strategies or guidelines for use by the general public.
• Explain the utility and mechanism of commercialization for clinical and translational research findings, the patent process, and technology transfer.

X. CULTURAL DIVERSITY
• Differentiate between cultural competency and cultural sensitivity principles.
• Recognize the demographic, geographic, and ethnographic features within communities and populations when designing a clinical study.
• Describe the relevance of cultural and population diversity in clinical research design.
• Describe cultural and social variation in standards of research integrity.
• Critique studies for evidence of health disparities, such as disproportional health effects on select populations (e.g., gender, age, ethnicity, race).
XI. TRANSLATIONAL TEAMWORK

- Build an interdisciplinary/ intradisciplinary/ multidisciplinary team that matches the objectives of the research problem.
- Manage an interdisciplinary team of scientists.
- Advocate for multiple points of view.
- Clarify language differences across disciplines.
- Demonstrate group decision-making techniques.
- Manage conflict.
- Manage a clinical and/or translational research study.

XII. LEADERSHIP

- Work as a leader of a multidisciplinary research team.
- Manage a multidisciplinary team across its fiscal, personnel, regulatory compliance and problem solving requirements.
- Maintain skills as mentor and mentee.
- Validate others as a mentor.
- Foster innovation and creativity.

XIII. CROSS DISCIPLINARY TRAINING

- Apply principles of adult learning and competency-based instruction to educational activities.
- Provide clinical and translational science instruction to beginning scientists.
- Incorporate adult learning principles and mentoring strategies into interactions with beginning scientists and scholars in order to engage them in clinical and translational research.
- Develop strategies for overcoming the unique curricular challenges associated with merging scholars from diverse backgrounds.

XIV. COMMUNITY ENGAGEMENT

- Examine the characteristics that bind people together as a community, including social ties, common perspectives or interests, and geography.
- Appraise the role of community engagement as a strategy for identifying community health issues, translating health research to communities and reducing health disparities.
- Summarize the principles and practices of the spectrum of community-engaged research.
- Analyze the ethical complexities of conducting community-engaged research.
- Specify how cultural and linguistic competence and health literacy have an impact on the conduct of community engaged research.

CHAPTER 2: PROGRAM ELIGIBILITY AND APPLICATION PROCESS

1. ELIGIBILITY

Our Program presumes that students enter with a working knowledge of basic medical terminology and major concepts of health and illness. People with degrees in medicine, nursing,
or the allied health professions, or simultaneously in training, ordinarily meet this requirement. The Admissions Committee will carefully review the applications from those without formal training but with work experience in the health professions and/or suitable undergraduate studies.

Applicants must possess a Bachelor’s Degree from an accredited college or university. While there are no specific prerequisites, an applicant’s transcript will be reviewed for demonstration of satisfactory performance in quantitative and qualitative methods and in social and Biomedical sciences. Students are selected on the basis of demonstrated past academic achievement.

2. APPLICATION PROCESS

MATRICULATING STUDENTS (STUDENTS FOR CONSIDERATION FOR CRTP, MSCR & PHD IN CLINICAL RESEARCH)

Applications and supporting documentation are reviewed throughout the year for admission to the upcoming Fall Term. Matriculation at other times during Spring I and Spring II is possible with the permission of the Program Director only for the CRTP and MSCR programs. PhD applicants, who, on the basis of their submitted application materials, are being seriously considered for the Program, may be invited for interviews. The requirement for these interviews may be exchanged for a telephone interview, if geographical considerations are overwhelming. The Admissions Committee of the Graduate School will consider all the data on each applicant before making its decision. Applicants should submit all materials in the checklist below. The Application Process should be completed online at the Programs Website as follows:

- Completed online Application Form:
- Official transcripts from all institutions of higher learning attended. These documents must be sent directly to the Icahn School of Medicine at Mount Sinai Admissions Office. (International Students: Please read the section titled “International Students” below for more specific details on transcript requirements)
- CV, Personal Statement
- Preliminary Research Plan (only applicable to MSCR and PhD applicants)
- Two signed original letters of recommendation. The authors of your recommendation letters must send their letters directly to the Admissions Office or upload the letters directly on the online application system. (Copies of letters or letters delivered or uploaded by the applicant will not be accepted.) If you are currently a Mount Sinai employee or have worked at Mount Sinai in the past a letter from your supervisor is required as one letter of recommendation.
- GRE, MCAT, OR USMLE scores should be sent to Icahn School of Medicine at Mount Sinai. (For the GRE, the code for Icahn School of Medicine at Mount Sinai is 2464.)
- Applicants for whom English is a second language may be requested to provide evidence of English language competency, such as scores from the Test of English as a Foreign Language TOEFL exam.
- A non-refundable application fee of $80
- Upon completion of your application and acceptance as a matriculating student, you will receive an email from the registrar’s office, when registration for classes is open.

*All applicants* must have a Bachelor's Degree from a recognized university or college, show evidence of satisfactory preparation in quantitative subject areas, and have an acceptable academic record.
**International Students** - graduates of foreign colleges or universities who have completed an academic program equivalent to an American bachelor's degree are eligible to apply for admission. International applicants are required to have their foreign transcripts translated into English by a certified foreign credential translation service (ex. WES, ECE, FIS). Applicants should request that these translated documents be sent directly to Icahn School of Medicine at Mount Sinai along with official original transcripts from their institution. Please contact the program administration should you have any questions. In addition, the TOEFL is required of all applicants (1) whose native language is not English and/or (2) whose education was not conducted in English. A computer test score of 250 or higher is expected. Applicants who received their first university degree in an English-speaking country may request an exemption from TOEFL.

Arrangements to take the TOEFL should be made in writing directly to TOEFL, Box 6151, Princeton, NJ 08541-6151, USA, or to their website at [www.toefl.org](http://www.toefl.org) or faxed to 609.771.7500. We must have test results in order to make a decision on your application.

All international students must contact the International Personnel Office after they have been accepted in the program to get information on getting appropriate visa. The office is located at 320 East 94th Street, 5th floor, between 1st and 2nd Avenue, New York, NY. They can be reached at 212-731-7744.

**NON-MATRICULATING STUDENTS (NON-DEGREE STUDENTS)**

Non-matriculating students may take up to 12 credits without matriculating for the full degree. If you are interested in taking courses in the Clinical Research Education Program as a non-matriculating student, please do the following:

1. All Non-Matriculating Students must first apply to the program online. Upon completion of your application and acceptance as a non-matriculating student, you will receive an email from the registrar’s office with information about how to register for classes and the deadlines for registration.

2. A completed application will include an updated resume, personal statement, one letter of recommendation and an $80 non-refundable application fee. Contact the Program Director to verify that your background and skills assure eligibility for the course and to receive permission to enroll. Please note: Courses may require that students have fulfilled certain pre-requisites. **Students will not be eligible to take a course if they lack the required pre-requisites.**

3. Non-matriculating students wishing to pursue one of our degree programs (CRTP, MSCR, or PhD) must apply to the Clinical Research Education Program and will undergo the same admission process and be evaluated based on the same criteria used for all applicants.
CHAPTER 3: CLINICAL RESEARCH EDUCATION PROGRAM REGISTRATION
PROCESS FOR COURSES, ELECTIVES AND INDEPENDENT STUDY

1. COURSE REGISTRATION & ENROLLMENT

Once students have completed the online application and have been officially accepted into a specific degree granting program or as a non-matriculating student, they will receive an email from the registrar’s office at the time registration begins for each term or semester, as the case might be.

Initial registration for classes for each Term must be completed before classes begin in order to avoid the late fee. The Registration Deadline is the final date for students to make changes to their selection of classes. Prior to this deadline, students are permitted to add or drop courses. The Registration Deadlines are communicated directly to the students by the Registrar’s office. After deciding to add or drop a course, any student who fails to change his/her initial Registration on the registration website before the Registration Deadline will not be eligible to take a course (if not enrolled) or to receive a tuition refund (if not withdrawn) for that Term.

Students will not be able to take a particular course if they lack the required pre-requisites. Please refer to the course description in the Curriculum Guide for information on a course’s pre-requisites.

2. INDEPENDENT STUDY

Three credits are the maximum number of credits that may be awarded per Independent Study. Each Independent Study credit requires 15 hours of face time with the Independent Study mentor and 30 hours of non-face time. Please note that while the total hours committed to the pursuit of the Independent Study may be sufficient for more than three credits or more than one elective, students will not receive any more than three credits for one project/course of study. Each student may complete no more than two independent study projects.

An Independent Study must be a unique experience. Material covered during an independent study project should be highly targeted and not simply a review of the regularly offered coursework. It is important to note that generally speaking independent study projects should not be attempts to take CLR courses that are offered routinely during the academic year at times that are more convenient for the student. Students should not expect independent study projects to exempt them from core course requirements without approval by the Track Academic Advisor and the Program Director.

Steps towards formalizing an Independent Study:

1. Meet with the Program Director to discuss your plans for your Independent Study at least 6 weeks prior to the start of the Independent Study.
2. Meet with the faculty sponsoring your Independent Study to discuss and plan the Independent Study at least 6 weeks before the start of the Independent Study.
3. Complete the Independent Study Proposal Form and submit it to the Program Office with the appropriate signatures at least 3 weeks before the start of the independent study. See Appendix C
4. Register for the Independent Study credits through the registration system before starting the Independent Study.
5. Complete the project/course of study once approved.
6. Complete the Independent Study Postscript Report and submit to the Program Office with appropriate signatures no later than 3 weeks after your project has been completed. See Appendix C
7. Request that your Faculty Sponsor complete the Independent Study Faculty Sponsor Form and submit it to the Program Office no later than 3 weeks after the study has been completed, Independent Study Faculty Sponsor Form. See Appendix C
9. Complete the Independent Study Student Evaluation of Faculty Form no later than 3 weeks after the study has been completed. See Appendix C

3. ELECTIVES OFFERED IN OTHER PROGRAMS OR AT OTHER INSTITUTIONS

Students are permitted to take any course listed in the CLR Curriculum Guide as an elective. Only courses listed in the Curriculum guide are approved for CLR credit.

If a student wishes to take a course in the Graduate Program at MSSM, which is not listed in the Curriculum Guide, he/she must request approval from the Program Director prior to registering for the class.

If a student wishes to take an elective course offered at a different institution, the student will need to submit a course description and a syllabus from the Institution offering the elective course, together with a completed Elective Approval Form (see Appendix C), to the Clinical Research Education office. Approval must be given from the Clinical Research Education Program Director prior to enrolling in the course.

Upon completion of the elective course, the student will need to complete the Evaluation Form for Transfer of Credit (see Appendix C) and submit it to the Program Office along with an official transcript from the institution where the course was taken. The form and transcript must be submitted in order for the elective to appear on a student’s CLR transcript.

CHAPTER 4: SATISFACTORY PROGRESS, ACADEMIC PROBATION AND ACADEMIC ADVISORY PROGRAM

1. PHD IN CLINICAL RESEARCH PROGRAM SATISFACTORY PROGRESS POLICY

PhD students in the CLR program must earn a minimum of a B in each of the required core courses in order to remain matriculated in the program. If a student earns less than a B in a required core course, he/she can re-take the course and must earn a B or better. However, if the student does not retake the course or retakes the course and earns less than a B, the student will be withdrawn from the program. Additionally, students are required to maintain an overall 3.0 Grade Point Average (GPA). Anytime a student’s GPA falls below 3.0 the Academic Advisory Committee will be consulted and a plan for remediation developed. In most cases the student will
meet with the Program Director or another member of the Academic Advisory Committee, develop an individual plan of remediation, and sign a statement of understanding that he/she is on academic probation.

The Academic Advisory Committee meets at the end of each term and reviews the progress of each student on probation. If the GPA has not improved in the subsequent term, the student will continue to meet with the Program Director or another Academic Advisory Committee member revising the remediation plan, as needed. If the student’s GPA has not reached 3.0 within two terms of having been placed on probation, the student will be asked to withdraw from the program. Notices of withdrawal are sent by certified mail.

2. MSCR AND CRTP SATISFACTORY PROGRESS POLICY.

MSCR students must earn an overall minimum of 3.0 GPA in the Core Curriculum. Anytime a student’s GPA falls below 3.0, the Academic Advisory Committee will be consulted and a plan for remediation developed. In most cases the student will meet with the Program Director or another member of the Academic Advisory Committee, develop an individual plan of remediation, and sign a statement of understanding that he/she is on academic probation.

The Academic Advisory Committee meets at the end of each term and reviews the progress of each student on probation. If the GPA has not improved in the subsequent term, the student will continue to meet with the Program Director or another Academic Advisory Committee member revising the remediation plan, as needed. If the student’s GPA has not reached 3.0 within two terms of having been placed on probation, the student will be asked to withdraw from the program. Notices of withdrawal are sent by certified mail.

3. ACADEMIC ADVISORY PROGRAM

The goal of the academic advisory program is to monitor the academic progress of students in the clinical research education program. The Core Academic faculty will serve as individual advisors to the students in our MSCR (excluding PORTAL students), and to PhD candidates. Each scholar will be assigned 2 academic advisors by the Program Directors based upon their initial specified area of research interest, articulated in your initial application to the program. The role of the advisor will be distinct from that of research mentor and career mentor. Specifically they will:

1) provide advice on elective coursework relevant to your area of research focus
2) review academic performance
3) assist in finding potential mentors related to possible research topics and projects of interest
4) track progress of degree completion
5) provide assistance with challenges that arise with regard to courses and/or research
6) provide advice on funding opportunities
7) serve as a second reader for your drafts and final Master’s Thesis

The student is required to meet with one of their assigned advisors at the end of Spring 1 of each year in the program. Students are asked to notify the program office of their scheduled appointment with their advisors. The Program Office will then forward the appropriate material for the advisors to review with the students. Notes of the meeting will be put into the students
file for review by the Program Directors. In addition, the student is also required to meet with the Program Director before the start of the Spring 2 term each year.

The Academic Advisory Committee will review the academic performance of any student with a GPA below 3.0. The Committee will make the final recommendation to the Program Directors regarding a student’s ability to remain in the Program should a student fail to bring his/her GPA to 3.0 or higher within two terms of having been placed on academic probation.

CHAPTER 5: GRADUATION PROCEDURES AND DEGREE CONFERRAL

1. OVERVIEW OF GRADUATION PROCEDURES

To ensure that all academic requirements are met in time for participation in the May graduation ceremony, students will be advised at the beginning of the Academic Year of the year they expect to graduate as to when they must have all their credits, their Master’s Thesis completed and all appropriate forms signed and turned into the Program Administration. Students who do not expect to make the May graduation deadline should speak to the Program Administrator and Program Director as soon as possible to make plans to finish the degree requirements in a timely fashion.

It is important to note that Diplomas are produced only once per year by Icahn School of Medicine at Mount Sinai and students who do not meet deadlines for a May or June graduation will not receive a diploma until the following May after they have completed all degree requirements. The Master of Science in Clinical Research and the PhD in Clinical Research itself can be conferred on three other occasions, September 30th, January 30th, and June 30th following completion of all degree requirements. If necessary, prior to receipt of the actual diploma, students can request a letter from Icahn School of Medicine at Mount Sinai Registrar’s office verifying that they have completed the degree requirements and confirming that the degree has been conferred.

2. GRADUATION APPLICATION FORM

Any student (whether MSCR, PhD in CR or Dual Degree student) intending to graduate in May must submit a Graduation Application Form no later than February 1st of the year that corresponds to their intended graduation. This form ensures that students have adequate time to attend to any outstanding issues. Additionally, it ensures that the Clinical Research Education Program has a record of how many students wish to participate in the Graduation ceremonies diploma. Graduation Application Form See Appendix D

3. OTHER REQUIREMENTS PRECEDING CONFERRAL OF DEGREE

The Master of Science in Clinical Research or the PhD in Clinical Research cannot be awarded until all of the student’s outstanding accounts have been cleared. These may include the Library, Real Estate Office (for students living in Mount Sinai housing), Student Health Services, the Financial Aid Office, Registrar’s Office and any other service provided or account outstanding at Mount Sinai.
Upon satisfactory completion of the above-mentioned requirements, payment of all outstanding fees, and submission of the Student Exit Form (MSCR and CRTP students only (see Appendix D)), Graduating Student Exit Survey (all students (see Appendix D)), and Student Check out form (PhD students only (see Appendix B)) the degree is awarded on the conferral date following the final Thesis deposit. Students will also be asked to meet with the Program Director or Co-Director for an Exit Interview prior to graduation.

CHAPTER 6: DEGREE REQUIREMENTS (CRTP, MSCR & PHD IN CLINICAL RESEARCH)

1. OVERVIEW OF GENERAL REQUIREMENTS

To complete the Clinical Research Training Program (CRTP) students must complete 26 credits of required coursework. The Master of Science in Clinical Research (MSCR) students are required to obtain a minimum of 38 credits, including a Masters Thesis. To complete the PhD in Clinical Research, trainees are required to complete 66 credits of coursework, including sitting for a qualifying exam, and submission of a thesis dissertation. Please refer to the Curriculum Guide for descriptive information on individual courses offered during a specific terms.

All students pursuing a specific degree in the Clinical Research Education Program will be assigned to an academic advisor, with complementary expertise, who is a member of the Clinical Research Education Core Faculty. The role of the academic advisor is outlined under the Academic Advisory Program section of this handbook.

2. MASTER OF SCIENCE IN CLINICAL RESEARCH (MSCR)

The Masters of Science in Clinical Research (MSCR) is designed as a 2 year program that provides an exceptional educational experience to outstanding health professionals, such as clinical / post-doctoral fellows, junior faculty, veterinarians, nurse Ph.D.s, allied health professionals, and other trainees (M.D., M.D./Ph.D., and 'basic science' Ph.D. students) with the knowledge, skills, and experience to successfully launch clinical and/or translational research-intensive careers. The MSCR has two main components: 1) graduate courses including biostatistics, epidemiology, research design, data analysis, informatics, bioethics and grant writing (for the complete breakdown & sequence of required courses and elective credits please see our curriculum guide; and 2) a mentored clinical research project leading to a Master’s thesis. The program is designed to be completed in 2 years. However, coursework can be taken over a longer period of time.

The attainment of a MSCR in Clinical Research requires

1. Successful completion of coursework
2. Satisfactory completion and deposit of thesis

Four tracks/training areas are offered within the MSCR Program:

1) Translational Research: Bench to Bedside
2) Clinical Trials Research
3) Population, Outcomes and Implementation Research
4) Molecular Epidemiology

Within the context of these specific tracks, students may choose to develop an area of concentration or focus, developing specific expertise in:

- General Clinical Research
- Health Services Research & Health Policy Research
- Behavioral Research & Cognitive Tools
- Biostatistics: Quantitative and Qualitative Methods
- Epidemiology: Basic, Molecular and Clinical
- Informatics & Bioinformatics

These areas of special focus build upon strengths reflective of the Icahn School of Medicine at Mount Sinai, Graduate School of Biomedical Sciences, and Mount Sinai’s Institutes and Departments.

DEVELOPMENT OF MASTER’S THESIS

Students should work early on with their Program Advisors and identified mentors to select an appropriate research project for their Master’s Thesis. The mentor identified by the student, with whom he/she is working, should complete the Research Agreement form, see Appendix A, indicating willingness to serve as a Master’s Thesis Advisor. This form should be submitted by the student to the Program office no later than 5pm on the Friday of the first week of classes in the fall of the second year of the Masters Program (for MSCR being completed in 2 years), no later than the same date of the third year (if MSCR being completed in 3 years) or no later than September 15th of the Scholarly year if in the PORTAL Program (Please see “PORTAL Thesis Procedure” section for more detailed information). The student is required to submit an outline (maximum of 3 pages) of the proposed thesis along with the Research Agreement form. The outline should include the following sections:

- Statement of purpose
- Background
- Hypothesis
- Specific Aims
- Research Design
- Methods

MASTER’S THESIS

Experience researching and writing a Thesis provides the student with an opportunity to explore and further develop ideas from lessons learned in the classroom, apply them to a specific research endeavor and demonstrate the student’s mastery of the essence of clinical/translational research within a particular area of interest.

All students enrolled in the MSCR are required to complete a Master’s Thesis and must obtain approval of their topic and plan from the Director or Co-Director of the Clinical Research...
Education Program, or in the case of the MD/MSCR, the Director of the PORTAL program, Karen Zier, PhD. Please see “PORTAL Thesis Procedure” section for more detailed information.

As part of the application to the MSCR program, the student is required to submit a proposed clinical research proposal. This proposal is anticipated to be further refined and/or revised, with submission of the proposed thesis outline submitted with the Research Agreement form. A first draft of the final thesis should be submitted for review by January 15\textsuperscript{th} of your second year or third year (if MSCR being completed in 3 years) in the program for May graduation, or by January 15\textsuperscript{th} of M4 if in the PORTAL Program.

**TIMELINES FOR THE MASTERS THESIS AND FORMS**

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<th>PORTAL students, Fourth Year of Medical School</th>
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<tbody>
<tr>
<td>Register for the Masters Thesis</td>
<td>Fall</td>
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<td>Fall of Scholarly year</td>
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<tr>
<td>Submit first draft of Thesis</td>
<td>By January 15\textsuperscript{th}</td>
<td>By March 1\textsuperscript{st}</td>
<td>July 15\textsuperscript{th}</td>
<td>November 15\textsuperscript{th}</td>
<td>January 15\textsuperscript{th} of M4</td>
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<tr>
<td>Submit final Thesis for review</td>
<td>By March 15\textsuperscript{th}</td>
<td>By May 1\textsuperscript{st}</td>
<td>August 15\textsuperscript{th}</td>
<td>December 15\textsuperscript{th}</td>
<td>March 15\textsuperscript{th} of M4</td>
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<tr>
<td>Submit Thesis to the Library</td>
<td>By April 15\textsuperscript{th}</td>
<td>By June 1\textsuperscript{st}</td>
<td>September 15\textsuperscript{th}</td>
<td>January 15\textsuperscript{th}</td>
<td>April 15\textsuperscript{th} of M4</td>
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All students are required to register for their Master’s thesis (course number CLR0001). This is most commonly done at the start of the second year (fall term). Students should register for a minimum of 5 credits but up to 8 credits. However, registration for more than 5 credits requires approval of the Program Director(s).

Once a student has completed the Master’s Thesis, he/she must complete a Master’s Thesis Approval form, which is signed by the thesis advisor and Program Director and submitted to the Program office. **Master’s Thesis Approval form** (See Appendix A)

At the completion of the Master’s Thesis an evaluation form must be completed by the student’s Master’s Thesis mentor and submitted to the Program Manager. **Research Thesis Evaluation Report** See Appendix A

When a final draft of the thesis is ready for submission to the Program, a Thesis Deposit form must be completed. **Master’s Thesis Deposit Form**. See Appendix A. The Thesis Advisor and Student will complete the Master’s Thesis Deposit Form and allocate a total of $2,000 to faculty who significantly contribute to the Student’s thesis project (e.g., Thesis Advisor, Second Reader, Consultant (biostatistician)).

Student should refer to the section on “Graduation Application Form” and “Other Requirements Preceding Conferral of Degree” on page 40 for more information about Graduation.
Once the student has submitted all of the appropriate forms, he/she must deposit the Master’s Thesis by the dates outlined in the table above. Please see Depositing your Master’s thesis guide (Appendix A) for complete details on how to deposit your thesis.

Students have 3 years to finish the Master’s Thesis after completion of all course work; if it is not finished within that timeframe the student will be withdrawn from the Program unless they have prior approval for an extension for special circumstances.

Please note that a student may submit, for their Master’s Thesis, a first author manuscript either submitted for publication, accepted for publication or published during their training which is reflective of their Master’s Thesis work. In this instance, a statement of purpose, introduction, and discussion regarding the findings and impact of the work needs to be added.

**ANNUAL BEST MSCR THESIS PRIZE**

Each year, prior to graduation, the best MSCR thesis will be selected and awarded a prize for the best thesis, to be presented at the annual graduation awards ceremony. The process for selecting the award recipient will be as follows: 1. Secondary reviewers read the thesis draft and provide feedback. Currently the Program Directors serve as the secondary reviewers. In future academic years, the core faculty for the Clinical Research Education Program will serve as the secondary reviewers. 2. Secondary reviewers read the final draft and offer any final corrections. 3. Secondary reviewers will also provide a critique of the thesis utilizing KL2 NIH review format and submit this to the Program Office.4. The highest scoring (utilizing current 1-9 NIH scoring system) thesis will be selected for the Clinical Research Education MSCR Prize

**3. DUAL MD-MSCR STUDENT/ PORTAL PROGRAM**

**PROGRAM OVERVIEW**

PORTAL is a strongly mentored, 5 year program for medical students designed accelerate the process through which discoveries made in the laboratory are brought to the patient’s bedside. The program offers a multidisciplinary approach to clinical investigation training in order to introduce students to the field of clinical/translational research and how it drives the practice of clinical medicine. Participants will be part of a select group of scholars that integrate learning clinical medicine with how to establish a career in clinical investigation from the very start of their medical education. Teaching medical students how to conduct high quality clinical research studies may produce better, more successful, and more satisfied clinical investigators to the benefit of both the students and society. Students who successfully complete the program will be awarded an MD and a Masters in Clinical Research (MSCR).

**PROGRAM STRUCTURE**

PORTAL students start training during year 1 of medical school and continue their development through their careers. Course work is taken during years 1 and 2, the Scholarly Year, and the final year of medical school. Most of the thesis work is done during the Scholarly Year. Information on coursework for PORTAL can be found at the program website [here](#). Please refer to the Curriculum Guide for descriptive information on individual courses offered during a specific terms. The curriculum offers rigorous didactic and hands on research training in clinical research methodology, including clinical trial and experimental design, data management, data analysis, research communication skills, e.g., abstract, manuscript, and grant writing, along with oral
presentation skills, and how to navigate regulatory requirements. Regular, informal sessions will also be scheduled to allow PORTAL students to meet successful clinical researchers in order to learn about their career paths, as well as to permit students to discuss issues of common interest with each other.

**Research and Mentoring**

The multiyear commitment to excellence by the student is made possible by strong faculty support, as well as institutional resources. Outstanding faculty members from diverse departments serve as mentors. Students will identify their area of research interest and be matched with an experienced, supportive clinical research mentor. In many cases, students will choose two mentors who represent different, though complementary disciplines, enabling them to have a more interdisciplinary experience.

During the course of the PORTAL program, students will have the opportunity to participate in an ongoing research project, as well as carry out an original research project in an area of their choice. Their original research will form the basis for a thesis. Thesis work will be guided by the faculty mentor and the program directors. Time for research is built into the program during the following periods and include, minimally,

- 8 weeks during the summer following the first year
- An 11 month Scholarly Year, following year 3 of medical school
- The 12 week INSPIRE program, during the final year of medical school
- Additional time may be arranged during elective periods on an individual basis

**Financing**

Students selected for PORTAL will receive full scholarships to cover the tuition of the MSCR degree. Participants also will receive a stipend during their Scholarly Year to cover living expenses, including health insurance. There is no medical school tuition during the Scholarly Year.

**Applying to the PORTAL Program**

Students apply to PORTAL at the same time they apply to the MD program. They will submit a brief supplemental application form that allows them to more fully describe their specific reasons for applying to the Mount Sinai MD/MSCR program. In addition to meeting the requirements for admission to the MD program, the applicant must have had research experience, preferably clinical research. Selected applicants will be interviewed.

**PORTAL Thesis Procedure**

Successful completion of the MSCR program involves submission of a thesis that is approved by the student’s thesis committee. It is expected that the bulk of the thesis work will be done during the student’s Scholarly Year. Thesis research will earn 9 credits.

Oversight of the student’s progress and thesis research will be the responsibility of the thesis committee consisting of the student’s mentor plus two additional faculty members. The latter will serve as advisors, as well as have the responsibility of approving the thesis. The student may suggest the names of faculty members they think would qualify as committee members,
based upon their area of expertise, but the ultimate decision will be that of the MSCR Program Directors.

PORTAL students must complete the existing MSCR approval process, although the timetable, reflected below, is modified. In order for the student to receive his/her degree along with the MD at the May graduation, please submit the following documentation:

- The Research Agreement Form, see Appendix A, including an outline of the proposed thesis topic (maximum of 3 pages), by September 15th of Scholarly year.

- The first draft of thesis by January 15th of M4*. The thesis must adhere to the guidelines outlined in the Depositing Your Master’s Thesis form, see Appendix A. The student’s thesis committee will review the draft and return to the student with any comments and recommendations no later than 4 weeks after receipt of the draft.

  - Please note that a student may submit, for their Master’s Thesis, a first author manuscript either submitted for publication, accepted for publication or published during their training which is reflective of their Master’s Thesis work. In this instance, a statement of purpose, introduction, and discussion regarding the findings and impact of the work needs to be added.

- The final thesis for review by March 15th of M4.

- The Master’s Thesis Approval Form, See Appendix A. Once a student has completed the Master’s Thesis, he/she must complete a Master’s Thesis Approval form, which is signed by the thesis advisor and Program Director and submitted to the Program office.

- The Master’s Thesis Evaluation report, see Appendix A, by March 15th of M4.

- The thesis to the library by April 15th of M4.

  *M4 refers to the final year of medical school and follows the Scholarly Year.

4. PHD IN CLINICAL RESEARCH

The Ph.D. in Clinical Research is designed for those outstanding candidates who are health professionals that desire a more intense educational experience to prepare them for a career in clinical or translational research. The program provides a strong didactic foundation combined with a mentored clinical research experience leading to a doctoral degree in Clinical Research.

4 tracks/training areas are offered within the Ph.D. in Clinical Research Program:

1) Translational Research: Bench to Bedside
2) Clinical Trials Research
3) Population, Outcomes and Implementation Research
4) Molecular Epidemiology
Within the context of these specific tracks, students may choose to develop an area of concentration or focus, developing specific expertise in:

- General Clinical Research
- Health Services Research & Health Policy Research
- Behavioral Research & Cognitive Tools
- Biostatistics: Quantitative and Qualitative Methods
- Epidemiology: Basic, Molecular and Clinical
- Informatics & Bioinformatics

- Outcomes Research
- Ethics
- Genomics & Personalized Medicine
- Drug Development
- Clinical Trials Research
- Translational Science

These areas of special focus build upon strengths reflective of the Icahn School of Medicine at Mount Sinai, Graduate School of Biomedical Sciences, and Mount Sinai’s Institutes and Departments.

The attainment of a PhD in Clinical Research requires

1. Successful completion of coursework
2. Satisfactory completion of Qualifying Exam as judged by the student’s respective Multidisciplinary Advisory Committee (MAC)
3. Approval of proposed thesis by MAC to allow a student to proceed with their dissertation research
4. Successful dissertation defense as deemed by the student’s MAC

MULTIDISCIPLINARY ADVISORY COMMITTEE (MAC)/DOCTORAL COMMITTEE

PhD candidates will form a Multidisciplinary Advisory Committee (MAC), which will also serve as the dissertation committee, no later than December 15\textsuperscript{th} of Year 2 but preferably before that to allow conversation about the student’s research to take place well in advance. The MAC will consist of the following 5 individuals, which does not include mentor(s):

- at least one member of the Clinical Research Education Program core faculty
- a biostatistician. If you choose a member of the core faculty as your biostatistician, you do not need another member of the core faculty in your committee. However, if that is the case, you will still need to fill that slot to make up a committee of 5 members.
- two faculty with expertise in the area of research and or discipline of the trainee
- one faculty member from a complementary discipline.

From the 5 required MAC members above, one member will be selected as the Chair of the Committee by the Program Leadership (see below for additional details)

Not more than two members of the above committee may be from a comparable academic setting, other than Mount Sinai. The majority of the dissertation committee, including the committee chair must be members of the Graduate School Faculty. Additional faculty, such as collaborators of the mentor, may be included as non-voting members on the committee. Non-voting committee members including faculty from Mount Sinai are those who have:

1. directly collaborated on the project
2. co-authored papers or abstracts with the student on any project and/or working on projects that will lead to future publications
3. been substantially involved in supervising the work or advising for the thesis work

Please note that the student’s mentor(s) cannot be present during any portion of the Thesis Proposal Oral Presentation. However, the mentor(s) must be present during the Dissertation Defense but must remain silent throughout the duration of the defense.

The Director, Co-Director or the PhD Track leader for the Clinical Research Education Program, The Director for CePORTED and the Graduate School Dean for Translational Biomedical Sciences must each approve the Committee roster and will select a senior member of the committee, to serve as the Chair of the Committee and will outline the duties of the reviewers and of the Committee. A copy of the Declaration for PhD in Clinical Research Form (see Appendix B) which includes the name of the dissertation mentor(s) and the MAC members must be provided to the Clinical Research Education Program Office by December 15th of year 2 if matriculated in 2011 or later, and by the start of year 3 for students matriculated in 2010. Students matriculated in 2009 should follow the instructions provided to them by the Clinical Research Program Office. The student will be responsible for obtaining signatures from their MAC members and the Program Office will assist the student in obtaining signatures from the program leadership (Director, Co-Director, and Graduate School Dean).

The doctoral committee has the responsibility to advise the student during the progress of the candidate’s research and has the authority to require that the research and dissertation meet a high quality standard, including the authority to require a rewrite of the thesis proposal and/or the written dissertation, in whole or in part. The student must meet with their MAC yearly and complete the Progress report form after each meeting (see Appendix B) along with the MAC. The form must be submitted to the CLR program office every year and before the defense.

The committee conducts the final oral examination and determines whether the dissertation meets the acceptable standards. It will be up to the committee as to when the student is ready to defend their dissertation. The student must submit the progress report form to the CLR program office as proof that the committee has met and decided that the student is ready to defend.

PHD QUALIFYING EXAM AND DISSERTATION

I. Program Milestones

A. Written Comprehensive Qualifying Exam and Thesis Proposal Oral Presentation: Students should confer with the Program Director or Co-Director as well as with their MAC as to their suitability and readiness for the written comprehensive qualifying exam and the Thesis Proposal Oral Presentation. For KL2 scholars, the written proposal and oral presentation can be done in parallel with the qualifying exam. For all others, 1) the qualifying exam must be done first (by the end of the student’s second year in the program and after they have completed the “Integrative Problem Solving in Clinical and Translational Research” course) 2) followed by the written thesis proposal, and 3) the oral presentation of the proposed thesis.
1. **Written Comprehensive Qualifying Examination and Submission of Thesis Prospectus:**

   **(a) Written Comprehensive Qualifying examination** - The written comprehensive qualifying examination will include pre-selected questions provided at the time of the examination. This exam will be administered twice a year at pre-selected times (January and June). Students must register for and attend the “Integrative Problem Solving in Clinical and Translational Research” course during their second year, prior to taking the exam. Students must submit a Written Comprehensive Qualifying Exam Registration form to the CLR program office at least 4 weeks prior to the scheduled exam. The CLR PhD committee will be required to sign the form indicating whether the student is ready to take the exam or not. Specific instructions regarding the exam will be emailed to students after the form is submitted and approved by the program. The examination will be assessed by the Core Faculty of the Clinical Research Education Program. The exam is worth a total of 100 points and students will have to score a total of 65 points and above in order to pass the qualifying exam. **Students will only be permitted to retake the qualifying exam once.** This policy is consistent with the Icahn School of Biomedical Sciences policy.

   **(b) Submission of Thesis Prospectus** in the format of an NIH proposal but reduced in size (6 pages in total with no more than 1.5 pages for Specific Aims, Background & Significance/Rationale). Hypothesis to be tested, null hypothesis and question to be asked need to be clearly articulated. Major emphasis should be on Methodology to be employed including Study Design and Statistical Analysis. Reasons for the approaches you chose should be articulated and potential pitfalls and alternative approaches highlighted. Preliminary Data can be included as well. Bibliography, survey &/or other validated or to be developed instruments, questionnaires, tables and figures that may be needed, will not count toward the page limit for the proposal. **This document must be submitted to the Committee at least four weeks in advance of the oral presentation.** The format of this proposal shall be as follows:

   i. **Formatting Instructions:**

      **Font:** Use Arial, Helvetica, Palatino Linotype or Georgia typeface, a black font color and font size of 11 points or larger (A Symbol font may be used to insert Greek letters of special characters; the font size requirement still applies). Type may be no more than 6 lines per inch.

      **Page Margins:** Use at least one half inch margins (top, bottom, left and right) for all pages.

      **Figures, Graphs, Tables, Charts, Figure Legends:**

      **Footnotes:** You may use a smaller type size (no smaller than 10 size font) but it must be in a black color, readily legible and follow the font typeface requirement. Color can be used in figures; however, all text must be in black font color, clear and legible.

      **Questionnaires, surveys, other validated or to be validated instruments:** The same font size as outlined for the proposal document should be employed.
2. **Thesis Proposal Oral Presentation:**

The Thesis Proposal Oral Presentation must be completed no later than six months after the successful completion of the written comprehensive qualifying examination and submission of the thesis prospectus (see 1a and 1b above). For KL2 Scholars, the Thesis Proposal Oral Presentation can be done in parallel with the written qualifying exam and written thesis prospectus. All students should submit a Thesis Proposal Oral Presentation Registration Form at least 4 weeks prior to the Thesis Proposal Oral Presentation, (see appendix B). The following suggestions are made regarding the format of the oral presentation:

The Thesis Proposal Oral Presentation will be conducted by members of the students MAC and will be led by the chair of that committee. The chair of the committee must enforce all rules of the Examination, including those pertaining to the role of the mentor. In addition, the Director or Co-Director of the Clinical Research Education Program or the PhD track leader must be present during the Thesis Proposal Oral Presentation.

The student's mentor cannot be present during any portion of the Thesis Proposal Oral Presentation. Before the Thesis Oral Presentation begins, the student will be asked to leave the room for a few minutes so the committee can discuss the student’s performance to date, the structure of the exam, the written thesis proposal and raise any specific points that would be important to discuss during the presentation. Once this review is completed, the student will be called into the room and the presentation will commence. The student should present their work using power point slides. Copies of the slides should be provided to the MAC on the day of the presentation. The student’s portion of the presentation should be approximately 30 minutes long.

The purpose of the Thesis Proposal Oral presentation is to assess the working knowledge of the student’s respective field of inquiry and the ability to demonstrate critical thinking and sufficient acumen regarding clinical research design, and analytical methods as they relate to their chosen field of inquiry. The committee should evaluate the student’s ability to:

1. evaluate and synthesize relevant literature
2. articulate and elaborate on specific aims
3. evaluate any preliminary data of relevance to the project, that might already be available
4. discuss experimental designs, qualitative &/or quantitative methods, and alternative strategies and methods for analysis, as it applies to the work planned

Once the committee is finished asking questions, the student will be asked to leave the room. At this point the committee should decide whether the proposal is accepted or not and if accepted, will it be with minor, major or no revisions and whether the Thesis Proposal Oral presentation should be re-presented. The student will only be permitted to re-present the thesis proposal once, within two months of the first attempt.

Within 24 hours of the presentation (or as soon thereafter as possible), the Chair of the student’s MAC overseeing the examination will meet with the student’s mentor to provide
a detailed summary of the student’s performance. It is critical for the mentoring process that the mentor is fully informed about this.

No extensions will be granted except under extenuating circumstances. Requests for extensions of established examination deadlines should be made at least 4 months prior to the deadline. Students who fail to meet the examinations deadlines will be placed on academic probation.

3. **Outcome of the Thesis Proposal Oral Presentation:**

Taking into account both the written thesis proposal and the Thesis Proposal Oral Presentation, all members of the MAC should sign the Thesis Proposal Oral Presentation Voting form (see appendix B) at the end of the presentation and the form must be returned by the Chair of the committee to the CLR program office immediately following the presentation. The following voting options are available to the MAC:

- Satisfactory without revisions
- Satisfactory with minor revisions (no re-presentation to the committee required)
- Satisfactory with major revisions (re-presentation to the committee required)
- Unsatisfactory

If the MAC determines that a re-presentation must occur, or that revisions must be made to the Thesis Proposal, the details, including a deadline of when the revisions are due, must be communicated to the student and the CLR program office, in writing, by the Chair of the committee within 2 days of the Presentation. If a re-presentation is required, a Thesis Proposal Oral Re-Presentation Registration form (see Appendix B) will need to be submitted to the Clinical Research Education Program Office formalizing this request. The student should then work with the Program Administrative Assistant to find a date and time within 90 days of the date the first Thesis Proposal Oral Presentation.

4. **Registration for the Written Comprehensive Qualifying Exam and the Thesis Proposal Oral Presentation**

Students must fill out the Written Comprehensive Qualifying Exam Registration Form (see appendix B) and submit the form with the appropriate signatures to the program office 4 weeks before the scheduled exam.

To schedule the Thesis Proposal Oral Presentation inclusive of thesis proposal (or re-presentation), the dissertation mentor(s) and the student should check the proposed date with the MAC members and communicate the proposed date with the CLR program office to find out which member of the CLR Program (the Director or Co-Director of the Clinical Research Education Program or the PhD track leader) will be available to attend the presentation. Once a date has been established the student will need to submit a copy of the Thesis Proposal Oral Presentation Registration form (or Re-Presentation form) (see appendix B) with the appropriate signatures to the Clinical Research Education Program Office at least 4 weeks prior to the presentation. The student is responsible for scheduling the presentation and should communicate with the Program Administrative Assistant to find a room for the presentation if needed. The
student is responsible for communicating the final date, time and location to the individuals involved in the presentation and to the program office. The student should also email their written thesis prospectus to their committee members, the member of the CLR program attending the presentation and to the Program Administrator at least 4 weeks prior to the oral presentation to give everyone enough time to review the written thesis. Failure to register and provide the appropriate information to the committee members and program office in a timely manner may result in a cancellation of the presentation. If a student does not register for a presentation that is conducted, the Clinical Research Education Program Office reserves the right to require a re-presentation or to require a notarized statement from the student and the Committee certifying the number of times the student has presented.

B. Admission to Candidacy

Admission to candidacy for the PhD degree in Clinical Research constitutes a promotion of the student to the most advanced stage of graduate study and provides formal approval to the candidate to devote essentially exclusive attention to the research and the writing of the dissertation.

To qualify for admission to candidacy, students must:

1. Be a student in good standing
2. Have completed required core coursework with a minimum of a B in each core course and have an overall grade point average (GPA) of 3.0
3. Have passed the Written Comprehensive Qualifying Exam and the Thesis Proposal Written and Oral Presentation
4. Have received approval of the proposed subject and plan of the dissertation from the dissertation committee following a prospectus meeting of the committee, to be held in conjunction with the Thesis Proposal Oral Presentation.

C. Doctoral Dissertation:

For the dissertation, the student along with their mentor must extend an invitation to an outside individual who is an acknowledged expert in the field to serve as an examiner during the dissertation defense. This person will be a voting member. Therefore, the dissertation committee will consist of the 5 MAC members chosen for the Thesis Proposal Oral Presentation, plus the additional outside examiner.

Written Document Format Options:

1. **First Option:** The first option is to submit three first authored manuscripts that have been accepted for publication in peer reviewed journals. **The three manuscripts must be thematically related to one another and to the dissertation proposal that was approved by the student’s five member dissertation committee and represent an original new body of work.** The manuscripts must be accompanied by an introductory chapter that discusses the implications of the research findings and provides a description of plans for future research.
2. **Second Option:** The second option is to submit a more traditional dissertation that includes, at a minimum, chapters describing background, methods, analyses/results and conclusions of the dissertation project.

Either option must involve a substantive piece of original and independent research grounded in an appropriate body of literature and theory. High priority – both during the process of selection of the dissertation research topic and in the evaluation of the product of the dissertation research will be placed on the extent to which the project is innovative and advances the field in which the student is working.

The written work must conform to the Mount Sinai Graduate School of Biomedical Sciences format, as outlined in the Graduate School of Biomedical Sciences handbook.

When the student has completed the written dissertation document, it must be read and approved by the Dissertation Committee. The student should submit the Dissertation to each member of the committee as early as possible, but no later than two weeks before the Defense. Committee members may reschedule the Examination if not given the appropriate amount of time to prepare for it. Before the final scheduling of the Defense, the student must meet with their committee to get approval from the committee to defend their thesis. The student must once again complete the Progress report form and obtain signatures from the entire MAC and submit the form to the program office no later than 4 weeks prior to the defense to indicate that this process has taken place and that the student has been given permission to defend their thesis. The student must complete the Dissertation Defense and Seminar Registration form along with the Report of Dissertation Defense form or Approval of Revised Dissertation form (see appendix B) and return this form to the Clinical Research Education Program Office. The student must include with the written document the statement of authorship page.

Students and the Dissertation Mentor(s) should have been made aware that revisions and even additional work/analysis may be requested by the Dissertation Committee. In either event, the Committee should decide and indicate in writing whether the whole committee needs to be reconvened to consider the new draft or whether a subcommittee (or just the Chair of the Committee) may approve the revised draft.

**Registration for the Dissertation**

To schedule the Dissertation Defense and Seminar, the dissertation advisor/mentor and the student should check the proposed date with the Committee members before submitting the appropriate Registration Form. The student will need to submit a Dissertation Defense and Seminar Registration form (see appendix B), with the appropriate signatures, to the Clinical Research Education Program Office at least 4 weeks prior to the Defense. The student is responsible for scheduling the Defense and should communicate with the Program Administrative Assistant to find a room for the exam. The student is also responsible for communicating the final date and time to the individuals involved. Failure to register in a timely manner may result in a cancellation of the Defense. If a student does not register for a Dissertation Defense that is conducted, the Clinical Research Education Program Office reserves the right to require a re-examination or to require a notarized statement from the student and the Committee certifying the number of times the student has been examined. The student is expected to bring the Report of Dissertation Defense form (see appendix B) on the day of the
Dissertation Defense. This Form needs to be signed and returned immediately following the completion of the Dissertation Defense to the Clinical Research Education Program Office. If the Committee determines that there are revisions to be made, the information will be communicated to the student in writing. The student will need to submit an Approval of Revised Dissertation form (see Appendix B) once the revisions have been made.

The Defense and Seminar:

The thesis defense is comprised of two parts, the public seminar and the closed session. Both parts must take place on the same day with the public seminar preceding the closed session. The public seminar will consist of a 45-60 minute power point presentation on the student’s work, open to the Mount Sinai scientific community, and will serve as the presentation to the MAC. Therefore, the committee chair must make sure that all members of the MAC, the outside examiner, the mentor(s) and a member of the CLR leadership be present for the public seminar since the student will not repeat the power point presentation during the closed session. The MAC and mentor(s) will be asked to remain silent during the public seminar and will reserve their questions for the private closed session. It is the student’s and dissertation mentor’s responsibility to appropriately announce the seminar to the public e.g. via email, and to the program at least 4 weeks prior to the Seminar. Once the student notifies the CLR program office of the date and location of the public seminar, the program office will communicate the information to the Graduate School in Biomedical Sciences office which will in turn send a school wide email to announce the seminar.

The closed session of the thesis defense, will take place after the public seminar. Once again, the committee chair must make sure that all members of the MAC, the outside examiner, the mentor(s) and a member of the CLR leadership be present for the defense. Only the MAC and the outside examiner are considered voting members. The Defense should take roughly 2 hours. Student’s mentors must attend the defense but must remain silent throughout the entire process. The purpose for the mentor’s presence is to allow him/her to assess first hand the student’s performance in order to subsequently assist them in addressing the observed deficiencies. If the mentor fails to remain silent, he/she may be asked by the chair of the committee to leave the room. Copies of the power point slides used during the public seminar must be provided to the MAC during the closed session. There is no limit to the number of questions the MAC might ask or how long it might take. Once the committee has finished asking their questions, the student and the mentor will be asked to leave the room so that the committee members can discuss the outcome of the defense. The student is then asked back into the room and the decision and comments are shared with the student.

The student is expected to bring the Report of Dissertation Defense form (see attached) on the day of the Dissertation Defense. This Form needs to be signed and returned immediately following the completion of the Dissertation Defense to the Clinical Research Education Program Office by the student. If the Committee determines that there are revisions to be made, the information will be communicated to the student in writing. The student will need to submit an Approval of Revised Dissertation form (see attached) once the revisions have been made.

Dissertation Deposit:

Once the student has successfully defended their dissertation, they will have a maximum of three months to deposit their written dissertation in the library. Students who
have not deposited their thesis within three months after their successful defense will be administratively withdrawn from the program. In the event that a student decides at a later date to either deposit or obtain a transcript they will need to pay a required fee.

Once a student has successfully defended the dissertation, made all of the revisions and is ready to deposit the Dissertation, she/he should deposit the dissertation electronically according to the instructions in The Graduate School of Biomedical Sciences Depositing your Doctoral Instructions document (see Appendix B). Students should submit the Student Checkout Form, the Clearance from the Real Estate Division for Deposit Form (see Appendix B), and The Graduating Student Exit Survey Form (see Appendix D) to the Clinical Research Education Program Office before depositing their dissertation. Failure to do this can result in a delay of the student’s graduation. Please refer to the section on “Graduation Application Form” and “Other Requirements Preceding Conferral of Degree” on page 41 for more information about Graduation.

The dissertation may be deposited at any time during the year, but the following deposit deadlines and enrollment requirements determine the date of the degree. No degree will be awarded unless the thesis is deposited in the library by one of the required due dates listed below.

<table>
<thead>
<tr>
<th>For the Degree to be awarded</th>
<th>You must Deposit by:</th>
<th>And be enrolled during the:</th>
</tr>
</thead>
<tbody>
<tr>
<td>September 30</td>
<td>September 15</td>
<td>Preceding Spring Semester</td>
</tr>
<tr>
<td>January 31</td>
<td>January 15</td>
<td>Preceding Fall Semester</td>
</tr>
<tr>
<td>May (MSSM Graduation)</td>
<td>April 15</td>
<td>Current Spring Semester</td>
</tr>
<tr>
<td>June 30</td>
<td>June 1</td>
<td>preceding Spring semester</td>
</tr>
</tbody>
</table>

The degree is awarded on September 30, January 31, June 30 or the date of the Icahn School of Medicine at Mount Sinai annual Commencement in May. Students depositing by January or April deadline, will receive their diploma at Commencement. Students depositing by the September deadline or the June deadline, may at the discretion of the Dean for Translational Science (or Associate Dean for clinical/Translational Research Education), participate in the prior May Commencement exercise, but will not receive their diploma until after September or June. By March 1, students must notify the Registrar of their intent to deposit their thesis on or before the April, September, or June deposit deadline in order to be included in the Commencement exercises of that year. Commencement information will be sent during the spring semester to the student’s last email address recorded with the Graduate School Office/Clinical Research Education Program. If the student fails to deposit their thesis by the end of their 5th year in the PhD program, their dissertation mentor must petition the Dean in writing for permission to extend the students status. The petition must include a timetable for completing the dissertation and must also be signed by the student.
CHAPTER 7: CLINICAL RESEARCH EDUCATION PROGRAM FORMS

All forms referred to in the Clinical Research Education Program Student Handbook can be found on Blackboard, under the CLR organization: https://learn.mssm.edu
Please be sure to use the appropriate forms for your program of study.

All other forms referred to in the Graduate School of Biomedical Sciences Handbook can be found on the ISMMS Website: http://www.mssm.edu/education/student-resources/registrar/graduate-school-forms