



Icahn  
School of  
Medicine at  
**Mount  
Sinai**

*Graduate School of  
Biomedical Sciences*



Icahn School  
of Medicine at  
**Mount  
Sinai**

*Conduits*  
The Institutes for Translational Sciences

## **CLINICAL RESEARCH EDUCATION PROGRAM (CRTP, MSCR, PH.D.)**



**CURRICULUM GUIDE  
ACADEMIC YEAR 2018-2019**

The Clinical/Translational Research Training 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 Ph.D. in Clinical Research.

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

**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.

PORTAL, a 5 Year MD/Masters in Clinical Research Program, is a strongly mentored program that offers a multidisciplinary approach to clinical investigation and how it drives the practice of medicine. From the very start of their medical education, students will be part of a select group of scholars that integrate learning about clinical medicine and developing the skills required to perform clinical investigation. Students eligible to apply to the PORTAL program are those who are applying for admission to Mount Sinai School of Medicine. In addition to meeting the requirements for admission to the M.D. program, applicants should have had some clinical research experience.

Three 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**  
**Behavioral Research & Cognitive Tools**  
**Biostatistics: Quantitative and Qualitative Methods**  
**Epidemiology: Basic, Molecular and Clinical**  
**Informatics & Bioinformatics**  
**Outcomes Research**  
**Ethics**  
**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.

The Clinical Research Education program is supported in part by Conduits, the Institutes for Translational Sciences, funded by award number UL1RR029887 from the National Center for Research Resources.

## Explanation of Course Numbering System

The following course guide includes courses that begin with the prefixes CLR, MPH, and BIO. The guide is organized according to the below areas of Research Focus.

Courses with the prefix “CLR” are those that are offered through the Clinical Research program.

Key for courses conducted by other programs:

- MPH: Masters of Public Health
- BIO: Masters of Biostatistics

### Guide to courses with the CLR prefix:

The first two numbers denote the research focus:

Research Focus	Page #
00 General Clinical Research	17
01 Health Services Research & Health Policy Research	22
02 Behavioral Research & Cognitive Tools	23
03 Biostatistics: Quantitative and Qualitative methods	25
04 Epidemiology: Basic, Molecular and Clinical	30
05 Informatics & Bioinformatics	33
06 Outcomes Research	36
07 Ethics	38
08 Genomics & Personalized Medicine	41
09 Drug Development	43
10 Clinical Trials Research	46
11 Translational Science	47

The third number denotes the level:

- 0 Introduction
- 1 Intermediate
- 2 Advance

The fourth is a number for the course itself.

## Clinical Research Courses

### **CLR0001                      Masters Thesis for Clinical Research                      5-8 credits**

Students should register for their Master's Thesis (5 credits) during the Fall Term of their second year while preparing to submit their Thesis. Students may be able to register during the Spring1/or spring 2 term for additional Master's Thesis credits (1-3) with permission of the Program Director.

Please refer to the Guide to Completing the Masters Thesis as a resource for the steps that need to be taken in fulfilling the Masters Thesis requirement.

### **CLR0002                      Independent Study in Clinical Research                      Variable credits**

An Independent Study is an elective option providing the student with an opportunity to delve more thoroughly into an area of specific interest to him/her.

Please note that an Independent Study Proposal should be submitted at least three weeks prior to the anticipated start of the proposed project/course of study. The proposal will be reviewed to ensure that the goals of the project meet the overall objectives of the Clinical Research Program. Approval of a form submitted less than three weeks prior to the anticipated start of the project/course of study will not be guaranteed. The student assumes any risk that missing appropriate deadlines may entail. Approval, when granted, is conditional upon the student completing all of the outlined requirements. The student must submit a Postscript Report and request that the faculty sponsoring the Independent Study submit an Evaluation Form.

Three credits are the maximum number of credits that may be awarded to any Independent Study. 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 courses offered routinely during the academic year. 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.
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.
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](#).
8. Review Postscript Report and Evaluation with your faculty sponsor.
9. Complete the [Independent Study Student Evaluation of Faculty Form no later than 3 weeks after the study has been completed](#).

Please note that there is a new opportunity for a 2 credit Independent Study:

Practicum in Secondary Analysis of Community and Population Data Sets: The Center for Community and Population Data Studies of CCARP announces an invitational workshop that will include a hands-on introduction to using SAS to analyze a variety of secondary data sets, and will offer faculty mentorship for the refinement of each participant's research question and data analysis. It is ideal for advanced MSCR, MPH or PhD students and for junior faculty. This workshop has been approved as an independent study for individuals enrolled in the Clinical Research Program. The competition will require submission of a brief structured abstract. While all secondary research proposals will be considered, we encourage applicants to consider proposals that will lead to projects that use data sets available through the New York Census Regional Data Center, a consortium made available to Mount Sinai through the Conduits Institute for Translational Sciences. Course leadership will include Dr. Larry Kleinman and (biostatistician) Emma Benn, MPH, DrPH Candidate. Enrollment is limited. For further information and forms email [Emma.Benn@mountsinai.org](mailto:Emma.Benn@mountsinai.org).

### **MSCR Elective offered in another Program or Institution**

A student may decide to enroll in a course offered by another Program here at Mount Sinai or elsewhere. If a student wishes to take a course for elective credit from Mount Sinai School of Medicine or Mount Sinai Graduate School of Biological Sciences, please consult the appropriate School's Course Catalogue. The Course Catalogues for the Medical School and the Graduate School of Biological Sciences are available online.

Please submit a course description and a syllabus from the Institution offering the elective course together with a completed Elective Approval Form to the Program Director of the Clinical Research Program.

**Approval must be given from the Clinical Research Program Director prior to enrolling in a course in another Program or Institution.** The student's request should be submitted on the Elective Approval Form and he/she must receive approval before the course begins.

An official transcript must be sent from the sponsoring institution upon the completion of the elective in order for it to appear on a student's transcript. Official transcripts must be sent directly from the institution to the Mount Sinai School of Medicine Registrar.

## **CLR0006                      Spectrum of Methods in Clinical Research 1**

Course Directors: Henry Sacks, MD, PhD

Term: Fall

3 credits

Methods in Clinical & Population Based Research: Part I covers fundamental concepts of relevance to the formulation of meaningful questions in clinical investigation and provides an overview of non-experimental, quasi-experimental and experimental study designs utilized in the conduct of clinical investigation.

The course is divided into 4 sections:

- 1) The Research Question & Stating the Hypothesis;
- 2) Finding the evidence & discerning the burden of disease;
- 3) Measurement Science & Sampling; and
- 4) Study Design

This course meets twice a week. The course consists of didactic and laboratory sessions and will utilize standard text materials, prepared case materials and journal articles highlighting key concepts. There will be assigned reading, homework and in class activities. The course will culminate in a final exam.

## **CLR0007                      Spectrum of Methods in Clinical Research 3**

Course Directors: Alan J. Moskowitz, MD and Inga Peter, PhD

Term: Spring 2

3 credits

The focus of the course is to introduce the state of the art methods and approaches used in genetic and genomic research and discuss how they are applied in clinical research and patient care. The topics discussed in the course include study design for genetic and genomic studies, genetics of complex diseases and traits, gene-environment interactions, including drug responses, genetic risk modification, epigenetics, microbiome, population genetics, and ethical issues. Also covered are the bioinformatics databases and tools that are essential for conducting omics investigations and the resources for personalized medicine research. Review of the Biobank and the de-identified database with study subject information will be provided to the students to demonstrate the use of this unique resource for conducting novel clinical investigations.

Pre-requisite: CLR0006 Spectrum of Methods in Clinical Research 1 or with Permission of the Program Director

## **CLR0011                      Grant Writing**

Course Director: Judy Swan, PhD

Term: Spring 2

1 credit

This course will familiarize students with the basic elements and approach to writing grants. Students will select a research topic, develop a research plan, and write a grant application in the appropriate format of the PHS 398 form for submission to a funding agency. Each grant section will be presented to the class by the students for critique and discussion. Student evaluation is based on class presentations and the final grant application, which can serve as the student's thesis proposal. Grant applications for both investigator-initiated research projects (e.g., NIH R01, R03, R21) and mentored career-development awards (e.g., K12, K23) will be covered.

Features of successful research grant applications will be presented and a description of the grant review process will be covered. The course also will cover the development of writing skills for publication and competitive grants, and explore principles of research strategy in the context of requirements of funding agencies. Effective scientific communication and writing skills are reviewed, institutional routing, and discussion of the NIH grant review process will be covered. Among the assignments are:

- Queries of the CRISP database
- Hypothesis and specific aim development
- Critique of extent literature
- Presentation of pilot data
- Integration of research methodology with solutions for potential methodological problems
- Construction of a grant budget and other critical documents, including a data safety and monitoring plan, human subject protection and informed consent, letters of support and other appendix materials

Each student prepares a grant proposal for extramural funding, which is critiqued by the course's "study section", comprised of members of the CRCA/MSCR Executive Committee and faculty.

### **CLR0012, CLR0014 Integrative Problem Solving in Clinical and Translational Research**

Course Director: Emilia Bagiella, PhD and Inga Peter, PhD

Term: Fall, Spring 1, Spring 2

2 credits

This course is focused on enhancing the trainee's critical thinking and analytical acumen in clinical translational research. The problem sets utilized in this class reflect an integration of Biostatistical, computational and study design methodology related to the foundational coursework completed for the PhD in Clinical and Translation Research.

The course is a year long course taking place in the Fall, Spring 1 and Spring 2 (registration will be in the fall and spring 1). Grades for the course will be assigned at the end of Spring 2

### **CLR0016 Spectrum of Methods in Clinical Research 2**

Course Directors: Janice Gabrilove, MD

Term: Spring 1

3 credits

This course builds upon the preceding course CLR0006 in a curriculum mapped fashion and explores the domain of interventional studies including quasi experimental and experimental designs, from first in man approaches, including Phase 0, proof of concept studies, Phase Ia and Phase Ib; Phase IIa and Phase IIb; Phase III, both superiority trials and Non Inferiority studies and Phase IV studies, including comparative effectiveness research, pragmatic trials and principles of pharmacovigilance. Principles of relevance to the design and conduct of small clinical trials including N-of-1, N-of-1 RCT, repeated measures, cross over designs are reviewed. Randomization methods, CONSORT < TREND < STROBE and SPIRIT guidelines & historical controlled trials are also reviewed. Specific issues of relevance to reproducible research in the context of interventional trials is discussed including types of missing data and methods to handle missing data as well as the utility of negative controls. The course format consists of didactic lectures, case based discussions and team based problems.



Pre-requisite: CLR0006 Spectrum of Methods in Clinical Research 1 or with Permission of the Program Director

**CLR0017 Clinical & Translational Research Journal Club & Seminar-Fall**  
**CLR0018 Clinical & Translational Research Journal Club & Seminar-Spring I**  
**CLR0019 Clinical & Translational Research Journal Club & Seminar-Spring II**

Course Directors: Russell McBride, PhD and Keith Sigel, MD

Term: Fall, Spring 1 & Spring 2

1 credit per term for a total of 3 credits

This class combines CLR0010-Clinical Research Journal Club & CLR0013-Clinical Research Seminar Series.

This class will meet weekly and will consist of a Journal Club alternating with a Seminar Series/Works in Progress.

The Journal Club will provide a forum for the development of critical thinking and fosters real time utilization of recently learned analytical tools and methodology. A structured format focused on dissecting and discerning the specific research question and hypothesis posed; the appropriateness of the experimental design and the nature of the statistical methods employed in a given article, is employed so as to facilitate the emergence of astute and critical readers of the scientific literature & to reinforce relevant issues being discussed in other didactic courses

The Seminar Series/Works in Progress classes, which meet on the alternate week, will include presentations by trainees & faculty, covering ongoing clinical research projects to facilitate constructive debate and discussion of specific research approaches and conceptual models under development. In addition, this forum will be used to cover specific additional topics of importance to clinical research, including: human subjects' research compliance; scientific presentation skills; mentor: mentee relationships; team science; & time management.

**CLR0020 Doctoral Thesis in Clinical Research** Variable credits  
Student should register for Doctoral Thesis credits according to their track course sequence.

**CLR0207 Culture, Illness & Community Health**

Course Directors: Gary Butts, MD, Edward Poliandro, PhD and Ann-Gel S. Palermo, MPH

Term: Spring 2

3 credits

This course considers Franz Boas' definition of culture as *culture is everything but natural science.*<sup>[1]</sup> Any interaction or encounter with another individual or group of individuals is in fact a cultural experience which occurs within a cultural context. Broadly, this course aims to demonstrate how culture is conceptualized, considered, and explored in a broad range of issues in the basic, clinical, and community arenas around health and illness and to distinguish the cultural context in each session. The course utilizes class room lecture and small group discussion sessions and a small group project to enable participants to integrate culturally effective approaches into the design and implementation of research across the translational spectrum that improve patient and community health outcomes and reduce health care disparities.

### Course Objectives:

At the end of this course the student should be able to:

- Demonstrate an understanding of one's own cultural context and its impact on patients, communities and on health care outcomes
- Analyze evidence of health care disparities from available resources
- Integrate culturally effective approaches into the design and implementation of research across the translational spectrum that improve patient and community health and reduce health care disparities

### **CLR0320                      Applied Biostatistics in Clinical Trials**

Course Director: Emilia Bagiella, PhD

Term: Spring 1

3 credits

This course will present the fundamental methods for the design and implementation of analysis for clinical trials. The course will emphasize randomized comparative studies, including protocol preparation, randomization, intention-to-treat, sample size, interim monitoring, adaptive designs, endpoints and reporting. The relationship between protocol design and analytic plan will be highlighted. The course has two broad aims: (1) to develop the skills necessary to be a more critical reader of medical literature and (2) to provide the basic statistical tools to aid in the design of clinical trial protocols.

### **CLR0421                      Molecular Epidemiology**

Course Director: Susan Teitelbaum, PhD

Term: Spring 2

3 credits

As in interdisciplinary science, molecular epidemiology integrates the use of biomarkers as measures of exposure, effect, and/or susceptibility with traditional epidemiologic methods in the study of disease etiology and progression. This course will cover the use of biomarkers in epidemiologic studies including issues associated with study design and data analysis as well as technical and ethical issues. Examples of studies that utilize molecular epidemiologic techniques to investigate various health outcomes will be presented. To gain an appreciation for the issues associated with the design and analysis of a molecular epidemiologic study, students will critically evaluate key papers, propose potential studies using biomarkers of exposure and/or disease from publicly available databases and carry out data analysis and interpretation of the results of their proposed studies.

Prerequisites:            MPH0420 Epidemiology III  
                                 MPH0802 Introduction to SAS Systems  
                                 MPH0311 Multivariable Methods (or equivalent)

## **CLR0501                      Computational Tools for Clinical Research**

Course Director: Alan Weinberg, MS

Term: Spring 2

3 credits

The overall objective of this course is to provide the researcher with a working knowledge of essential tools for the acquisition, management and analysis of data. The data acquisition section of the course reviews the various methods for collecting primary data in the setting of clinical trials and registries. The course will review direct collection of data from electronic health records and primary data entry via electronic data capture systems, both local and web-based. It will cover principles of case report form design, compliance with good clinical practice standards and with 21CFR part 11. It will review specialized software for managing multicenter studies, which address a variety of functions, including trial registration, randomization, tracking, site communication and performance measures.

The data management portion of the course will review fundamental concepts of a database. It will review both pc-based and server-based data base management systems (DBMS), with a focus on Microsoft Access, a commonly used, pc-based, relational DBMS. The course will review relational database design, forms-based database queries, and standard query language (SQL). It will also cover issues related to connecting databases to the outside world, including database security.

The data analysis section of this course provides an introduction to the SAS language with practical examples. It covers writing SAS code, manipulating data files, and using SAS functions and procedures. It builds on prior statistical coursework, covering descriptive statistics, hypothesis testing, chi-square testing, linear regression and correlation, analysis of variance, logistic regression and survival analysis using SAS.

Pre-requisite:                      MPH0300 Introduction to Biostatistics

## **CLR0610                      Meta-analysis, Decision Analysis and Cost-effectiveness Analysis**

Course Director: Henry Sacks, MD, PhD, Bart Ferket, MD, PhD

Term: Spring 2

3 credits

The goals of this course are to provide students with a theoretical understanding and hands on experience in literature synthesis methods. Areas to be covered include meta-analysis, decision analysis, and cost-effectiveness analysis. The course will provide a review of each method within an interactive computing environment. Students will be given opportunities to learn how to develop an appropriate question and to use RevMan and TreeAge software for assignments on each topic.

Learning objectives include:

- Describe uses of meta-analyses/systematic reviews  
  Learn how to do meta-analyses/systematic reviews
- Describe uses of decision analysis  
  Learn how to do decision analysis
- Describe uses of cost-effectiveness analysis  
  Learn how to do cost-effectiveness analysis

Pre-requisite:                      CLR0006 Spectrum of Methods in Clinical Research 1 or  
   MPH0400 Introduction to Epidemiology

**CLR0700****Professionalism and Ethical Issues in Clinical Research**

Course Director: Rosamond Rhodes, PhD

Term: Spring 2

2 credits

This seminar will explore the complex issues raised by human subject research. The seminar will begin with a review of some of the landmark cases of unethical use of human subjects in research; the policies that shape our current understanding of the ethical conduct of research, and the mechanisms for research oversight that have been instituted. Then, through reading a broad selection of seminal articles and papers from the recent literature, seminar presentations, and discussion, we shall engage in a conceptual analysis of a number of controversial and pressing issues.

We shall be discussing the moral and public policy aspects of topics such as research design, risk-benefit assessment, informed consent, the use of “vulnerable” subjects, research without consent, confidentiality, inducements, conflicts of interests, disclosure of research findings, tissue use, vaccine development, and international research. In addition to exploring the moral landscape of this rich and provocative domain, the seminar should clarify and inform participants’ understanding of basic moral concepts such as autonomy and justice. It should also serve as a model for approaching other issues in applied ethics.

**CLR0810****Genetic Epidemiology**

Course Director: Inga Peter, PhD, Ruth Loos PhD

Term: Spring 1

3 credits

This course is designed to introduce students to the theory and practice of genetic epidemiology. The goal of genetic epidemiology is to identify genetic mechanisms and gene-environment interactions involved in the etiology of complex diseases and related traits. An in-depth discussion of designs and methodologies involved in conducting population-based genetic epidemiologic studies will be offered. An overview and practical of the currently available software for genetic epidemiologic analyses will be given. The lecture material will be supplemented with discussions of published studies and computer labs using real and simulated data. Students will be exposed to tools needed to critically review literature in genetic epidemiology & human genetics.

Prerequisites:

MPH0400 Epidemiology I

MPH0300 Intro to Biostatistics or

MPH0800 Intro to Advanced Biostatistics

MPH0812 Applied Linear Models I or

MPH0822 Applied Linear Models II

Suggested course but not required: MPH0802 Introduction to SAS systems

## **CLR1010                      Clinical Trials Management**

Course Director: Janice Gabrilove, MD

Term: Fall

1 credit

In this course students will learn the essentials of coordinating and managing the day-to-day operations of a clinical research study, from the planning site logistics and constructing timelines for study initiation visit to closing out a study. Students will learn how to estimate staff requirements, prepare realistic budgets and timelines and review source documents (Case Report Forms (CRFs), protocols and study budgets). Students will also learn the role and responsibilities of each member of a clinical research group, process of recruitment, informed consent, confidentiality and communication with patients, regulatory authorities and collaborating investigators. Students will also learn the basics of data management and regulatory compliance, including measurement of patient baselines; preparation, logging and tracking CRFs; cross checking documentation for accuracy, source documentation; preparing for an audit and responding to data queries.

## **CLR1111                      Basics: Theoretical fundamentals of translational oncology**

Course Director: Doris Germain, PhD, Guy Montgomery, PhD

Term: Fall

3 credits

The purpose of this module is to provide students with scientific, conceptual, methodological and practical knowledge about translational medicine. This course will cover aspects related to study design, development and implementation. Special emphasis will be dedicated to areas related to biomarker discover and validation.

Learning Objectives:

- To define the basic principles of translational research and how to apply them in oncology.
- To understand the main disease models able to recapitulate human cancer.
- To describe the regulatory process for conducting research using human samples.
- To apply translational research principles in clinical trial design utilizing case based studies

## **CLR1112                      Advanced Technologies and Tools in Translational Research**

Course Director: Augusto Villanueva, MD, PhD, Robert Sebra, PhD

Term: Fall

2 credits

The objective of this course is to provide the student with an overview of the mainstream genomic technologies currently used in translational research studies, with a particular focus on sequencing based approaches. This is not a statistics course, so we will not dedicate much energy to discuss advanced mathematical concepts.

### **CLR1113                      Application of Translational Research in Oncology**

Course Director: Josep Llovet, MD, PhD, William Oh, MD, Adriana Malone, MD

Term: Spring 1

3 credits

The course will summarize the main mechanisms involved in cancer development, maintenance and regression, and how they can be exploited therapeutically in oncology. Mainstream molecular alterations in solid tumors and precision medicine will be discussed. A specific emphasis will be dedicated to the role of the tumor microenvironment (e.g., immune system) in cancer monitoring and therapeutics.

### **CLR1114                      Drug Development: From Discovery to Commercialization**

(formerly CLR901)

Course Director: Scott Friedman, MD

Term: Spring 1

2 credits

This course will provide a comprehensive overview of the regulatory, methodological and scientific pathways for drug development within the field of oncology. The cycle of drug development will be discussed and cover stages from drug discovery, screening, regulatory considerations and compliance, manufacturing and drug delivery, to clinical deployment. Woven into these themes are aspects related to intellectual property and commercialization. Aside from the scientific and practical aspects of the cycle, a wider perspective on drug discovery is also illuminated. Experts in the fields of economics will share their findings on the fiscal impact of new medicines, and specialists in ethics will discuss the compassionate use of investigational new drugs.

Learning objectives include:

- To delineate the regulatory steps in drug development.
- To understand how translational research principles can be applied to speed up the implementation of diagnostic and therapeutic interventions
- To discuss the future trends in drug development and novel approaches for anti-cancer target discovery

### **CLRTBD                      Tools in Qualitative and Mixed-methods Research in Clinical and Translational Science**

Course Director: Ksenia Gorbenko, PhD

Term: Spring 1

3 credits

Clinical and translational researchers frequently face a number of challenges in their work when traditional statistical approaches are used exclusively to plan clinical studies. These include low clinical trial participation, failed interventions due to low engagement of stakeholders or misunderstanding of causal mechanisms affecting outcomes, low engagement of trainees due to lack of understanding of their experience. This course will provide tools to address these and other challenges. This is an applied introductory course in qualitative, community-based, and mixed-methods research intended for graduate students and researchers in clinical and translational science with minimal or no experience in qualitative methodologies. Students will examine assumptions behind the quantitative and qualitative research approaches, learn to identify research questions appropriate for qualitative research. Students will be introduced to common types of qualitative (ethnography, interviews, and focus groups), community-based

participatory research (CBPR, e.g. Photovoice), and mixed-methods research. This course combines lectures and class discussions with hands-on exercises to help students design a research project, collect and analyze qualitative data, present findings, and prepare a manuscript for publication.

## **Biostatistics Courses**

### **MPH0300 Introduction to Biostatistics**

Course Director: Chris Gennings, PhD

Term: Fall

3 credits

Students will learn how to conduct descriptive and univariate analyses of data from a well-designed public health or medical study and how to interpret the results of the analyses. Students will learn how to present numerical summary measures derived from large data sets as well as appropriate use of graphical displays. Basic concepts of probability theory will be covered, along with notions of conditional probability, illustrated with measures for assessing efficacy of diagnostic and screening tests. Important probability distributions, such as the Normal and binomial, will be discussed, and students will be able to solve problems involving probabilities calculated from these distributions.

Students will learn how to perform the three basic types of statistical inference: point estimation, hypothesis testing, and confidence intervals. In particular, students will learn how to apply the t-test to compare two means, and how to apply the analysis of variance (ANOVA) to compare three or more means. Non-parametric tests will be illustrated as alternatives to t-tests or ANOVA when the assumption of Normality is in doubt. Students will learn how to use chi square methods to analyze categorical data. Students will also learn how to recognize censored data arising from historical or concurrent prospective studies, how to apply techniques of survival analysis to generate Kaplan-Meier curves, and how to use the log-rank test to test for differences between curves. Simple linear regression and correlation will be discussed as methods for examining the relationship between two continuous variables, along with ways to evaluate the appropriateness of the regression model that has been fit to the data. Logistic regression models will be introduced as a method for the analysis of data from case-control studies, with emphasis on the estimation of an adjusted Odds Ratio.

In the outside project, students will have the opportunity to assess the appropriateness of use of statistical methods in the published literature.

### **MPH0400 Introduction to Epidemiology**

Course Director: Stephanie H. Factor, MD, MPH

Term: Fall

3 credits

This introductory course focuses on the fundamental concepts of epidemiology and its application to the field of public health. The course will provide students with an insight to epidemiologic methods and how they can be used to study health outcomes in human populations. Students will learn the elements of epidemiology, such as causation, study design, measures of effect, and potential biases. Practical and theoretical training will include lectures, small group discussions, and readings.

## **MPH0412                      Epidemiology II**

Course Directors: Stephanie Factor, MD

Term: Fall

3 credits

Epidemiology is the study of the occurrence and distribution of health-related events, states, and processes in specified populations. This includes the study of the determinants influencing such processes and the application of this knowledge to control relevant health problems. This course will provide students with a strong foundation in the core epidemiologic concepts that guide the design and analysis of modern epidemiologic studies including counterfactuals, confounding, effect measure modification, measurement error and bias. Students will learn how these concepts relate to practical considerations within various epidemiologic study designs, including their potential impact on study outcomes. In parallel with lectures and assigned readings, lab sessions will guide students through practical demonstrations and applications of these concepts including the construction of causal diagrams and the use of SAS software for epidemiologic design and analysis.

Prerequisites:                      MPH0400 Introduction to Epidemiology  
   MPH0300 Introduction to Biostatistics or  
   MPH0800 Introduction to Advanced Biostatistics;  
   SAS proficiency

## **MPH0420                      Epidemiology III**

Course Director: Jeanette Stingone, PhD, MPH

Term: Spring 2

3 credits

Building upon the foundations of epidemiologic methods and design introduced in previous courses, Epidemiology III will cover the theoretical and practical considerations of analysis and interpretation of data generated from epidemiologic studies. Through lectures and guided analysis of epidemiologic datasets, students will learn the analytic approaches and modelling techniques used to investigate exposure-disease relationships within various epidemiologic study designs. This course will also include more advanced topics such as mediation analysis and the use of sensitivity analyses to quantify the impact of potential biases. As part of this course, students will perform an independent analysis of epidemiologic data to demonstrate mastery of the presented content. Students can use any statistical software they prefer for assignments, but all course examples, sample code and programming support will be provided using SAS only.

Pre-requisite:                      MPH0412 Epidemiology II

## **MPH0621                      Seminar in Applied Clinical Epidemiology and Health Services Research**

Course Director: Jeffrey Weiss, PhD and Jenny J Lin, MD

Term: Full Year Course

3 credits

This seminar focuses on current methodological, analytical and logistical issues in clinical epidemiology and health services research. The course helps participants develop, refine, implement, and evaluate a quantitative clinical epidemiology or health services research study. Attendees also learn to critically evaluate the methodological strengths and weaknesses of key clinical research designs including: retrospective and prospective cohort studies, patient and



physician survey research, secondary dataset analysis, and interventional studies. All seminar members must present a research proposal during the one year period, as well as participate actively in critique and feedback to other presenters. The course is primarily intended for clinician trainees in the MPH outcomes research track or Masters of Science in Clinical Research (MSCR) program but welcomes all students interested in outcomes research analysis.

Pre-requisites:           MPH0300 Introduction to Biostatistics or  
                                  MPH0800 Introduction to Advanced Biostatistics  
                                  MPH0400 Introduction to Epidemiology

This class meets on alternate weeks.

## **MPH0624                   Outcomes Research Methods**

Course Directors: Juan Wisnivesky, MD and Henry Sacks, MD, PhD

Term: Spring 1

3 credits

The goals of this course are to provide students with a theoretical understanding and hands on experience in advanced epidemiology and outcomes research methods. The course will provide a review of each method within an interactive computing environment. Assignments requiring computer analysis of clinical data will be provided. Areas to be covered include meta-analysis, decision analysis, cost-effectiveness analysis, propensity score analysis, instrumental variable analysis, clinical prediction rules, and analysis of repeated measurements.

Pre-requisites:           MPH0300 Introduction to Biostatistics or  
                                  MPH0800 Introduction to Advanced Biostatistics  
                                  MPH0311 Multivariable Methods

## **MPH0800                   Introduction to Advanced Biostatistics**

Course Director: Alan Weinberg, MS

Term: Fall

3 credits

This course provides a thorough introduction to the fundamentals of biostatistics--numerical and graphical summaries of data, hypothesis testing, and estimation. The emphasis is on concepts and problem solving and not on the underlying mathematical theory. Specific topics include general principles of study design, sampling distributions, testing equality of population means (e.g., t-tests), simple categorical data analysis (e.g. chi-square tests), analysis of variance, correlation, simple linear regression, and an introduction to multiple linear regressions. This course is intended for students in the biostatistics or epidemiology tracks of the MPH Program, the PhD students in the Clinical Research Program, and highly recommended for other PhD students in programs with rigorous, quantitative expectations.

Prerequisite:           Placement exam. Please contact Program Office for further details.

## **MPH 0802                   Statistical Computing with SAS**

Course Director: John Doucette, PhD

Term: Spring 1 & 2

2 credits

This course provides students with the skills needed to utilize SAS systems for data management in order to prepare datasets for statistical analysis. In addition, procedures that are used to conduct basic statistical analyses and produce graphical output will be covered. Students will be given hands on-training using sample data provided by the instructor as well as (optionally) data from their own work. The lectures will take place in the Levy Library where SAS is available to the students during course instruction.

Pre-requisites: MPH0300 Introduction to Biostatistics or  
MPH0800 Introduction to Advanced Biostatistics

## **MPH0812 Applied Linear Models 1**

Course Directors: Ghalib Bello, PhD

Term: Spring 1

3 credits

Regression analysis is a widely used set of methods for exploring the relationships between response variables and one or more explanatory variables. This course provides an introduction to regression methods for a single continuous response variable. Both linear and curvilinear regression models are considered. A brief introduction to regression of a single binary response will also be considered. The emphasis is on concepts and application rather than on underlying theory. As mathematical results are presented without proof, students are not required to be proficient in calculus or matrix algebra.

Pre-requisites: MPH0300 Introduction to Biostatistics or  
MPH0800 Introduction to Advanced Biostatistics

## **MPH0822 Applied Linear Models 2**

Course Director: TBD

Term: Spring 2

3 credits

This course provides a comprehensive overview of regression methods for analysis of categorical (binary and count) data and survival data, with applications to epidemiological and clinical studies. Topics discussed include logistic regression analysis, log linear model for contingency tables, Poisson regression, Kaplan-Meier survival curves, and Cox (proportional hazard) regression analysis. The emphasis is on concepts and application rather than on underlying theory. As mathematical results are presented without proof, students are not required to be proficient in calculus or matrix algebra.

Pre-requisite: MPH0812 Applied Linear Models I

## **BIO6400 Biostatistics for Biomedical Research**

Course Director: Emilia Bagiella, PhD , Emma Benn, DrPH, MPH

Term: Fall

3 credits

This course covers the basic tools for the collection, analysis, and presentation of data in all areas of basics, clinical and translational research. Central to these skills is assessing the impact of chance and variability on the interpretation of research findings and subsequent implications on

the understanding of disease mechanisms, drug discovery and development, and applications to clinical practice. Topics covered include: general principles of study design including internal and external validity; probability and sampling distributions, theory of confidence intervals and hypothesis testing; review of methods for comparison of discrete and continuous data including one-sample and two-sample tests, correlation analysis, linear regression, sample size and power. Additionally, students will learn to apply their statistical knowledge to complex real-world challenges, while gaining introductory statistical computing proficiency in R and SAS.

**BIO6500                      Probability and Inference 1**

Course Director: John Spivack, PhD

Term: Fall

3 credits

This course covers basic material in Probability Theory, which is necessary for all work in Biostatistics, especially as a foundation for Statistical Inference. We will introduce the basic terminology and concepts of probability theory, including sample and outcome spaces, random variables, discrete distributions and probability density functions.

**BIO8500                      Probability and Inference 2**

Course Director: John Spivack, PhD

Term: Spring 1

3 credits

Introduction to the theory of statistics focusing on the basic concepts and approaches to estimation and hypothesis. Specific topics include a study of common probability distributions, definitions of moments, the law of large numbers and central limit theorem, maximum likelihood, likelihood ratio tests, and decision theory. Knowledge of calculus (integration and differentiation) is required; however, an introduction and review will be provided.

Pre-requisites:            BIO6500 Probability & Inference I, or permission of the Course Director.

**BIO9200                      Analysis of longitudinal data**

Course Directors: Mayte Suarez-Farina, PhD

Term: Spring 2

3 credits

The aim of this course is to provide a systematic training in both the theoretical foundations and the model building strategies of linear regression models for MS/MPH and PhD students who have already had some data analysis experience. The course presents modern approaches to the analysis of longitudinal data. Topics include linear mixed effects models, generalized linear models for correlated data (including generalized estimating equations), computational issues and methods for fitting models, and dropout or other missing data. Students should take this class at the end of tier second year.

Pre-requisites:            MPH0800 Introduction to Advanced Biostatistics

## **Additional Resources**

For further information on the Clinical Research Education Program please visit the website by clicking [here](#). You may also enter the following link into your browser.

<http://icahn.mssm.edu/education/masters/clinical-research/education>

For general information about the Mount Sinai Medical Center and Icahn School of Medicine at Mount Sinai, please enter the following link into your browser.

(For MSMC) <http://www.mountsinai.org/>

(For MSSM) <http://icahn.mssm.edu/>

To contact the program directly, please reach out to:

### **Program Leadership**

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### **Administrative Staff**

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Christine Acevedo  
Administrative Assistant  
212-824-7014  
Email: [christine.acevedo@mssm.edu](mailto:christine.acevedo@mssm.edu)

## **Additional Resources (continued)**

### *Admissions Office*

212-241-6696 or [admissions@mssm.edu](mailto:admissions@mssm.edu)

### *Registrar Office*

Nelson Pe  
Luke Phillips  
212-241-6691 or [registrar@mssm.edu](mailto:registrar@mssm.edu)

### *Financial Aid*

For information on financial aid at Icahn School of Medicine at Mount Sinai, and our financial aid process, please contact:

Dale Fuller  
Office of Student Financial Aid  
Tel: (212) 241-5245  
E-mail: [dale.fuller@mssm.edu](mailto:dale.fuller@mssm.edu)

### *Library Services*

#### Levy Library

The Levy Library supports the education, research, and clinical information needs of the Mount Sinai Medical Center. The library provides an extensive collection of biomedical databases, e-journals, e-books, and print resources. The recently renovated library, located on Annenberg 11, is an inviting environment designed to facilitate research, study, and collaboration.

The 33,000 square foot Gustave L. and Janet W. Levy Library provides quiet study areas as well as space for collaboration and teaching. It offers a large collection of books and journals (primarily in electronic format) and important reference and database information resources. The library licenses productivity software for faculty and student use including statistical packages, analysis software, Adobe and Microsoft products and security software. Personal computers in the library allow for on-site accessing of the collection, and are also available to teach users how to navigate electronic resources and software.

<http://icahn.mssm.edu/about/ait/levy-library>

#### Library Cards

Incoming students will be registered to use the library upon presentation of their ID card at the Circulation Desk. A barcode will be affixed to the ID card that must be presented to check out all materials and use of the Media Resource Center computers.

A schedule of fines for overdue material is posted at the Circulation Desk.

## Reference and Database Systems

Reference librarians provide instruction in the use of the library and its resources, including print and computer-based materials, audiovisuals, and bibliographic and full-text databases, journals, and books. The curriculum includes library science and medical informatics components and there are computers in the reference area of the library for database searching, Internet access, and use of full-text information sources on the library network.

Librarians also provide guidance in information search strategy and assist in location and verification of bibliographic and factual data. Reference services are provided at the Reference Desk and by telephone (ext 47793).

## Media Resource Center

A Media Resource Center (MRC), located on the 10th floor of the Annenberg Building, contains resources to assist in learning. Audiovisual programs and related hardware which supplement the curriculum are also available in the Associated Alumni Audiovisual Center of the MRC. Included are slides, video and audiocassettes, videodiscs, and x-rays. Thirty-five computers are networked to a school-wide network that supports educational programs. Media Resource Center staff work with faculty on developing course materials that are available through <http://webed.mssm.edu>. In addition to required course materials, there are reviews, tutorials, and patient simulations in basic and clinical sciences available in the MRC. Computer software is available which supports word processing, file management, electronic spreadsheet, statistical analysis, and other functions. Printers are available to print results.

Additional computers are located in a classroom where numerous educational programs are offered, including basics of microcomputers, how to access informational data bases such as the National Library of Medicine's MEDLINE file, Internet resources, e-mail, and use of various software packages. Instruction is provided both to groups and individuals. Another 36 computers are available for student use in the multidisciplinary laboratories on the 12th and 13th floors of the Annenberg Building. Computers are also located in the Levinson Student Center in the Annenberg lobby.

## Electronic Mail and Archives

Every student will be assigned an MSSM e-mail. The principal manner of communication between students, faculty, and administration is e-mail. Every student should check his/her e-mail daily. Mail can be accessed from computers in the library, the laboratories or from home. Accounts are created by the Levy Library Support Desk. E-mail class lists are created by library staff for use by class members and faculty. The Library's Support Desk staff provides support to students living in Aron Hall as they connect to the School's network. On the back of the agreement for e-mail service is the code of conduct for using e-mail. All students must be aware of and abide by these policies.

<http://www.mssm.edu/about-us/services-and-resources/computer-services/policies/email-usage>

Documentation, including paper records, oral histories, video recordings, photographs, artifacts and memorabilia relating to The Mount Sinai Hospital, Mount Sinai School of Medicine, and The Mount Sinai Medical Center are available in the Archives. Among the earliest records are the original minutes of the Hospital Board dating from 1852. The Archives is open by appointment (ext 47239).

## Index to Courses

Course Number	Title	Page #
<b>Offered through the Clinical Research Education Program:</b>		
CLR0001	Masters Thesis for Clinical Research	5
CLR0002	Independent Study Clinical Research	5
CLR0006	Spectrum of Methods in Clinical Research 1	7
CLR0007	Spectrum of Methods in Clinical Research 3	7
CLR0011	Grant Writing	7
CLR0012 CLR0014	Integrative Problem Solving in Clinical and Translational Research	8
CLR0016	Spectrum of Methods in Clinical Research 2	8
CLR0017	Clinical & Translational Research Journal Club & Seminar - Fall	9
CLR0018	Clinical & Translational Research Journal Club & Seminar – Winter	9
CLR0019	Clinical & Translational Research Journal Club & Seminar - Spring	9
CLR0020	Doctoral Thesis for Clinical Research	9
CLR0207	Culture, Illness & Community Health	9
CLR0320	Applied Biostatistics in Clinical Trials	10
CLR0421	Molecular Epidemiology	10
CLR0501	Computational Tools for Clinical Research	11
CLR0610	Meta-analysis, Decision Analysis and Cost-effectiveness Analysis	11
CLR0700	Professionalism and Ethical Issues in Clinical Research	12
CLR0810	Genetic Epidemiology	12
CLR1010	Clinical Trials Management	13
CLR1111	Basics: Theoretical Fundamentals of Translational Oncology	13
CLR1112	Advanced Technologies and Tools in Translational Research	13
CLR1113	Application of Translational Research in Oncology	14
CLR1114	Drug Development: From Discovery to Commercialization	14
CLRTBD	Tools in Qualitative and Mixed-methods Research in Clinical and Translational Science	14
<b>Offered through the Masters in Public Health Program:</b>		
MPH0300	Introduction to Biostatistics	15
MPH0400	Introduction to Epidemiology	15
MPH0412	Epidemiology II	16
MPH0420	Epidemiology III	16
MPH0621	Seminar in Applied Clinical Epidemiology and Health Services Research	16
MPH0624	Outcomes Research Methods	17
MPH0800	Introduction to Advanced Biostatistics	17
MPH0802	Statistical Computing with SAS	17
MPH0812	Applied Linear Models 1	18
MPH0822	Applied Linear Models 2	18
<b>Offered through the Masters of Biostatistics Program:</b>		
BIO6400	Biostatistics for Biomedical Research	18
BIO6500	Probability and Inference I	19
BIO8500	Probability and Inference II	19
BIO9200	Analysis of Longitudinal Data	19

