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 2015-2016

Welcome!

We are delighted that you either have joined one of our outstanding clinical and translational research education programs or are considering doing so.

We have designed these programs specifically to cultivate career development in clinical and translational research for outstanding health professionals. These programs provide opportunities to obtain a:

     1) Clinical Research Training Program (CRTP) Certificate;
     2) Masters of Science in Clinical Research (MSCR); or
     3) Ph.D. in Clinical Research.

The coursework for the Masters and Ph.D. programs are designed to complement a significant mentored research experience, while the Certificate program offers a more flexible introduction to clinical/translational research.

We are convinced that these training opportunities will stimulate outstanding candidates to become leaders in translational science, in fields as diverse as the development or testing of novel therapeutic and interventional strategies and innovative health services research involving communities and populations.

This Curriculum Guide provides a description of the courses that we offer in this program, including both requirements and electives. In addition to the electives found here, the Mount Sinai Graduate School provides many alternative electives, depending upon your interests and career goals. We hope you find this Guide informative. Good luck! We look forward to working with you.

Sincerely,

Janice Gabrilove, M.D.
Director
Masters of Science and Ph.D. in Clinical Research
Co-Director, PORTAL

Alan J. Moskowitz, M.D., FACP
Co-Director, Masters of Science and Ph.D. in Clinical Research
Co-Director, PORTAL

Karen Zier, Ph.D.
Director, PORTAL

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
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.

Course Sequence: Clinical Research Training Program (CRTP)

Term	Course Number	Title	Credits
Fall	MPH0300	Introduction to Biostatistics	3
Fall	CLR0700	Professionalism and Ethical Issues in Clinical Research	2
Fall	CLR0006	Spectrum of Methods in Clinical Research 1	3
Spring 1	MPH0311	Multivariable Methods	3
Spring 1	MPH0400	Introduction to Epidemiology	3
Spring 1	CLR0016	Spectrum of Methods in Clinical Research 2	3
Spring 2	MPH0623	Applied Analysis of Epidemiologic and Outcomes Research Data	3
Spring 2	CLR0501	Computational Tools for Clinical Research	3
Spring 2	CLR0007	Spectrum of Methods in Clinical Research 3	3
		Total Required Credits	**26**

Course Sequence: Masters of Science in Clinical Research Program (MSCR)

Term	Course Number	Title	Credits
Fall-Yr1	MPH0300	Introduction to Biostatistics	3
Fall-Yr1	CLR0700	Professionalism and Ethical Issues in Clinical Research	2
Fall-Yr1	CLR0006	Spectrum of Methods in Clinical Research 1	3
Spring1-Yr 1	MPH0311	Multivariable Methods	3
Spring1-Yr 1	MPH0400	Introduction to Epidemiology	3
Spring1-Yr 1	CLR0016	Spectrum of Methods in Clinical Research 2	3
Spring2-Yr 1	MPH0623	Applied Analysis of Epidemiologic and Outcomes Research Data	3
Spring2-Yr 1	CLR0501	Computational Tools for Clinical Research	3
Spring2-Yr 1	CLR0007	Spectrum of Methods in Clinical Research 3	3
Spring2-Yr1	CLR0011	Grant Writing	1
Fall, Spring1, Spring2 -Yr 2	CLR0017, CLR0018 & CLR0019	Clinical & Translational Research Journal Club & Seminar Series (Full Year Course)	3 in total (1 credit per term)
Fall-Yr 2	CLR0001	Master's Thesis for Clinical Research[1]	5
Spring1 or Spring2-Yr2	CLR0001	Master's Thesis for Clinical Research[1]– additional credits; **only when appropriate and with permission of Program Director**	3
		Electives[2] Specific to the Concentration/Focus(number of credits necessary will depend on the number of credits registered for the Master's Thesis)	*0-3*
		Total Required Credits (Years 1& 2 less Thesis & Electives)	**30**
		Total Credits (Thesis & Elective Credits)	**38**
	[1] Clinical Research Masters Thesis Design and Conduct, a maximum of 1 credit for 45 hours of research and writing with not less than 2/3 or 66% time of research. [2] Additional credits can be fulfilled through selection of other specific course work, independent study and or additional credits accrued through thesis research project (see above) selected taken from offerings in the graduate school and medical school. Courses taken at other institutions can be applied on a case by case basis for the MSCR, but tuition will need to be paid to the respective institution offering that course.		

By the start of Spring 1/Spring 2 of their second year (or third year if MSCR being completed in 3 years), students will have submitted a first draft of their thesis proposal. Please refer to the Student Handbook for complete Master's thesis guidelines and forms.

Course Sequence: PORTAL

Term	Course Number	PORTAL PROGRAM CURRICULUM	Credits
Term	**Course Number**	**Course Name**	**Credits**
Fall			
Yr1	CLR0006	Spectrum of Measurements in Clinical & Translational Research: Qualitative and Quantitative Methods 1	3
Yr 2	MPH0300	Introduction to Biostatistics	3
*SY	CLR0700	Professionalism and Ethics in Clinical Research	2
*SY	CLR0001	Clinical Research Masters Thesis Design and Conduct	3
*SY		Elective	3
*SY	CLR0017	Clinical and Translational Research Journal Club and Seminar Series	1
Winter			
Yr1	CLR0016	Spectrum of Measurements in Clinical & Translational Research: Qualitative and Quantitative Methods 2	3
Yr2	MPH0311	Multivariable Methods	3
*SY	CLR0001	Clinical Research Masters Thesis Design and Conduct	3
*SY	CLR0018	Clinical and Translational Research Journal Club and Seminar Series	1
Spring			
Yr1	CLR0007	Spectrum of Measurements in Clinical & Translational Research: Qualitative and Quantitative Methods 3	3
Yr 2	NA	Preparation for USMLE step 1	
*SY	CLR0501	Computational Tools for Clinical Research	3
*SY	MPH0623	Applied Analysis of Epidemiologic and Outcomes Research Data	3
*SY	CLR0011	Grant Writing	1
*SY	CLR0001	Clinical Research Masters Thesis Design and Conduct	2
*SY	CLR0019	Clinical and Translational Research Journal Club and Seminar Series	1
		Total Credits	**38**
* Scholarly Year		Elective may be taken in any term of the SY	

By January 15th of Y4, students will have submitted a first draft of their thesis proposal. <u>Please refer to the Student Handbook for complete Master's thesis guidelines and forms.</u>

Course Sequence: Ph.D. in Clinical Research Program.

A total of 66 credits and successful completion and submission of the Dissertation are required to complete the PhD Program. The number of credits of required coursework, Doctoral thesis and electives vary depending on the PhD track. The required coursework for each track is outlined below:

Clinical Trials Track
Year 1

Term	Course Number	Title	Credits
Fall	MPH0800	Introduction to Advanced biostatistics	3
Fall	CLR0700	Professionalism and Ethical Issues in Clinical Research	2
Fall	CLR0006	Spectrum of Methods in Clinical Research 1	3
Spring 1	MPH0812	Applied Linear Models 1	3
Spring 1	CLR0016	Spectrum of Methods in Clinical Research 2	3
Spring 2	MPH0822	Applied Linear Models 2	3
Spring 2	CLR0501	Computational Tools for Clinical Research	3
Spring 2	CLR0007	Spectrum of Methods in Clinical Research 3	3
Spring 2	CLR0011	Grant Writing	1
		Total Required Credits (Year 1)	**24**

Year 2

Term	Course Number	Title	Credits
Fall	CLR1010	Clinical Trials Management	1
Fall	CLR0017	Clinical & Translational Research Journal Club & Seminar Series (Full year Course)	1
Fall	CLR0012	Integrative Problem Solving in Clinical and Translational Research (full year course)	1
Fall	MPH0801	Introduction to Probability	3
Spring 1	CLR0320	Applied Biostatistics in Clinical Trials	3
Spring 1	CLR0018	Clinical & Translational Research Journal Club & Seminar Series	1
Spring 1	CLR0014	Integrative Problem Solving in Clinical and Translational Research (full year course)	1
Spring 2	CLR0901	The Drug Development Process	1
Spring 2	MPH0624	Outcomes Research Methods	3
Spring 2	CLR0019	Clinical & Translational Research Journal Club & Seminar Series	1
Spring 2		Integrative Problem Solving in Clinical and Translational Research (full year course, do not need to register for the course this term)	
		Total Required Credits (Year 2)	**16**

Year 3

Term	Course Number	Title	Credits
Fall	CLR0020	Doctoral Thesis for Clinical Research	8
Spring 1	CLR0020	Doctoral Thesis for Clinical Research	8
Spring 2	CLR0020	Doctoral Thesis for Clinical Research;	Minimum 7 Maximum 10
		Electives Specific to the Concentration/Focus (number of credits necessary will depend on the number of credits registered for the Doctoral Thesis)	0-3
		Total Required Credits (Year 3)	**26**

By the end of their second year, candidates will have taken and passed a qualifying examination and will submit their Thesis proposal. Please refer to the Student Handbook for complete PhD guidelines and forms.

A minimum of 2 credits in Doctoral Thesis are required for the Clinical Trials PhD track. Student may register for up to 3 additional credits of Doctoral Thesis for a maximum of 26 credits or register for up to 3 credits of electives specific to their track. These electives should be chosen in the context of a student's clinical research concentration and focus. In addition, opportunities for independent study exist to further enhance core knowledge in an area of specialized interest, but must be consistent with the guidelines for pursuing independent study.

Bench to Bedside Track
Year 1

Term	Course Number	Title	Credits
Fall	MPH0800	Introduction to Advanced biostatistics	3
Fall	CLR0700	Professionalism and Ethical Issues in Clinical Research	2
Fall	CLR0006	Spectrum of Methods in Clinical Research 1	3
Spring 1	MPH0812	Applied Linear Models 1	3
Spring 1	MPH0400	Introduction to Epidemiology	3
Spring 1	CLR0016	Spectrum of Methods in Clinical Research 2	3
Spring 2	MPH0822	Applied Linear Models 2	3
Spring 2	CLR0501	Computational Tools for Clinical Research	3
Spring 2	CLR0007	Spectrum of Methods in Clinical Research 3	3
Spring 2	CLR0011	Grant Writing	1
		Total Required Credits (Year 1)	**27**

Year 2

Term	Course Number	Title	Credits
Fall	CLR0017	Clinical & Translational Research Journal Club & Seminar Series (Full Year Course	1
Fall	CLR0012	Integrative Problem Solving in Clinical and Translational Research (full year course)	1
Fall	MPH0801	Introduction to Probability	3
Spring 1	CLR0018	Clinical & Translational Research Journal Club & Seminar Series	1
Spring 1	CLR0014	Integrative Problem Solving in Clinical and Translational Research (full year course)	1
Spring 1	CLR0320	Applied Biostatistics in Clinical Trials	3
Spring 2	CLR0901	The Drug Development Process	1
Spring 2	CLR0019	Clinical & Translational Research Journal Club & Seminar Series	1
Spring 2		Integrative Problem Solving in Clinical and Translational Research (full year course, do not need to register for the course this term)	
		Total Required Credits (Year 2)	**12**

Year 3

Term	Course Number	Title	Credits
Fall	CLR0020	Doctoral Thesis for Clinical Research	10
Spring 1	CLR0020	Doctoral Thesis for Clinical Research	10
Spring 2	CLR0020	Doctoral Thesis for Clinical Research;	Minimum 4 Maximum 7
		Electives Specific to the Concentration/Focus (number of credits necessary will depend on the number of credits registered for the Doctoral Thesis)	0-3
		Total Required Credits (Year 3)	**27**

By the end of their second year, candidates will have taken and passed a qualifying examination and will submit their Thesis proposal. Please refer to the Student Handbook for complete PhD guidelines and forms.

A minimum of 24 credits in Doctoral Thesis are required for the Bench to Bedside PhD track. Student may register for up to 3 additional credits of Doctoral Thesis for a maximum of 27 credits or register for up to 3 credits of electives specific to their track. These electives should be chosen in the context of a student's clinical research concentration and focus. In addition, opportunities for independent study exist to further enhance core knowledge in an area of specialized interest, but must be consistent with the guidelines for pursuing independent study.

Outcomes Implementation
Year 1

Term	Course Number	Title	Credits
Fall	MPH0800	Introduction to Advanced biostatistics	3
Fall	CLR0700	Professionalism and Ethical Issues in Clinical Research	2
Fall	CLR0006	Spectrum of Methods in Clinical Research 1	3
Spring 1	MPH0812	Applied Linear Models 1	3
Spring 1	MPH0400	Introduction to Epidemiology	3
Spring 2	MPH0822	Applied Linear Models 2	3
Spring 2	CLR0501	Computational Tools for Clinical Research	3
Spring 2	CLR0007	Spectrum of Methods in Clinical Research 3	3
Spring 2	CLR0011	Grant Writing	1
		Total Required Credits (Year 1)	**24**

Year 2

Term	Course Number	Title	Credits
Fall	CLR0017	Clinical & Translational Research Journal Club & Seminar Series	1
Fall	CLR0012	Integrative Problem Solving in Clinical and Translational Research (full year course)	1
Fall	MPH0801	Introduction to Probability	3
Spring 1	CLR0018	Clinical & Translational Research Journal Club & Seminar Series	1
Spring 1	CLR0014	Integrative Problem Solving in Clinical and Translational Research (full year course)	1
Spring 2	MPH0821	Analysis of Longitudinal Data	3
Spring 2	MPH0624	Outcomes Research Methods	3
Spring 2	CLR0019	Clinical & Translational Research Journal Club & Seminar Series	1
Spring 2		Integrative Problem Solving in Clinical and Translational Research (full year course, do not need to register for the course this term)	
		Total Required Credits (Year 2)	**14**

Year 3

Term	Course Number	Title	Credits
Fall	CLR0020	Doctoral Thesis for Clinical Research	10
Spring 1	CLR0020	Doctoral Thesis for Clinical Research	10
Spring 2	CLR0020	Doctoral Thesis for Clinical Research;	Minimum 4 Maximum 5
		Electives Specific to the Concentration/Focus (number of credits necessary will depend on the number of credits registered for the Doctoral Thesis)	Minimum 3 Maximum 4

		Total Required Credits (Year 3)	28

By the end of their second year, candidates will have taken and passed a qualifying examination and will submit their Thesis proposal. <u>Please refer to the Student Handbook for complete PhD guidelines and forms.</u>

A minimum of 24 credits in Doctoral Thesis are required for the Clinical Trials PhD track. Student may register for an additional 1 credit of Doctoral Thesis for a maximum of 25 credits or register for a 1 credit elective course specific to their track. In addition, students are required to register for 3 credits of elective coursework. These electives should be chosen in the context of a student's clinical research concentration and focus. In addition, opportunities for independent study exist to further enhance core knowledge in an area of specialized interest, but must be consistent with the guidelines for pursuing independent study.

Explanation of Course Numbering System

The following course guide includes courses that begin with the prefixes CLR, MPH, BSR, MGC and MSN. 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
- MGC: Masters of Genetics Counseling
- BSR: Basic Science Research
- MSN: M.D. Program

Guide to courses with the CLR prefix:

The first two numbers denote the research focus:

The third number denotes the level:

- 0 Introduction
- 1 Intermediate
- 2 Advance

The fourth is a number for the course itself.

General Clinical Research

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

Course Directors: Henry Sacks, M.D., Ph.D.
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.

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

Course Directors: Henry Sacks, M.D., Ph.D.
Term: Spring 1   3 credits

Methods in Clinical & Population Based Research: Part II is divided into two sections.

The first provides an in depth focus on study design and analysis, including randomized clinical trials, early proof of concept trials, phase II trials, including futility designs; phase III efficacy trials, small population clinical trials and n-of-1 studies.

The second section of the course focuses on study implementation and conduct and will include the following topics: responsible conduct of research, good clinical practice; responsibilities of the principal investigators; working with the IRB; patient selection, allocation and recruitment; protocol adherence, adverse events and adverse event reporting; data and safety monitoring plans and monitoring boards; regulatory bodies and funding.

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

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

Course Directors: Janice L. Gabrilove, M.D., Alan J. Moskowitz, M.D. and Inga Peter, Ph.D.
Term: Spring 2   3 credits

Methods in Clinical & Population Based Research: Part III is divided into four sections.

The first focuses on the use of specific databases & analytical programs in the conduct of clinical research. The format for this section of the course includes lecture and laboratory sessions.

The second section of the course focuses on "Omics" & clinical research and covers genomics, proteomics, microarray technologies, methylation arrays, and bioinformatics principles. Also covered are the clinical and genomic databases that are essential for conducting omics clinical investigations and the resources and tools for personalized medicine research. Review of the Biobank and access to the de-identified database will be provided to the student to demonstrate the use of this unique resource for conducting novel clinical investigation.

The third section of the course will provide an initial introduction to health services research, including topics concerning health care disparities, community engagement & participatory research; and comparative effectiveness research.

Finally, the last segment of the course will focus on practical aspects of clinical research including, graphic presentation of data and scientific writing as well as an overview of the nuts and bolts of securing peer review funding as well as opportunities for new clinical investigators, in particular.

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

MPH0003   Current Topics in Clinical Preventive Medicine

Course Directors: Richard A. Bordowitz, M.D., Elizabeth J. Garland, M.D., M.S.
Term: Every other Spring 1   3 credits

This course builds on the fundamental aspects of clinical prevention and the United States Preventive Services Task Force Guidelines. Designed for the healthcare professional, the course will include discussions about new evidence-based approaches that guide clinicians regarding the appropriateness and utility of new preventive services, screening tests, guidance for counseling patients, and an examination of current interventions at the community level, in addition to current controversies and research in the prevention field. This course is limited to licensed medical professionals with the exception of those who receive permission from the course director.

BSR1003   Responsible Conduct of Research

Course Director: Charles V. Mobbs, Ph.D.
Term: Fall   1 credit

This course meets for eight 2-hr sessions to explore a variety of ethical and policy issues that may arise in basic and clinical scientific research. Topics that are covered include scientific misconduct; mentoring; data management and record-keeping; ownership of data and issues of sharing data, reagents; responsible authorship (plagiarism, when to publish, redundant publications, different kinds of publication and journals) and peer review; use of human subjects or tissue in biomedical research; use of animals in biomedical experimentation; use of hazardous materials in research; conflict of interest; research grants, training grants, fellowships; and self-delusion in science. Trainees participate in this course in the fall semester of their first year of

support. The format for each session is an initial half hr lecture followed by discussion period; all students are expected to read, in advance of the class, an assigned chapter in Frances L. Macrina's text, "Scientific Integrity, An Introductory Text with Cases" (Third Edition, 2005). The second half of the session involves a case discussion. The class is divided into small groups of 6-8 students who are asked to review, under the supervision of a faculty member, a case taken from the course textbook, after which each student is expected to write a one-page analysis of the case. In the final half-hour of the session, each group presents its case and comments on their discussions. A single case is selected for a more in depth discussion among the students. The final assignment requires that students write their own case with questions and answers on any of the topics covered in class. Institutional experts, including the Director of the IRB (for human subjects research), ACVC (for animal research), and Technology Transfer (for the discussion on information technology), are invited to lead specific sessions. Attendance at all sessions is mandatory; any student who misses a session is required to write an essay or answer questions that cover central concepts of the session that was missed. Students are not allowed to make-up more than two sessions.

In addition, each training area is asked by the Graduate School to sponsor two values-related sessions for its faculty and students, usually including postdoctoral students as well as pre-doctoral students, each year. RCR education in the actual research setting is a critical component of the whole RCR program. All trainees are provided with copies of the specific policies of the School of Medicine Handbook for Research and copies of the following specific policies of the School of Medicine: responsibilities of authors and data retention, press relations, manuscript policy, policy and procedures on ethical practices in research (including procedures for handling allegations of misconduct in research and policy and procedures on protecting whistleblowers), use of Mount Sinai's name, conflict of interest in research, policies on intellectual property (ownership and commercial development) and policy on harassment.

CLR0012, CLR0014   Integrative Problem Solving in Clinical and Translational Research

Course Director: Emilia Bagiella, Ph.D. and Inga Peter, Ph.D.
Term: Fall, Spring 1, Spring 2   2 credits

This course is focused on enhancing the trainees 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

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: Lawrence Kleinman, M.D., M.P.H. and Janice L. Gabrilove, M.D.
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 & faulty, 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.

CLR0011   Grant Writing

Course Director: Judy Swan, Ph.D.
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.

MPH0001   **Introduction to Public Health**

Course Directors: Philip J. Landrigan, M.D., M.Sc. and Lisa Littman, M.D.
Term: Fall   3 credits

This introductory course will provide a broad overview of public health – its history, triumphs and challenges, as well as its prospects for the future. The course will provide a strong foundation for students entering the Master of Public Health Program. A principal goal of the course is to give students an understanding of the structure and function of the public health system in the United States and internationally. Some of the leading figures in public health in this country and abroad will be invited to present lectures, and they will provide students with a sense of the breadth and depth of public health as well as a sense of the extraordinary range of career opportunities that exist in this ever changing field.

MPH0010   **Zoonoses: An Emerging Public Health Issue**

Course Director: Stephanie H. Factor, M.D., M.P.H.
Term: Spring 2   3 credits

Zoonoses, diseases transmitted from animals to humans, are increasingly being recognized as emerging or re-emerging disease threats to public health. This course will explore the interactions between physicians, veterinarians, and public health professionals; provide an understanding of the public health consequences of these diseases; and explore preventive measures. Finally, we will set the framework for discussions of agents of bioterrorism and the public health response to these threats. The course attracts top speakers from across the country in the fields of public health, infectious diseases, veterinary medicine, and the biomedical sciences.

MPH0021   **Seminar in Applied Preventive Medicine**

Course Director: Elizabeth J. Garland, M.D., M.S.
Term: Full Year Course   2 credits

This weekly seminar focuses on current local, national, and international issues in public health and preventive medicine. Discussions center on critical review of the published literature in public health and include topics related to health policy and management, economic and legal issues, and the impact of these issues on the health of populations. On a rotating basis, each student is responsible for setting the agenda and chairing seminar discussions.

Pre-requisites: MPH0400   Introduction to Epidemiology
                            MPH0300   Introduction to Biostatistics

Students who are not Residents in the Department of Community & Preventive Medicine must receive permission from Course Director prior to enrolling in this course.

Health Services Research & Health Policy Research

MPH0104   Healthcare in Communities and the Public Sector

Course Director: TBA
Term: Spring 2   3 credits

A major focus of this class is on understanding how community life and health are related. Students will learn how to analyze communities, compare data regarding the health status of communities and to compare selected communities to each other. Case material will be used to emphasize the multiple ways one can assist communities as a whole and those at risk for health problems. Exemplars will be offered by guest lecturers involved in community change. Social and economic factors will be identified that affect community health status.

MPH0105   Health Economics and Policy Implications

Course Directors: Melissa D.A. Carlson, Ph.D., M.B.A.
Term: Spring 1   3 credits

Health economics is the study of both the efficiency and equity of health and healthcare. Factors that distinguish health economics from other areas include extensive government intervention, intractable uncertainty, asymmetric information, and externalities. This course will discuss each of these factors and the ways in which these factors are the underpinnings of many public health initiatives and programs. Rather than transform students into health economists, this course endeavors to empower students with the economic concepts and terminology to understand and critically evaluate healthcare policy proposals and health economic research in the scientific literature. This course will cover economic theory related to the organization, financing and delivery of public health and healthcare; cost-benefit, cost-effectiveness, and cost-utility analyses; and global health system comparisons. This course requires student presentations and involvement in discussions and debates to enhance oral communication skills.

Behavioral Research & Cognitive Tools

CLR0207　　　　　　**Culture, Illness & Community Health**

Course Directors: Gary Butts, M.D., Edward Poliandro, Ph.D. and Ann-Gel S. Palermo, M.P.H.
Term: Spring 2　　　　　　　　　　　　　　　　　　　　　　　　　3 credits

This course considers Franz Boas' definition of culture as *culture is everything but natural science.*[1] 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

MPH0201　　　　　　**Introduction to Socio-Behavioral Health**

Course Directors: Mary Foley, M.S., Ed.D. and Michael A. Diefenbach, Ph.D.
Term: Spring 2　　　　　　　　　　　　　　　　　　　　　　　　　3 credits

This core course provides an overview of the social and behavioral sciences and their importance in the interdisciplinary field of public health. A primary emphasis is on the social ecological model, its application to public health issues, and its use in the development of policies, strategies, interventions and programs. The course content will introduce students to several relevant social and behavioral theories as well as a range of community health assessment and planning models used by public health professionals in both domestic and international venues. In addition, some lectures will focus on specific diseases that have a detrimental effect on public health and finally, a few lectures are reserved to provide students with insight into public health organizations. Through a series of assignments, students will enhance their knowledge and awareness of the role of social and behavioral sciences in public health and its relevance to their specific discipline.

This course will be capped at 30 students. Registration will be based on first come, first- served basis.

BSR1703   **Neural Basis of Behavioral Plasticity and Cognitive Processes**

Course Director: Matthew Shapiro, Ph.D.
Term: Spring 1- Spring 2   3 credits

Neural Basis of Behavioral Plasticity & Cognitive Processes: The aim of this course is provide students an in-depth overview of current topics, concepts and experimental methods in the neural basis of behavioral plasticity. The course is required for all students in the Neuroscience MTA, and the prerequisites are Principles of Neurobiology I and II, or prior approval of the course directors. The course will follow a "vertical integration" approach in which each system is considered at multiple levels of analysis, from molecular biology to behavior in whole organisms. Class will meet three times per week and follow a lecture/discussion format. Students will be responsible for extensive reading and the discussion of original research articles or reviews assigned for each section of the course. The course is divided roughly into 3 sections: Plasticity, Learning, and Neural Representation, Multiple Memory Systems, and Metaplasticity: Motivation, Development, and Disorders.

MSN601   **Brain & Behavior**

Course Director: Daniel P. Perl, M.D.
Term: Fall   3 credits

The nervous system is perhaps the most complicated human organ system. Possessing basic knowledge and understanding of its anatomy, function and pathophysiology is essential for any physician. This interdisciplinary course addresses structural, functional, and biochemical aspects of the nervous system, and introduces students to neurologic illnesses commonly encountered in clinical practice. Through patient-based small group discussions students gain insight into the scientific basis for evaluation and treatment of clinical phenomena such as pain, weakness, depression, coma, sleep disorders, stroke, etc. The goal is to enable each student to reach a basic understanding by which normal and abnormal nervous system functioning can be interpreted. The Psychopathology component of Brain & Behavior introduces students to the basic pathophysiology of a range of mental illnesses, and prepares students for the Year 3 Psychiatry clerkship. This component of the course is taught in seminar format and small groups facilitated by practicing psychiatrists.

Enrollment requires prior permission from the Course Director.

Biostatistics: Quantitative and Qualitative Methods

MPH0300   **Introduction to Biostatistics**

Course Director: James H. Jr. Godbold, Ph.D.
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.

MPH0800   **Introduction to Advanced Biostatistics**   3 credits

Course Director: Emilia Bagiella, Ph.D.
Term: Fall

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 testing equality of population means (e.g., t-tests), simple categorical data analysis (e.g. chi-square tests), analysis of variance, correlation, and simple linear regression. This course is intended for students in the biostatistics or epidemiology tracks of the MPH Program and the PhD students in the Clinical Research Program.

MPH0305   **Introduction to Qualitative Research Methods**

Course Director: Carol Horowitz, M.D., M.P.H.
Term: Fall   3 credits

Heart disease, toxicants in food and water, HIV/AIDS, bio-terrorism and avian flu – we live in an ever-changing landscape of risks where information alone does not necessarily lead us to practice good health behaviors. How people perceive, comprehend and prioritize the health information around them powerfully effects what they act on.

This course provides the student with an understanding of how attitudes and perceptions of an individual or group can impact their priorities and actions. Qualitative methodologies bring an enhanced understanding to quantitative research. The qualitative research methods we will cover in this course include: ethnographic/participant observation, in-depth interviews, focus groups, panels and small-scale surveying. Students will be required to design and conduct small field research activities throughout the semester. Methods and findings will be critiqued and refined with class input and participation.

MPH0311   Multivariable Methods

Course Director: John T. Doucette, Ph.D.
Term: Spring 1   3 credits

This intermediate-level biostatistics course involves in-depth study of statistical methods that examine the relationship among multiple (i.e., more than 2) variables at the same time. The methods covered include linear regression, logistic regression and Cox proportional hazards models. Students will also learn about tests of model fit, regression diagnostics, representation of categorical independent variables and transformations of dependent variables. Students are shown how to apply these methods using statistical software (SPSS®) and how to interpret the resulting computer output.

Pre-requisites: MPH0300 Introduction to Biostatistics
                              MPH0400 Introduction to Epidemiology (may be taken concurrently)

MPH0320   Research Methods

Course Director: Mary Foley, M.S., Ed.D.
Term: Spring 2   1 credit

Research Methods encompasses a set of fundamental skills and tools necessary for approaching the process of developing and answering a research question, being a future investigator, or an informed consumer of information in the marketplace. This course provides a solid and practical framework enabling students to successfully embark upon their Master's Theses. As a prerequisite in the conduct of research, it prepares students to conceptualize, propose, design, and write research papers in general, and the Thesis in particular.

Topics covered include the characteristics of a research study, formulating a research question, experimental research designs, survey construction, data analysis and interpretation, and evaluation of research. Also addressed are strategies for conducting literature searches, research ethics, informed consent, and elements of a research proposal. Students will be required to complete IRB training, HIPPA training, data security training, and outline a research proposal for their Master's Thesis project by the end of this course.

This course is graded on a Pass/Fail basis. This course will be capped at 30 students. Registration will be based on first come, first serve availability.

Pre-requisite course: MPH0001 Introduction to Public Health.

MPH 0801   Introduction to Probability

Course Director: Michael Parides, Ph.D.
Term: Fall   3 credits

This course provides an introduction to probability models emphasizing applications in medicine and biology.   In addition to presenting basic probability theory and models, a variety of topics important in statistics will be covered, including: random variables; discrete and continuous probability distributions; conditional probability, joint probability, expectation and variance; independence; sampling distributions, combinatorics, and permutations.

MPH 0802   Introduction to SAS Systems
Course Director: TBD
Term: Spring 2   2 credits

This course is focused on an understanding of the how to utilize SAS systems for data management and manipulation in order to prepare for statistical modeling.   The course is designed for MPH students that will be using statistical software in their future work.   Students will be given hands on training by using their own datasets as well as data provided by the instructor.   The lectures will take place in the Levy Library where SAS is available to the students during course instruction.

Pre-requisite: Introduction to Biostatistics or Introduction to Advanced Biostatistics

CLR0320   Applied Biostatistics in Clinical Trials

Course Director: Emilia Bagiella, Ph.D.
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.

BSR1010   Biostatistics

Course Director: John P. Mandeli, Ph.D.
Term: Fall   3 credits

The purpose of this course is to familiarize students with basic principles of probability and statistics as applied to biomedical research. No prior knowledge of statistics is required. Our goal is to prepare students for critical reading of the scientific literature and for applying basic statistical methods to their own research. The course will be taught using SPSS; the

fundamentals of SPSS will be presented. Topics covered include laws of probability, probability distributions and density functions (binomial, normal), the central limit theorem, confidence intervals, hypothesis testing, statistical power and sample size estimation, t-tests, nonparametric methods, chi-square tests, simple linear regression and correlation, one-way analysis of variance, two-way analysis of variance, principles of experimental design, completely randomized design, randomized block design, and factorial treatment designs.

MPH0820   Statistical Inference

Course Director: John Spivack, Ph.D.
Term: Fall, 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: Introduction to Probability or permission of the Course Director.

MPH0821   Analysis of longitudinal data

Course Directors: Emilia Bagiella, Ph.D.
Term: Spring 1   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.

MPH0812   Applied Linear Models 1

Course Directors: Michael Parides, Ph.D.
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: Introduction to Biostatistics or Introduction to Advanced Biostatistics

MPH0822   **Applied Linear Models 2**

Course Director: Michael Parides, Ph.D.
Term: Spring 1   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.

Epidemiology: Basic, Molecular and Clinical

MPH0400   **Introduction to Epidemiology**

Course Director: Stephanie H. Factor, M.D., M.P.H.
Term: Spring 1   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.

MPH0410   **Epidemiology of Infectious Diseases**

Course Directors: Preeti Pathela, D.P.H.
Term: Spring 2   3 credits

Epidemiology of Infectious Diseases builds upon the concepts presented in Introduction to Epidemiology (P400), stressing the importance of considering the host, environment and disease agent in transmission dynamics. The nineteenth and twentieth centuries witnessed advances in prevention, treatment, and study of infectious diseases and the misconception that infectious diseases were disappearing. The study of infectious diseases leads to the continual development of vaccines, antibiotics, and technology, prompting epidemiologists to develop more advanced methods to monitor disease, investigate patterns of disease transmission, and evaluate innovative prevention modalities. The past thirty years have brought to light both new and re-emerging problems in the epidemiology of infectious diseases, including HIV, SARS, avian influenza, arboviruses, antimicrobial resistance, and the threat of bioterrorism.

Through varied lectures, this course will enable students to gain an understanding of the principles of infectious disease epidemiology, including modes of transmission, quantification of occurrence and risk, and methods for preventing disease at the population level. Students will also participate in various classroom exercises, during which they will investigate outbreaks, create surveillance plans, present evidence of a disease threat, and recommend prevention and control measures.

Pre-requisites: MPH0400 Introduction to Epidemiology
                         MPH0300 Introduction to Biostatistics

MPH0412   **Epidemiology II**

Course Directors: Stephanie Factor, M.D.
Term: Fall   3 credits

This course provides instruction in the analysis and interpretation of data from various epidemiological study designs. SAS is used to demonstrate epidemiological and statistical concepts in data analysis. SAS will be used to demonstrate epidemiological and statistical concepts in data analysis.

Topics: Cross-sectional studies

Tabular methods:
        Basics, adjustment for confounding
    Unconditional logistic regression and linear regression
        Basics, indicator variables, confounders, hypothesis testing,
        interactions, choosing the best model
Case-control studies
    Unconditional logistic regression
        Goodness-of-fit and c-statistic
    Dose-response relation
Matched case-control studies
    Conditional logistic regression
    Ordinal logistic regression
Cohort Studies
    Poisson regression
        Best fit
    Cox regression
    Correlated data analysis

Prerequisites: Intro to Epidemiology, Biostatistics, Multivariable Methods or Applied Linear Models I, SAS proficiency

MPH0420   **Epidemiology III**

Course Director: Paolo Boffetta, MD, M.P.H.
Term: Spring 1   3 credits

CLR0421   **Molecular Epidemiology**

Course Director: Susan Teitelbaum, Ph.D.
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)

CLR0810 **Genetic Epidemiology**

Course Director: Inga Peter, Ph.D., Ruth Loos Ph.D.
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
                        MPH0311 Multivariables Methods   **or**
                        MPH0812 Applied Linear Models I

        Suggested course but not required: MPH0802 Introduction to SAS systems

Informatics & Bioinformatics

CLR0500   **Principal Topics in Biomedical Informatics**

Course Directors: Brett Trusko, Ph.D.
Term: Spring 2   3 credits

This course is designed to introduce the fundamental principles of biomedical informatics. It is taught so that individuals with various backgrounds, including those with medical, nursing, library science, research, computer science, or other backgrounds, can become familiar with information management and computer applications in health and biomedicine. The course includes a survey of the entire AMIA (American Medical Informatics Association) 10 by 10 Informatics curriculum requirements.

CLR0501   **Computational Tools for Clinical Research**

Course Directors: Alan J. Moskowitz, M.D.
Term: Spring 2   2 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

CLR0520   **Advanced Topics in Biomedical Informatics**

Course Directors: Brett Trusko, Ph.D.
Term: Spring 2   3 credits

This course will provide the learner with a detailed view of the state of the art in clinical Informatics. The course will describe current EHR and research design efforts enabled by EHR implementations. Additionally, students will discuss, define and examine the current standards for Health Information Exchange (HIE) and will specifically define standards such as the Clinical Document Architecture (CDA) and the Clinical Care Document (CCD) in the context of HITSP's C32 construct. We will examine how these HIE structures will enable clinical decision support to help ensure best practice of health and healthcare in support of clinical informatics, evidence-based patient care, clinical decision support, bioinformatics and architectural design strategies.

Pre-requisite: CLR0500 Principle Topics in Medical Informatics

BSR2107   Bioinformatics

Course Director: Avi Ma'ayan, Ph.D.
Term: Fall   2 credits

This course will cover approaches to the usage of standard databases such as GenBank and SwissProt as well as interaction databases such as KEGG (Kyoto Encyclopedia of Genes and Genomes), BIND Bimolecular Interation network Database), PPID (Protein-Protein Interaction Database), DIP (Database of Interacting Proteins) and HPRD (Human Protein Reference Database). Discussions will focus on database schema, extraction toll capabilities and limitations of these databases.

MPH0005   Geographic Information Systems (GIS) For Public Health

Course Director: Christopher D. Goranson, MGIS, GISP
Term: Spring 2   1 credit

Geographic Information Systems (GIS) are used by public health professionals to better understand relationships between health and the environment, the geographic and temporal transmission of disease, and access to health care. This rapidly-changing field is seeing an expansion in the application of geography to better understand a number of health outcomes, thanks in part to new web-based tools and desktop technologies that make the use of GIS data and methods more accessible to a broader audience. This hands-on course will focus on the fundamentals of geographic information and how the technology can be applied to public health. Topics covered include an introduction to key considerations for applying GIS to public health; how to find and prepare demographic and health data for mapping; standard cartographic principles; geocoding; and an introduction to spatial analysis methods. The course will also illustrate how geographic data can be moved between more traditional GIS software (ESRI's ArcGIS) and newer technologies (Google Earth and open source GIS applications).

BSR1900   DTE Makers Studio
Course Director: Kevin D. Costa, PhD, James C. Iatridis, PhD and Geoffrey W. Smith, JD
Term: Fall   3 credits

DTE Makers Studio is a semester-long studio course designed to explore different ways of solving problems by using technology to create physical models. The hands-on studio will meet as a group for lecture once per week to discuss various aspects of problem identification, problem solving, and making things. Students will work outside of the weekly group meetings to implement these lessons in the completion of a project that will require each student to design and make a component of a larger system being developed by the class as a team.

BSR5900   DTE Directed Reading
Course Director: Kevin D. Costa, PhD, James C. Iatridis, PhD and Geoffrey W. Smith, JD
Term: Fall   1 credit

DTE Directed Reading is a semester-long course designed to supplement the Biomedical Sciences (BMS) Core by discussing weekly BMS topics in the context of the Design, Technology and Entrepreneurship MTA's focus on the discovery, design, development, and delivery of technology-based solutions to critical biomedical problems**.**

BSR3002   QED Project

Course Director: Geoffrey Smith
Term: Fall, Spring 1, Spring 2   2 credits

The Q.E.D. Project provides a hands-on, team-based, technology development experience for students. Over the course of an academic year, student-led teams will learn to define a specific problem, invent a technology-based solution to the problem, and build a prototype solution for it. These solutions will be evaluated based on innovation, practicality, ease of use and adoption, economic impact, and commercial potential.

Outcomes Research

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.

Pre-requisites: MPH0400 Introduction to Epidemiology
                       MPH0300 Introduction to Biostatistics

Students who are not clinical fellows matriculated in the MPH or MSCR program must receive permission from the Course Director prior to enrolling in this course.

This class meets on alternate weeks and is graded on a Pass/Fail basis.

MPH0623   **Applied Analysis of Epidemiologic and Outcomes Research Data**

Course Director: Juan Wisnivesky, M.D.
Term: Spring 2   3 credits

This course is focused on learning the application of statistical methods for the analysis of epidemiologic and patient-oriented observational data. The emphasis will be on hands-on experience, involving case studies with real data and using the statistical software SPSS. The focus will be on choosing and on implementing the appropriate statistical methods to analyze and interpret different types of data. Attention will also be paid to the theory behind these tests and on testing the validity of the assumptions. The course will cover data management, exploratory data analysis, model formulation, goodness of fit testing, and other standard procedures, including linear regression, analysis of variance, logistic regression, and survival analysis. Prospective students are invited to propose a data set of their choice for use as case study material. The grade will be based on the homework, midterm, and a final exam. This course will be particularly well suited to students who are actively involved in an epidemiology, outcomes, health services, or a survey research project that is entering the data analysis phase.

Pre-requisites: MPH0300 Introduction to Biostatistics
                       MPH0311 Multivariable Methods

MGC1100   Introduction to Interviewing and Counseling Methodology

Course Director: Randi E. Zinberg, M.S.
Term: Spring 2   1 credit

The course will introduce the genetic counseling students to fundamental interviewing skills and the counseling methodologies to provide the foundation for which they will build their experience. Content from this module will be reinforced throughout the three semesters of Topics in Genetic Counseling.

MPH0624   Outcomes Research Methods

Course Directors: Juan Wisnivesky, M.D. and Henry Sacks, M.D., Ph.D.
This course represents & reflects a joint effort between the MPH and CLR Programs
Term: Spring 2   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 provide with each topics. Areas to be covered include 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
                         MPH0311 Multivariable Methods

Ethics

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

Course Director: Rosamond Rhodes, Ph.D.
Term: Fall   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.

CLR0710   **Ethics and Professionalism II**

Course Directors: Rosamond Rhodes, Ph.D. and Kurt Hirschhorn, M.D.
Term: Fall   2 credits

This course will build upon Ethics and Professionalism I and explore advanced topics in a small group setting with extensive participation by students in faculty led discussions. The course will meet for two hours each week. By the end of this course participants should be able to:

- Refer to the historical evolution of research ethics and the development of protections for human subjects.
- Identify and employ the guiding principles of research ethics.
- Evaluate clinical studies in terms of ethical considerations.
- Review the research ethics literature and use it in addressing questions related to clinical research.
- Justify decisions about the ethical conduct of research in terms of reasons that other reasonable clinicians could accept.

MGC1102   **Medical Ethics**

Course Directors: Stefan Baumrin, Ph.D., J.D. and Daniel A. Moros, M.D.
Term: Spring 1, Spring 2   4 credits

This course examines "classic" and emerging issues in biomedical ethics paying particular attention to the history of medicine and the nature of scientific thought as it relates to medical

ethics. While many issues in biomedical ethics seem timeless such as our concerns about the withholding of treatment, abortion, truth-telling - others have arisen out of the development of an increasingly scientific medicine beginning in the 1700s. It is the availability of well confirmed effective treatments that forces us to wrestle with such questions as the propriety of medical intervention over the objection of the patient, the treatment of children over the objection of their parents, the right of all citizens to health care, the regulation of the sale of body parts for transplantation, and numerous circumstances arising out of assisted reproduction. In the not too distant past, it would have seemed bizarre to consider the adjudication of competing rights when one woman contracts to rent the uterus of a surrogate to bear through in vitro fertilization the embryo formed from the egg of a third individual. The current revolution in biotechnology, microelectronics and nanotechnology continuously produces new issues. What is the meaning of confidentially in a world where an enormous amount of information about each of us can be extracted rapidly from numerous searchable databases? What is the moral status of the embryonic stem cell derived from a discarded embryo, or a non-human animal? How are we to regulate cloning and our ability to shape and alter the human genome? We now implant electrodes into the brains of patients with Parkinson's disease and essential tremor. Soon we may be treating depression, disorders of impulse control, anxiety and phobias electronically. Does such technology present different issues as compared with today's drug and surgical therapies? We will also be challenged by the products of bioengineering. We already have prosthetics that remarkably link the brain directly to external mechanical devises and further alter the meaning of disability.

In medical ethics both the past and the future need to inform out vision of proper behavior and decision making. In our world of rapidly advancing technology, much medical ethics policies misread and mishandle the present and construct rules with an eye towards an idealized past, while failing to consider a fast approaching future.

An aim of this course is to prepare philosophers to enter into medical institutions with the preparation necessary to be helpful additions to the provision of health care in ethically acceptable ways.

CLR0720   Theories of Bioethics (Bioethics, Policies and Cases)

Course Directors: Rosamond Rhodes, Ph.D. and Ian R. Holzman, M.D.
Term: Spring 1, Spring 2   3 credits

Most people who consider the ethical rules that should govern the practice of medicine assume that the ethics of medicine is no different from the rest of morality. For that reason, people who write about medical ethics draw on the classical sources of ethical insight. They discuss autonomy in Kantian terms, allocation of scarce resources in utilitarian terms, access to health care in terms of rights, and professionalism in terms of virtues. This dominant view was articulated by K. Danner Clouser in his *Encyclopedia of Bioethics* article on "Bioethics" where he explained that "bioethics is not a new set of principles or maneuvers, but the same old ethics being applied to a particular realm of concerns." This strategy is most prominently expounded by Beauchamp and Childress in the six editions of their *Principles of Medical Ethics* and further explained by Gert, Culver, and Clouser in *Bioethics: A Return to Fundamentals*. The authors of those volumes identify the common features of morality, and show how to apply them to the practice of medicine.

This course will explore the major theoretical approaches to bioethics, including principlism, common morality, virtue theory, casuistry, and constructivist bioethics. We shall read and discuss this literature in the context of cases from the practice of medicine. Our study will be guided by two goals. First, we shall try to understand how these theories inform our thinking about medical ethics. Second, we shall try to assess whether these theories are actually appropriate to the practice of medicine. Do any of them actually identify an appropriate framework for the ethical practice of medicine? Do they provide a useful guide to the ethical practice of medicine? Do they offer helpful tools for resolving controversies within medical practice?

Genomics & Personalized Medicine

MSN625　　　　　　　　**Medical Genetics**

Course Directors: Brian M. Kirmse, M.D. and Peter J. McGuire, M.B.B.Ch.
Term: Fall　　　　　　　　　　　　　　　　　　　　　　　　　　3 credits

This course is offered each winter over a four week period from the third week in January through the second week in February. This course consists of twenty-six hours of lecture and two hours of small group workshops. The course emphasis is on major "themes" and principles of human medical genetics with emphasis on molecular genetics (linkage, gene mapping, and molecular diagnosis), Mendelian genetics (risk assessment and pedigree analysis), cytogenetics (autosomal and sex chromosome syndromes, chromosomal rearrangements, and the chromosomal basis of cancer), biochemical genetics, population genetics, clinical genetics (dysmorphology, the genetic basis of birth defects and common diseases), prenatal diagnosis, genetic counseling, and genetics, ethics and the law.

Enrollment requires prior permission from the Course Director.

BSR1401　　　　　　　　**Genetics and Genomic Sciences**
BSR1402
BSR1403

Course Director: Edward H. Schuchman, Ph.D.
Term: Spring 1-Spring 2　　　　　　　　　　　　　　　　　　　1-3 credits

The overall goal of this course is to provide students with topical training in the field of Genetics and Genomic Sciences. Three 1 credit modules will be offered. Students can register for each module independently and all Ph.D. and M.D./Ph.D. students are encouraged to participate. Modules only will be offered if a minimum of three students register. In order to satisfy the GGS Core requirement, all three modules must be successfully completed. Each module will last about one month and will be presented in a journal club/seminar format. The exact date and time for each module will be arranged to accommodate the schedules of all students as well as the module Director. Grades will be based on the presentations and performance on a short essay exam at the end of each module.

BSR1401: Module I: Epigenetics and Chromosomes - Peter E. Warburton, Ph.D. and Martin J. Walsh, Ph.D.

This course will present recent publications regarding the epigenetics of chromosome and chromatin structure and function. This will include discussion of chromosome segregation, considering the centromere specific histone H3 variant CENP-A and the role of heterochromatin in centromere function and chromosome cohesion. Topics will also include histone covalent modifications and possible roles in embryonic and pluripotent stem cell differentiation and the impact on gene regulation and transcription. Specific topics will focus on the genomic control of chromatin architecture and modification by master developmental regulators (Polycomb, Trithorax, etc.) in specifying cell lineages using recent epigenetic methodologies.

BSR1401: Module II: Cancer Genomics & Genetics - John A. Martignetti, M.D., Ph.D.

BSR1401: Module III: MicroRNAs in Health and Disease - George A. Diaz, M.D., Ph.D.

The discovery that RNA molecules can regulate the expression of genes has been one the most important advances in biology in decades. In just a few short years it has transformed our understanding of cell regulation, and is now poised to have a major impact on the treatment of disease. This course explores our emerging understanding of RNA regulation with a particular emphasis on RNA interference (RNAi) and microRNAs. The course will begin with a background lecture on the mechanisms of RNAi and microRNA regulation. Subsequent sessions will focus on the relevance of RNA regulation in biology and disease, and in scientific research and experimental therapies. The course will be relevant to anyone interested in gene regulation, or in the applications of RNAi. Student evaluation will be based on leading and participating in discussions.

Pre-requisite: BSR Core I or equivalent

BSR2400   Translational Genomics

Course Directors: Analisa DiFeo, Ph.D. and Andrew J. Sharp, Ph.D.
Term: Spring 1-Spring 2   2 credit

The influence of Genomics is vast and affects all areas of biology, thus this course will be useful to all those who plan to do biomedical research. This course is an introduction to the goals, principles, tools, and many applications of genetics/genomics. The focus of this course will be on the human genome and in particular on naturally occurring DNA sequence variations and their impact on molecular physiology, clinical phenotypic expression, the diversity populations, and human evolution. Emphasis in on the latest advances in genetics/genomics, the use of genetic tools in understanding complex biological pathways and disease, and the translation of genomic information on clinical care. By the end of the course, the students will have a working knowledge of the current genomic technologies, approaches and types of databases and computational tools available with an overall understanding of how genomics can be used to probe disease biology.

BSR4401   Journal Club in Genetics and Genomic Sciences

Course Directors: Peter E. Warburton, Ph.D. and Edward H. Schuchman, Ph.D.
Term: Fall & Spring 2   1 credit

This course is mandatory and open only to GGS Ph.D. and M.D./Ph.D. students. Each student presenter chooses a paper that is highly relevant to their own research project or plan. The presenter gives 5-10 minutes of introduction on the topic of the paper and their research, and the students present the papers Figure by Figure. For the final 20 to 30 minutes, the presenting student presents a progress report about their own work, and the impact that the chosen paper has made.

Drug Development

CLR0901   **The Drug Development Process**

Course Directors: Janice L. Gabrilove, M.D. and Ming-Ming Zhou, Ph.D.
Term: Spring 2   3 credits

This course will cover strategies for drug discovery and the requirements for preclinical evaluations of new drug targets. Target identification & validation; small molecule & biological therapeutics; drug evaluation process and licensure; patent applications, INDs, NDAs and issues related to clinical trials and regulatory requirements also will be addressed.

BSR1800   **Systems Biomedicine: Molecules, Cells & Networks**

Course Directors: Stuart C. Sealfon, M.D. and Terry A. Krulwich, Ph.D.
Term: Fall   6 credits

This active-learning course will introduce core biochemical, cell biological and molecular mechanisms together with basic bioinformatic and systems biology concepts and applications in the context of human biomedical research. The emphasis is 'top-down', beginning with a pathophysiological condition studied from a clinical perspective and moving towards explication of the molecular and metabolic logic, regulatory circuits and cell and tissue specific properties that distinguish the disease and normal state.

The goals of this course are to provide students with an appreciation of the complexity of biological systems across scales and to give insight into pathophysiology as a basis for scientific enquiry and development of new therapeutic strategies. Students will be guided to relevant textbook material and current reviews, and will participate in analyses of primary journal articles to enhance their study of scientific method and to illustrate a variety of experimental, and computational, approaches to contemporary translational biomedicine. Problem sets and the methodologies for handling large data sets, including epidemiological and genetic data, will be introduced.

This course is 6 credits with a journal club included in the body of five modules. The first module will be Introduction to Systems Biomedicine and will include an introduction to modeling using Matlab. The subsequent modules will focus on Diabetes; these will focus on Diabetes, Cancer, Renal Disease and Drug Abuse.

BSR1801   **Pharmacology**

Course Directors: Maria A. Diverse-Pierluissi, Ph.D. and Joseph Goldfarb, Ph.D.
Term: Spring 1-Spring 2   4 credits

This course presents an overview of the basic concepts of pharmacology and drug design. The first set of lectures and conferences (15-20 hrs) deals with principles of pharmacology relevant to all drugs including absorption, distribution, metabolism, excretion, pharmacokinetics, pharmacodynamics and targets of drug action. The second part of the course will integrate the lectures of the medical school pharmacology course on cardiovascular and renal drugs with discussion forums and web-based problem sets.

Goals and objectives: This course is designed to teach graduate students the principles underlying the interactions between drugs, toxins, hormones, and transmitters and living organisms, including: 1) principles of pharmacodynamics and 2) principles of pharmacokinetics such as: absorption, distribution, excretion, elimination and iotransformation, with special emphasis on metabolism by cytochromes P450, and 3) how to analyze the mechanism of action of a drug based on the target.

Format: A combination of didactic lectures and group-based discussions will be used. Every unit of concepts will be followed by a 2-hour discussion session. The purpose of this discussion session will be to integrate the concepts discussed in class. Every discussion session will have two components: a) a clinical research paper or a case study and b) a basic science paper or a problem set.

Evaluation: Discussion forum: The papers and questions will be posted in WebEd a week prior to the discussion session and the students will be asked to post their answers by the day before the session. Take-home exam papers will be presented by the student in the discussion session.

MPH0110   Pharmacoeconomics

Course Director: Renee J.G. Arnold, Pharm.D.
Term: Spring 1   3 credits

How important is cost in health policy decisions? In the current healthcare environment in the US, there is rationing of healthcare, often not on an objective basis. Authorities in many countries are using cost-effectiveness analyses (CEA) to make reimbursement decisions and cost of treatments and diagnostics (e.g., mammograms) are being hotly debated. How are these analyses being done? Learn the principles of CEA, get hands-on experience and tutorials with software often used for these types of evaluations, hear a key pharmaceutical company researcher discuss his challenges in use of CEA in emerging markets/third-world countries, see user-friendly computer programs that have been developed based on these analyses and debate the use of CEA in making life-or-death reimbursement decisions. This introductory course focuses on the major concepts and principles of pharmacoeconomics, with particular emphasis on modeling, methodologies and data sources. Students will learn about the international use of pharmacoeconomics in drug approval, regulation and pricing. Examples of pharmacoeconomic models used by the pharmaceutical industry and in government will illustrate the theoretical lessons.

BSR2104   Introduction to Computer Modeling & Macromolecules

Course Director: Mihaly Mezei, Ph.D.
Term: Spring 1-Spring 2   3 credits

The course introduces the students to the state of the art molecular modeling tools by working through the tutorial exercises of several different commercially available molecular modeling packages (Insight from Molecular Simulation, Sybyl from Tripos), academic software (Grasp from Columbia University and VMD from University of Illinois at Urbana-Champaign). The tutorials were developed either by their vendors to be accessed on-line (Insight and Sybyl), described in the user guides (VMD) or produced locally (Grasp). Students are expected to work through these tutorials, make appropriate notes and become sufficiently familiar with them to be able to carry out an independent project that will be assigned by the Instructor. This, of course

might require the use of the 'regular' part of the manual, help facilities, and consultations with other users. An additional component is the use of Web resources (e.g., the Protein Data Bank).

The course involves weekly scheduled meeting where both technical problems (possible program bugs) and problems relating to the underlying theory are discussed. Near the end of the course each student is given an assignment. At the end of the course a report is requested that contains a critical evaluation of the modeling softwares learned and the description of the work on the assignment together with the Results and Conclusions.

The modeling functions that will be acquired through the course include the following:

- Creation of various molecules on the screen.
- Manipulation of molecules: Color, label, measures of geometrical parameters, display of surfaces.
- Energy minimization of structures.
- Comparison of structures.
- Docking of molecules.
- Creation of biopolymers (polypetides and nucleic acids).
- Manipulation and visualization of biopolymers:
    o coloring by residue
    o subunit
    o ribbon diagrams
    o surfaces

Students will have to have an account on the Silicon Graphics systems that has an on-line hypertext (HTML) copy of the Facility Guide of the Molecular Modeling Core that describes the various computers of the Core and their modes of utilization, including available software. There is also an on-line document that contains a brief introduction to Unix that will enable you to keep your account in order.

This course is based on state-of-the-art approaches and resources and hence is in a permanent state of development. Student and user feedback are expected in order to assess the adequacy of the tutorial material and to be able to recognize and respond to the need for additional sources of information.

MSN610   Pharmacology

Course Director: Joseph Goldfarb, Ph.D.
Term: Fall   3 credits

The pharmacology course presents an overview of the general principles governing the actions of drugs on the human body and on invading organisms, as well as the way drugs enter, are distributed in, and eliminated from the body. The therapeutic and adverse actions of major classes of clinically used drugs are discussed. The course goal is not to teach therapeutics per se, but the pharmacological basis for rational drug prescribing. Clinical case presentations and problem-solving sessions are conducted in intermediate to large group formats by basic science and clinical faculty.

Enrollment requires prior permission from the Course Director.

Clinical Trials Research

CLR1020   **Advanced Topics in Clinical Trials Research**

Course Director: Janice L. Gabrilove, M.D.
Term: Spring 2   3 credits

This course will cover advanced topics related to the conduct of interventional & therapeutic clinical studies. Topics to be included are: consort statement and design in clinical trials; intent to treat analyses; Cochrane analyses and systematic reviews; available data analyses; non-inferiority trials; equivalence trials; novel Phase I deigns; optimum biologic dose & Phase Ib design; Integrative Phase I/II trials; alternative to standard Phase I/II and Phase II design; health related quality of life instruments in clinical research; and censored data.

CLR1010   **Clinical Trials Management**

Course Director: Janice Gabrilove, M.D.
Term: Fall   3 credits

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.

Translational Science

BSR5501   **Seminars in Immunology**

Course Director: Julie Magarian Blander, Ph.D.
Term: Fall, Spring 1, Spring 2   1 credit

This course combines two seminar series hosted by the Immunology Institute at Mount Sinai.

The first series features a monthly seminar given by an invited speaker who is a prominent scientist in immunology. Students are expected to familiarize themselves with the speaker's research areas. Students are expected to attend a luncheon with the speaker which provides them with an opportunity to meet with the speaker and ask questions or engage in discussions.

The second series is a weekly work-in-progress seminar presented by students and post-docs on their research. Students will be required to present in this seminar series starting in their 3rd year.

Attendance in both seminar series is required.

Detailed schedules are posted online at the Immunology Institute Website.

BSR6501   **Advanced Molecular & Cellular Immunobiology**

Course Director: Huabao Xiong, M.D., Ph.D.
Term: Fall   1-3 credits
3 modules: can be taken as single module

The advanced topics course highlights specific areas in immunobiology for in depth study. This is organized as a series of interactive seminars where students are given current papers to read, present and discuss in a focused fashion. Students will gain an appreciation of current areas of active research and can extrapolate these to concepts in general immunobiology.

Pre-requisite: Immunology

BSR2103   **Course in Mathematics & Computations for Scientists**

Course Director: Lawrence Sirovich, Ph.D.
Term: Fall   3 credits

The courses objective is to present a broad and extensive mathematical background for scientists, and prospective scientists, having limited background in mathematics or a desire to brush up. Although only elementary skills will be assumed, i.e., the course will be self contained, aptitude and dedication will be necessary for success in this course. Lectures will make use of intuitive concepts, a geometrical perspective and the basic commonsense of mathematics. Thus convincing arguments will replace mathematical rigor and as a result a relatively large range of advanced topics will be covered. Topics will include: Calculus & Advanced Calculus; Differential Equations; Linear Algebra; Data Analysis; Modeling; Complex and Fourier Analysis; Probability & Statistics; Stochastic Modeling; Dynamical Systems; Dimension Reduction; Applications to Biochemical Systems.

Grades and course credit will be based on computational homework that will be assigned. An effort will be made to hold a computational lab for Sinai participants at Sinai. Prospective students should meet with Professor Sirovich to discuss whether the course will meet their needs (Contact Ellen Paley at 212-241-3948 or ellen.paley@mssm.edu). The course will be given at the Courant Institute of NYU and students should enroll by first contacting the Graduate School registrar (Nelson Pe).

BSR6202   **Advanced Topics in Tumor Biology**

Course Directors: Matthew J. O'Connell, Ph.D. and Qin Yu, Ph.D.
Term: Fall   1-3 credits

Advanced Topics in Tumor Biology is a three module course in which students may take one, two, or all three modules for credit. Each module is a credit course consisting of journal article-based student presentations in particular topics that are relevant to tumor biology. The focus will be on areas of specifically related to tumorigenesis. This is a semester long course, lasting 15 weeks.

Module I: Tumorigenesis, Invasion and Metastasis - Qin Yu, Ph.D.

Module II: Diagnosis and Treatment of Breast Cancer - Doris Germain, Ph.D.

Module III: Designer Drugs in Cancer Chemotherapy - Matthew J. O'Connell, Ph.D.

Pre-requisite: BSR Core II or equivalent

BSR1301   **Advanced Topics in Developmental and Stem Cell Biology**
BSR1302
BSR1303

Course Director: Robert S. Krauss, Ph.D.
Term: Spring 1-Spring 2   1-3 credits

Advanced Topics in Developmental and Cell Biology I is a 3-module course that represents the Core III for the Developmental and Stem Cell Biology MTA. Many topics of interest here have previously been covered in the Advanced Topics in MCBDS course.

BSR1301: Module I (done with GGS): Epigenetics and Chromosomes - Peter E. Warburton, Ph.D. and Martin J. Walsh, Ph.D.

This course will present recent publications regarding the epigenetics of chromosome and chromatin structure and function. This will include discussion of chromosome segregation, considering the centromere specific histone H3 variant CENP-A and the role of heterochromatin in centromere function and chromosome cohesion. Topics will also include histone covalent modifications and possible roles in embryonic and pluripotent stem cell differentiation and the impact on gene regulation and transcription. Specific topics will focus on the genomic control of chromatin architecture and modification by master developmental regulators such as Polycomb, Trithorax, etc. in specifying cell lineages using recent epigenetic methodologies.

BSR1302: Module II: Reprogramming and Cardiac Regeneration - Xiajun (John) Li, Ph.D. and Chenleng Cai, Ph.D.

Reprogramming and regenerative biology have become important areas of modern biology. Indeed, cell-replacement therapies hold great potential for various human diseases, including cardiovascular diseases. This module will give an overview of evolving concepts and technologies in reprogramming and regeneration. It will start with the classical papers on reprogramming involving nuclear transfer, nuclear cloning and induced pluripotent stem cells. Then it will focus on cardiac development and regeneration that has potential for broad therapeutic applications. Following an introductory class on cardiac development and congenital heart diseases, the key signaling pathways, transcription factors and microRNAs involved in cardiac differentiation and lineage development will be surveyed. Last, recent advances in cardiac repair and regeneration will be discussed.

BSR1303: Module III (done with CAB): Stem Cells in Cancer and Development - Kateri Moore, D.V.M., Robert S. Krauss, Ph.D. and Matthew J. O'Connell, Ph.D.

Pre-requisite: BSR Core II or equivalent

BSR4501   Journal Club in Immunobiology

Course Directors: Patricia Q. Cortes, Ph.D. and Adrian T. Ting, Ph.D.
Term: Fall, Spring 1, Spring 2   1 credit

This course follows an intensive small group discussion format that critically evaluates original research articles in the area of immunology. The articles are selected by the presiding faculty member, and include recent important advances in immunology or investigations that provide conceptual advances relating to long-standing problems. The analysis will include background to the research, the hypothesis tested, the experimental methods used, as well as interpretation and discussion of results. This is a discussion class and participation is required. Students are also expected to discuss the implications of the research, the new questions it raises, and how it relates to the rest of the field. Grading will be based on class participation and extent of preparation. This class is required for students beginning in their second year until they successfully pass their thesis proposal exam. First year students interested in immunology are encouraged to attend. Attendance is required for all classes.

BSR4301   Journal Club in Developmental and Stem Cell Biology

Course Director: Michael Rendl, M.D.
Term: Fall, Spring 1, Spring 2   1 credit

Presentations of papers from the primary literature by students; each student to present at least once per year.

BSR4801   Journal Club in Pharmacological Sciences
Course Directors: Maria A. Diverse-Pierluissi, Ph.D. and Eric A. Sobie, Ph.D.
Term: Fall, Spring 1, Spring 2   1 credit

The Pharmacology Journal Club is a part of the Integrated Training Program in Pharmacological Sciences. The club meets biweekly with papers presented by the graduate students who also discuss their own work. The setting is informal and lunch is provided. Each paper is chosen by the presenting student and usually reflects some aspect of pharmacology/therapeutics in a broad sense. Topics discussed over the past year include general studies on signaling/development to biofilms, opioid receptor trafficking, and therapeutic approaches to HIV. The papers are distributed as PDF files by e-mail a few days before the meeting.

BSR2002   Translating Science
Course Director: Ross L. Cagan, Ph.D.
Term: Spring 1   2 credits

Translating Science is a one semester, two credit course that focuses on the thinking behind clinical and translational aspects of biology. It is required of students in the CAB, DCSB, GGS, IMM, MIC and SMD MTAs and is designed to complement the Spring 2 semester of Biomedical Sciences. Grading is attendance plus two essays on topics chosen by the course directors.

Thesis, Independent Study & Elective

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.

CLR0020   **Doctoral Thesis in Clinical Research**   Variable credits

Student should register for Doctoral Thesis credits according to their track course sequence.

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.

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.

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.
www.mssm.edu/clred

For general information about the Mount Sinai Medical Center and Mount Sinai School of Medicine, please enter the following link into your browser.
(For MSMC) http://www.mountsinai.org/
(For MSSM) http://www.mountsinai.org/Education/School%20of%20Medicine

To contact the program directly, please reach out to:

Program Leadership

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Professor of Medicine & Oncological Sciences
Director, Clinical Research Education Program
Co-Director, PORTAL Program (5 year M.D./MSCR)
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Professor Medicine, Clinical Immunology
Professor, Immunology Institute
Director, PORTAL Program (5 year M.D./MSCR)
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Email: fatima.nabizada-pace@mssm.edu

Christine Acevedo
Administrative Assistant
212-824-7014
Email: christine.acevedo@mssm.edu

Additional Resources (continued)

Admissions Office

212-241-6696 or admissions@mssm.edu

Registrar Office

Nelson Pe
212-241-6691
Email: nelson.pe@mssm.edu

Financial Aid

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

Dale Fuller
Office of Student Financial Aid
Tel: (212) 241-5245
E-mail: 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://www.mssm.edu/about-us/services-and-resources/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).

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