CLINICAL RESEARCH EDUCATION PROGRAM
(CRTP, MSCR, Ph.D.)

CURRICULUM GUIDE

ACADEMIC YEAR 2009-2010
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 (MSCR) and Ph.D. in Clinical Research

Lawrence Kleinman, M.D., M.P.H.
Co-Director, Masters of Science and Ph.D. in Clinical Research
Director, The K12 Program
The Clinical/Translational Research Training Programs of The Mount Sinai Graduate School of Biological Sciences are designed to foster the development of future leaders in patient oriented research. These training opportunities are intended to encourage the development of critical thinking necessary to conduct innovative hypothesis driven, independent and collaborative clinical/translational scientific research, in an effort to improve patient care and the wellbeing of society. In particular, we hope to enhance the research opportunities of clinical scientists as well as enhance the ability of basic scientists to better position themselves to translate the promise of their respective discoveries into the clinical arena, in a meaningful way with significant impact.

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

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

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.

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

1) Translational Research: Bench to Bedside
2) Therapeutic and Clinical Trials Research
3) Population, Outcomes and Implementation Research
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 Mount Sinai School of Medicine, Graduate School of Biological 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), 2009-2010**

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<tr>
<th>Term</th>
<th>Course Number</th>
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<tbody>
<tr>
<td>Fall</td>
<td>MPH0300</td>
<td>Introduction to Biostatistics</td>
<td>3</td>
</tr>
<tr>
<td>Fall</td>
<td>CLR0004</td>
<td>Designing Clinical &amp; Public Health Research</td>
<td>2</td>
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<tr>
<td>Fall</td>
<td>CLR0700</td>
<td>Professionalism and Ethical Issues in Clinical Research</td>
<td>2</td>
</tr>
<tr>
<td>Fall</td>
<td>CLR0005</td>
<td>Spectrum of Measurements in Clinical &amp; Translational Research: Qualitative and Quantitative Methods</td>
<td>2</td>
</tr>
<tr>
<td>Winter</td>
<td>MPH0311</td>
<td>Multivariable Methods</td>
<td>3</td>
</tr>
<tr>
<td>Winter</td>
<td>MPH0400</td>
<td>Introduction to Epidemiology</td>
<td>3</td>
</tr>
<tr>
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<td>CLR0005</td>
<td>Spectrum of Measurements in Clinical &amp; Translational Research: Qualitative and Quantitative Methods</td>
<td>2</td>
</tr>
<tr>
<td>Spring</td>
<td>MPH0623</td>
<td>Applied Analysis of Epidemiologic and Outcomes Research Data</td>
<td>2</td>
</tr>
<tr>
<td>Spring</td>
<td>CLR0500</td>
<td>Principle Topics in Medical Informatics</td>
<td>3</td>
</tr>
<tr>
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<td>Spectrum of Measurements in Clinical &amp; Translational Research: Qualitative and Quantitative Methods</td>
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**Total Required Credits** 24
## Course Sequence: Masters of Science in Clinical Research (MSCR), 2009-2010

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<tr>
<td>Fall, Winter, Spring-Yr 2</td>
<td>CLR0010</td>
<td>Clinical &amp; Translational Research Seminar Series (Full Year Course)</td>
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<tr>
<td>Fall, Winter, Spring-Yr 2</td>
<td>CLR0013</td>
<td>Clinical &amp; Translational Research Journal Club (Full Year Course)</td>
<td>1</td>
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<tr>
<td>Fall, Winter, Spring-Yr 2</td>
<td>CLR0001</td>
<td>Clinical Research Masters Thesis Design and Conduct¹</td>
<td>5-10</td>
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<tr>
<td>Winter-Yr 2</td>
<td>CLR0011</td>
<td>Grant Writing</td>
<td>1</td>
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**Electives² Specific to the Concentration/Focus** 0-5

**Total Required Credits (Years 1 & 2 less Thesis & Electives)** 28

**Total Credits (5 Thesis & 5 Elective Credits)** 38

**Total Credits (10 Thesis & 0 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 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.
Course Sequence: Ph.D. in Clinical Research, 2009-2010

A total of 54 credits of required coursework and 12 credits of electives is needed to matriculate in the Ph.D. for clinical Research. The required coursework is outlined below:

### Year 1

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<td>Fall, Winter, Spring</td>
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<td>1</td>
</tr>
<tr>
<td>Winter</td>
<td>CLR0011</td>
<td>Grant Writing</td>
<td>1</td>
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</tbody>
</table>

**Total Required Credits (Year 1)** 29

In their first year, students must be enrolled in a Research Practicum course, one credit per term for a total of 3 credits. By the end of their first year, candidates must also pass a qualifying examination.
### Year 2

<table>
<thead>
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</thead>
<tbody>
<tr>
<td>Fall</td>
<td>CLR0312</td>
<td>Applied Biostatistics in Translational &amp; Clinical Research</td>
<td>4</td>
</tr>
<tr>
<td>Fall</td>
<td>CLR0012</td>
<td>Clinical Research Protocol Development Presentation and Publication</td>
<td>4</td>
</tr>
<tr>
<td>Winter</td>
<td>CLR0901</td>
<td>The Drug Development Process</td>
<td>3</td>
</tr>
<tr>
<td>Winter</td>
<td>CLR0021</td>
<td>Data &amp; Data Management</td>
<td>3</td>
</tr>
<tr>
<td>Spring</td>
<td>CLR0207</td>
<td>Culture, Illness &amp; Community Health</td>
<td>3</td>
</tr>
<tr>
<td>Fall, Winter &amp; Spring</td>
<td>CLR0010</td>
<td>Clinical &amp; Translational Research Seminar Series (Full Year Course)</td>
<td>2</td>
</tr>
<tr>
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<td>CLR0013</td>
<td>Clinical &amp; Translational Research Journal Club (Full Year Course)</td>
<td>1</td>
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**Total Required Credits (Year 2)** 20

By the end of their second year, candidates must also submit and defend their Thesis proposal.

Candidates are required to continue to participate in the Clinical and Translational Research Seminar Series in their third year onwards and will receive 1 credit per term. Candidates may begin their Dissertation Research in their second year.

16 credits of elective coursework is needed in order to matriculate into the Ph.D. in Clinical Research, in addition to the successful submission and completion of a dissertation, reflective of your clinical investigative work completed. These electives can be chosen from an array of courses within the larger graduate school offerings. 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:

<table>
<thead>
<tr>
<th>Research Focus</th>
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</thead>
<tbody>
<tr>
<td>00 General Clinical Research</td>
<td>10</td>
</tr>
<tr>
<td>01 Health Services Research &amp; Health Policy Research</td>
<td>16</td>
</tr>
<tr>
<td>02 Behavioral Research &amp; Cognitive Tools</td>
<td>18</td>
</tr>
<tr>
<td>03 Biostatistics: Quantitative and Qualitative methods</td>
<td>20</td>
</tr>
<tr>
<td>04 Epidemiology: Basic, Molecular and Clinical</td>
<td>23</td>
</tr>
<tr>
<td>05 Informatics &amp; Bioinformatics</td>
<td>24</td>
</tr>
<tr>
<td>06 Outcomes Research</td>
<td>26</td>
</tr>
<tr>
<td>07 Ethics</td>
<td>28</td>
</tr>
<tr>
<td>08 Genomics &amp; Personalized Medicine</td>
<td>31</td>
</tr>
<tr>
<td>09 Drug Development</td>
<td>33</td>
</tr>
<tr>
<td>10 Clinical Trials Research</td>
<td>36</td>
</tr>
<tr>
<td>11 Translational Science</td>
<td>37</td>
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</tbody>
</table>

The third number denotes the level:

- 0 Introduction
- 1 Intermediate
- 2 Advance

The fourth is a number for the course itself.
# General Clinical Research

**CLR0004 Designing Clinical & Public Health Research**

Course Directors: Henry Sacks, M.D., Ph.D. and Albert Siu, M.D., M.S. Ph.D.

Required course for CRTP, MSCR & Ph.D.

Term: Fall  

2 credits

The goal of this course is to teach students to identify the strengths and weaknesses of various study designs, contrast and compare research methodologies relevant to various clinical research questions, and select & employ appropriate research study methods for clinical research, including prospective and retrospective study designs, cohort, case-control, clinical trials, studies of diagnostic tests, secondary data analysis, decision analysis, cost-effectiveness analysis, and meta-analysis.

In addition, students will learn to design a clinical research protocol for an identified clinical question: develop a research question; select study subjects and variables; develop hypotheses; determine sample size; demonstrate familiarity with essentials of grant writing; and, identify methods to obtain funding.

**CLR0005 New Spectrum of Measurements in Clinical & Translational Research: Qualitative and Quantitative Methods**

Course Directors: Lawrence Kleinman, M.D., M.P.H., Janice L. Gabrilove, M.D. and George A. Diaz, M.D., Ph.D.

Required course for CRTP, MSCR & Ph.D.

Term: Fall, Winter & Spring  

6 credits

This course provides a survey of quantitative and qualitative methodology currently utilized in cutting edge clinical/translational research. The course will review the application of established and emerging molecular, cellular and genomic methodology of relevance to the study of disease pathogenesis, diagnosis and intervention through to approaches employed to assess interventions of utility for populations at large in the community. This course will also utilize case based studies of translational & clinical research, derived from key examples in the published literature that best exemplify appropriate and inappropriate use of a specific methodology to answer a focused clinical/translational research question.

**MPH0003 Current Topics in Clinical Preventive Medicine**

Course Directors: Richard A. Bordowitz, M.D., Elizabeth J. Garland, M.D., M.S. and Emily Senay, M.D., M.P.H.

Term: Every other Spring  

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

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.
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.

CLR0010  Clinical and Translational Research Seminar Series

Course Directors: Lawrence Kleinman, M.D., M.P.H., Janice L. Gabrilove, M.D. and Mark
Woodward, Ph.D.
Required course for MSCR & Ph.D.
Term: Fall, Winter & Spring
This series will include presentations by trainees & faculty, covering ongoing clinical research projects (formerly known as “Works in Progress: WIP” seminar series) 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; career options in clinical research; entrepreneurship; IND & NDA applications; Patents; and funding.

CLR0021 New Data & Data Management
Course Director: TBD
Required course for Ph.D.
Term: Winter 3 credits
This course will focus on database management systems for clinical research including strategies for data management, and systems to hold patient contact information, exam schedules, reimbursement records, etc. Use of systems to analyze the study data or to format the data for export to a statistical analysis package also will be covered. At the conclusion of this course, students will
- Understand the basics of developing a small, multi-table relational database for a research study
- Be capable of planning (and budgeting for) data management in a research study

This will be hands on laboratory based course with students actively participating by creating their own management systems and analyzing data sets. Each week will begin with a didactic one hour session followed by a two hour small group or workshop activity. Topics to be covered include: roles and responsibilities of a principal investigator: research records; data coding systems and data entry; creating forms; database management systems (DBMS) for clinical Research; creating tables and relationships; quality assurance and audits; budgeting for data management in a clinical research study. Database and data analysis workshops will also be held.

CLR0011 Grant Writing
Course Director: David Vlahov, Ph.D.
Required course for MSCR & Ph.D.
Term: Winter 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 RO1, R03, R21) and mentored career-development awards (e.g., K12, K23) will be covered. Features of successful research grant applications will be presented and a description of the grant review process will be covered. The course also will cover the development of writing skills for publication and competitive grants, and explore principles of research strategy in the context of
requirements of funding agencies. Effective scientific communication and writing skills are reviewed, institutional routing, and discussion of the NIH grant review process will be covered. Among the assignments are:

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

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

CLR0012 New Clinical Research Protocol Development Presentation and Publication
Course Director: TBD
Required course for Ph.D.
Term: Fall 4 credits

In this course, students will receive initial instructions on the development of a clinical study protocol including completion of a study background and justification as well as defining inclusion and exclusion criteria. In addition, this course will focus on the preparation of oral and poster presentations of ongoing research as well as manuscripts for peer review publications. Topics will include use of electronic editing tools, flow, preparing a sufficient biostatistics section, creation of effective abstracts, etc. Workshop sessions focused on how to respond to peer reviews will utilize actual examples from faculty submissions. Students also will receive instruction in effective creation of posters and have the opportunity to make presentations that will be critiqued by the faculty.

CLR0013 Clinical and Translational Research Journal Club
Course Director: Lawrence Kleinman, M.D., M.P.H., Janice L. Gabrilove, M.D. and Mark Woodward, Ph.D.
Required course for MSCR (yr 2) & Ph.D. (1-4)
Term: Fall, Winter & Spring 1 credit

The seminar series will meet each week and will alternate each week to include: 1) a Works in Progress Series that will provide an overview of the clinical research activities of the faculty and advanced students, and will be focused to reinforce relevant issues being discussed in other didactic courses; 2) a Journal Club that will provide foundation skills for critically reading and evaluating a clinical research article and in which students will be assigned an article to evaluate and present, which will emphasize an understanding of basic epidemiologic research design and biostatistical concepts; 3) an ethics seminar series that will meet monthly and include presentations of clinical research ethics issues by students as they are encountered in their own studies as well as case presentations by faculty. Students will actively participate in the series.
and be responsible for preparing their cases for discussion.; and 4) a seminar series of speakers, both from within the institution and invited from outside, who will cover a range of topics relevant to clinical research.

**MPH0001 Introduction to Public Health**

Course Directors: Philip J. Landrigan, M.D., M.Sc. and Leonardo Trasande, M.D., M.P.P.
Term: Fall 2 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 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.

**MPH0012 Flood, Pestilence & Plague: Communicating Complex Emergencies**

Course Director: Christina Zarcadoolas, Ph.D.
Term: Every other Fall 3 credits

The terrorist attacks of September 11, 2001, Hurricane Katrina and the ongoing concern about pandemics of avian and swine flu can be used to demonstrate both weaknesses and strengths in the public health system in the United States. Much criticism points beyond infrastructure problems and toward communications problems – e.g. federal, state and local officials’ inadequacies in communicating with each other and the general public. Many have become more convinced that surviving a serious, complex emergency involves pre-planning, and effective situational response. Both demand clear communication with the public. Aside from sporadic directions to the public concerning a wide range of potential hazards, there has been no focused effort to advance the general public’s abilities to attend to, understand and act on risk communication, disaster preparedness information and emergency decision-making. Internationally, where man-made and natural disasters coupled with political and social strife
have been more ubiquitous, “complex emergencies” demand responses mindful of a broad range of socio-political-economic factors. This course will use a case study approach to investigate the strengths and weaknesses of current emergency and disaster preparedness approaches in the United States.

**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: Introduction to Epidemiology
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: Gary Rosenberg, Ph.D.
Term: Spring  3 credits
Health care leaders and policy makers seek to maximize the promise and minimize the problems associated with providing health services to all Americans. In order to achieve this goal, it is necessary to become familiar with the health care industry, the social, political and economic forces that shape current policy and organizational practices. This course is designed to meet that end.

We do this by examining how the crisis of health care costs have shaped the response to those who finance the delivery of care, those who provide the services, and those who seek care. A major focus of the class is on understanding the public health system, community-based care, community assessment and the development of market-based managed care as an alternative to government-sponsored health care reform. These responses will be judged against the competing and sometimes conflicting goals of access, quality and efficiency of care.

You should come away from this class with a broad understanding of how and why the health care system operates in the way that it does and where you will be positioned as future leaders and policy makers of this system.

MPH0105  Health Economics and Policy Implications
Course Directors: Leonardo Trasande, M.D., M.P.P. and Melissa D.A. Carlson, Ph.D., M.B.A.
Term: Winter  3 credits
Economics provides the tools to illustrate and analyze the costs of making alternate choices, offering an opportunity to more fully understand the decision-making process. Using an established set of criteria to evaluate the use of scarce resources, economists attempt to explain and predict outcomes. The study of economics as it relates to the healthcare industry is different from basic economics because individuals do not have complete knowledge of their healthcare needs and treatment options. As patients, consumers must rely upon healthcare professionals, who, in turn, are confronted with a myriad of challenges as the management and treatment of disease is not without its uncertainties. This course will discuss the role and importance of economics in the micro- and macro-context faced by healthcare professionals and the industry-at-large.

MPH0120  Complex Healthcare Problems
Course Director: Jonathan M. Metsch, D.P.H.
Term: Winter  3 credits
Health care administration, planning and program development, in various clinical settings (e.g., hospital, health department, home care agency, community health center, long term care facility) is complicated: the process is disorderly, never sequential; it typically involves multiple disciplines trained in different problem solving strategies; is colored by political considerations
which are usually not clearly articulated; frequently moves very quickly. Therefore, the Management Leadership Team is constantly facing Complex Problems.

Complex Problems are predicaments where the decision-maker(s) must integrate or reconcile at least two competing priorities that may not be complementary. Complex problems fall into several categories including having to reach agreement on goals while simultaneously evaluating options; where goals are clear but political support is not; where the definition of the problem keeps changing and consensus has to constantly be reestablished; and where there are so many variables it is difficult to determine actual possible outcomes.

Case material used to explore Complex Problems is based on actual situations faced by Dr. Metsch as a hospital system CEO for seventeen years. Cases focus on, e.g., integrated healthcare delivery systems; clinical program development; regionalization of health care services; the collapse of Medicaid and the implosion of safety-net providers; the mythology of quality assurance and evidence-based medicine; how health care policy is really made "Under-the-Radar; getting a "Seat at the (Public Policy) Table," and strategic planning for small not-for-profit health agencies.

Building on the powerful concept of Evidenced Based Medicine, case solutions are developed using a robust, multi-disciplinary, integrative notion of Evidenced Based management decision-making.
**Behavioral Research & Cognitive Tools**

**CLR0207 Culture, Illness & Community Health**

Course Directors: Gary C. Butts, M.D., Mary Foley, M.S., Ed.D. and Edward Poliandro, Ph.D.

Required course for Ph.D.

Term: Spring 3 credits

Culture is defined as the integrated pattern of human behavior that includes thoughts, communications, actions, customs, beliefs, values and institutions of a racial, ethnic, religious or social group. Using various methods such as case presentations, small group discussions, and collaborative, introspective and self-directed learning experiences, participants will enhance their appreciation of culture as a predominant force in shaping behavior, values and systems that effect health. Through this course, participants will also enhance their competencies necessary to provide effective health care and to conduct research with diverse patients and communities.

**MPH0201 Introduction to Socio-Behavioral Health**

Course Directors: Mary Foley, M.S., Ed.D. and Michael A. Diefenbach, Ph.D.

Term: Winter 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.

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

Course Director: Matthew Shapiro, Ph.D.

Term: Spring 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.
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.
Required course for CRTP, MSCR & 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 the 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.

MPH0311  Multivariable Methods

Course Director: John T. Doucette, Ph.D.
Required course for CRTP, MSCR & Ph.D.
Term: Winter 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: Introduction to Biostatistics
Introduction to Epidemiology (may be taken concurrently)
Applied Biostatistics in Translational & Clinical Research

Course Director: Mark Woodward, Ph.D.
Required course for Ph.D.
Term: Fall
4 credits

The biostatistics course for the Ph.D. program will be a section specifically presented for these students. This course will cover the following topic areas: data presentation; numerical summary measures; probability; Bayes’ theorem; screening diagnostic tests; ROC curves; probability distributions; binomial distributions; poisson distribution; normal distribution; sampling distributions; central limit theorem; confidence intervals; student’s t-distribution; hypothesis testing; 1 sided and 2 sided tests; types of error; power; comparison of means; non-parametric methods; survival analysis; life table; Kaplan –Meier; Log-rank test; contingency tables – chi square; McNamar’s test; Odds ratio and relative risk; mantel-haenszel test; correlation; simple linear regression; multiple regression; logistic regression; analysis of variance; multiple comparisons procedure.

Research Methods

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

Research Methods encompasses a set of fundamental skills and tools necessary for approaching the process of developing and answering a research question or being 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. The course is an essential component to understanding how to organize research: helping students to conceptualize, develop, propose, design, and write research papers, in general, and the Thesis, in particular.

This 1 credit course will be graded on a Pass/Fail basis.

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

Applied Biostatistics in Clinical Trials

Course Director: Michael K. Parides, Ph.D.
Elective course for MSCR or Ph.D. in CR; required for students in the MSCR/Ph.D. concentrating on Clinical Trials research.
Term: Winter
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.
Epidemiology: Basic, Molecular and Clinical

MPH0400  Introduction to Epidemiology
Course Director: Stephanie H. Factor, M.D., M.P.H.
Required course for CRTP, MSCR & Ph.D.
Term: Winter 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: Tiffany Harris, Ph.D. and Preeti Pathela, D.P.H.
Term: Spring 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: Introduction to Epidemiology
Introduction to Biostatistics
Informatics & Bioinformatics

CLR0500 Principal Topics in Biomedical Informatics
Course Directors: Peter L. Elkin, M.D. and Brett Trusko, Ph.D.
Required course for CRTP, MSCR & Ph.D.
Term: Spring 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.

CLR0520 New Advanced Topics in Biomedical Informatics
Course Directors: Peter L. Elkin, M.D. and Brett Trusko, Ph.D.
Term: Spring 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-requisites: 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 Interaction 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 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).
Outcomes Research

MPH0621  Seminar in Applied Clinical Epidemiology and Health Services Research

Course Director: Alex D. Federman, M.D.
Term: Full Year Course 2 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:  Introduction to Epidemiology
                 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.
Required course for CRTP, MSCR & Ph.D.
Term: Spring 2 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:  Introduction to Biostatistics
                Multivariable Analysis
MGC1100  Introduction to Interviewing and Counseling Methodology

Course Director: Randi E. Zinberg, M.S.
Term: Spring 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.
Term: Spring 3 credits

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

CLR0700  Professionalism and Ethical Issues in Clinical Research
Course Director: Rosamond Rhodes, Ph.D.
Required course for CRTP, MSCR & Ph.D.  (MSCR) 2 credits  (Ph.D.) 3 credits
Term: Fall
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, 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 New  Ethics and Professionalism II
Course Directors: Rosamond Rhodes, Ph.D. and Kurt Hirschhorn, M.D.
Term: TBD
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.

CLR0711  Medical Ethics
Course Directors: Stefan Baumrin, Ph.D., J.D. and Daniel A. Moros, M.D.
Term: Winter, Spring
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 our 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: Winter, Spring 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 1-3 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.
The discovery that RNA molecules can regulate the expression of genes has been one of 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-requisites: BSR Core I or equivalent

BSR4401 Journal Club in Genetics and Genomic Sciences

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

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 New Drug Development Process**

Course Directors: Janice L. Gabrilove, M.D. and Ming-Ming Zhou, Ph.D.

Required course for Ph.D.

Term: Spring  
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  
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 transformation, 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: Winter 3 credits
This course provides an introduction to 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.

Pre-requisites: Introduction to Public Health
Health Policy & Economics

BSR2104  Introduction to Computer Modeling & Macromolecules
Course Director: Mihaly Mezei, Ph.D.
Term: Spring 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 (polypeptides and nucleic acids).
- Manipulation and visualization of biopolymers:
  - coloring by residue
  - subunit
  - ribbon diagrams
  - 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 New Advanced Topics in Clinical Trials Research

Course Director: Janice L. Gabrilove, M.D.
Term: Spring 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 designs; 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: Rosemarie Gagliardi, Ed.D.
Term: TBD 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 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-requisites: Immunology

BSR2103 Course in Mathematics & Computations for Scientists
Course Director: Lawrence Sirovich, Ph.D.
Term: Fall 3 credits

The course 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-requisites: BSR Core II or equivalent

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

Course Director: Robert S. Krauss, Ph.D.

Term: Spring 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.
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.

Pre-requisites: 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 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, Winter, Spring 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 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.
Thesis, Independent Study & Elective

CLR0001  Masters Thesis  5-10 credits

Students register for their Masters Thesis on or before the Winter Term of their second year while preparing to submit their Thesis.

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

CLR0002  Masters Independent Study  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 six 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 six 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 your Academic Advisor to discuss and plan the Independent Study.
2. Complete the Independent Study Proposal Form.
3. Meet with the Program Director to discuss your Independent Study.
4. Complete the project/course of study once approved.
6. Request that your Faculty Sponsor complete the Independent Study Evaluation Form and submit it to the Program Coordinator.
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.

Elective Approval Form

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/gradschool/mscr/

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

Janice L. Gabrilove, M.D.
Professor of Medicine & Oncological Sciences
Director, Clinical Research Education Program
Co-Director, PORTAL Program (5 year M.D./MSCR)
Email: janice.gabrilove@mssm.edu

Lawrence Kleinman, M.D., M.P.H.
Associate Professor of Health Policy and Pediatrics
Co-Director, Clinical Research Education Program
Co-Director, PORTAL Program (5 year M.D./MSCR)
Email: lawrence.kleinman@mssm.edu

Additional Research Leadership:

Lakshmi A. Devi, Ph.D.
Associate Dean for Academic Enhancement and Mentoring
Professor Pharmacology and Systems Therapeutics
Professor Psychiatry
Email: lakshmi.devi@mssm.edu

Karen Zier, Ph.D.
Associate Dean for Medical Student Research
Professor Medicine, Clinical Immunology
Professor, Immunology Institute
Director, PORTAL Program (5 year M.D./MSCR)
Email: karen.zier@mssm.edu

Administrative Staff

Jennifer Chow
Program Manager
212-824-7322
Email: jennifer.chow@mssm.edu
Additional Resources (continued)

Rose Vallines
Administrative Assistant
212-824-7292
Email: rose.vallines@mssm.edu

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

Housing

Students in the CLR Program are currently not eligible for Mount Sinai Housing.

The Library

The Gustave L. and Janet W. Levy Library is located on the 10th and 11th floors of the Annenberg Building. Entrance and exit are through the passenger elevator lobby on the 11th floor. Mobility impaired persons who wish access to the 10th floor of the Levy Library must make arrangements with the Library Circulation Supervisor (212) 241-7791 (internal ext. 47791).

The Library accommodates over 200 users at tables and carrels and in individual and group study rooms. The Library's extensive online collection includes over 5,000 biomedical periodical titles; thousands of electronic books, including over 600 core health sciences textbooks; and more than 150 electronic databases. The print collection totals over 25,000 textbooks and monographs and more than 500 current journal subscriptions in the fields of biomedicine and health sciences. The Library also houses audiovisual materials, including slides, x-rays, and video and audio cassettes. Computer applications such as Microsoft Office Suite, SPSS, EndNote, Adobe Photoshop and more are available from over 75 Internet enabled workstations throughout the Library. Access to the collection is via online catalog and databases as well as
print indexes. Materials not in the collection can be obtained through the various interlibrary loan cooperatives in which the library participates.

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.

Please refer to the Library Web site, http://www.mssm.edu/library, for extensive information on library programs and services, and for access to online library resources.

**Electronic Mail**

Students should sign up for an e-mail account through the Medical School Computing Help Desk, located in the Levy Library. Mail can be accessed from computers in the Library, the laboratories or from home. E-mail is our primary method of reaching you with important announcements.

The Program Administration will provide information regarding requirements, courses, schedules and any changes, special events, and other relevant information on a regular basis.

Please note Course Directors often communicate with students enrolled in their classes via the WebEd e-mail system. An e-mail sent through this system must be accessed via the WebEd site; this system is separate and distinct from the general mssm.edu e-mail system.

Non-matriculating students are not eligible for mssm.edu e-mail accounts and should provide the Program Administration with an e-mail address at which they can be contacted.
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