NYU GROSSMAN SCHOOL OF MEDICINE
MS in Clinical Investigation
Course Descriptions

A Population Health Equity Approach to Aging and Alzheimer's Disease

This introductory course in special topics in Alzheimer's disease and healthy aging focuses on important issues relevant to conducting research in older adult populations and innovative methods to support best practices in developing, disseminating, and implementing evidence-based strategies for improving health and advancing health equity among older adult communities. Topics include structural competency and social determinants in aging and Alzheimer's disease research; community and patient engagement in diverse older adult populations; use of systems science, implementation science, and group participatory modeling research; and emerging research in reducing multi-morbidity and Alzheimer's disease disparities. The course reviews National Institutes of Health (NIH) guidelines and applies multi-level frameworks to aging and Alzheimer's disease disparities with a focus on social, policy, and behavioral interventions at the community and systems level. This class is intended for students at the graduate level. No prior knowledge about aging and Alzheimer's disease and health disparities is required.

Course Directors: Chau Trinh-Shevrin, DrPH, and Matthew Lee, DrPh, MPH
Credits: 3

Advanced Biostatistical Analysis

Students in this course gain expertise in performing and interpreting multiple regression analysis and applying these methods to their own research data. The course focuses on analytic methods, assumptions, diagnostics, modeling options, tests of significance, and interpretation in multiple linear and logistic regression analysis.

Course Directors: Alan L. Mendelsohn, MD, and Michael G. Tunik, MD
Credits: 3

Advanced Epidemiology

The objective of this course is to develop an understanding of, and familiarity with, epidemiologic concepts and methods. The lecture session presents additional epidemiologic methods and concepts beyond the basic epidemiology, and review relevant statistical methods and their applications in epidemiologic studies. The following lectures are taught: causality, disease frequency, different types of descriptive, observational and experimental study designs, association, bias, confounding, interaction, multivariate analysis, and error measurement. In addition to lectures, lab sessions include data analyses using Statistical Package for the Social Sciences (SPSS) to answer research questions and discussions of methodological issues. The lab session prepares students with practical skills in conducting and analyzing epidemiologic studies.

Course Director: Keng-Yen Huang, MPH, PhD
Credits: 3

Advanced Methods in Observational Data Analysis

This course builds on prior training in introductory biostatistics and epidemiology to extend understanding of core concepts and methods by providing applied training in the conduct of secondary data analysis studies. Using an existing data source, students identify a research question; define a causal model, specific aims, and hypotheses; gain experience in management and conditioning of the data; conduct stratified analyses to assess effect modification and confounding; implement the backward elimination method of model building using logistic regression to obtain multivariable results; and interpret results with respect to the strength and precision of estimates, selection and information bias, and confoundedness, missingness, and generalizability. Students are trained in and use Statistical Analysis System (SAS) or Stata for all data cleaning, conditioning, and analysis. In addition, advanced topics in statistics, such as the use of propensity scores to address confounding and use of mixed models for clustered data, are introduced.

Couse Director: Joy D. Scheidell, MPH, PhD
Credits: 3

Analytic Techniques for Healthcare Delivery Science

This course provides students with an introduction to quantitative and qualitative analytical techniques most often used in healthcare delivery science (HDS). By the end of the course, participants have a clear understanding of the role these methods can play in HDS research, an understanding of a variety of approaches to collection and analysis of both quantitative and qualitative data, and their application to research questions of varying kinds and stages in a project. Lectures provide a foundation of knowledge on each concept supported by supplementary readings and a study design plan incorporating both quantitative and qualitative components. The course features exposure to a variety of real-world projects both research and operational that incorporate these analytic techniques. Emphasis is placed on mixing methods (such as how to effectively, efficiently incorporate both quantitative and qualitative data into collection and reporting), and thinking critically about approaching data collection and analysis in challenging real-word healthcare environments.

Course Directors: Simon A. Jones, PhD, and Allison P. Squires, PhD
Credits: 3

Biomolecular Medicine

The goal of this course is to familiarize students with a broad array of current technologies that may be useful in answering their scientific questions. Students are also introduced to faculty members who may be able to assist them in advancing their projects. For those students whose projects do not require use of such technologies, the course strives to improve their ability to understand the background science and literature pertinent to their scientific interest.

Course Director: Vinh P. Pham, MD, PhD
Credits: 3

Biotechnology Industry, Structure, and Strategy

Biotechnology started as a science, referring to the use of living cells as factories to produce proteins through the manipulation of genes. Today, biotechnology refers to an industry, with the top companies in the sector exceeding some of the major pharmaceutical companies in market capitalization.

No longer are biotechnology companies confined to using recombinant DNA technology alone. The moniker is assigned today to any small company engaged in any life sciences–related research directed toward developing a commercial product, using any scientific means.

Belonging to the sector usually also implies a culture—small, nimble, and visionary; practical and cash-constrained but willing to risk it all. Although some of these characteristics are more idealized than realized, it is certainly the case that even though the key factors for success in a development-stage company include the same scientific, analytic, and managerial talents that exist in "big pharma," the context is different. Biotechnology companies must incorporate some additional skills to ensure survival and nontraditional systems to support success.

Course Director: Jay D. Kranzler, MD, PhD
Credits: 3

Clinical Research Methods

This course provides an overview and in-depth introduction to principles of clinical research, utilizing reading, protocol development, problem sets, and seminars. Brief mini-lectures to review concepts are followed by in-depth discussions built on assigned reading and exercises. Each student develops a research protocol following in an iterative process in which practical feedback is received in individual and small group protocol review sessions. By the end of the course, students write and present a research protocol that describes in detail the aims, background, and study plan for an investigation to address the question formulated by the student.

Course Director: Mark D. Schwartz, MD
Credits: 3

Clinical Trials Design

This course reviews the design, development, implementation, and analysis of clinical trials. The course provides students with the ability to reconsider and present their own research in terms of development as randomized therapeutic or observational trials by reviewing core ethical and design principles including sample size calculation, outcome measure selection, and data collection. Students also present research

articles in a journal club format in order critically evaluate published research for sound trial design. Furthermore, experts in various areas of clinical research discuss their own work and key information regarding trial interpretation.

Course Director: Amit Saxena, MD
Credits: 3

Drug Development in a New Era

Bringing a new chemical entity, drug, or device to the consumer market is a necessary but intricate, expensive, complicated, and time-consuming process. There are different avenues of drug discovery and product development (for example, industry vs. academic), and many aspects of development focus on satisfaction of regulatory requirements mandated by the U.S. Food and Drug Administration (FDA) and other regulatory agencies. The FDA's Center for Drug Evaluation and Research (CDER) asserts that their mission is "to promote and protect public health by ensuring that safe and effective drugs are available to Americans." As such, preclinical, pharmacokinetic, pharmacodynamics, stability, and toxicity trials, as well as clinical trials (I through IV) and post-marketing surveillance are elements that are important for researchers (and those who propose to gain expertise in the basic and environmental health sciences) to understand as prerequisites for U.S. and global market approval. Furthermore, protocol planning, safety monitoring, and data and cost analysis are essential parts of this interdependent and collaborative process involving individuals from a diverse range of disciplines, including basic and clinical sciences, statistics, management, legal, and marketing departments.

As we enter a new decade of discovery, it is essential that translational researchers, medical, biological, and basic scientists have a prerequisite understanding of the process of drug and device development. Core tenets involve integration of resources within the global economy and public health domain. This course provides an overview of this innovative, multidisciplinary process.

To ensure that an interesting and broad range of topics are covered, invited lecturers are from the academic and private sectors and comprise physicians and non-medical professionals. Presentations range in content from bench discoveries to marketing strategies and run for 90 minutes, followed by a 30-minute discussion period.

Course Director: Gabrielle Gold-von Simson, MD
Credits: 3

Economic Evaluation in Health and Medicine

The purpose of this course is to introduce concepts and techniques used in the economic evaluation of healthcare interventions and develop a specific research question; apply best practices of model building; and conduct analysis and interpret results. This course focuses on the methods of cost-effectiveness analysis. Decision analysis in general, and cost-effectiveness analysis in particular, is an approach to help decision makers systematically and simultaneously compare a full range of options, apply all relevant evidence (what is known and unknown), consider consequences of action (or inaction), and incorporate patient preferences. This course provides an understanding of the foundations of decision analysis and cost-effectiveness analysis, with sufficient detail regarding the mechanics and methodologies to prepare students to both interpret and critique the literature of cost-effectiveness analysis and construct these analyses themselves.

Course Directors: Ronald S. Braithwaite, MD, and Heather T. Gold, PhD
Credits: 3

Grant Writing

This course provides a practical overview of the biomedical grant application process, including selection of the research focus and appropriate funding mechanisms, development of effective collaborative and mentoring relationships, building a research team, and planning and writing the scientific components of a research plan and/or career development and mentoring plan. This course is open to NYU faculty and fellows who are training or working in disciplines for which extramural individual funding in translational science is available. The course format includes interactive presentations on specific sections of the grant application or application process, relevant assigned readings, small group work, and dedicated time to grant preparation. The course content is largely based on the preparation of NIH grant applications, but is also relevant to grant applications for other funding sources. Each student is responsible for writing their current grant section assignment and critiquing the work of other students.

Course Directors: Stuart D. Katz, MD, and Ryan C. Branski, PhD
Credits: 1

Health Disparities and Health Equity in Community Health

Students in this course have the opportunity to explore health disparities through a variety of texts, peer-reviewed scientific journals, news articles, seminars, and reflections. Classes begin with lectures from nationally recognized experts from diverse disciplines. Guided course discussions explore lecture content and questions and issues that are most relevant to select communities or populations are explored for debate. Lectures are followed by student-led discussions of assigned readings, designed to enhance students' ability to critically interpret key issues in health disparities. Lectures are supplemented with assignments designed to enhance students' abilities to effectively identify and explore issues related to health disparities in the media, react to emerging health disparities literature using theory-informed and evidence-based arguments, and a final presentation to comprehensively explore a health disparities issue on a topic chosen by the student.

Course Director: Radhika Gore, PhD
Credits: 3

Health Services Research

The goals of this course are threefold: first, to provide students with an overview of the conceptual models, study designs, methods, and key concepts commonly used in health services research; second, to train students in use of Stata statistical software (Version 15, StataCorp, College Station, Texas); and third, to provide hands-on experience with conduct of a secondary data analysis to address an health services research question. Using national and/or local survey data, students gain experience in data management, cleaning and conditioning, and conduct of preliminary analyses.

Course Director: Maria R. Khan, PhD, MPH
Credits: 3

Healthcare Delivery Science

This course provides a comprehensive introduction to healthcare delivery in the United States and to principles of care redesign to enable students to develop core competencies in healthcare delivery science. By the end of the course, students have a clear understanding of fundamentals of healthcare policy and organization, and are able to apply quality improvement, engineering, and implementation science principles to care delivery problems. Lectures provide a foundation of knowledge on each concept, supported by supplementary readings and individual development of a plan for an implementation project.

Course Director: Leora Horwitz, MD
Credits: 3

Independent Mentored Research

The centerpiece of the MSCI program is engagement in mentored research. A multidisciplinary mentor team, including the primary mentor and two members from our executive committee, meet regularly with trainees to stimulate, guide, and supervise their development and completion of the project. The primary mentor is selected by the trainee and the executive committee based on the trainee's research interests.

Project choice and development begin in the Clinical Research Methods course. In spring of year 1 and fall of year 2, each trainee spends substantial time doing the detailed work related to preparing to implement the project, obtaining Institutional Review Board approval, and seeking supplementary research funding if appropriate. In the second year, trainees devote most of their time to completing the project, preparing a final report and presentation, and developing grant applications based on this work. Trainees give regular works-in-progress presentations as part of the Integrative Seminar.

Trainees work independently with mentoring from faculty at NYU Grossman School of Medicine. Projects are rigorous, scholarly, and original studies of important problems in public health. Trainees are expected to design, conduct, analyze, and synthesize their project in the context of current literature and theory. Progress is monitored in regular meetings with mentors throughout the year. A final written and oral presentation is made and evaluated by a Master's Thesis Committee. Faculty feedback is provided at each stage of the independent research project. Grades are based on students' participation in individual and research team activities, effective progress in achieving objectives above, and the quality of the final products (abstract, presentation, and manuscript).

Course Director: Michael H. Pillinger, MD
Credits: 10

Integrative Seminar I, II, III, and IV

The one-credit Integrative Seminar series (I, II, III, and IV) of courses is required for MSCI candidates conducting original translational research projects.

The seminar meets for 60 minutes once weekly each semester for 4 consecutive semesters over 2 years and provides each student a structured forum for presenting and discussing all aspects of their research as it progresses from start as a concept to finish as a manuscript submitted for publication.

Course Directors: Michael H. Pillinger, MD; Claudia S. Plottel, MD; Arthur H. Fierman, MD; and Mark D. Schwartz, MD
Credits: 4

Introduction to Behavioral Medicine: Theory, Practice, and Policy of Health Behavior Models

The course surveys behavior change models and provides examples of how they are applied to effect change in health behaviors (such as diet and nutrition, physical activity, stress, sleep, smoking, and adherence to treatment), as well as how these models can be implemented at the population level to inform policy. Specifically, the course explores how healthy and unhealthy behaviors are developed and maintained and how behavioral interventions can target each of these domains and constructs to promote positive health behaviors and wellbeing. This class is intended for students at the graduate level. No prior knowledge about psychology or health behavior change is required.

Course Director: TBD
Credits: 3

Introduction to Biomedical Entrepreneurship

Great ideas have little impact if you keep them to yourself, but taking them to the next level can be daunting. Luckily, the Biomedical Entrepreneurship Program is here to help! This course teaches you how to take novel ideas and turn them into marketable drugs, devices, and digital health solutions. Participants have a chance to learn from, and interact with, leaders in relevant fields and start building a support system to help along the way.

Course Director: Sadhana M. Chitale, PhD
Credits: 3

Introduction to Biostatistical Analysis

This course is designed to provide a broad introduction to biostatistical analytic techniques. Foundations of biostatistical analysis including measures of central tendency and dispersion, distributions, p-values, confidence intervals and sample size/power considerations are addressed. Analytic methods covered in this course include comparisons of means (z-tests, t-tests, repeated measures, one-way analysis of variance), chi-square tests, correlation, and simple regression. Both parametric and non-parametric methods are discussed. The emphasis is on applicability to types of research questions common within medical research, with a hands-on approach to utilization and interpretation of output utilizing SPSS.

Course Directors: Alan L. Mendelsohn, MD, and Michael G. Tunik, MD
Credits: 3

Introduction to Dissemination and Implementation Science

This course provides a comprehensive introduction to dissemination and implementation (D&I) science research to enable students to develop core competencies in D&I science. The course enhances students' ability to conceptualize and think through D&I research problems, apply theory, and employ approaches to improve implementation outcomes with increasing independence. Students complete outside readings throughout the course and are expected to successfully apply an implementation science framework to a prepared research question by the end of the course.

Course Directors: Keng-Yen Huang, PhD, MPH, and Erin Rogers, DrPH, MPH
Credits: 3

Introduction to Health Informatics

The healthcare system generates vast amounts of data of many different kinds, which are used by an enormous variety of stakeholders. Understanding the complexity of this system requires training in the field of health informatics, which is founded on socio-technical science that addresses the interaction of information technology, individuals, and organizations. This course provides an introduction to the field of health informatics, which studies information and communication processes in patient care, population health, clinical research, and related areas. The learning style is strongly student-driven, using "flipped classroom," participatory exercises, teamwork, and presentations. Throughout the course, students work together in teams to define a project, analyze related literature, develop plans, and give a presentation in the final week.

Course Director: Stephen B. Johnson, PhD
Credits: 3

Machine Learning

The course covers the core principles and key techniques of machine learning, which is the study of algorithms that learn from data and experience. Topics including classification, concept learning, tree-based methods, artificial neural networks, Markov models, and others. Both theory and practice are covered.

Course Directors: David Fenyö, PhD, and Wenke Liu
Credits: 3

Meta-Analysis and Systematic Reviews

This course trains students to conduct a systematic literature review, considered by many investigators to be the highest level of evidence for answering clinical questions. This graduate-level course comprises didactic classroom sessions and lectures on the topic as well as the hands-on conducting of a systematic review on a topic. Students are taught how to perform each step in a review and apply it to a topic of interest that they either choose at the beginning of the class or have provided to them. Lab sessions focus on practical aspects of meta-analysis. Analyses are performed using RevMan software, which is available as a free download. At the completion of this course, students should be able to formulate key questions for a systematic review, organize a literature search, identify which literature databases to search, abstract relevant information from studies in a systematic manner, rate the scientific quality of each study, create evidence tables and summary tables, summarize the studies' findings, and interpret findings. The final deliverable for the course is a systematic literature review presentation.

Course Director: Timothy Roberts, MPH, MLS
Credits: 3

Molecular Signaling and Drug Development

The cumulative cost of developing a new, "successful" drug is now well over a billion dollars, and the reward of improved health and quality of life is priceless. The major contributing cost to drug development is the number of failures that occur for each success. It has become clear that understanding the molecular signaling pathways that either cause or modify disease processes are key to identifying drug targets with high efficacy and low toxicity. The objective of this course is to develop entity specific paradigms that can help predict successful drug development trajectories. Experts in their respective fields discuss disease specific signaling pathways with the goal of identifying critical steps that could be targeted by drug therapy.

Our highlighted public health disease is diabetes, arguably one of the most significant determinants of public health and a leading cause of mortality and morbidity in the United States. In addition to diabetes drugs, we discuss other drugs with challenging development paths that turned out to be successful therapies, and by contrast, we discuss other drugs that failed in the late stages, some after reaching the market. By understanding these paths and failures, future researchers are able to predict, design, and anticipate success in drug discovery and development, thus bridging the gap between healthcare need and return. Furthermore, this course exposes students to new technologies (hardware and software), developing receptor and pathway networks, prediction models, and challenges with designing animal models and clinical trials. By the end of the course, students are capable of launching their own drug development project from target selection through experimental testing.

Course Director: TBD
Credits: 3

Principles of Population Health Science

This course introduces students to the field of population health science, or the study of relationships between many health determinants or health outcomes in large populations. This course aims to provide students with a basic understanding of the socioeconomic, behavioral, cultural, and healthcare-related determinants of population health. This course is meant to complement other courses in population health sciences (such as biology, epidemiology, and biostatistics) and provide a broad range of topics in these areas.

Course Director: Maria R. Khan, PhD, MPH
Credits: 3

Programming for Data Analysis

This is an introductory class for beginners in R programming for data analysis. This Zoom-based class addresses getting up and running with R and R Studio, data types, data structures, the use of functions and their arguments, data cleaning/transformations, and data visualization, hypothesis testing in R, and basic regression.

Course Director: Fred LaPolla, MLS
Credits: 2

Scientific Integrity and the Responsible Conduct of Research

The purpose of this course is to familiarize participants with the basic ethical issues confronting scientists in biomedical and clinical research. The course includes reading, lectures, and group discussions. Each student is required to attend all sessions of the course.

The course covers many topics in research ethics and research integrity. Topics include ethical considerations for human subjects and animal use as well as scientific integrity in data management, authorship, and publication. Additional topics include research misconduct, conflict of interest, and laboratory safety.

The course is designed to meet or exceed all NIH requirements for instruction in the responsible conduct of research, as updated in NOT-OD-10-019, November 24, 2009.

Course Director: Carolyn R. Chapman, PhD
Credits: 0

Translating Cancer Discovery into Clinical Practice

This course is designed to educate students and postdoctoral fellows about the importance of translational research in oncology as well as opportunities for their own research to impact diagnosis and treatment of human cancer. Specifically, it focuses on the growing cross-talk between basic science research and clinical practice that guides development of novel approaches in managing cancer patients. Thus, the course's overarching objective is to emphasize the value of collaboration across oncology disciplines as well as between basic and clinical scientists.

The course reviews emerging concepts and therapeutic approaches to cancer that cultivate discussions about approaches to challenging issues thereby highlighting opportunities related to diagnosis and treatment of the most common human tumors.

The first half of the course (which ends with a mid-term exam) lays the foundation for the general principles of oncology (cancer biology, pathology, clinical genomics, and principles of chemotherapy, radiotherapy, and drug discovery). The second half of the course focuses on specific cancer modules (gastrointestinal, breast, prostate, melanoma, leukemia, brain, and lung cancer) with an interdisciplinary focus. The course meets twice a week and includes a lecture and discussion format.

Course Director: Theodore P. Nicolaides, MD
Credits: 4

Writing for Scientific Publication

The goal of this course is to develop the learner's scientific writing skills in order to be successful in publishing peer-reviewed papers about their research. The curriculum is designed as a scaffolding to help students iteratively write the sections of the paper with feedback along the way. Students are expected to complete a publishable scientific paper over the course of the semester through iterative drafts with feedback in class and from an assigned virtual editor. Students deepen their appreciation and skill in concise, scientific story-telling and their success in getting their papers published.

Course Directors: Arthur H. Fierman, MD, and Mark D. Schwartz, MD
Credits: 2