



Weill Cornell Graduate School of Medical Sciences

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Clinical Investigation Courses

Advanced Seminars in Ethics of Clinical Research

Recent public debates about conflicts of interests, exploitation of human subjects, and scientific fraud have brought to the forefront the importance of ethical reflection in the context of biomedical investigations. This course examines various ethical aspects that arise when conducting biomedical research. In order to evaluate such ethical concerns this course will review and critically analyze the philosophical underpinnings of current guidelines and regulations for the responsible conduct of research. Different aspects of doing research where moral decision-making is necessary will be considered as well as discussion of investigators' responsibilities as members of the scientific community and gatekeepers of public trust in science.

Bioinformatics Workshop

This focus of this workshop is on web-based bioinformatics tools. At the end of the course, trainees will be expected to have a solid foundation in using fundamental tools of bioinformatics and how they apply to clinical and translational investigation.

Clinical Trials Design and Analysis

This course will provide an overview of how to design, conduct, and analyze clinical trials. Completion of this course will lead to an understanding of the theoretical and practical aspects of clinical trials related to the strengths and limitations of randomized clinical trials; theoretical and practical aspects of randomization, stratification, and blinding; challenges of designing and implementing single-center and multi-center clinical trials; major issues in the analysis of clinical trials; role of clinical trials in the drug development process; and investigators' roles and responsibilities in conducting clinical trials.

Community-Based Scientific Research in Health & Aging

This course is designed to introduce interdisciplinary researchers to the principles and practices of community-based scientific research in health research, gerontology, and geriatrics. The course consists of a series of expert presentations from researchers and practitioners involved in community-based research projects intended to benefit the elderly in New York City. Individual seminar topics will range from theoretical presentations of different models of community-based and other types of translational research models (e.g., CBPR, action research, and related methods that engage community participation), methodological education, ethical issues in community-based research, specific community research projects, and funding and publication issues. A primary emphasis is on exposure to interdisciplinary activities, diverse perspectives, and values provided by researcher and community-practice presenters.

Data Management for Clinical Research

This course is designed to familiarize individuals with computer technologies and procedures essential in current clinical research, and will cover practical topics such as creating

research databases, safeguarding patient confidentiality, regulatory issues, data and file system security, data transfer over networks, and backup systems. In addition, it will cover basic concepts in medical informatics essential for data sharing including principles of database design, medical vocabularies, data standards, data warehousing, and Internet technologies.

Economic Evaluations in Health Care

This advanced course will provide an in-depth exposure to techniques used by health economists and other health services researchers to conduct economic evaluations of health care technologies and programs. Participants will learn how to critique economic evaluations using cost-effectiveness and cost-benefit approaches, and will be introduced to tools they can use to apply these techniques to their own research projects.

Foundations of Clinical Research

The goal of this course is to provide an overview of the methodological foundations for research involving human subjects, while gaining an understanding of core epidemiological concepts, theory and applications of commonly used biostatistical methods, and investigative methods of clinical interventions.

Foundations of Epidemiology

This course is designed to train students to conduct epidemiologic research of the highest quality. Through a combination of video-conferencing and live lectures and in-class questions/answers discussion sessions, students will learn how to evaluate research conducted by others and how to apply epidemiologic principles to health-related specialties including clinical medicine and health services. The course will provide students with an introduction to basic and intermediate epidemiologic methods to build the foundation for further work in epidemiology either as practicing epidemiologists or as sophisticated users of epidemiologic information.

Genetic Medicine Workshop

This workshop will provide students with hands-on experience in gene therapy, including vector development, stem cell isolation and characterization, relevant analytic methods, and studies with experimental animals and humans. Students can elect to participate in any of the three 3-month rotations in the DNA Vector Core, the RNA Vector Core, and/or the Stem Cell Core. During these rotations, students will interact with the Analysis and Experimental Animal Cores as necessary. Students will acquire skills taught in these particular cores. Aspects of core training will be supplemented by informal lectures.

Grant Writing and Scientific Journalism: Inspiration, Writing, and Education

This course will focus on strengthening scientific writing skills. Students will develop and write a formal research proposal in an area of personal interest; write an article for a scientific journal; critically evaluate the merits of specific approaches to scientific problems and compose formal critiques; and develop an article that effectively presents scientific work to the general public.

Immunology I & II

This two-part series will provide a fundamental understanding of immunology-focused research. This course will give a comprehensive overview of basic immunology beginning with innate immune responses, followed by a study of the main aspects of acquired immunity. Important topics will include: specific interactions of target cells and T cells that are regulated by the MHC molecule and peptide antigens on the target cell and the antigen specific T cell receptor; generation and molecular structure of B and T cell antigen receptors; signaling through immune receptors; the development of antigen specific T and B cells; and specific roles of some cytokines/lymphokines.

Introduction to Bioinformatics and Statistical Genomics

This course will focus on statistical analysis of genomic data. It will provide an introduction to probability and statistics, with applications to DNA sequence analysis, phylogenetic inference, population genetics, genetic mapping, motif identification, and macromolecular structure prediction. By the end of the course, the students will acquire a basic understanding of the statistical analysis of genomic data.

Introduction to Biostatistics in Clinical Research

This course is an introduction to the fundamental statistical issues in designing clinical research studies. Its primary emphasis is on understanding the design and analytic methods of clinical research from a statistical perspective. Lectures and discussions will focus on the following: exploratory data analysis; basic concepts of statistical analysis; construction of hypothesis tests and confidence intervals; the development of statistical methods for analyzing data; development of mathematical models used to relate a response variable to explanatory or descriptive variables; and an introduction to statistical analysis of microarray and genomic studies.

Logic and Experimental Design

This course will focus on experimental strategies used by biomedical scientists to understand both normal and pathophysiological processes. Lecture topics will cover biochemical, cellular, molecular, immunological, genetic, and bioinformatics approaches. The goal of the course is to equip students with fundamental knowledge needed to develop independent patient and translational research proposals, and to critically evaluate the work of others.

Microarray Workshop

This course is designed to give students an overview of microarray technologies and their applications in the biomedical field, leading to design and analysis of microarray experiments. The course will cover the latest techniques and theories and is organized around a combination of lecture and practical sessions.

Molecular Biology and Genetics in Clinical Research

The aim of this course, composed of both lectures and workshops, is to introduce the following: basic concepts and principles of molecular biology and molecular genetics; basic technology of molecular biology in translational research; and contemporary concepts and technology of molecular genetics and molecular biology as related to clinical research and clinical medicine. Topics will include the human genome, gene structure, gene expression, gene mutations, gene interference, gene cloning, gene therapy, and animal models of human diseases. Both basic and contemporary technologies will be covered, including DNA, RNA and protein isolation, DNA amplification, mutation detection, mRNA and protein determination, microarray, proteomics, and database searching.

Molecular Modeling

This workshop will introduce students to powerful computational tools used for studying biological systems. It will demonstrate that in many cases, computational study can be informative, if not conclusive, and will make research much more effective with little investment. The workshop will focus on commercial software packages such as InsightII from Accelrys. At the end of the workshop trainees are expected to run some molecular modeling software independently.

Neuroscience 444- Drug Development: A Business Approach (Club Bio-Med)

This course will educate students about the processes involved in drug and medical device development and commercialization. Upon completion of the course, students will be better equipped to compete and collaborate with big pharmaceutical companies. The course will include presentations on drug development, the FDA, patent law, clinical trials, pricing

policy, drug sales, financial analysis, and related topics. It will also include presentations on specific biotechnology and pharmaceutical companies including an analysis of present and future performance. Students will be expected to actively participate in 15 meetings over a two-year period (there are 10 meetings each year), follow a single company for a year, and formally present a company and evaluate its prospects.

Pharmaco-Economics

This course will provide an overview of the methodologies currently used in pharmaco-economic research and will equip students with the necessary skills to conduct research and assemble a reimbursement dossier for a new drug. These dossiers are currently required for a drug to be listed in the formularies of national health care systems abroad and managed care organizations within the U.S. Each student will be required to prepare a reimbursement dossier using data reported in the literature, and the reports will be discussed and critiqued during the last session.

Physical Principles of Biomedical Imaging

This survey course will cover basic physical, biochemical, computational, and engineering principles underlying current medical imaging techniques, including magnetic resonance imaging, positron emission tomography, radionuclide production and radiochemistry, optical imaging, X-ray computed tomography, and ultrasound. The goal of the course will be to provide students with a broad knowledge of the concepts and implementation strategies of various imaging methods relevant in current research and clinical practice. Practical applications will be used to illustrate the main themes of the course. Tours of the Biomedical Imaging Core Facility and other imaging laboratories will augment the formal course material. At the end of the course students will be able to identify appropriate imaging strategies for clinical research and have a working knowledge of the major techniques available to the investigator.

Physiologic Genomics

This course will utilize a journal club and discussion seminar approach to study the process of gene regulation using cardiovascular organogenesis and function as a model for study. The course will focus on fundamental advances in our knowledge in genomics and how genes regulate the structure, organization, and activity of the heart and vasculature. Weekly sessions will address topics that range from molecular to cellular to tissue to organ to organismal clinical events. Each week students will be assigned one to three journal articles relevant to the particular topic. With the assistance of the faculty facilitator, students will discuss key concepts in detail, determine major findings, and discuss future avenues for basic and clinical investigation.

Principles of Clinical Pharmacology

This course is designed to present basic principles for understanding the rationale behind development of drug therapy with consideration of the factors involved in individual variability, pharmacokinetics, and pharmacogenomics. Topics will include: dose-response, drug efficacy and potency, drug absorption, distribution, metabolism and excretion, drug addiction, drug use in pregnancy, chemotherapy, and the principles behind drug-to-drug interactions.

Responsible Conduct of Research

The objectives of this course are to heighten students' awareness of ethical considerations relevant to the conduct of research; inform students of federal, state, and institutional policies, regulations, and procedures; and provide students with critical analysis and problem solving skills for ethical decision-making.

Statistical Genomics

This course will provide the students with an introduction to statistical methods used in population genetics, phylogenetics, and molecular evolution. Module I will review basic ideas in probability theory and statistics. Basic population genetic models, and how ideas from probability theory can be used to characterize and make inferences regarding population genetic models, are shown. Module II will review ideas from the theory of Markov chains and shows how these ideas can be used to model the evolution of DNA sequences. Module III will detail statistical methods used for estimating evolutionary trees (phylogenetics). Module IV will cover statistical methods used for making inferences in the field of molecular evolution. Methods for testing hypotheses regarding molecular evolution will be discussed with particular focus on methods for evaluating the molecular clock, detecting variation and correlation in the rate of evolution among difference sites in a DNA sequence and methods for detecting Darwinian selection at the level of the DNA sequence. Module V will survey statistical methods used in population genetics, including an introduction to Kingman's coalescent, classical methods for detecting Darwinian selection, and maximum likelihood methods for estimating parameters.

Statistical Inference in Population Genetics

This course will cover statistical inference in molecular population genetics. It will begin by considering tests of selective neutrality and build up the theorists' toolbox enabling students to understand how to estimate population genetic parameters in relatively complex demographic or selective models using modern statistical techniques. Topics will include: standard coalescent, coalescent with population size change, coalescent with migration and population subdivision, coalescent with recombination, Markov Chain, Monte Carlo algorithms, importance sampling, full likelihood inference, summary and composite likelihood inference, and Bayesian inference.

Statistical Methods for Observational Studies

This course will introduce students involved in clinical research to the distinction between randomized clinical trials and observational studies. It will discuss the statistical background for causal inference and teach statistical methods such as propensity score analysis and instrumental variable analysis for drawing the best possible inference from observational studies. Published literature utilizing large secondary databases such as NHANES and SEER-Medicare will be discussed to motivate future studies that can be planned. Steps for systematic literature review and various methodologies for meta-analysis will be taught. At the end of the course, students will be able to rigorously design and write data analysis plans for observational studies. They will also be able to analyze data (using STATA) for summarizing epidemiological studies, for using multiple regression analyses (linear, logistic, and survival), to adjust for confounders, and for performing propensity score analysis and meta-analysis.

Survey Research & Questionnaire Design

This course will provide an overview of survey research methods for health-related research with patients, providers, community members, or other population groups. Students learn the conceptual and practical aspects of collecting self-report data from research participants (e.g., behaviors, intentions, knowledge, attitudes, etc.). Topics will include measurement terminology, psychometric properties (reliability and validity), advantages and disadvantages of different assessment strategies and data collection modalities, matching research questions to variables and measurement strategies, and ways to efficiently recruit and retain participants in survey research. Practical aspects of survey design are covered including questionnaire format and layout, characteristics of good survey items, pilot testing, item reduction, and ways to minimize survey and item non-response and other potential sources of bias. Students will gain an understanding of survey research by designing research projects in their areas of interest that involve collecting self-report data.