# CLINICAL RESEARCH

# MAS COURSE DESCRIPTIONS

## REQUIRED CORE COURSES:

### Biostatistics I - 2 units - CLRE-253

In this course you will gain an understanding of the principles of measurement of clinical data, learn to recognize data types, and to correctly identify statistical methods appropriate for analysis of a given clinical data set. You will gain experience in assembling a clinical dataset in formats suitable for analysis by STATA or other comparable statistical packages. You will also learn skills for conducting graphical and numerical exploratory data analysis, comparative tests of categorical, ordinal, and continuous data, linear and logistic regression analysis, and survival analysis by life table and Kaplan-Meier techniques.

### Biostatistics II - 2 units - CLRE-254

This course gives you the skills to understand and conduct advanced bio-statistical analyses including: multiple linear and logistic regression, survival analysis, and Cox and extended Cox regression. You will become familiar with person-time rate analysis, Poisson regression, and longitudinal data analysis in the presence of missing values and varying measurement times. This course is a pre-requisite for taking advanced stat courses. (You may take an advanced stat course simultaneously with this course.)

### Data Management/Informatics - 2 units - CLRE-255

This course will provide you with an orientation to database design and management, and covers key issues regarding data handling for clinical research and clinical trials. You will also become familiar with technology assessment and decision-making methods and analysis.

### Epidemiology I - 2 units - CLRE-251

This course exposes you to the basic principles of epidemiology, including etiology, transmission, outbreak investigation, disease surveillance, screening, and study design.  Students will learn about cross-sectional, case-control, cohort and intervention study designs, their strengths and limitations, and how to make the proper choice of study design for conducting your own research. You will learn to identify and calculate the correct measure of risk for each study design, recognize major sources of bias, confounding and misclassification, and understand design and analysis methods of dealing with each, while becoming familiar with criteria to differentiate association from causation.

### Epidemiology II - 2 units - CLRE-257

This course is designed to introduce you to researchers in various epidemiological content areas, including (but not limited to) spatial, environmental/occupational, cancer, nutrition, tobacco and perinatal/reproductive epidemiology.  Students will be exposed to a variety of methodologic considerations, including study design and conduct, measurement issues, bias, and data analysis and interpretation relevant to the unique exposures and outcomes in each content area.  Students will gain an understanding of the application of epidemiologic methods, and will be introduced to research possibilities.

### Health Services Research - 2 units - CLRE-252

The main goals of this course are to educate you in identifying the most effective ways to organize, manage, finance, and deliver high quality care; reduce medical errors; and improve patient safety. You will learn about

three major aspects of health care: the effectiveness and quality of the care, access to care, and its cost. Data sources and methods (e.g., program evaluation, qualitative research, and survey research) which are used to evaluate the effects and outcomes of the health care system on people's health will also be introduced in the course.

### Patient-Oriented Research I - 2 units - CLRE-250

In POR I you will learn and apply the basic elements of design, implementation, and analysis of interventional research. You will develop and present a concept proposal for a clinical trial to your peers and the course faculty and submit it as a product of the course.

### Patient-Oriented Research II - 2 units - CLRE-256

POR II builds on POR I by reviewing the ethical and regulatory basis for human research. You will prepare a proposal to the UCSD (institutional Review board (IRB), participate in a mock IRB meeting as both an applicant and reviewer, and submit the completed IRB proposal as the final written submission for the course.

### Scientific Communication Skills - 2 units - CLRE-259

This course covers the key elements of scientific communication skills that are designed to enhance your ability to be a successful clinical researcher. Topics covered in the course include the secrets of making good oral presentations and engaging the audience, learning how to write and prepare abstracts, acquiring the basics of grant writing and submission, and gaining knowledge on how grants are reviewed. The course includes a mock grant study section.

### Translational Research Fundamentals - 2 units - CLRE-236

Students learn principles and practices of translational medicine applied to discovery and development of drugs, devices, and diagnostics.  Topics covered include biomarkers, intellectual property, omics, translational imaging, pharmacogenomics-driven treatment, and discovery and development of diagnostics, stem cell therapies, and drugs.


# PROFESSIONAL DEVELOPMENT:

### Professional Development Seminar Series - CLRE-258

There are currently two different seminars. Both are required for MAS students.  The series of seminars on professional development will focus on skills and knowledge to enhance your ability as a clinical researcher to be successful.

- *Professional Development Seminar:  Project Management and  Research Budgeting*
  Student will learn basic project management skills for medical research projects. Research Project Management is the application of knowledge, skills and techniques to execute research projects effectively and efficiently. It's a strategic competency for organizations, enabling them to tie project results to research and development goals — and thus, better compete in their markets or increase their ability to get and maintain research funding. Topics include Good Clinical Practice, planning and managing resources, monitoring progress, managing risk, engaging stakeholders, tools for project management, setting and meeting goals, quality monitoring, multisite studies, and maximizing the chances of successfully carrying out clinical and health research studies.  In the Research Budgeting portion of the class, scholars will gain a solid understanding of Study Set Up and Management, Effective Study Budget Preparation and Negotiation, Billing and Financial Management, Auditing, Research Compliance and Ethical Considerations.

- *Professional Development Seminar: Communication and Professional Skills*

The clinical research scientist's professional skills impact his or her ability to communicate, lead, influence, make decisions, collaborate, provide feedback, and manage conflict. The objective is to strengthen one's workplace 'soft skills' through self-awareness, new knowledge, and skill practice. The Myers-Briggs Type Indicator will serve as a baseline for understanding communication styles and what may limit our effectiveness. Each session builds in complexity and requires professional goal setting.

# INDEPENDENT STUDY:

All three courses are required for MAS students.

## ISP Seminar Series A– 2 units - CLRE-295A

Students conduct an extensive literature search leading to the background and hypothesis/specific aim of their Independent Study Project, culminating in a written paper and class presentation for faculty and peer feedback. Mentorship topics will be discussed by guest speakers.

## ISP Seminar Series B– 2 units - CLRE-295B

Students present a Research-In-Progress talk related to their ongoing Independent Study Project (ISP) work. They will submit an institutional review board (IRB) proposal/report including a Master protocol that would be submitted to the IRB. This will include the data management plans including case report forms, data analysis plans, sample size calculations and budget. Mentorship and career development topics will be discussed by guest speakers from academia and industry. *Prerequisites:* ISP Seminar Series A (CLRE 295A)

## Independent Study Project – 2 units - CLRE-297

Students conduct a high-level clinical research project that integrates what they have learned in their formal coursework. The ISP will include their coursework in CLRE 295A and 295B and be presented as a final report that includes a complete description of the project including the study manual, study results, statistical analysis and a discussion of the findings. Students will make an oral presentation of their ISP to their 3 member ISP committee comprised of faculty and industry advisors. The ISP is an independent, creative scholarly activity, and students will be graded on their written and oral presentations. *Prerequisites:* ISP Seminar Series A & B (CLRE 295A, CLRE 295B) and department approval.

# MAS ELECTIVE COURSES:

## Experiential Learning in Clinical Research (Minimum of 4 units required):

### Experiential Learning in Clinical Research - 2 units - CLRE-270

This experiential course builds on the knowledge gained in the core curriculum through hands-on lab and simulation-based exercises. Students will learn basic lab methods and communication skills pertinent to engaging subjects in clinical research.

### Experiential Learning in Clinical Research: Applied Topics in Scientific Communication - 2 units - CLRE-270

This course is designed to complement and apply certain fundamental principles in the CLRE Scientific Communication course by providing a deep-dive into processes, strategies, and activities associated with publishing in the peer-review literature. Specifically, the course will provide instruction on key topics including research topic formulation, journal content types, how to draft specific manuscript elements, targeting

journals and the submission process, navigating the peer-review process, types of research tools and software, how to conduct academic presentations, and strategies for translation and dissemination. In total, students will be taken through the full journey of publishing in the peer-review and also taught skills on how to ensure their research is impactful.

### Qualitative Research - 2 units - CLRE-232

This course provides skills in designing and carrying out a qualitative study useful for program management (planning, monitoring and evaluation) and ensuring quality in healthcare delivery. The methods included in the course are a sample of commonly used qualitative methods: structured and unstructured interviews, participatory learning methods, group and individual methods.

### Translational Regenerative Medicine - 2 units - CLRE-237

This course covers the basics of regenerative medicine for understanding what is a stem cell targeted therapy and what are the principles for taking a cell-based product from pre-clinical to first-in-human clinical studies. Topics covered include the regulatory, ethical, and study design considerations for developing stem cell targeted therapies. Students will grasp the complexities of stem cell targeted therapies and be able to understand the framework for developing new products. This course provides a good overview for those entering a field that may deliver stem cell therapies, stem cell targeted treatments, or other cellular based therapies (e.g., car-t-cell).

### Applied Translational Research - 2 units - CLRE-238

Students will gain a comprehensive and integrative operational understanding of an entire life science innovation cycle, from drug idea to market and back, through case studies done by mining publicly disclosed information in teams mentored by biopharmaceutical professionals. *Prerequisites:* Translational Research Fundamentals (CLRE 236) or consent of department.

### Applied Translational Research II - 2 units - CLRE-239

Building upon the case studies laid out in Applied Translational Research (CLRE 238), this course will analyze in depth specific issue(s) by emulating the biomedical industry modus operandi. Mentored student teams will analyze publicly available information, develop a business case, and defend it in front of a jury of biomedical industry research and development (R&D) leaders. In the process, students will learn and apply teamwork and brainstorming techniques and tools. *Prerequisites:* Applied Translational Research (CLRE 238) or consent of department.

## Advanced Statistics Electives (Minimum of 4 units required):

### Analyzing Medical Data Using R - 2 units - CLRE-262

This course will introduce the R Statistical Platform and help to build proficiency for data analysis. You will perform your own analysis of the data, using linear regression methods, ANOVA, logistic regression, and regression methods for survival data. You will gain an understanding of the assumptions, areas of applicability, and limitations of these statistical methods. *Prerequisites:* Biostatistics I (CLRE 253) or consent of department.

### Advanced Statistics Using R - 2 units - CLRE-267

This course introduces biostatistical methods used in more advanced clinical research work, including longitudinal data analysis, meta-analysis, predictive modeling (LASSO, random forests, neural networks), competing risks survival analysis. Uses the the R statistical package. *Prerequisites:* Analyzing Medical Data Using R (CLRE 262) or consent of department.

### Clinical Decision Analysis - 2 units - CLRE-264

This course will provide you with an introduction to the use of decision sciences in health care. You will gain skills to be able to construct and evaluate an appropriate decision analysis probability tree, value health outcomes, use sensitivity analysis, and understand how to conduct a cost-effectiveness analysis.

### Advanced Regression Methods - 2 units - CLRE-265

This course will expose and familiarize you with important advanced statistical methods such as methods for numeric outcomes (Linear regression), non-linear regression, binary outcomes (Logistic regression), counts (Poisson regression), and categorical outcomes (Log-linear models.)  *Prerequisites:*  Biostatistics I & II (CLRE 253 & CLRE 254) or consent of department.

### Longitudinal Data Analysis - 2 units - CLRE-263

This class will introduce you to the statistical methods and techniques for analyzing medical data from longitudinal studies using PASW/SPSS software. You will gain an understanding of the challenges and statistical issues for designing and analyzing longitudinal studies, recognizing and using longitudinal data analysis methods, and performing analysis.  *Prerequisites:*  Biostatistics I & II (CLRE 253 & CLRE 254) or consent of department.

## General Electives (Minimum of 2 units are required):

### CER/Comparative Effectiveness Research - 2 units - CLRE-266

CER is the conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor health conditions. This course will provide you with an update on CER methods and a review of the critical literature in this emerging field.

### Behavioral Science Research - 2 units - CLRE-268

The objective of this course is to provide you with instruction in contemporary methods and statistical analyses in behavioral science research. This course will teach you hands-on practical skills in developing and validating assessment measures, designing and evaluating clinical trials in behavioral sciences, dissemination and implementation methods, and translational research. By the end of the course, you should be better able to critique behavioral science research and develop research projects and grant proposals that may include behavioral aspects.

### Molecular and Cellular Basis for Disease - 3 units - MED-224

Lectures on the molecular and cellular mechanisms of pathogenesis. Topics will include Alzheimer's disease, cell surface and nuclear receptors in disease, signal transduction by oncogenes in cancer cells, AIDS, human diseases affecting glycosylation pathways, rheumatoid arthritis, and arteriosclerosis.

### Current Trends in Biomedical Informatics - 1 units - MED-262

Weekly talks by researchers introduce students to current research topics within BMI. Speakers are drawn from academia, health care organizations, industry, and government. This is a required course for the Biomedical Informatics track, and an elective for the Bioinformatics and Systems Biology track.

### Bioinformatics Applications to Human Disease - 4 units - MED-263

Students learn background knowledge and practical skills for investigating the biological basis for human disease. Using bioinformatics applications, they: (1) query biological and genetic sequence databases relevant to human health, (2) manipulate sequence data for alignment, recombination, selection, and phylogenetic analysis, (3) normalize microarray data and identify differentially expressed genes and biomarkers between patient groups, (4) annotate protein data and visualize protein structure, and (5) search the human genome and annotate genes relevant to human diseases.

### Principles of Biomedical Informatics - 4 units - MED-264

Students will understand the main challenges of computing with phenotypes, how to integrate molecular data into electronic medical records and clinical trial records. They will get an introduction to medical decision making, consisting of introduction to decision theory, clinical decision support systems, clinical predictive models, as well as biomedical ontologies, standards, and data repositories. Students will know how to structure and query clinical data sets, and how the most commonly used privacy technologies can be used to avoid confidentiality breaches in de-identified disclosed datasets.

### Modeling Clinical Data/Knowledge for Computation - 2 units - MED-267

This course will describe existing methods for representing and communicating biomedical knowledge. The class will describe existing health care standards and modeling principles required for implementing data standards, including biomedical ontologies, standardized terminologies and knowledge resources.

### Statistics Concepts for Biomedical Research - 4 units - MED-268

This course focuses on standard statistical methods and experimental design as well as predictive modeling, natural language processing and information retrieval. The course also provides in-depth coverage of evaluation methods and design of experiments for machine learning and statistical learning methods. Students perform statistical analyses using R statistics software and critique statistical results in published research.

### Clinical Decision Support Systems at the Point of Care - 4 units - MED-269

Students learn about modeling knowledge to facilitate improved decision-making. The course includes review and discussion of case studies of specific health-related decision-support systems. Through discussions, assignments, and group projects, students learn the analytic techniques behind decision support systems as well as topics within decision-making under uncertainty, decision analysis, and evaluation of decision support systems.

### Occupational and Environmental Health - 2 units - FPM-246

Introduction to history/epidemiology of work-related disease. A review of occupationally-related health problems (heart disease, pneumoconiosis, peripheral neuropathy, sterility, birth defects, psychiatric disease and disability. Major modalities of prevention and control will be presented and the role of health practitioners, government, management and labor will be reviewed. Course will include guest lecturers, films, videotapes, and field visits to local industries and/or clinicians treating occupational disease.

### Emerging and Re-emerging Infectious Diseases - 2 or 4 units - FPM/MED-287

This course is designed to increase students' understanding and skills required to diagnose, study, prevent, and control emerging and re-emerging infectious diseases. This course will focus on contributing factors in emergence, surveillance, epidemiology, prevention and methodology for studying these diseases. (Offered alternate fall quarters).

### Cultural Perceptions about Health/Disease - 4 units - FPM-270

The U.S. is characterized by significant ethnic and cultural diversity due to historic and ongoing immigration. The purpose of this course is to examine issues related to ethnic and cultural diversity and how culture may impact health beliefs, health status, and utilization of health services. The course examines issues faced by health providers and researchers who work with diverse populations in domestic or international settings. We will also explore the concept of cultural competence and how it may be achieved. Relevant socio-cultural theories will also be addressed. We will employ several strategies to accomplish these objectives including didactic studies, student-centered learning, and case studies. Students will prepare a final paper and present findings to colleagues and invited instructors.

### Introduction to Biomedical Natural Language Processing - 4 units - MED-277

Biomedical Natural Language Processing (BioNLP) is an essential tool in both biomedical research and clinical applications.  Students taking this course will learn how to process free text data and their integration with other types of biomedical data with BioNLP.