

Clinical Research

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Program Description

The Master of Advanced Studies (MAS) in Clinical Research offers a broad-based curriculum in clinical research methodology and integrates classroom instruction with practical training to provide students with the knowledge and skills necessary to produce valid, credible research. Linking the academic and professional scientific communities, the program is appropriate for physicians, pharmacists, nurses with advanced training, psychologists, and biomedical scientists employed in biomedical firms, hospitals, and pharmacies. The program aims to accommodate the varying needs of the students through its modular approach to instruction, a part-time year-round schedule, and a choice of general electives organized by tracks.

The MAS in Clinical Research is a part-time, self-supporting degree program with a flexible course schedule designed for working professionals and academics. The UCSD graduate division confers the MAS degree and the Department of Medicine in the UCSD School of Medicine is responsible for the academic

management of the curriculum. UCSD Extension administers the program and provides student advising and career counseling services.

Admission

New students are admitted in the fall, winter, spring, and summer quarter of each academic year. Prospective candidates should submit and complete the official UCSD online graduate application for admission, the application fee, one set of official transcripts from each institution attended after high school, three letters of professional letters of recommendation, and a current resume or c.v. The GRE/GMAT is not required; however, it is strongly recommended that candidates possess, or currently be pursuing, a graduate degree in a scientific or health-care related field and also have some level of experience in scientific or clinical research. In some instances candidates without an advanced degree may be admitted to the program if they have demonstrated substantial professional experience in the field at increasing levels of responsibility. The application deadlines are July 15 (fall), October 15 (winter), January 15 (spring), and April 15 (summer).

Program of Study

The part-time master's degree program is designed to be completed in two to three years, depending upon a participant's time to devote to the program. Classes are typically scheduled in the late afternoons and an occasional Saturday for seminars. The thirty-six-unit degree is comprised of sixteen units of core clinical modules, four units of seminar courses, six units of general electives, four units of advanced statistics electives, and six units of an independent study project.

COURSES

CORE CURRICULUM—CLINICAL MODULES

CLRE 250. Patient-Oriented Research I (2)

This course will develop and apply the theory of clinical trials design and analysis, discuss the practical issues of financing and implementing clinical trials, and describe issues of monitoring trials and working in cooperative groups. The scholar will design and present to a group of peers a concept sheet for a phase I/II and phase II/III clinical trial.

CLRE 251. Basic Epidemiology (2)

Scholars will recognize and understand different types of study designs, the relative strengths and lim-

itations of each, and the proper choice of study design in conducting their own research. They will also be able to identify and calculate the correct measure of risk for each study design. Participants will recognize major sources of bias, confounding and misclassification, and understand design and analysis methods of dealing with each. They will also be familiar with criteria to differentiate association from causation.

CLRE 252. Health Services Research (2)

Scholars will evaluate relevant outcomes in patient-oriented research from the patient (quality of life) and societal (economic) perspectives and locate potential resources for assessing the relevant outcomes in a wide variety of study designs. They will also be able to describe the relative strengths of different health services research approaches to a clinical problem. Finally, they will understand the components of clinical practice guidelines, including patient preferences, and how these guidelines both depend upon as well as inform patient-oriented research.

CLRE 253. Basic Biostatistics (2)

Scholars will understand principles of measurement of clinical data, recognize data types, and correctly identify statistical methods appropriate for analysis of a given clinical data set. They will gain experience in assembling a clinical dataset in formats suitable for analysis by STATA or other comparable statistical packages. They will learn skills to conduct 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.

CLRE 254. Advanced Biostatistics (2)

Scholars will understand and conduct advanced biostatistical analyses including: multiple linear and logistic regression, survival analysis, and Cox and extended Cox regression. The scholar will also be familiar with person-time rate analysis with Poisson regression and longitudinal data analysis in the presence of missing values and varying measurement times. *Prerequisite: Basic Biostatistics, CLRE 253.*

CLRE 255. Data Management and Informatics (2)

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

CLRE 256. Patient-Oriented Research II

This course will review the ethics and basic regulatory issues for research involving human subjects; the principles of data management for clinical research, including architecture, access and confidentiality, and integrity of databases; and skills in graphic and verbal presentation of research data. Scholars will prepare a mock submission to an IRB for peer review and practice presenting graphic and tabular data. *Prerequisite: Patient-Oriented Research I, CLRE 250.*

CLRE 257. Advanced Epidemiology

Scholars will select the appropriate sampling method and determine the sample size necessary for specific projects and adjust for confounding. Participants will be familiar with several specialized analytic techniques, including matched, cluster, and meta-analyses. They will also be familiar with methodological issues, unique to ecological, behavioral, and genetic studies. *Prerequisite: Epidemiology I, CLRE 251.*