

CMED (CMED)

CMED 401. Intro to Clinical Research and Scientific Writing. 3 Units.

This seminar brings in numerous experts to cover a variety of essential issues and concepts in clinical research and scientific writing. The overarching goal is for students to produce a short but well-crafted research proposal. Topics for reading and discussion include general principles of research design and proposal development; key concepts and issues in biostatistical science for study planning, data management, analysis, interpretation, and presentation; modern medical library informatics; ethical issues in clinical research and necessary rigmarole; technical writing emphasizing research proposals; designing studies of diagnostic tests; outcomes research and medical decision making; clinical genomics research.

CMED 402. Statistical Science for Medical Research. 3 Units.

A rigorous, practical introduction to core concepts and methods in statistical planning, managing, and analyzing data, and interpreting and communicating biostatistical information. Seminar sessions: discuss readings, work through realistic examples using popular commercial software. Project sessions: individuals in small groups discuss their own examples and receive on-the-spot feedback. Topics: types of data and common distributions; database and statistical software; understanding and describing data with simple statistics and effective tables and graphics; statistical transforms (log, logit) and what they imply, basic inference tests, confidence intervals, and related sample-size analyses involving categorical data (analyzing proportions), ordinal data (analyzing ranks), continuous data (analyzing means), and time-to-event data with censoring. A substantial introduction to statistical modeling unifies seemingly diverse methods to induce a cohesive, flexible, and broad understanding of biostatistics. Medical students enrolled in CRSP must complete CCLCM Introduction to Clinical Research, IBIS 431 and IBIS 490 to satisfy the CRSP 401, 402 and 403 series. Prereq: Must be enrolled in School of Medicine.

CMED 403. Introduction to Clinical Epidemiology. 3 Units.

Using multiple learning modalities, including case-based seminars, computer-based interactive learning, journal club, and readings from texts as well as contemporary clinical literature, students will receive a rigorous introduction to methods of research in clinical epidemiology. Topics to be covered will include human subjects protections; legal and ethical components of clinical research; measures of disease frequency; basics of clinical study design; nature of and analysis of risk factors; cohort study design and analysis; case-control study design and analysis; confounding; interaction; bias; survey research; diagnostic tests; disease screening; design, analysis, and reporting of clinical trials; meta-analysis; decision analysis; cost-effectiveness analysis; and a brief introduction to health services research. Medical students enrolled in CRSP must complete CCLCM Introduction to Clinical Research, IBIS 431, and IBIS 490 to satisfy the CRSP 401, 402, and 403 series. Prereq: Must be enrolled in School of Medicine.

CMED 404. Clinical Research Seminars. 1 Unit.

The Clinical Research Seminars series is intended to give students a broad exposure to issues unique to clinical research as well as career development. Students attend seminars on relevant clinical research topics offered either on the Case or CCF campuses, and will write a short summary of each seminar attended. A total of 12-14 one-hour seminars per semester is required for successful completion of the course. Students are expected to take two semesters. Prereq: Must be enrolled in School of Medicine and consent of CCLCM Office.

CMED 405. Clinical Research Seminars. 1 Unit.

The Clinical Research Seminars series is intended to give students a broad exposure to issues unique to clinical research as well as career development. Students attend seminars on relevant clinical research topics offered either on the Case or CCF campuses, and will write a short summary of each seminar attended. A total of 12-14 one-hour seminars per semester is required for successful completion of the course. Students are expected to take two semesters. Prereq: Must be enrolled in School of Medicine and consent of CCLCM Office.

CMED 450. Clinical Trials. 3 Units.

Design, organization and operation of randomized controlled clinical trials and intervention studies. Topics include legal and ethical issues in design; application of concepts of controls; masking and randomization; steps required for quality data collection; monitoring for evidence of adverse or beneficial treatment effects; elements of organizational structure; sample size calculations and data analysis procedures and mistakes. Prereq: Must be enrolled in School of Medicine.

CMED 458. Statistical Modeling with Applications in Clinical Research. 3 Units.

Statistical modeling methods and strategies for analyzing data in clinical research, including randomized and non-randomized clinical trials. Standard Normal-theory, logistic, and Cox proportional hazard regression methods, emphasizing that these tools provide a unified schema to use linear models for continuous and categorical predictors of outcomes that are continuous, binary, or time-to-event with censoring. Repeated measures analysis using summary measures versus modern mixed models. Spline models for non-linear relationships. Extending the logistic model for ordinal outcomes. Propensity analysis. Software: R. Prereq: Must be enrolled in School of Medicine and consent of CCLCM Office.

CMED 499. Independent Study in Clinical Trials. 3 Units.

A survey of the various aspects of clinical trial investigation to provide the student a first-hand perspective on the day-to-day conduct of clinical investigation from the perspective of investigating physicians, clinical trial coordinators, compliance and regulatory officers, and core laboratory personnel. Students will develop a specific plan with the course directors that will total 40-50 hours of discussion and direct participation. Prereq: CMED 450. Must be enrolled in the School of Medicine and consent of CCLCM Office.

CMED 500. Scientific Integrity in Biomedical Research. 0 Unit.

This course covers a wide variety of topics in ethics for biomedical researchers including Institutional Review Boards for human and animal experimentation, requirements of the Health Insurance Portability and Accountability Act (HIPAA), informed consent, and de-identification of patient data in research databases. Issues of data ownership, responsibilities of authorship, and conflicts of interest are also discussed. Prereq: Enrolled in School of Medicine. Must have completed 1.5 years.

CMED 601. Clinical Research Project. 9 Units.

Clinical research project leading toward the completion of a type B Masters of Science in Biomedical Investigation - CRSP.