

The University of Texas Southwestern Medical Center

Department of Clinical Sciences & UT-STAR (CTSA)

Didactic Course Offerings - For Information Purposes Only - Subject to Change

Course#	Course Name	Hours	Offered To	Course Description
Summer Courses				
DCS 5103	Clinical Research Questions & Methods	1	All	Defining and developing a research question; distinguishing between correlative and mechanistic questions, matching methods to questions, understanding bias and confounding, random and systemic error, quantifying clinical information.
DCS 5122	Cross Cultural Clinical Research (CCCR)	1	All	Theoretically driven, empirically based applied course for clinical researchers to strengthen awareness, knowledge, and skills in various multicultural/cross cultural/diversity competencies necessary to design, develop, and implement clinical research in diverse populations.
DCS 5107	Responsible Conduct of Research	1	All	Regulatory requirements of clinical research (IRB, GCP, HIPAA, and investigational filings), ensuring patient safety, interactions with government and industry, contract negotiations, successful strategies and tactics.
Fall Courses				
DCS 5101	Biostatistics Laboratory I	1	All	Biostatistics Laboratory I is designed to coordinate with and support the concurrent Biostatistics for Clinical Science course. In this lab, students will be introduced to biostatistical methods through case studies. Topics include conceptualizing research questions, collecting and preparing data, analyzing data, and reporting results.
DCS 5301	Clinical Research Design & Analysis	3	All	Basic and intermediate level principles in research design; formulation of the research question; identifying primary and secondary structures; use of control groups and pre-specified hypotheses; surrogate measurements; analysis of incomplete data; meaning of P values and confidence intervals; identification of bias and flaws in study design.
DCS 5115	Clinical Research: From Proposal to Implementation	1	All	Basic elements for a research proposal and implementation will be covered. Topics include regulatory approvals; continuing regulatory oversight; monitoring patient safety; recruitment; clinical assessments, data treatment, data collection, entry and auditing; provision of experimental tests/tasks; data analyses; publication planning.
DCS 5309	Conceptual Biostatistics for the Clinical Investigator	3	All	Conceptual approach to statistical analysis of biomedical data. Review of fundamental statistical principles focusing on explanation of the appropriate scientific interpretation of statistical tests rather than the mathematical calculation of the tests themselves. The course covers All topics typically used in biomedical publications, including data description, summary statistics, p values, and non-parametric tests, analysis of variance, correlation, regression, and statistical power & sample size estimation.

DCS 5201	Developing & Validating Measures in Clinical Research	2	All	This course concerns principles of creating, evaluating and validating instruments and scales for the quantification of human responses and clinical events and the influence and interaction of physiological and behavioral factors. Students will engage in some data analysis so that they can better interact with psychometric specialists. Much of this course necessarily deals with statistics, but the stress is on practical considerations of constructing measures. Emphasis is given to what is generally known as “quality of life” measures. Much of the course involves the basics of factor analysis which is essential to the analysis of scales.
DCS 5391	Mathematical Biostatistics for the Clinical Investigator	3	All	Traditional, mathematical approach to statistical analysis of biomedical data. Topics include data description, summary statistics, elements of probability, distributions of random variables including applications of the binomial and normal distributions, estimation and confidence intervals, hypothesis testing, analysis of variance, correlation and regression and contingency tables. Additional topics include statistical power, sample size, and study design.
DCS 5114	Preparing a Journal Report	1	All	General writing skills and strategies; how to prepare an empirical article including tips on writing the abstract, introduction, aims, methods, results, and discussion/conclusion sections of a peer reviewed journal article. Students will be required to submit a journal article and review others' articles.

Spring Courses

DCS 5207	Outcomes & Health Services Research	2	All	This course covers the methods used in outcomes and health services research which includes research design, theory, measurement, methods of analysis and evaluation of published research. Course objectives are: 1) Describe basic concepts, definitions, and types of outcomes and health services research; 2) Understand structure, process, outcomes and underuse, misuse, overuse conceptual models; 3) Identify common approaches and challenges to measuring cost, quality, access, and equity in health and health care; 4) Describe experimental and observational research designs used to assess the impact of health services (drugs, devices, procedures, strategies, delivery and financing systems) on patient-oriented, clinical, and resource use outcomes.
DCS 5302	Biostatistics for Clinical Sciences II	3	All	Linear and Logistic regression models (control of confounding and predictive models); categorical data analysis (binomial and Poisson distributions, analysis of paired categorical data, nonparametric methods for ordinal data); survival analysis (Kaplan-Meier curves. Hazard functions, types of censoring, log-rank tests and generalized Wilcoxon tests, Cox regression model).
DCS 5102	Biostatistics Laboratory II	1	All	Computer lab designed to carry out statistical analyses on commonly encountered experimental designs, using actual data. Extensive instruction in the use of commercially available statistical software packages.
DCS 5203	Clinical Pharmacology & Drug Development	2	All	Pharmacokinetics; pharmacodynamics; drug absorption, distribution, metabolism/elimination; drug-drug and drug-disease interactions; preclinical drug development (Phase I, II, III and IV); proof-of-concept and dose-finding studies; post-marketing surveillance.
DCS 5116	Clinical Research Protocol Development	1	All	Practical aspects of research protocol conceptualization and development. Enrollees will learn how to translate a research question into a hypothesis; how to identify and describe hypothesis appropriate study subjects and study measurements; select a specific study design appropriate to the research question and resources available; synthesize the elements into a study plan; develop a statistical section and analytical plan. Protocols developed by the enrollees will form the primary basis for group discussions.
DCS 5307	Epidemiology for the Clinical Investigator	3	All	Concepts of multivariate causality; criteria for establishing causality; risk; rates; incidence, prevalence and attack rates; incidence density; crude, specific and adjusted rates; relative risk, odds ratio, case-fatality rate and attributable risk; sampling error, selection bias, information bias, definition bias, and confounding; statistical techniques to control for bias; variables; overview of statistical analysis; multiple comparisons correction; study designs to avoid bias: survey and sample selection, cross-sectional, cohort, case-control; prospective vs. retrospective; attributes of cohort studies; design principles of case-control studies; types of control groups; strategies of matching in case-control studies; experiential introduction to statistical computing for different types of clinical epidemiology studies.

DCS 5205	Health Economics in Clinical Research	2	All	Measuring health care cost and health outcomes for cost-outcome studies from clinical trials data, assessing treatment effects and costs from observation databases, computing cost-outcome ratios.
DCS 5208	Clinical Research Management & Leadership	2	All	This course is a structured review and discussion of the basics of management and leadership theory and practice. Topics include project management and budgeting, information systems, leadership style, effective interviewing and hiring techniques, conflict resolution, and the basics of organizational culture. Predominant theories and research, as well as shared experiences of the instructor and the group will be discussed in order to enhance each participant's effectiveness as a manager and leader. It will be a combination of assigned readings, didactic lectures, active group discussion, a mid-term project and final examination.

Semester Varies

DCS 5106	Grant Writing & Funding Strategies	1	All	This course will review the different types of federal grant mechanisms as well as grants or contracts from research foundations, advocacy organizations and industry. How to write a persuasive, well-reasoned application will be the main focus of the course including the budget, resources and environment, preliminary data, and the research plan.
DCS 5105	Ethics in Clinical Science	1	All	Introduction to ethical reasoning and related processes, techniques of settling disagreements among people, treatment versus research, informed consent, clinical research relevant to third parties, dealing with unexpected scientific and clinically important findings, getting what you want from mentors, consent and risk issues with unproven biological markers, conflicts of interest/duty, handling misconduct and fraud, ethics of subject recruitment, compensating for injuries or medical errors in research, talking to media, public policy advising, authorship order and publications, gender and ethnicity in sciences careers. One hour REQUIRED credit will be earned if the student attends at least 75% of lectures throughout the school YEAR. Six sessions are absolute requirements (marked with an asterisk). Should a student miss any of these required sessions, makeup credit can be earned by obtaining lecture topic from Aida Ramirez-Boyce then submitted and 200-word essay to Dr. Sadler for approval.
DCS 5109	Genetic & Molecular Science for the Clinical Investigator	1	All	Topics covered in the course include: concepts and techniques in molecular biology and genetics; identification of genes and mutations; linkage analysis; molecular and cellular biomarkers; single nucleotide and restriction fragment length polymorphisms; microarray analysis and proteomics; pharmacogenomics; acquisition and storage of samples.
DCS 5113	Advanced Clinical Research Design & Analysis	1	All	Review of journal articles in terms of design and analysis.

Practicum

DCS 5311	Practicum - Mentored Clinical Research	3	Scholars	The student will actively participate on a research project that addresses a research question identified by his/her Scientific Mentor. In doing so he/she will participate actively in the development of protocols; the submission of IRB documents; the accrual of patients; the analysis of data; and the preparation of presentations. The research project must be a prospective designed study that is hypothesis-driven and likely to lead to interpretable data. The results of the study will be described in a research paper to be <u>authored by the Scholar.</u>
DCS 5602/5311	Practicum - Mentored Clinical Research	6	All, except for Scholars	The students will be the lead investigator on a research project that addresses a research question identified by his/her senior clinical investigator mentor. In doing so he/she will participate actively in the development of protocols; the submission of IRB documents; the accrual of patients; the analysis of data; and the preparation of presentations. The research project must be a prospective designed study that is hypothesis-driven and likely to lead to interpretable data. The results of the study will be described in a research <u>paper to be authored by the trainee.</u>
DCS 5308	Practicum - Critical Literature Review	3	All	Trainees and scholars will conduct a thorough review of the literature pertinent to their focused area, critically analyze the evidence, and identify specific questions that need to be prospectively addressed in future research. The findings will be presented at a peer research conference, be summarized in a will-written analytical manuscript and be <u>submitted for publication in a peer reviewed journal.</u>
DCS 5310	Practicum - Independent Research Project	3	Scholars	When carrying out the independent research, the scholar will function as the principle investigator who oversees a multidisciplinary research team. The ultimate goal of the independent research project is to obtain preliminary data of sufficient quality and quantity that would Allow the student to be highly competitive for successful extramural <u>peer-review.</u>
DCS 5312	Practicum - Grant Application	3	All	The students will develop a formal grant application for a career development award, which will be internally reviewed defended and revised prior to initiation of an independent research project. The research question must not be derivative from the work of his/her mentor.

Other

Various	Courses at the UT School of Public Health in the division of Health Promotion & Behavioral Sciences	varied	All	<i>Courses may be available for elective credit at the UT School of Public Health. Advanced approval required.</i>
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