

Clinical Research Management

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Courses

Visit online course listings to view semester offerings for U80 CRM (<https://acadinfo.wustl.edu/ucollege/>).

U80 CRM 250 Fundamentals of Clinical Research Management I

This introductory course provides the basic foundation for clinical research. We examine the historical evolution of research, linking it to the current regulations and guidelines for good clinical practice. Course material includes research roles and responsibilities, institutional review boards, phases of drug development, the informed consent process, human subject protections, and an overview of study conduct. Credit 3 units.

U80 CRM 251 Fundamentals of Clinical Research Management II

This course focuses on the application of principles and theories covered in Fundamentals of Clinical Research Management I. Students will develop and complete documents for a specific assigned protocol. This will include completing institutional review board paperwork, writing an informed consent, developing source documents, and critiquing research articles. Prerequisite: Fundamentals of Clinical Research Management I or instructor permission. Credit 3 units. UColl: OLI

U80 CRM 318 Introduction to Data & Information Management in Health Sciences

This course presents the basic principles for understanding the design, conduct, analysis, and endpoints of clinical trials. We will review statistical terminology and explain trial design from a clinician's point of view, including theoretical and practical aspects of randomization, stratification, blinding, and single center versus multicenter trials. Additional topics include hypothesis formulation, commonly used research designs, statistical significance, confidence intervals, and statistical tests. Credit 3 units. UColl: OLI

U80 CRM 325 Research Ethics and Regulatory Affairs

This course will provide an understanding of the ethical guidelines, issues, and challenges of conducting research on human subjects. We will explore issues such as conflicts of interest, genetic testing, limits of confidentiality, risk, and the distinction between compliance and ethics. As we learn about protecting research groups and interests and explaining rights and liabilities, we will study health care legislation and regulations, guidelines, contractual matters, and the complex regulatory framework that governs human subject research. Finally, we will learn to use an ethical problem-solving model in clinical research. Same as U80 CRM 525. Credit 3 units. UColl: ML, OLI

U80 CRM 326 Drug-Induced Diseases: Detection, Prevention, and Management

A drug-induced disease (DID) is the unintended effect of a drug that results in mortality or morbidity with symptoms sufficient to prompt a patient to seek medical attention and/or require hospitalization. There have been great advances in drug therapy that have had tremendous beneficial impact on patient outcomes. However, the effects of drugs are not always beneficial; drugs are also capable of causing new diseases or exacerbating those that already exist. Some of these diseases are well known and transient (e.g., diarrhea, weight gain). Others, like liver disease and diabetes, are neither. This course will explore these issues in a novel, disease-specific way that will be accessible to a wide range of students: clinical research managers, medical students, nurses, pharmacists and other allied health professionals. The course will include weekly readings from the textbook or other sources. Regular group discussions will be important, addressing how this new knowledge can be applied to students' professional or personal practices. Same as U80 CRM 526. Credit 3 units. UColl: OLI

U80 CRM 330 The Business of Clinical Research

An overview of the business elements of clinical research, this course covers drug and device development, the regulatory environment, finance, corporate structures, and the clinical trials office. We will consider stakeholders including pharmaceutical and device industries, academic and private research centers, government agencies such as the National Institutes of Health, nonprofit agencies and a variety of other organizations such as American Diabetes Association and the National Cancer Institute. We also will study local, state, and federal regulations, as well as international and global issues that impact the business of clinical research. Credit 3 units. UColl: OLI

U80 CRM 350 Practicum/Capstone

This course provides student-specific guidance and experience in a clinical research environment. Students will engage in practical experiences in a field and therapeutic area of their choice, or, if desired, get exposure to diverse clinical research settings. The practicum will take place in departments within Washington University outpatient research settings, and pharmaceutical and device industry settings. Students already working in a clinical research environment will have the option of completing a research project with instructor approval or a hybrid between the practicum and the capstone in order to fit their goals. Prerequisite: completion of all other courses for the undergraduate degree and undergraduate certificate in the Clinical Research Management Program. May be concurrent with final course. Credit 3 units. UColl: OLI

U80 CRM 353 Pharmacology for Clinical Research

This course presents the basic principles of pharmacology and their application to clinical research management to help ensure safe and effective management of drug trials. We will study the foundations of pharmacology, including the principles of drug absorption, distribution, metabolism and excretion, drug binding sites and interactions, and drug development. We also will examine pharmacological problems with special populations, and the emergent area of pharmacogenetics. In the second half of the course we will review important drug classes, with an emphasis on understanding "Investigator's Brochures," including drug action and place in therapy, pharmacology, toxicity, chemical properties, and kinetics. Credit 3 units.

U80 CRM 4350 Exploring Project Management in Clinical Research

This course aims to explore basic concepts of project management with direct application to clinical research. Students will better understand criteria defining a project and product (versus operations), roles and responsibilities of a project manager, various methodologies (e.g. agile, waterfall, etc.), and planning tools (e.g. Microsoft Project, Jira, Teams). Student experiences in clinical research will be integrated into course discussions to explore application of project management skills and practice important team-building skills (e.g. effective meeting principles). Additionally, the course will incorporate a variety of learning resources from the Project Management Institute (PMI), LinkedIn, and professional research organizations (e.g. ACRP) into class discussions and project assignments. One or more (modified) research protocols will be used for hands-on experience applying project management strategies.

Same as U80 CRM 535

Credit 3 units. UColl: OLI
