

# Clinical Research Management

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## Courses

Visit online course listings to view semester offerings for U80 CRM (<https://courses.wustl.edu/CourseInfo.aspx?sch=U&dept=U80&crslvl=5:8>).

### U80 CRM 500 Fundamentals of Clinical Research Management

This course provides the basic foundation for the application, concepts, and theories of clinical research. We explore the historical evolution of research, linking it to current regulations and guidelines for good clinical practice. Additional course topics include research roles and responsibilities, institutional review boards, phases of drug development, the informed consent process, human subject protections, and an overview of study conduct. Students will complete institutional review board paperwork, including writing an informed consent and developing source documents. Undergraduate students register for U80 250.

Credit 3 units. UColl: OLH, OLI

### U80 CRM 505 Current and Emerging Topics in Clinical Research

This course will explore current and emerging advances in clinical research design and conduct review and discussion of recent guidance documents from the FDA in response to the 21st Century Cures Act and other sources. Students will gain familiarity with the Act and its implementation via exploration and critical review of recent FDA Guidance Documents and supplemental materials. Additional emerging topics may be identified and explored by the instructor and students. At the conclusion of this course students will be able to effectively communicate recent and emerging innovative and technological advances in clinical research design and conduct, and identify key implications and application. Prerequisite: U80 500 - Fundamentals of Clinical Research Management (note: requirement can be waived for students with established clinical research experience and instructor's approval)

Credit 3 units. UColl: OLI

### U80 CRM 509 Health and Society

This course examines topics of how public and personal health are affected by societal and institutional forces. We will use a historical perspective to explore the complex interplay between individual genetic susceptibilities and an evolving environment, where traditional metabolic signals are not always operative, often replaced by synthetic materials that the receptors have not encountered before through evolution. We will explore how sleep, food, and leisure have been changed by industrial, economic, political, and cultural developments (globalization). We will take a close look at the roles of urban planning, industrial farming, industrial food production / processing, animal husbandry, and the attendant evolving role of the family as well as the education of the individual. We will scrutinize global climate change, as it influences infectious disease vectors, pandemics, pollution, and

related political and economic forces that do not promote societal health and well-being. Finally, we will focus on the role of the mind-brain in communication with the environment and needed in health and healing. Through critical reading of medical journal articles and newspapers we will discuss related ethical and policy questions relevant to disease prevention and public health.

Credit 3 units. UColl: OLI

### U80 CRM 512 Advanced Data & Information Management in Health Sciences

This course will cover the education and training in data and information management as it applies to Health Sciences, pulling from aspects of different fields: domain specific (clinical or public health) and analytic (biostatistics and database management) using different software tools. We will examine data types and data repositories to include best practices in data acquisition and management. This course will scrutinize tools for data storage and data manipulation and delve into relational and non-relational databases. Concepts in epidemiology and biostatistics will be presented along with discussion on health informatics.

Credit 3 units. UColl: OLI

### U80 CRM 515 Medical Writing for Clinical Research

This is a graduate-level intensive writing course that will guide students in developing a competitive research grant proposal. Written work, guided by each student's needs and interests, will cover all sections of a research grant application, manuscript writing, progress reports, and other forms of reporting scientific findings to the public. We also will compose mock NIH grant applications. By the end of the course, each student will produce a comprehensive portfolio that includes a grant proposal, manuscript, and press release to the public.

Credit 3 units. UColl: OLI

### U80 CRM 518 Drug and Device Development

This course will provide an overview of the commercial development pathways for both pharmaceuticals and medical devices, from inception to market. Through lectures and discussions, students will gain an appreciation for the role clinical study programs play in the broader scope of product development. Class topics will include preclinical, clinical, regulatory, and marketing factors which influence discovery and development of new medical products.

Credit 3 units. UColl: OLI

### U80 CRM 522 Compliance, Legal, and Regulatory Issues

This course will examine the legal framework governing clinical research with human subjects in the United States. An overview of the legal system including U.S. sources of law, the interplay between the federal and state systems and the role of case law, legislatures and regulatory agencies in shaping current law and policy will be provided. Federal and state law governing clinical research from proposal to completion will be examined. At the conclusion of this course, students will be able to identify the current sources of law, policy and persuasive authority in clinical research compliance. Students will also be able to identify areas of concern and potential new or amended regulation in clinical research.

Credit 3 units. UColl: OLI

### U80 CRM 525 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. Credit 3 units. UColl: ML, OLI

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**U80 CRM 526 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. Credit 3 units. UColl: OLI

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**U80 CRM 529 Industry Partnering: Collaborations in Translational Research**

Innovative new products are the life blood of the biopharmaceutical industry. In the U.S., most discovery research originates at the university level and is transferred via licensing agreements to industry partners or to start-up biotech companies for final development and commercialization. The process of moving this innovation from the lab to industry and then to the patient is the focus of this course. The course examines the market for intellectual property that exists between academic institutions and the private sector and explores commercialization of translational research through collaboration with industry partners. In addition to studying the complex relationship between science and business, the course employs a case study methodology to illustrate specific examples of the translational process from lab to marketed product. Credit 3 units.

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**U80 CRM 535 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. Credit 3 units. UColl: OLI

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**U80 CRM 5430 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.

Same as U80 CRM 330

Credit 3 units. UColl: OLI

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**U80 CRM 555 Health Care Policy**

This course examines important and complex developments in contemporary health care policy. We begin with an historical overview, then look at the structure of current health care delivery, and identify political and economic challenges moving forward. In particular, we will critically examine methods and principles for evaluating health care costs and measuring policy effectiveness. The course also addresses unintended consequences of health care policies, special interests and political agendas, and the influence of major institutional forces on clinical and translational research. Case studies and guest speakers will help illustrate current ethical dilemmas and other real challenges to contemporary health care and reform.

Credit 3 units. UColl: OLI

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**U80 CRM 562 Leadership and Change in Health Care Services**

Students engage in the advanced study of leadership, integrating theory, research, and application in a diagnostic approach. Leadership skills for managing planned organizational change are developed through group discussions, class exercises, case studies, and the application of organizational approaches to change and innovation. Topics include personal effectiveness, team building, and creating learning environments in organizations.

Credit 3 units.

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**U80 CRM 588 Epidemiology for Clinical Research**

The purpose of this course is to provide an understanding of the use of epidemiological concepts and methods in clinical research. Two primary foci are included: 1) common applications of epidemiologic principles and analytic tools in evaluating clinical research questions; and 2) student development of skills to review and interpret the medical literature and utilize publicly available datasets to address clinical research questions.

Same as M88 AHBR 588

Credit 3 units.