Clinical Research Management

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Courses

CAPS-CRM 5000 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.
Typical periods offered: Fall, Spring

CAPS-CRM 5005 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.
Typical periods offered: Summer

CAPS-CRM 5030 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.
Typical periods offered: Fall

CAPS-CRM 5050 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.
Typical periods offered: Fall, Spring

CAPS-CRM 5070 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.
Typical periods offered: Spring

CAPS-CRM 5080 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.
Typical periods offered: Fall, Spring

CAPS-CRM 5110 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.
Typical periods offered: Fall, Spring

CAPS-CRM 5120 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
Typical periods offered: Spring

CAPS-CRM 5125 Drug-Induced Diseases: Detection, Prevention, and Management
A drug-induced disease (DID) is the unintended effect of a drug taht 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.
Typical periods offered: Fall, Spring

CAPS-CRM 5140 Introduction to Biomedical Informatics and Its Application to Clinical and Translational Research
Biomedical Informatics (BMI) is a multidisciplinary field that encompasses individual areas of bioinformatics, computational biology, translational informatics, imaging informatics, medical informatics and hospital informatics. It involves all aspects of management, analysis, organization, and sharing of information in health care and biomedical science. This course aims to provide an overview of biomedical informatics and its application in facilitating clinical and translational research and in accelerating the application of research findings to clinical practice. The course will consist of introductory lectures outlining the prinicples of biomedical informatics, current use of informatics in clinical and translational research and quality improvement initiatives, and practical hands-on training in the use of local informatics tools to manage and execute biomedical research studies.
Credit 3 units.

CAPS-CRM 5155 Principles of Management in Health Care
This course enables students to explore the theoretical framework and practical application of classic management principles so that they can function effectively in a variety of organizational settings in the provision of health care services. Topics include the management process; managerial decision making and planning; negotiation skills; organization design; and leadership.
Credit 3 units.

CAPS-CRM 5160 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.
Typical periods offered: Fall, Spring

CAPS-CRM 5161 Introduction to 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.
Typical periods offered: Summer 4, Summer 3, Summer 2, Summer 1, Summer, Spring, Fall

CAPS-CRM 5175 CRM Independent Study: Fundamentals 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. For students in the Master of Science in Clinical Research Management and by advisor permission, only. Students enrolled in U80 550 and 551 join the foundational courses U80 250 and 251 for 1.5 units each, in place of taking U80 500.
Credit 1.5 units.
Typical periods offered: Fall

CAPS-CRM 5178 CRM Independent Study: Fundamentals 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. For students in the Master of Science in Clinical Research Management and by advisor permission, only. Students enrolled in U80 550 and 551 join the foundational courses U80 250 and 251 for 1.5 units each, in place of taking U80 500.
Credit 1.5 units.
Typical periods offered: Spring

CAPS-CRM 5190 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.
Typical periods offered: Spring

CAPS-CRM 5210 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.
Typical periods offered: Fall, Spring

CAPS-CRM 5220 Building High Performance, Team-Based Organizations
This course examines the factors that are most critical in developing high-performance, team-based organizations. We pay particular attention to the assessment of organizational climate, and analyze steps organizational leaders must take to make the transition to a team-based approach. We also examine important systems and processes that support this design.
Credit 3 units.

CAPS-CRM 5230 Epidemiology for Clinical Research
The purpose of this course is to provide individuals an understanding of the use of epidemiological concepts and methods both to in clinical research, in clinical issues, and in understanding medical literature concerning these issues. The course includes 1) discussion of theoretical concepts related to the application of epidemiology in clinical research, and 2) practical applications of the concepts covered.
Credit 3 units.
Typical periods offered: Spring

CAPS-CRM 5270 Principles of Pharmaceutical Safety
The purpose of this course is to present fundamentals on pharmacovigilance within the pharmaceutical industry, and application of these approaches within clinical research and for overall patient safety regarding medications and medical devices. Students will learn how pharmacovigilance operates throughout the clinical trial process, as well as throughout the life cycle of a medication or medical device once it is US Food & Drug Administration (FDA)-approved.
Credit 3 units.
Typical periods offered: Summer

CAPS-CRM 5340 The Essentials of Biomedical Scientific Reviewing, Writing, and Presenting
This course will provide the most fundamental techniques for effectively reviewing, writing and presenting scientific information. The goal of this course is to help students understand scientific communication better. They will become familiar with the structure of scientific papers, grants and presentations and will learn to critically evaluate each form of communication. Students will learn the characteristics of outstanding scientific writing and presenting, including academic style, coherence, clear data presentation and word choice through classroom exercises and mock presentations. Classes will consist of a lecture (1 hour) followed by a classroom exercise (1.5 hours). Students will be graded on classroom exercises and writing assignments. Prerequisites: General Biology I and General Biology II.
Credit 3 units.

CAPS-CRM 5999 Independent Study in Clinical Research Management
For Graduate Students. Requires completed proposal form, permission of Department Coordinator and Dean in University College.
Credit 1-3 units.
Typical periods offered: Fall, Spring, Summer