Clinical Research Management Certificate

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Courses

CAPS-CRM 2000 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.
Typical periods offered: Fall

CAPS-CRM 2001 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.
Typical periods offered: Spring

CAPS-CRM 3001 Internship in Clinical Research Management
Requires signed proposal and approval from Internship Coordinator, Faculty Supervisor and Advisor in University College
Credit 3 units.
Typical periods offered: Fall, Spring, Summer

CAPS-CRM 3006 Evidence-Based Decision Making
Policies can fail because of weak foundational support. Many times, there are no detailed strategic objectives and no clear and measurable success criteria, or these may not be aligned with strategic goals. This course is an introduction to developing policy. Using information about COVID-19 in St. Louis as a case study, this course highlights the intersection of culture; government; leadership; and social determinants such as sex, gender, and poverty. To develop the skills used to evaluate and solve problems, students will learn to critically examine the following: (1) the concept of health (broadly defined); and (2) how data are used to develop policies and programs for communities.
Credit 3 units. UColl: SSC

CAPS-CRM 3010 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 multi-center trials. Additional topics include hypothesis formulation, commonly used research designs, statistical significance, confidence intervals, and statistical tests.
Credit 3 units.
Typical periods offered: Fall

CAPS-CRM 3026 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 3030 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 3050 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.
Typical periods offered: Fall, Spring

CAPS-CRM 3051 Practicum/Capstone for CRM
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 WashU 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. Student must have completed all other courses for the undergraduate degree or undergraduate certificate in the Clinical Research Management Program. May be concurrent with final course.
Credit 3 units.
Typical periods offered: Summer 4, Summer 3, Summer 2, Summer 1, Summer, Spring, Fall

CAPS-CRM 3350 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 4035 Individual and Organizational Introspection
The primary objective of this course is for students to systematically consider and evaluate themselves and the organization in which they work to determine individual and organizational effectiveness. The course provides a framework for students to be introspective about their personal growth objectives, their strengths and weaknesses in an organizational context, and their desire for future career direction. There will be five class meetings spread relatively evenly over the semester with most of the work completed on an individual basis.
Credit 3 units.

CAPS-CRM 4085 Synaptic Change in the Nervous System
In this course, we study synapses and how they are modified by experience in development, learning, and memory. Topics include the impact of different types of synapses on neural function; activity-dependent synaptic organization during nervous system development; the link between synaptic plasticity and learning and memory; circuitry and mechanisms of explicit and implicit memory formation; and synaptic organization and function in aging. We also learn how learning and memory are altered in mood disorders and addiction, as well as how they are affected by sleep and exercise. Prerequisites: Introduction to Psychology and previous course work in biology.
Credit 3 units.

CAPS-CRM 4351 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.

CAPS-CRM 4390 Modern Genetics
This course focuses on the concepts of Mendelian genetics, linkage analysis, gene mutation, genomics, cancer genetics, genetics of model organisms, and population genetics. We will focus on gaining experience in data analysis and experimental design and on developing problem-solving skills. Analytical thinking and the ability to integrate mathematical analysis with a firm understanding of biological events are essential to this course. Prerequisite: General Biology I.
Credit 3 units.

CAPS-CRM 4999 Independent Study in Clinical Research Management
Requires completed proposal form, permission from Department Coordinator and Advisor in University College.
Credit 3 units.