Clinical Research Management

The Master of Science in Clinical Research Management is designed for experienced professionals working in academic research centers or private industry who seek to extend their knowledge or advance their careers. The program addresses the science of clinical research through topics such as epidemiologic principles and tools, research design, ethical issues, and data analysis, as well as the business of clinical research through topics such as regulatory requirements, product development, and grant funding.

As an experienced health science or related business professional, students will update skills, strategies, and resources for developing and managing products, treatment protocols, and other processes associated with clinical research and patient care. With the Master of Science in Clinical Research Management, students will prepare for leadership positions in academic and health care research centers or related private sector organizations, such as the pharmaceutical, diagnostic, and medical device industries.

Phone: 314-935-6700
Website: https://ucollege.wustl.edu/programs/graduate/masters-clinical-research-management

Degree Requirements

Master of Science in Clinical Research Management

The Master of Science in Clinical Research Management is a 30-unit program, including 24 units of required course work and 6 units of authorized electives.

Required Courses: 24 units

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<tr>
<th>Code</th>
<th>Title</th>
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<tr>
<td>CRM 500</td>
<td>Fundamentals of Clinical Research Management</td>
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<td>CRM 512</td>
<td>Advanced Data &amp; Information Management in Health Sciences</td>
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<td>CRM 515</td>
<td>Medical Writing for Clinical Research</td>
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<td>CRM 518</td>
<td>Drug and Device Development</td>
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<td>CRM 522</td>
<td>Compliance, Legal, and Regulatory Issues</td>
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<td>Leadership and Change in Health Care Services</td>
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University College also offers a Graduate Certificate in Clinical Research Management (http://bulletin.wustl.edu/grad/ucollege/cert-clinical-research).

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. Prerequisite: bachelor's degree.
Credit 3 units. UColl: OLH, OLI

U80 CRM 509 Health and Society

This course examines how personal health and well-being are affected by institutional and societal forces. We use an historical perspective in studying, for example, how sleep, leisure, and other aspects of personal health have been changed by industrial, economic, political, and cultural developments such as urban planning, food processing, animal husbandry, and the role of the family doctor. We also take a close look at environmental factors (e.g., global warming) and related political and economic forces that produce and exacerbate chronic diseases. Finally, we critique how personal health and the health care industry have been influenced by major institutional forces such as the insurance and pharmaceutical industries, professional licensure, government-sponsored research, and the media. We read case studies and medical journals to understand and discuss related ethical and policy questions.
Same as U86 HCARE 309
Credit 3 units.

U80 CRM 512 Advanced Data & Information Management in Health Sciences

Credit 3 units.

U80 CRM 513 Designing Outcomes of Clinical Research

This course covers how to select a clinical research question, outline a research protocol, and execute a clinical study. Topics include: subject selection, observational and experimental study designs, sample size estimation, clinical measurement, bias and confounding, and data management. The course is designed for health care professionals who wish to conduct patient-oriented clinical research. Students incorporate research design concepts into their own research proposal. The course consists of lectures, weekly problem sets, weekly reading assignments, outlining a research protocol, and a final exam.
Same as M17 CLNV 513
The process of moving this innovation from the lab to industry
biotech companies for final development and commercialization
via licensing agreements to industry partners or to start-up
biopharmaceutical industry. In the U.S., most discovery
Innovative new products are the life blood of the
Translational Research
U80 CRM 529 Industry Partnering: Collaborations in
research.

In particular, we will critically examine methods and
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. Cases studies and guest
speakers will help illustrate current ethical dilemmas and other
real challenges to contemporary health care and reform.
Credit 3 units.

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.

This course provides 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.

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.

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.
Same as M88 AHBR 532
Credit 3 units.

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. Cases studies and guest
speakers will help illustrate current ethical dilemmas and other
real challenges to contemporary health care and reform.
Credit 3 units.

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students in developing a competitive research grant proposal.
Written work, guided by each student’s needs and interests, will
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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.

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 will also 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.

This course examines important and complex developments in
contemporary health care policy. We begin with an historical
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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. Cases studies and guest
speakers will help illustrate current ethical dilemmas and other
real challenges to contemporary health care and reform.
Although this course meets over two weekends, students are
expected to complete much of the course reading prior to the
weekend sessions, and complete a paper after the weekend
session.
Credit 3 units.

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.