Clinical Research Management

The Bachelor of Science in Clinical Research Management is designed for students in the early stages of a career in clinical research as well as more experienced individuals such as investigators, coordinators, and sponsor representatives who want to expand their knowledge and skills in the field.

The program lays a foundation in principles and applications from the basic sciences and then covers in greater depth the processes necessary for the management of studies that develop drugs, devices, and treatment protocols for patient care.

This customized undergraduate program focuses on the scientific methods of clinical research, good clinical practice, research ethics, and the regulatory guidelines that protect human subjects, all of which are integral components of clinical trial management in academic research or pharmaceutical industry settings.

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Degree Requirements
Bachelor of Science in Clinical Research Management

All University College undergraduate students must satisfy the same general-education requirements (http://bulletin.wustl.edu/undergrad/ucollege/bachelors/#degreerequirements). Requirements specific to the major include the following:

Required Courses: 38 units

<table>
<thead>
<tr>
<th>Code</th>
<th>Title</th>
<th>Units</th>
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</thead>
<tbody>
<tr>
<td>Bio 101</td>
<td>General Biology I (with Lab)</td>
<td>4</td>
</tr>
<tr>
<td>Bio 102</td>
<td>General Biology II (with Lab)</td>
<td>4</td>
</tr>
<tr>
<td>Bio 3221</td>
<td>Human Anatomy &amp; Physiology I (Lecture Only)</td>
<td>3</td>
</tr>
<tr>
<td>Bio 3231</td>
<td>Human Anatomy &amp; Physiology II (Lecture Only)</td>
<td>3</td>
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<tr>
<td>CRM 250</td>
<td>Fundamentals of Clinical Research Management I</td>
<td>3</td>
</tr>
<tr>
<td>CRM 251</td>
<td>Fundamentals of Clinical Research Management II</td>
<td>3</td>
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<tr>
<td>CRM 318</td>
<td>Introduction to Data &amp; Information Management in Health Sciences</td>
<td>3</td>
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Total Units 38

| CRM 325 | Research Ethics and Regulatory Affairs   | 3     |
| CRM 330 | The Business of Clinical Research        | 3     |
| CRM 350 | Practicum/Capstone                       | 3     |
| CRM 353 | Pharmacology for Clinical Research       | 3     |
| Phil 233 | Biomedical Ethics                         | 3     |

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 306 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.
Same as U86 HCARE 306
Credit 3 units. UColl: OLI, SSC

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 emerging 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.