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 or 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 in 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 integral components of clinical trial management in academic research or pharmaceutical industry settings.

Phone: 314-935-6700
Website: http://ucollege.wustl.edu/programs/undergraduate/bachelors-clinical-research-management

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:

Required Core Courses: 38 units

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<thead>
<tr>
<th>Code</th>
<th>Title</th>
<th>Units</th>
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<tbody>
<tr>
<td>Bio 101</td>
<td>General Biology I</td>
<td>4</td>
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<tr>
<td>Bio 102</td>
<td>General Biology II</td>
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<tr>
<td>Bio 3221</td>
<td>Introduction to Anatomy and Physiology I</td>
<td>3</td>
</tr>
<tr>
<td>Bio 3231</td>
<td>Introduction to Anatomy and Physiology II (Without Lab)</td>
<td>3</td>
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<tr>
<td>CRM 250</td>
<td>Fundamentals of Clinical Research Management I</td>
<td>3</td>
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<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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<tr>
<td>CRM 325</td>
<td>Research Ethics and Regulatory Affairs</td>
<td>3</td>
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<td>CRM 330</td>
<td>The Business of Clinical Research</td>
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<tr>
<td>CRM 350</td>
<td>Practicum/Capstone</td>
<td>3</td>
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U80 CRM 353 Pharmacology for Clinical Research 3
U80 CRM 323 Biomedical Ethics 3
Total Units 38

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.

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.

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 conflict 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.

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.

**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.

**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 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.