



New Program Report

Date Submitted:

03/01/2024

Institution

Washington University

Site Information

Implementation Date:

3/1/2024 12:00:00 AM

Added Site(s):

Selected Site(s):

CIP Information

CIP Code:

510711

CIP Description:

A program that prepares individuals, under the supervision of physicians, nurses, or other health care professionals, to perform medical office or facilities management services and perform one or more clinical allied health specialties. Includes instruction in health care management; medical office administration; medical law and regulations; training in one or more diagnostic, treatment, therapy, or laboratory specialties at the assistant level or above; and applicable professional standards and ethics.

CIP Program Title:

Medical/Health Management and Clinical Assistant/Specialist

Institution Program Title:

Bachelors in Science in Integrated Studies: Clinical Research
Management

Degree Level/Type

Degree Level:

Bachelor's Degree

Degree Type:

Bachelor of Science

Options Added:

Collaborative Program:

N

Mode of Delivery

Current Mode of Delivery

Hybrid

Online

Student Preparation



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Special Admissions Procedure or Student Qualifications required:

* 6 Units Of Transferable College-level Course Work

At least six units of transferable college-level course work; or

*at least six units of course work taken at CAPS and proof of high school completion, General Educational Development (GED) or High School Equivalency (HSE).

*2.7 Minimum GPA

Specific Population Characteristics to be served:

n/a

Faculty Characteristics

Special Requirements for Assignment of Teaching for this Degree/Certificate:

Faculty in this program must meet University's standard faculty qualifications.

Estimate Percentage of Credit Hours that will be assigned to full time faculty:

33%

Expectations for professional activities, special student contact, teaching/learning innovation:

Online and hybrid faculty are required to take a three-week training in online pedagogy and tools.

Additionally, all faculty are incentivized to take our six-week Course Design Institute. The trainings promote best practices for adult learners.

Student Enrollment Projections Year One-Five

Year 1	Full Time: 0	Part Time: 6	
Year 2	Full Time: 0	Part Time: 10	
Year 3	Full Time: 0	Part Time: 15	Number of Graduates: 0
Year 4	Full Time: 0	Part Time: 18	
Year 5	Full Time: 0	Part Time: 20	Number of Graduates: 10

Percentage Statement:

100.00

Program Accreditation

Institutional Plans for Accreditation:

Higher Learning Commission

Program Structure

Total Credits:

120

Residency Requirements:

None

General Education Total Credits:

42

Major Requirements Total Credits:

38

Course(s) Added

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COURSE NUMBER	CREDITS	COURSE TITLE
U11 304	3	Exposition
U80 325	3	Research Ethics and Regulatory Affairs
U11 111	3	Analytical Writing
U80 353	3	Pharmacology for Clinical Research
U29 102	4	General Biology II [with lab]
U11 324	3	Writing for Public Speaking
U29 3221	3	Introduction to Anatomy and Physiology I
U80 250	3	Fundamentals of Clinical Research Management I
U29 101	4	General Biology I [with lab]
U29 3231	3	Introduction to Anatomy and Physiology II
U09 300	3	Introductory Psychological Statistics
U11 331	3	Technical Writing
U80 330	3	The Business of Clinical Research
U22 233	3	Biomedical Ethics
U80 350	3	Practicum/Capstone
U80 251	3	Fundamentals of Clinical Research Management II
U03 117	3	Quantitative Reasoning
U80 318	3	Introduction to Data and Information Management in Health Sciences
U25 323	3	Introduction to Quantitative Methods
U11 203	3	Critical and Researched Writing

Free Elective Credits:

27

Internship or other Capstone Experience:

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.

Assurances



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I certify that the program will not unnecessarily duplicate an existing program of another Missouri institution in accordance with 6 CSR 10-4.010, subsection (9)(C) Submission of Academic Information, Data and New Programs.

I certify that the program will build upon existing programs and faculty expertise.

I certify that the institution has conducted research on the feasibility of the proposal and it is likely the program will be successful. Institutions' decision to implement a program shall be based upon demand and/or need for the program in terms of meeting present and future needs of the locale, state, and nation based upon societal needs, and/or student needs.

Contact Information

First and Last Name: Jodie
Lloyd

Email: jylloyd@wustl.edu

Phone: 206-898-4993

Course Number	Course Title	Credit Hours	Description
U29 101*	General Biology I [with lab]	4	First part of a two-semester rigorous introduction to basic biological principles and concepts. The first semester covers the molecular and cellular basis of life, bioenergetics, signal transduction, DNA and protein synthesis, and the function of whole organisms (physiology). Laboratory two evenings per week. Laboratories include traditional wet labs as well as inquiry-based, on-line labs. Restricted to University College students, post-baccalaureate premedical students, others with University College permission.
U29 102*	General Biology II [with lab]	4	Second semester of a two-semester sequence that provides a broad but rigorous introduction to basic biological principles and concepts. The second semester covers DNA technology and genomics, the genetic basis of development, the mechanisms of evolution, the evolutionary history of biological diversity, plant form and function, and ecology. Laboratory two evenings per week. Laboratories include traditional wet labs as well as inquiry-based on-line labs. Restricted to University College students, post-baccalaureate premedical students, others with University College permission.
U22 233*	Biomedical Ethics	3	A critical examination, in light of contemporary moral disagreements and traditional ethical theories, of some of the moral issues arising out of medical practice and experimentation in our society. May include euthanasia, genetic engineering, organ transplants, medical malpractice, the allocation of medical resources, and the rights of the patient.
U29 3221*	Introduction to Anatomy and Physiology I — Lecture Only	3	This is the lecture-only option of Human Anatomy and Physiology. It is the first of a two-semester sequence that examines all major organ systems in the human/mammalian body. The emphasis is on understanding normal function and processes at the gross, cellular, and molecular levels as well as some discussion of pathology and disease. The first semester covers basic principles of cellular physiology, histology, digestion, bone, muscle, and the nervous system. Optional weekly discussion and review sections are also offered during which case studies are discussed as a means of applying and reviewing lecture material A student may not receive credit for both L41 Biol 303A and L86 PBPM 3221. Priority given to students enrolled in the Post-Baccalaureate Premedical program.
U29 3231*	Introduction to Anatomy and Physiology II (Without Lab)	3	Students wishing to take Anatomy and Physiology II lecture without the lab should register for this course.
U80 250*	Fundamentals of Clinical Research Management I	3	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.

U80 251*	Fundamentals of Clinical Research Management II	3	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.
U80 353*	Pharmacology for Clinical Research	3	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.
U80 325*	Research Ethics and Regulatory Affairs	3	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.
U80 330 *	The Business of Clinical Research	3	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.
U80 318*	Introduction to Data and Information Management in Health Sciences	3	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.

U80 350*	Practicum/Capstone	<p>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.</p>
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U11 111 Analytical Writing 3

This course is about reading well and writing deliberately, and it views those two acts as intimately related. Students will read as writers, studying the strategies that writers use to write persuasively and then practicing those strategies in their own writing. The course offers a method for close reading (based on finding meaningful patterns); it offers practice linking claims with evidence for those claims, and it offers practice organizing papers using such skills as well-written summaries, theses, transitions, topic sentences, and paragraphs.

U11 203 Critical and Researched Writing 3

This course teaches students to engage critically with scholarship, to construct convincing arguments, and to write persuasive research papers. Students will study how other writers achieve these goals and then use a proven model of researched writing to write an argument and paper about a text of their own choosing that includes the accurate use of primary and secondary sources. Students will concentrate on a single research project throughout the semester, and attention will be given to revision and organization, library research strategies, academic citation conventions, and electronic search engines and sources. This course is required for all University College undergraduate degree candidates and must be taken at Washington University. Prerequisite: U11 101 or U11 111. The prerequisite can be waived by permission of the instructor based on an assessment taken prior to the beginning of the course.

U11 304 Exposition 3

Online version of the course U11 304, and fulfils the same program requirements. This advanced composition course considers style in relationship to audience and purpose, asking the writer to engage more consciously with writing conventions, and to explore strategies appropriate to various writing situations, from the more experimental and performative to the more formal and scholarly. The course will involve frequent practice in analyzing and critiquing, with special attention to techniques of organization, argument, and emphasis. Prerequisite: Critical and Researched Writing 3 (U11 203 or U11 203M). This course is fully online.

U11 3120 Argumentation 3

This advanced writing course examines the strategies of argumentation, exploring such elements of argument as the enthymeme, the three appeals, claim types, and fallacies. Prerequisite: U11 203 or 203M. This course is fully online.

U11 324	Writing for Public Speaking	<p>A course in organizational communications drawing upon the "means of persuasion" from classical rhetoric to PowerPoint. Practice in writing, speaking, and listening in the various formats: paper, oral presentations, and Internet. Comparative analysis of what works best with varying topics, situations, audiences, and purposes. Prerequisite: U11 203 or 203M. This course will count toward major in English for day students. For those whose professions require them to present complex information precisely, logically, and efficiently. Examination of the audiences for technical writing and effective methods of organizing information to meet their needs. Variety of formats: letters, memos, trip reports, progress reports, proposals, and informal reports.</p>
U11 331	Technical Writing	<p>3 Prerequisite: U11 203 or 203M.</p>
U03 117	Quantitative Reasoning	<p>Online version of the course U74 117. The objective of this course is to help students develop the ability to reason and think quantitatively and critically in order to make informed decisions about issues that they will confront in their personal lives and in their lives as citizens. It will provide students with the quantitative skills needed in their future college course work and their careers. In addition, it will emphasize written and oral communication. This course is fully online.</p>
U09 300	Introductory Psychological Statistics	<p>Descriptive statistics including correlation and regression. Inferential statistics including non-parametric and parametric tests of significance through two-way analysis of variance. Course emphasizes underlying logic and is not primarily mathematical, although knowledge of elementary algebra is essential. Prerequisite: U09 Psych 100</p>
U25 323	Introduction to Quantitative Method	<p>This course introduces the basic concepts of data analysis and statistical computing, both increasingly used in the social sciences and the humanities. The emphasis is on the practical application of quantitative reasoning and data analysis. The general goal is to provide students pragmatic tools for assessing statistical claims and conducting their own basic statistical analyses. Topics covered include basic descriptive measures, measures of association, sampling and sample size estimation, and simple linear regression. Assignments are based on real-world data and problems in political science. Basic math skills (algebra) are recommended.</p>

*Concentration Requirements