CLINICAL RESEARCH, CERTIFICATE IN (POST-BACCALAUREATE CERTIFICATE)

The post-baccalaureate Certificate in Clinical Research educates students in the conduct of clinical (human) research studies and trials. The focus of the curriculum is in the foundational knowledge necessary to understand basic clinical research and trial study design, statistics and data management; ethical principles to respect and protect the rights and welfare of individuals participating in clinical research; and select regulations and guidelines to guide activities related to new biopharmaceutical and medical device product development.

Students will develop the essential knowledge and understanding to organize, coordinate and administer clinical research studies and trials working with participants in a culturally aware manner; supporting and performing quality data collection; and applying ethical, regulatory and compliance requirements. Students who complete the certificate will be well-prepared to be effective and successful members of the clinical research workforce.

Note: This program is not eligible for the issuance of student immigration documents.

Student learning outcomes

1. Students demonstrate a comprehensive understanding of human subject research protection and VCU's commitment to the protection of research participant rights, safety and welfare.
2. Students apply principles of good clinical practice to learning, case studies and lived experience demonstrating commitment to clinical research professional practice in an ethical and responsible manner in accordance with current regulations and ethical best practice.
3. Students identify and demonstrate comprehension of the intersection of cultural awareness, research and health care equity and access issues, representative participant recruitment and data collection, and overall study design in current clinical research practice.
4. Students plan for clinical research professional continuing education and implement a tracking system for CE hours to ensure practice-related knowledge and skills remain current.

VCU Graduate Bulletin, VCU Graduate School and general academic policies and regulations for all graduate students in all graduate programs

The VCU Graduate Bulletin website documents the official admission and academic rules and regulations that govern graduate education for all graduate programs at the university. These policies are established by the graduate faculty of the university through their elected representatives to the University Graduate Council.

It is the responsibility of all graduate students, both on- and off-campus, to be familiar with the VCU Graduate Bulletin as well as the Graduate School website (http://www.graduate.vcu.edu/) and academic regulations in individual school and department publications and on program websites. However, in all cases, the official policies and procedures of the University Graduate Council, as published on the VCU Graduate Bulletin and Graduate School websites, take precedence over individual program policies and guidelines.

Visit the academic regulations section for additional information on academic regulations for graduate students. (https://bulletin.vcu.edu/academic-regs/)

Graduation requirements

As graduate students approach the end of their academic programs and the final semester of matriculation, they must make formal application to graduate. No degrees will be conferred until the application to graduate has been finalized.

Graduate students and program directors should refer to the following graduation requirements as published in the Graduate Bulletin for a complete list of instructions and a graduation checklist.

Visit the academic regulations section for additional information on graduation requirements. (https://bulletin.vcu.edu/academic-regs/grad/graduation-info/)

Apply online today. (https://www.vcu.edu/admissions/apply/graduate/)

Degree:	Semester(s) of entry:	Deadline dates:	Test requirements:
Certificate	Any	Rolling admission	Non-native English speakers see requirements outlined below.

The admission requirements outlined below apply to all students.

All applicants to the post-baccalaureate Certificate in Clinical Research program are required to:

- Submit a completed application and the application fee
- Provide an official undergraduate transcript(s) from the U.S. regionally accredited university or college conferring the undergraduate degree documenting a minimum cumulative 2.5 GPA (A life science, health care discipline, social/behavioral science or mathematics/statistics degree is preferred, not required.)
  - International students will submit an official transcript evaluation from a recognized foreign educational credentials evaluation service accredited by the National Association of Credential Evaluation Services or the American Association of Collegiate Registrars and Admissions Officers.
- Provide three letters of recommendation
- Submit a current resume or CV
- Submit a statement of intent (500 word maximum) outlining: 1) the applicant's career goals and how the certificate program would help meet those goals; 2) any prior work and life experiences related to the applicant's interest for the certificate program; and 3) the applicant's preparedness to successfully complete the certificate program.

Optional documents to provide: Current certificates of completion for the Collaborative Institutional Training Initiative program in:

1. Basic human subjects protection module
2. Good clinical practice module (either social/behavioral clinical trials or biomedical clinical trials).

Applicants without current CITI certificates of completion have until the end of their first semester in the program to complete and submit CITI certificates of completion for both modules.

Non-native English speakers will provide evidence of proficiency in English by one of the following:

- A test of English as a Foreign Language minimum composite score of 100 for the internet-based test or 600 for the paper-based score
- An International English Language Testing System minimum score of 6.5 on the academic exam

Curriculum requirements

The curriculum requires 12 credits beyond the bachelor's degree and will prepare graduates for employment within the clinical research ecosystem. Students will complete nine required credit hours focusing on federal clinical research regulations, basic principles of clinical trial design and data management, ethical conduct of research and multicultural communication skills, with an additional three elective credit hours from a set of predetermined courses. The curriculum focuses on educating students in the basic core competency domains for the conduct of clinical research as outlined by the Joint Task Force for Clinical Trial Competency, including scientific concepts and research design; ethical and participant safety considerations; investigational products development and regulation; clinical study operations (good clinical practice); study and site management; data management and informatics; and communication and teamwork.

Students are expected to obtain a minimum grade of B in all courses to demonstrate competency in the course areas at the level of a certificate program. Courses may be taken in any order and as offered during the course of study. No prerequisites are required other than those listed in the admission requirement section.

Degree requirements

Course	Title	Hours
Required courses (nine credits total)		
BIOS 606	Clinical Trials	3
or CCTR 630	Design Implications in Clinical Trials	
CCTR 520	Fundamentals of Research Regulation	2
OVPR 601	Scientific Integrity	1
or OVPR 602	Responsible Scientific Conduct	
or OVPR 603	Responsible Conduct of Research	
WRLD 302	Communicating Across Cultures	3
or ALHP 300	Communication Strategies in Health Services	
Elective course options		
Students must select course(s) from the following:		3
ADLT 400	Developing Intercultural Competencies in the Workplace: Diversity, Inclusion and Equity	
ALHP 410	Professional and Clinical Ethics	
CCTR 640	Team Science: Theories and Practice	
CCTR 690	Research Seminar in Clinical and Translational Sciences	
HADM 646	Health Care Organization and Leadership	
PHLT 580	Public Health Ethics	
SBHD 605	Introduction to Social and Behavioral Sciences	
SBHD 608	Health Communication	
Total Hours		**12**

The minimum number of credit hours required for this certificate is 12.

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