Certificate Program in

Clinical Research Conduct and Management

Advance Your Career in Class or Online
Learn everything you need to know to begin an exciting career in the growing field of clinical research. Offered online or in a hybrid online-classroom format, this professional certificate provides a thorough overview of the regulations and guidelines that govern clinical trials, a human testing procedure that is an essential part of the drug development process for biopharmaceutical companies.

At UC Berkeley Extension, get the training you need to assume the roles and responsibilities necessary to run clinical trials. In addition, you can prepare to enter or advance in a career as a monitor, clinical research associate (CRA), project manager, or study coordinator at biotechnology and pharmaceutical companies, contract research organizations, and investigational sites.

You can complete this streamlined set of accredited courses within one year. For your convenience, you can enroll in the online format or hybrid format (50 percent classroom and 50 percent online instruction). With hybrid courses, you engage directly with the instructors, many of whom are industry professionals from leading Bay Area biotechnology companies. For additional flexibility, you can move freely between the hybrid and online formats, as long as you complete all courses in sequential order.

Whether you’re new to clinical research or already working in the field, UC Berkeley Extension offers you the skills to succeed.
Clinical Research Conduct and Management

Required Courses

4 Courses, 12 Semester Units, 180 Hours of Instruction

• **Introduction to Clinical Research: Clinical Trial Phases and Design** PB HLTH X400.2

  Review the drug development process, the principles of good clinical practice, the clinical trial phases and design, the principal players in clinical research, and regulatory strategies for developing medical devices and medical terminology. Become an expert in Food and Drug Administration (FDA) regulations, the International Conference on Harmonisation (ICH), Good Clinical Practices (GCP), and procedural guidelines.

• **Clinical Trial Planning: Protocol Development, Data Management and Clinical Site Activities** PB HLTH X400.3

  Learn the processes and procedures inherent to planning clinical trials including protocol development, case report form design, IRB submission, site selection, development and negotiating site contracts and budgets, and pre-study visits.

• **Clinical Trial Implementation: Site Initiation, Subject Recruitment, Monitoring and Safety** PB HLTH X400.4

  Get a thorough look at the role of clinical trial monitors. Review in detail the various aspects of study monitoring, such as data review, safety reporting, and drug accountability. Study global drug development and subject recruitment and retention, topics that are crucial to meeting study timelines.

• **Clinical Trial: Data Analysis, Regulatory Audits, Vendor Selection and Project Management** PB HLTH X400.5

  Learn the clinical study report and other procedures at study close-out to prepare yourself for regulatory audits and inspections. Get an overview of project management and vendor selection in clinical research.

Learn More Visit extension.berkeley.edu/cert/clinical.html
Curriculum Requirements

The curriculum consists of 4 required courses for a total of 12 semester units (180 hours of instruction). This professional certificate is taught in both a hybrid format that consists of 50 percent classroom instruction and 50 percent online instruction and an online format.

The hybrid format enables students to participate in the classroom in addition to taking online courses. Students can pick and choose which courses they want to take in the classroom and which they prefer to take online. In the online format, students take all four required courses online. In both the hybrid and online programs, all courses must be taken sequentially.

You can enroll in courses via the website, as well as register for the certificate at extension.berkeley.edu/cert/register.

All coursework must be completed within five years of registering for the certificate. However, requirements may be updated based on new developments in the field of study; we recommend completing the curriculum in a timely fashion.

Completion Requirements

You must take all courses for a letter grade. To receive the certificate, you must maintain an overall minimum 2.5 grade point average, with a grade of C or better in each course. The certificate can be completed in two semesters (one year).

How to Register for Your Certificate

To register for the Certificate Program in Clinical Research Conduct and Management, complete the form at extension.berkeley.edu/cert/register. Mail it as it indicates, and include the nonrefundable certificate registration fee.

We recommend that you register for the certificate before you begin your second course in the curriculum.

You may enroll in the certificate courses without registering for the Certificate Program in Clinical Research Conduct and Management.
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Professional Organizations

UC Berkeley Extension is an approved provider of continuing education units (CEUs) by the California Board of Registered Nursing (BRN). Provider 00226. All courses in this certificate are also accepted by the Association of Clinical Research Professionals (ACRP) as fulfilling the educational requirement for certification.

Value of a UC Berkeley Professional Certificate

As the continuing education arm of UC Berkeley, UC Berkeley Extension is a respected provider of adult and professional education. A UC Berkeley Extension professional certificate is approved by a UC Berkeley academic advisory board and widely recognized as proof of the successful completion of a high-caliber, in-depth course of study. UC Berkeley Extension is accredited by the Western Association of Schools and Colleges.

Additional Information

To learn more about the Certificate Program in Clinical Research Conduct and Management, contact science@unex.berkeley.edu, call (510) 642-1062, or visit extension.berkeley.edu/cert/clinical.html. For more information about the online learning experience, visit extension.berkeley.edu/online.