Resources Available

Clinical Research Guidebook
This is a compendium of UC Davis processes and administrative procedures with links and contact information. The Guidebook aligns with Clinical Research Process Maps and provides a step-by-step guide to assist with navigation of clinical trials administrative procedures in an easy to follow, at-a-glance format. Highly recommended for all investigators and staff. The Guidebook is in an online searchable format.

Process Maps
Process maps depict the flow of clinical research processes at UC Davis. The maps are tightly linked with the Guidebook and enable study teams to efficiently navigate the administrative landscape at UC Davis.

Standard Operating Procedures (SOPs)
We maintain multiple SOPs pertinent to clinical research. SOPs contain non-binding recommendations and step-by-step instructions on how to deal with a particular process.

Contact Us

Kate Marusina, Ph.D., M.B.A.
Director, Clinical Trials Office
916-703-9177
kmarusina@ucdavis.edu

Visit our website to find additional information about all of these resources, as well as a list of Clinical Trials Office contacts.

https://health.ucdavis.edu/ctsc/area/clinicaltrials/index.html

Join the Clinical Trial Listserv
Timely updates related to procedural changes in the clinical trial administrative process, announcements, information about recent events and upcoming training and education seminars. Contact us to join.

Read the Newsletters
Short informational articles covering updates, explanations, and announcements affecting the conduct of clinical research at UC Davis.

Access the Clinical Trials Blog
An interactive, open-format forum to exchange information and post questions.

Use our Study Management Tools
A repository of tools and templates useful for study management, including protocol templates, helpful checklists, and various documents frequently requested by sponsors.

How to Stay in Touch
Clinical trials start-up and management
Clinical Research Coordinator pool
Education and training
Monitoring and quality assurance
Coverage analysis and budgets
IRB support
FDA submissions

The UC Davis CTSC is a member of the national CTSA consortium and supported by award U11 TR001860 from the National Institutes of Health’s National Center for Advancing Translational Sciences. The Clinical and Translational Science Awards (CTSA) is a registered trademark of DHHS.
Services Offered

**Package Plans:**

**Complete Study Management**  
Management of your entire clinical trial, from beginning to end.

**Study Start-up**  
Includes all start-up activities, such as budget preparation and negotiation, IRB and contract support, logistics, and other approvals as needed. The approved study is transferred to the department at the site initiation visit.

**Individual Services:**

**Clinical Trial Consultation**  
A no-cost, preliminary discussion to determine the scope and needs of a specific project.

**Clinical Research Coordinators (CRCs)**  
The CRC Pool provides trained and credentialed CRCs for short-term projects. Services include data management, query resolution, assistance with regulatory paperwork, study start-up and close-out, and patient enrollment.

**IRB Preparation and Review**  
Preparation or review of IRB applications, modification requests, or annual reports.

**FDA Application (IND/IDE)**  
Preparation and submission of Investigational New Drug/Device application, amendments, exemptions, annual and safety reports. Maintenance of communication with FDA.

**Monitoring and Quality Assurance**  
Assistance with monitoring and quality assurance of investigator-initiated and industry-initiated trials. We help to ensure compliance with GCP, FDA and IRB regulations, as well as with UC Davis Health policies regarding clinical research. We aim to provide proactive and educational regulatory and data quality assessment.

**Coverage Analysis**  
Development of billing grids for protocols, consultation on EMR research functionality, and assistance with research billing questions. In-service training options include: developing coverage analysis; explanation of routine costs and services not billable in a trial; use of tools available on the CTSC website for developing billing grids; and guidance on the existing policies and procedures related to clinical trials billing.

**Rates for Services**  
Visit our website for current rates.

---

**Education and Training**

**“Brown Bag” Seminars**  
Held monthly, these seminars feature content experts from around the nation, who discuss new and exciting developments in clinical research and offer expert advice in the field of knowledge.

**Clinical Research Coordination Training**

**CRC 1.0 – Introductory Course**  
is designed for department administrators, research staff, and faculty who are just beginning their clinical research career. Provided twice a year.

**CRC 2.0 – Basic Course**  
is designed for those who wish to improve their competency from study initiation to close out, in compliance with Good Clinical Practice (GCP) Guidelines. The course specifically addresses local implementation of GCP in performing day-to-day clinical research activities at UC Davis.

**CRC 3.0 – Leadership and Professionalism Conference**  
is offered once a year in combination with the Recognition and Awards Ceremony for outstanding clinical research staff.

**CRC Mentoring Program**  
One-on-one mentoring for UC Davis clinical research coordinators and other research staff in a functional CRC role, with an emphasis on FDA-regulated clinical trials (i.e., drugs, devices, or dietary supplements). This program provides up to 10 hours of face-to-face training with a Clinical Trials Resource Group Mentor. Offered for a nominal fee.