Resources Available

Clinical Research Guidebook
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. The Guidebook is divided into 13 activities, from study initiation to closure. Highly recommended for all investigators and staff.

Process Maps
Interventional, non-interventional and social-behavioral maps depicting the flow of 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. A supplemental checklist bridges the Guidebook and process maps serve as tools for those who wish to track their progress.

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.

Join the Clinical Trial Listserv
Receive 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
Monthly digest of short informational articles covering updates, explanations, and announcements affecting the conduct of clinical research at UC Davis. Monthly webinars supplement the newsletter content with slide presentations and live demonstrations.

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.

Contact Us
Kate Marusina, Ph.D., M.B.A.
Manager, Clinical Trials
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 Resource Group contacts.
http://www.ucdmc.ucdavis.edu/clinicaltrials
**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 FDA, GCP, and IRB regulations, as well as with UC Davis Health System SOPs and P&Ps regarding clinical research. We aim to provide proactive and educational (rather than “for cause”) 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.

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**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 specifically designed for department administrators, staff and faculty who may not be directly involved in clinical research or are just beginning their clinical research career. Provided on demand.

**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 – Advanced Course** is offered to those managing multiple complex trials. Invited professional trainers deliver advanced, in-depth topics in an all-day, lecture and breakout format.

**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.