Resources Available

Clinical Research Guidebook
A compendium of UC Davis processes and administrative procedures with links and contact information. The guidebook follows 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 to all investigators and staff. Download/order the Guidebook at http://intranet.ucdmc.ucdavis.edu/ctsc/area/clinicaltrials/guidebook/index.shtml.

Process Maps
Interventional, non-interventional and social-behavioral maps depict 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.

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Rates for Services
Services Offered

**Clinical Trial Consultation Services**
A preliminary discussion to determine the scope and needs of a specific project.

**Overview of UC Davis Clinical Trials Processes and CTSC Services and Resources**
An overview of Clinical Trial services, educational opportunities, and supporting materials, including the Clinical Trial Resource website. Ask any question related to clinical trial regulatory and administrative processes!

**IRB Application Preparation/Review**
Preparation or review of an IRB application, annual report, or modification.

**FDA Application (IND/IDE)**
Consultation on Investigational New Drug/Device exemptions, preparation/submission of complete IND/IDE packets, amendments, annual and safety reports; communication with FDA.

**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 with drugs, devices, or dietary supplements. This program is provided for a maximum of 10 hours of face-to-face training with a Clinical Trials Resource Group Mentor. Department funding is required for the trainee to enter the program.

**CRC for Hire**
The CRC for hire program provides trained & credentialed CRCs for both long- and short-term projects. Services provided include data management, query resolution, assistance with regulatory paperwork, study start-up and close out and patient enrollment.

**Monitoring and Quality Assurance**
Assistance with monitoring and quality assurance to investigator-initiated and industry-initiated trials. This program helps ensure compliance with FDA, GCP, and IRB regulations, as well as with UC Davis Health System SOPs and P&Ps as related to clinical research. The activities offered aim to provide a proactive and educational (rather than “for cause”) regulatory and data quality assessment.

**Budgeting & Billing**
Provide hands-on development and application of a Billing Grid based on the specific needs of your department. In-service training sessions include: development of your patient service billing, Coverage Analysis, explanation of routine costs, services not billable in a trial, tools available on the CTSC website for developing the Billing Grid, and guidance on the existing policies and procedures related to clinical trials billing.

* contact us 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 address new developments in clinical research, new information of general relevance to clinical research and provide expert advice from leaders in the field of knowledge.

**Clinical Research Coordinating - Basic 2.0**
Regularly held small group study of best practices for CGP implementation. Class includes case study, discussion, and an online quiz at the end of class to assess knowledge gained. Content experts include experienced coordinators and PIs.

**Newsletters**
This monthly digest contains updates, explanations and announcements affecting the conduct of clinical research at UC Davis in a series of short informational articles. The information is repeated on monthly calls where the information is illustrated by slide presentation and live demonstrations.

**Clinical Trial Blog**

**Clinical Trial Listserv**
Monthly updates related to procedural changes in clinical trials administrative process. The newsletters also contain clinical trials announcements, recent events and upcoming training and education seminars. Contact us to join the listerv.