CTSC Services Catalog

Updated 11-17-14

Regulatory & Clinical Trial Management Services

Clinical Trials Consultation - Project Specific	Conduct a preliminary discussion to determine the scope and needs of a specific project.
Complete Study Start-up	Supports investigators with protocol analysis, study logistics, budget, contract, IRB documents, FDA approval and other necessary activities for the approval. Study coordination continues up to 6 months after signing of the Clinical Trial Agreement. • Available by request • Cost recovery from Sponsor Payments: http://www.ucdmc.ucdavis.edu/clinicaltrials/Forinvestigators/rates.html
Overview of UC Davis Clinical Trials Processes and CTSC Services and Resources	Provides an overview of Clinical Trials services, educational opportunities, and supporting materials, including how to use the Clinical Trial Resource website and where to find information. Answers questions related to clinical trials administrative process.
IRB Application Preparation / Review	Preparation or review of an IRB application.
Monitoring/QA Services	Provides consultation on monitoring/QA study-specific needs, performing monitoring visits, regulatory audits and data quality verification. Specifically oriented to support investigator-initiated studies that use drugs, devices or dietary supplements.
FDA Application (IND/IDE)	Provides consultation on IND/IDE exemptions, preparation of complete IND/IDE submissions and amendments, communication with FDA, assistance with annual report preparation/submission.
CRC Mentoring Services	This formal mentoring program for new CRCs begins with the CRC Competency checklist to identify knowledge gaps. A customized training schedule will be created using a recorded or upcoming in-person training to fill the knowledge gaps. A customized mentoring plan for face-to-face interactions, observation and training, and an assessment of competency upon the completion will be provided.

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.
Coverage Analysis: Billing Grid	Prepares Billing Grid for a specific protocol. Includes CPT coding, identification of a payor and explanation of billing rules.
A Grant Budget: Budget Analysis for Patient Care Services	CPT coding and/or Billing Grid preparation to identify costs for patient care services.
Coverage Analysis: In-Service	Uses a specific protocol as a case study to demonstrate the Coverage Analysis principles and process, including qualification for Medicare billing and preparation of billing grids.
Clinicaltrials.gov	A UC Davis Protocol Administration System (PRS) Administrator assists in opening clinicaltrials.gov sub-accounts for each investigator. This service also provides an overview of the clinicaltrials.gov national registry requirements and process, including how to setup a study and keep the listing up-to-date.
Industry Outreach	Preparation of industry outreach marketing materials to design and execute an industry outreach campaign, with the goal of identifying potential new clinical trials sponsors.
The UC Davis Clinical Research Guidebook, 2013 Edition	UC Davis Clinical Research Guidebook for sale ($20)
The CRC Guide to Coordinating Clinical Research (CenterWatch)	The CRC's Guide to Coordinating Clinical Research for sale ($25)