CLINICAL TRIALS OFFICE – SERVICES FOR INVESTIGATORS AND STUDY TEAMS

COMPLIMENTARY SERVICES
Our clinical trials team offers personalized assistance to navigate the UC Davis research infrastructure and manage research processes
- Provide project consultation
- Create Coverage Analysis
- Identify research procedure fees
- Add your study to ClinicalTrials.gov
  - Assist with study registration and results reporting
- Recruit on StudyPages (studypages.com/ucdavis)
  - Create a customized, online presence for participant recruitment
  - Facilitate social media campaigns
  - Access a collection of patient-facing brochures

STUDY TEAM MENTORING
Our experienced clinical research coordinators offer mentoring and support to investigators and staff to conduct clinical research
- Review and organize your study documents
  - Assemble regulatory binders
  - Draft study visit checklists and schedules
  - Design source documents
  - Analyze sponsor start-up materials (i.e., site recruitment logs, source documentation, EMR checklist)
- Assist with Clinical Research Billing
  - Associate research patients, visits, and procedures in EMR
  - Review EMR Billing Report to ensure charges are routed correctly
  - Set up studies in the Bridge
- Improve research processes
  - Schedule ancillary services (i.e., imaging, investigational drug service, phlebotomy, laboratory)
  - Interpret study-specific items (i.e., lab and specimen processing)
  - Participate in mock first patient visit
  - Document consent process and assist with informed consent
  - Perform periodic QA audits throughout the study
  - Develop close-out procedures

For more information: health.ucdavis.edu/ctsc/area/clinicaltrials
REGULATORY ASSISTANCE

Our regulatory analysts offer mentoring and support to investigators and staff with IRB submissions, protocol development, and regulatory compliance

- **Develop investigator-initiated protocols**
  - Guide investigators through IRB’s HRP-503 (investigator-initiated protocol template)
  - Develop feasibility and resource allocation plan
  - Provide referrals to ethics consultations on request

- **Assist with IRB submissions**
  - Review IRB submission packages for completeness
  - Guide response to IRB requests for modifications to secure IRB approval
  - Train research staff to use IRBNet
    - Link CITI trainings to projects in IRBNet
    - Create new studies/projects in IRBNet
    - Explain and interpret fields in critical IRB forms (initial review application and post approval submission)
  - Assist with IRB ancillary approvals through completion
    - Radiation Use Committee (RUC)
    - Pathology (Laboratory)
    - Cancer Center Scientific Review Committee (CCSRC)
    - Conflict of Interest Committee (COIC)
    - Institutional Biosafety Committee (IBC)
    - Stem Cell Research Oversight Committee (SCROC)
    - Information Technology Evaluations for Research
  - Clarify IRB reporting criteria and timelines for Reportable New Information (RNI)
    - Process flow map and checklists
    - What, when, and how to report
  - Develop Corrective and Preventative Action (CAPA) plans
    - Role of CAPA in regulatory compliance
    - How to report noncompliance
  - Prepare for sponsor and regulatory agency audits
  - Guide through single IRB review requirements and reliance processes
  - Advise on CITI account management
    - Transfer credentials from previous institutions
    - Pull current/past certificates

- **Investigational New Drug (IND) and Investigational Device Exemption (IDE) development**
  - Review IND/IDE applications for content and completeness
  - Review IND exemption requests
  - Assist with mandatory reports to the FDA

COMPREHENSIVE STUDY MANAGEMENT (custom pricing)

We utilize a team approach to manage clinical studies of all types and stages of development

**Study Startup**

Our team will complete all startup activities, such as budget preparation and negotiation (with department approval), IRB submissions, contracts, development of study logistics, and ancillary approvals as needed. The study is transferred to your department at the site initiation visit.

**Full Study Management**

Our team manages your entire clinical trial from the beginning to end, including startup, study management, sponsor invoicing and close-out. Your department’s responsibilities include management of KFS (Kuali Financial System), receipt and deposit of industry payments, and monthly payments to the CTO for services.

**Regulatory Portfolio Maintenance**

Our regulatory team manages the entire IRB portfolio for the department or for individual studies, from protocol evaluation to IRB submission through close-out.

**Clinical Research Coordination**

Our coordinator team manages clinical research projects at any point in the study life cycle, for any period of time, from site qualification through close-out.