CHAPTER #2
Study Feasibility and Start Up

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CHAPTER #2: Study Feasibility and Start Up

2.1 Request CTSC Assistance

The UC Davis Clinical and Translational Science Center (CTSC) can provide a wide range of consultation services during all stages of studies, and specifically during the project development and start-up phases. All applicants interested in consultation services from CTSC are asked to fill out an Application for Resource Use (AFRU, http://www.ucdmc.ucdavis.edu/ctsc/). You will need your UC Davis Login ID and Kerberos passphrase to create the request.

2.2 Clinical Trials Resource Group

Moving high quality and novel clinical translational research from a concept to a successful completion and then to the knowledge dissemination requires an organizational structure that supports the generation and exploration of new ideas, creates novel collaborations among new and seasoned investigators drawn from complementary fields of expertise, and provides a supportive management system that can facilitate and monitor the entire process in a streamlined fashion.

Clinical Trials Resource Group is as a key resource that facilitates high impact research, with essential regulatory and financial services, and access to clinical research space that enables investigators to use shared resources. The team provides a simple, consistent and focused point of contact for investigators, and facilitates the development and implementation of feasible, scientifically sound and well designed studies.

The Clinical Trials Resource Group is comprised of clinical research coordinators, regulatory analysis and budget specialists for planning, design, regulatory and feasibility assessments for projects and clinical staff to launch and perform the study. The team provides a coordinated and timely response at the start-up phase of trials, as well as comprehensive support for the implementation of trials that move forward.

Services. The Clinical Trials Resource Group develops and implements processes to streamline clinical studies, to enhance quality and to accelerate the pace of conducting and disseminating outstanding human research. The team does that by providing infrastructure that encourages the use of shared resources, and by the team approach to regulatory, design, safety and operations to shepherd clinical trials from concept to completion.
Training and Education. The Clinical Trials Resource Group maintains a comprehensive training and education program for clinical research staff based on the CTSA Competency Domains. We also offer Clinical Research Coordinator Mentoring program for any new hires who wish to have a support of experienced staff. We recognize and celebrate the outstanding UCDHS clinical research staff during our annual Coordinator Recognition Event and the Award Dinner.

Improvement of local clinical trials processes. We continually identify, evaluate, and streamline institutional clinical research processes using LEAN or other appropriate methodologies. We prepare and disseminate process improvement materials, such as Process Maps, the UC Davis Guidebook, Interactive website, blogs, listserv, webinars etc.

Visit our Comprehensive Website at: www.ucdmc.ucdavis.edu/clinicaltrials

2.2.1 Clinical Trials Services

We offer two types of services:

1. Package Deals:
   - Study Start Up
   - Full Study Management

For Study-Start Up, our team completes all start up activities, such as budget preparation and negotiation, IRB, contract documents, development of study logistics, and other approvals as needed. We transfer the study to the Department at the Site Initiation Visit. A typical study start up may take up to 6 months, and has a value of $20,000 or more, depending upon the complexity of the study. The Department is not charged during the start-up time; we recover our fees after the completion of the project, when the check is received from the study sponsor.

During Full Study Management the team manages your entire clinical trial from the beginning to the end. Costs are recovered directly from sponsor payments.

2. Individual Services, such as:
   - IRB and FDA applications preparation and submission
   - Coverage Analysis and budgets
   - Coordinator support
   - Data entry

These services are recharged on hourly basis. For current rates, see: http://www.ucdmc.ucdavis.edu/clinicaltrials/Forinvestigators/rates.html
Individual services include:

1. Coverage Analysis for investigator-initiated and industry-initiated studies
   A Coverage Analysis is mandatory for all studies that include billing of patient care services in the UC Davis Health System. The Principal Investigator is ultimately responsible for ensuring that the Qualifying Clinical Trials (QCT) Form and Billing Grid are accurate. Both forms must be approved and signed by the principal investigator. The Department will store a paper or electronic copy on file (in the Study Financial Binder) for audit purposes. The qualification of a clinical trial and the final Billing Grid are required for upload in the BRIDGE. CTSC SOPs #4, #6 and #13 provide further information http://intranet.ucdmc.ucdavis.edu/ctsc/area/clinicaltrials/sops/index.shtml

2. Budget Estimates for Grant-sponsored or Department-sponsored Studies
   When the research team develops the description of the study (clinical trials protocol) and needs help with preparation of study budgets, team is strongly encouraged to contact the CTSC Clinical Trial Resource group [http://www.ucdmc.ucdavis.edu/ctsc/area/clinicaltrials/] for feasibility analysis to ensure compliance with clinical research billing requirements, and to prepare correct budgets for patient care costs and other critical regulatory activities. Briefly, the CTSC Clinical Trial Resource group will provide analysis of:
   - The **billing matrix of patient care services/procedures** involved in the protocol (called Coverage Analysis).
   - **Hospital/clinic costs for study-related procedures and services** that are not covered by insurance and therefore must be paid by study budgets.
   - **Operational Feasibility**
   - **Regulatory Requirements (FDA and IRB)**
   - **Other Clinical Trial Expenses**
   For detailed description see Chapter #4 and CTSC SOP#6

3. Coordinator for Hire
   Clinical Trials Group provides CRC-for-Hire on hourly recharge basis. The service is available as the Comprehensive Clinical Trial Management or a la carte (hourly).

4. Monitoring and Quality Assurance
   The Clinical Trials Resource Group offers assistance with monitoring and quality assurance to investigator-initiated studies. This service helps ensure compliance with FDA, GCP, and IRB regulations, and UC Davis Health System SOPs and P&Ps as related to clinical research. The activities provided offer a proactive (rather than “for cause”) regulatory assessment and has a strong educational component. The program is offered to investigator initiated studies that are otherwise not monitored/audited by another entity. The Clinical Trials Resource Group also helps with preparation for the FDA and sponsor audits.
   When writing a grant proposal consider including costs for monitoring of the study, as these costs could be quite substantial. Contact the CTSC Clinical Trials Resources Group for details http://www.ucdmc.ucdavis.edu/clinicaltrials/Monitoring/index.html.
5. IRB documents

The Clinical Trials Resource Group can help with IRB document preparation according to the latest IRB requirements. In particular, this service aims to assist with rapid start-up for industry-initiated trials.

6. IND/IDE Preparation and Submission

The Clinical Trials Resource Group provides consultation on Investigational New Drug/Device exemptions, preparation/submission of complete IND/IDE packets, amendments, annual and safety reports, and communication with FDA.

2.3 CTSC Biostatistics

The CTSC Biostatistics Group assists researchers with all sizes and types of projects, from simple data analyses to large, multi-center clinical trials. Specific services we can provide include grant proposal preparation, study design/sample size calculation, statistical analysis plan, data analysis and interpretation, statistical advice only, manuscript review and preparation, response to reviewer comments.

For more information see [http://www.ucdmc.ucdavis.edu/ctsc/area/biostatistics/index.html](http://www.ucdmc.ucdavis.edu/ctsc/area/biostatistics/index.html)

2.4 CTSC Clinical Research Center (CCRC)

The CCRC provides clinical research expertise and resources to UC Davis investigators. Resources include unique facilities and equipment, as well as highly experienced staff who are trained in human subjects’ protection, good clinical practices, protocol implementation and compliance.

The CCRC is a 3,500sf, state-licensed outpatient clinic located in the Cypress Building on UCDHS campus. It has four infusion chairs, a single hospital bed, a procedure room, two general exam rooms, two private interview/testing rooms, two phlebotomy stations, an exercise physiology lab with a DEXA machine, and a specimen processing room.

The CCRC staff is available to support research activities throughout the UC Davis, as well as communities within Sacramento and neighboring counties, including participants’ homes.

- **Clinical Research Nurses:** Highly skilled clinical research nurses implement protocol-specific procedures and provide direct nursing care for all subjects enrolled in research studies. CCRC nurses are committed to subject safety and protocol fidelity. CCRC nurses are certified in chemotherapy administration, conscious sedation, and ACLS/PALS. A Nurse Practitioner is also available to provide expanded services to investigators.

- **Laboratory and Phlebotomy Services:** Highly skilled laboratory staff support investigators with sample collection, simple/complex sample processing; DNA/RNA isolation; preparation of samples for proteomics and flow cytometry; multiplex cytokine/chemokine and metabolic analyses.
• **Nutrition and Exercise Physiology Services:** A Research Dietitian performs nutritional status assessments, food record processing and analysis, nutritional education/counseling to optimize health status and research protocol adherence, and metabolic and calorie-controlled meal planning/preparation. An Exercise Physiologist performs metabolic, exercise, and spirometry testing, body composition/bone density measurements, and provides data analysis for investigators.

  Mailing Address:
  CCRC Cypress
  Cypress Building, Suite D
  2221 Stockton Blvd
  Sacramento, CA 95817
  916-703-5600

  For more information see [http://www.ucdmc.ucdavis.edu/ctsc.area/crc/index.html](http://www.ucdmc.ucdavis.edu/ctsc.area/crc/index.html)

2.5 **CTSC Research Ethics**

The Research Ethics Consultation Service is a free service available to all biomedical researchers at UC Davis who seek advice regarding ethically complex aspects of their biomedical research.


2.6 **CTSC Community Engagement**

The Community Engagement Consultation Service provides opportunities for researchers and community members interested in healthcare research to get expert feedback on how to engage communities around research ideas, proposals, evaluations, and ongoing projects.

For more information, see: [http://www.ucdmc.ucdavis.edu/ctsc.area/engagement/index.html](http://www.ucdmc.ucdavis.edu/ctsc.area/engagement/index.html)

2.7 **CTSC Biomedical Informatics**

CTSC Biomedical Informatics provides data management, database development, data retrieval from EMR and training services. Various research tools are available to make the process of research faster. REDCap (Research Electronic Data Capture) is a secure web application for building and managing online databases for research. REDCap provides audit trails for tracking data manipulation and user activity, as well as automated export procedures for seamless data downloads to Excel, PDF, and common statistical packages. Also included are a built-in project calendar, a scheduling module, ad hoc reporting tools, and advanced features, such as branching logic, file uploading, and calculated fields.

For more information see [http://www.ucdmc.ucdavis.edu/ctsc.area/informatics/index.html](http://www.ucdmc.ucdavis.edu/ctsc.area/informatics/index.html)