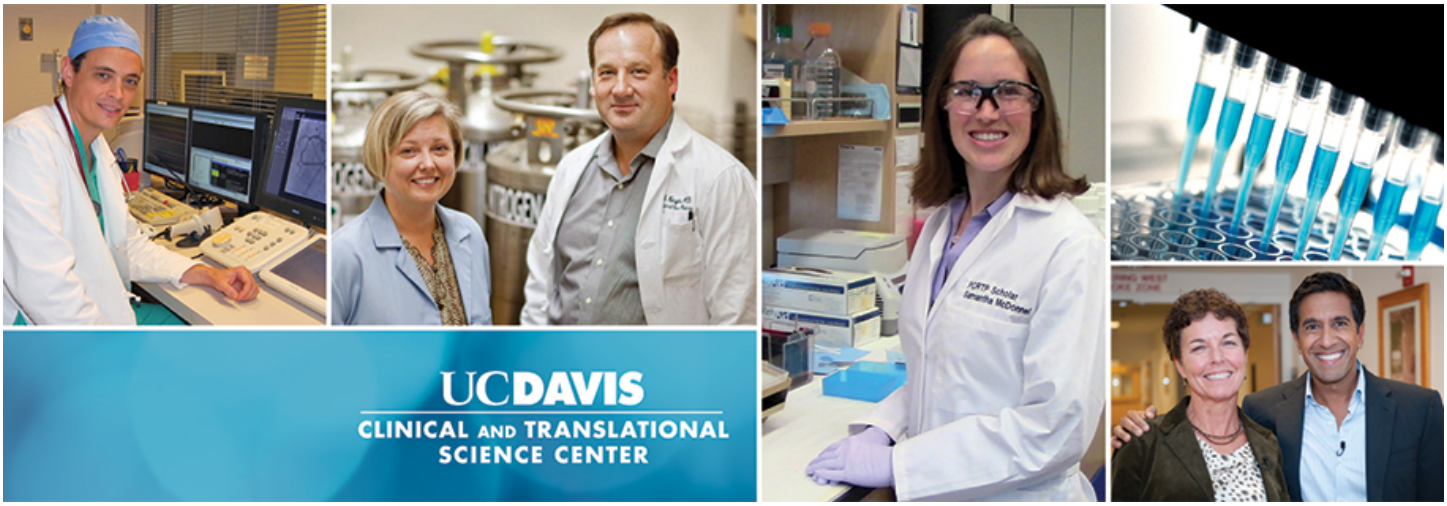
UC DAVIS CLINICAL AND TRANSLATIONAL SCIENCE CENTER

CTSC Services Catalog

A Guide to CTSC Services for Investigators



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Bioethics	
Bioethics Consultation-General NOTE: Contact Dr. Yarborough directly to request a consultation at mark.yarborough@ucdmc.ucdavis.edu.	Conduct a preliminary discussion to address ethical issues in a research project.

Biomedical Informatics	
BMI Consultation - General	Conduct a preliminary discussion to determine the scope and needs of a specific project.
Data Management Services	Provides assistance with • data specifications, • consistent terminology, • text for use in the informatics sections of grant applications, • cohorts of de-identified data to establish study feasibility, • assistance in preparation of a data set for statistical analysis.
Build Electronic Data Capture Databases and Forms	REDCap is a tool, developed by Vanderbilt University, with self-service online web forms that are used to create databases and surveys for clinical research. REDCap is ideal for the management of all clinical and translational research data.
Data Retrieval from EMR	Extraction of identified or de-identified, IRB-approved clinical data for retrospective analysis and prospective follow-up. Commonly used following a Cohort Discovery.
Terminology Services (i.e., ICD-9, ICD-10, HL7)	Service to establish consistent terms used for research data sets.
Training: Cohort Discovery, Data Explorer, REDCap, Research Volunteer Registry, SciVal, Velos and Data Management Systems	Both one-on-one as well as medium-size group training are available.

Biostatistics	
Biostatistical Consultation - General	Conduct a preliminary discussion to determine the scope and needs of a specific project.
Study Design/Protocol Development	A proper study design is critical for ensuring that the data collected in a study will support a defensible evaluation of a study's aims. Through this service, a biostatistician will work with an investigator to design a study, including, as appropriate, • determining the structure of the study (e.g., two-arm study, case-control study, cross-over, etc.), • defining the control population, • clarifying inclusion and exclusion criteria, • establishing randomization procedures, • developing matching criteria and/or strata, and • specifying interim analysis procedures. The statistician will write relevant sections of the grant or protocol. Please allow at least 6 weeks prior to the submission date for assistance with

	study design/protocol development.
Sample Size/Power Calculations	Research studies and clinical trials need to have a sufficient, but not excessive, number of subjects to be able to detect a meaningful change in the primary outcome of interest. Through this service, a statistician will determine the number of subjects needed to assess a study's primary aim at an appropriate level of statistical power. It is advisable to engage a biostatistician in developing the study design, defining outcome measures, and other aspects of the proposal, and not just with a sample-size calculation.
Grant Proposal Preparation	Grant proposals typically require several sections specifically involving statistics, such as the sample size justification and a statistical analysis plan detailing the methods that will be used to evaluate the primary and secondary aims of the study. A biostatistician can assist in preparing these sections of a grant proposal by working with the investigator on all aspects of grant proposal development, including • refining the study's specific aims, • developing the study design, • determining sample size requirements, and • preparing a statistical analysis plan. The biostatistician will prepare the relevant sections of the grant proposal. Please consult with the CTSC Biostatistics Core at least 6 weeks prior to the submission deadline for a grant proposal.
Statistical Analysis Plans	Statistical analysis plans describe the statistical methods that will be used to evaluate the hypotheses of a study. Typically, these plans are prepared as part of a grant proposal or clinical trial protocol. Through this service, a CTSC biostatistician will develop a plan for statistically analyzing an investigator's study questions and communicate this plan to the investigator either verbally or through a written plan.
Data Collection and Data Management Guidance	Identifying what data to collect and how to store and manage the data are important to define prior to initiating a research study or clinical trial. Under this service, a biostatistician will work with an investigator and biomedical informatics staff to identify what data to collect in a study, develop a data dictionary, and define the database structure. These tasks are important for ensuring that the data necessary for assessing a study's aims are collected and are stored in a manner conducive to conducting the proposed statistical analyses.
Data Safety and Monitoring Board (DSMB)Participation	A biostatistician will serve on the DSMB for your clinical trial and conduct statistical assessments defined in the study protocol for the DSMB.
Statistical Analysis and Interpretation of Data	A biostatistician will work with an investigator to analyze study data and interpret the results. The statistician will • develop a statistical analysis plan that addresses the study aims, • conduct the analyses, • prepare graphs and tables to illustrate the findings, and • provide a written report of the analytical methods and results to

	the investigator.
Manuscript Preparation and Review	A biostatistician will prepare a description of the statistical analyses conducted, describe the results of the study and provide figures and tables as necessary to illustrate the results. This service is typically limited to projects for which the biostatistician has conducted the data analysis for the project.
Response to Reviewer Comments	Biostatisticians can assist investigators in responding to reviewer comments involving statistics. Under this service, the biostatistician will review the submitted manuscript and reviewer comments, and provide input to the investigator on how to the respond to the comment.
Statistical Advice	For investigators conducting their own analyses, biostatisticians are available to provide advice. This service is appropriate for investigators with a focused, one-time question. Investigators may also select this service if they need help defining what statistical services they need.

Clinical Research Center	
CCRC Consultation - General	Conduct a preliminary discussion to determine the scope and needs of a specific project.
CRC - Study Coordination/Management	Services available include • budget preparation and review, • subject recruitment, • source document and CRF development, • subject visit support, and • protocol training.
CRC - Regulatory Support/Management	IRB preparation and review, monitoring, and audit preparation.
Research Dietitian - Consultation	Initial consultation to clarify research needs prior to finalization of protocols involving nutrition intervention/evaluation.
Research Dietitian - Food Intake Analysis	Analysis of food records with ESHA Food Processor Nutrient Analysis Software. Administer 24 hour recall, satiety and food frequency software questionnaires.
Research Dietitian - Meal Planning	Metabolic and calorie-controlled meal planning.
Research Dietitian - Nutritional counseling education	Development of educational materials based on the needs of the study protocol. Provide nutrition or exercise education via phone, class or individual appointment.
Exercise Physiologist - Initial Consultation	Consultation to assist investigators in developing protocols involving exercise physiology, intervention body composition, and energy metabolism.

Exercise Physiologist - Extended Consultation	Help investigators process, analyze and interpret the data derived from the study in a useful, meaningful format and help interpret what the results means with regard to health and metabolism.
Exercise Physiologist - Body Composition Measurement (Anthropometric Measurements)	Multiple noninvasive, quantitative techniques for determining body fat composition by measuring, recording, and analyzing specific dimensions of the body, such as height and weight; skin-fold thickness; and circumference at the waist, hip, and chest.
Exercise Physiologist - Body Composition Measurement (Bioelectrical Impedance Spectroscopy (BIS))	Noninvasive method used for determining total body water, as well as changes in body composition specifically, fat free mass, fat mass and total body fat.
Exercise Physiologist - Body Composition Measurement/Bone Density Measurement (Dual energy X-ray absorptiometry (DEXA))	Assessment of bone density in the spine, hip and forearm as well as body composition (body fat and lean mass), using the most recent NHANES reference data.
Exercise Physiologist - Energy Expenditure (Activity Monitoring)	Polar 810i heart rate monitors and Actigraph GT1M accelerometers are used to measure heart rate, activity, and energy expenditure in the lab or in the field.
Exercise Physiologist - Energy Expenditure (Exercise Testing)	The Quinton Q-Stress System directly interfaces with the Quinton TM55 treadmill for performing cardiac exercise testing or basic stress tests. The treadmill can also be used in protocols requiring fitness training.
Exercise Physiologist - Energy Expenditure (Indirect Calorimetry)	The ParvoMedics metabolic cart measures energy expenditure at rest and during exercise as well as measuring the thermic effect of food on metabolism during a controlled diet.
Exercise Physiologist - Exercise Planning and Patient Education	Develop educational materials based on the study protocol. Provide exercise education via phone, class or individual appointment.
Exercise Physiologist - Hand Held Dynamometry	The hand-held dynamometer (HHD) is a portable device used to measure hand or grip strength. For example, It can be used to measure strength changes due to trauma or various neurological changes.
Exercise Physiologist - Manual Muscle Testing	Manual muscle testing is used to determine the degree of muscular strength changes resulting from disease, injury or atrophy. It is a means of testing the function and strength of individual muscles and/or groups.
Phlebotomist	Can be provided at locations throughout the community, including a subject's home.
Lab Technician	Simple specimen processing.
Lab Technician	Complex specimen processing.

Lab Technician	DNA/RNA isolation.
Lab Technician	Multiplex cytokine/chemokine and metabolic analyses.
Lab Technician	Specimen shipping.
Nurse Practitioner	History and physical, focused assessments.
Nurse Practitioner	Invasive procedure (i.e., skin biopsy, fat biopsy).
Nurse Practitioner	Clinical monitoring.
Nurse Practitioner	Specialized orders and flow sheets.
Clinical Research Nurse	Adverse Event documentation and management.
Clinical Research Nurse	Biopsy assist (i.e., fat, muscle, and liver).
Clinical Research Nurse	Central line access and site care.
Clinical Research Nurse	Chart reviews.
Clinical Research Nurse	Chemotherapy administration.
Clinical Research Nurse	Conscious sedation.
Clinical Research Nurse	Continuous infusions (investigational or approved drugs).
Clinical Research Nurse	Continuous pulse and BP monitoring.
Clinical Research Nurse	5L cardiac monitoring and 12 Lead EKG.
Clinical Research Nurse	Glucose monitoring.
Clinical Research Nurse	Insulin clamp.
Clinical Research Nurse	IV and Oral Glucose Tolerance Testing.
Clinical Research Nurse	Peripheral line access and maintenance.
Clinical Research Nurse	Serial blood sampling (PK/PD Studies).
Clinical Research Nurse	Source document and Case Report Form development.
Clinical Research Nurse	Specimen processing.
Clinical Research Nurse	Standardized orders and flow sheets.
Clinical Research Nurse	Qualitative data collection.

Community Engagement	
CE Consultation - General	Conduct a preliminary discussion to determine the scope and needs of a specific project.
Recruitment and Retention	Train investigators how to work with underserved communities to recruit for clinical trials and create health partnerships.
Community Service for Health Researchers	Expose investigators to the opportunities to serve on community boards of organizations working with health researchers.

Health Disparities Data	Provide access to data on health disparities in the Sacramento region and California, by population and disease.
Cultural/Linguistic Training	Provide customized *Culturally and Linguistically Appropriate Services* (CLAS) training for health systems staff and management.
Racial/Ethnic Data Collection	Train researchers how to collect sensitive racial and ethnic data within health systems.
Connect with Health Researchers	Train community members and organizations how to form health partnerships with researchers working in community priority health areas and how to serve on Health System boards.
Community Review Board	Solicit feedback from a panel of community members on a research proposal—particularly for PCORI or other patient/community oriented proposals.

Concierge	
Concierge Service	Upon request, our Concierge Service will help you navigate through CTSC services, processes, and resources. We can coordinate services and provide suggestions to augment your research program.

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)