Investigator Support Services

Under the leadership of Dr. Arash Naeim and the CTSI, listed below are new support services designed to transform, advance, and optimize clinical research infrastructure, workflows, and support.

Office of Regulatory Affairs (ORA)

The Clinical and Translational Science Institute Office of Regulatory Affairs (CTSI-ORA) provides a broad spectrum of support for Clinical Investigators and their study teams in the conduct and navigation of the clinical research process.

Services provided by this office include: Scientific and Feasibility Review, Data and Safety Monitoring, internal monitoring and auditing support, FDA and Sponsor inspection/audit preparation and guidance, ClinicalTrials.gov registration and results reporting assistance, FDA IND/IDE guidance and support, regulatory binder preparation, and more.

Coordination Services & Education (CSE)

Coordination Services & Education (CSE) is a resource within the Office of Clinical Research (OCR) that assists UCLA faculty, staff and clinical research teams with the regulatory, financial and compliance-related components of clinical research during study activation, conduct and closeout of a clinical trial. CSE includes three dedicated teams focused on advancing contributions in study activation, study conduct and study team training and education.

- Study Activation Team
- Clinical Research Coordinator Team
- Education and Training

Faculty Advice & Consultative Services

As Director of the Faculty Advice and Consultative Services, Isidro Salusky, MD, provides faculty advice and consultation to investigators within the CTRC. Dr. Salusky will work closely with the Scientific Review and Data Safety and Monitoring Committees to resolve scientific and regulatory issues associated with specific clinical research protocols and principal investigators. In conjunction with the Office of Regulatory Affairs, he will also participate on the CTRC Study Prioritization Committee to represent the Investigator community and perspectives when important decisions are required.

Research Quality & Clinical Research Ombudsmen

Serving as Director of Research Quality and Clinical Research Ombudsperson, Sandra Binder will be looking for global ways to improve clinical research efficiency and provide a high degree of customer service. She will also be responsible for looking into specific issues around studies that may seem stuck in the study start-up process.

FDA Affairs

The University of California, Los Angeles, Clinical Translational Science Institute (CTSI) has released a website

featuring tools, templates, guidance, and go-to for clinical research called ResearchGo. Under the direction of Marlene Berro, MS, RAC and her team of FDA specialists, Amanda Gonzales, MPH, RAC and Jenny Ahn, BSN, RN, RAC, this virtual Clinical Research Resource provides a single portal to a wealth of resources, expertise, and best practices for investigators and research staff to facilitate efficient, compliant and ethical study conduct and management. In addition to ResearchGo, they will provide support for investigators submitting or holding an IND or IDE at all stages of an investigation. Please contact Director of FDA Affairs, Marlene Berro MS, RAC for additional information.

Clinical Translational Research Center (CTRC)

Clinical and Translational Research Centers support and supervise human studies and clinical trials in all therapeutic areas and within all age groups. Special access to resources and facilities at the 4 partner campuses: Cedars-Sinai, Charles Drew University, Lundquist/Harbor-UCLA, & UCLA. **Noah Federman, MD,** has assumed the new role of Medical Director of the CTRC. As an on-site Medical Director, Dr. Federman will focus on utilization review, quality assurance, and medical protocol development as well as CareConnect, integration optimize the study start-up and scheduling of CTRC studies. In addition, **Marjorie "Margie" Weiman**, RN, MSN, CPHON, serves as Co-Director for CTRC Nursing and will ensure the highest quality care is being provided in an efficient and compliant manner aligned with the UCLA Health System.

CTRC meetings are held every other Wednesday. A complete application and all requested documents must be received at CTRCServices@mednet.ucla.edu by 5pm the Wednesday prior to the scheduled CTRC Operations Committee meeting date. An incomplete submission may delay review.

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