FACILITIES AND OTHER RESOURCES:

Southern California Clinical and Translational Science Institute

The Southern California Clinical and Translational Science Institute (SC CTSI) was established in 2008 by leveraging institutional support from USC and Children's Hospital Los Angeles and a large Clinical and Translational Science Award from the NIH. The SC CTSI is an organization devoted entirely to improving the success of clinical and translational science with services and tools that support researchers and their work. From initial research concept to engaging the community, the programs provide a wide range of expertise in translational research to help researchers fulfill "bench to bedside" healthcare goals.

SC CTSI is designed to support investigators from any unit at USC and CHLA, community partners, and affiliated institutions including LA County Department of Health Services. For assistance with designing and conducting studies, researchers can access comprehensive and integrated consultation services at both USC and CHLA in several domain areas.

The USC and CHLA Clinical Research Support Offices (CRSO) provide efficient and cost-effective research support to facilitate high-quality, efficient, and safe clinical research and trials. CRSO staff brings expertise in implementing, conducting, and monitoring clinical research studies and trials from start-up to closeout, supporting both novice and experienced clinical investigators and study teams.

- Our Research Navigators connect investigators with the services and support needed to conduct high-quality, efficient, and safe clinical research and trials. This includes study design, feasibility assessment, regulatory and IRB approval, participant recruitment, study implementation and coordination, registration and billing, study closeout, etc.

- Clinical Research Coordinator Pool: Our Clinical Research Coordinator (CRC) pool supports research studies throughout USC and CHLA. CRCs are centrally managed and trained, ACRP and/or SOCRA-certified and they collectively provide a broad range of knowledge and expertise about conducting clinical research studies and trials. Bilingual staff members are available for conducting research with diverse populations, and some CRCs are phlebotomy certified. The CRCs are available on a fee-for-service basis to join your study team to help implement and conduct all aspects of a study from startup to closeout.

- Research Nursing: Research nurses facilitate clinical research by conducting protocol-specific study activities. A nurse practitioner is also available at the USC site. CHLA nurses can travel to clinics or inpatients when needed to facilitate patient participation. All our nurses are PALS certified, are trained to support specimen processing and shipping, and can assist with clinical research participant registration and hospital billing. Procedures include detailed assessments of research participants; peripheral blood-draws; blood draws from central venous catheters; research medication administration; oral glucose tolerance tests; and other research protocol specific clinical interventions.

- Clinical Trials Unit (CTU): The SC CTSI supports two CTUs, one located at the Keck School of Medicine and the other at CHLA; both support inpatient and outpatient clinical trials and research studies for research teams. The USC capabilities include DEXA scan, EKG, infusion equipment, serial pK and pD sample procurement and processing. The USC CTU also contains refrigerators, freezers and dry ice for shipment of samples, as well as a sample processing center. The CHLA CTU space comprises three outpatient exam rooms, a blood draw center, neuropsychology assessment rooms, and specimen processing facilities for studies involving pediatric populations. Both facilities operate on a combination of institutional support and cost share for all direct services provided to research teams. The Keck CTU includes 4,500 square feet of administrative offices on the first floor of the hospital and research-only exam rooms and other facilities on the fourth floor of the hospital. CHLA's CTU is located on the first floor in the main hospital building, in a 1,625 square foot outpatient facility, alongside the Children's Health Imaging Research Program, with four dedicated patient care areas for research participant evaluations and interventions, as well as a research laboratory for specimen processing.

- Clinical Research Specimen Processing and Shipping: Research specimen processing and preparation services are available to support for both investigator-initiated and sponsor-supported clinical research studies. Staff support basic to complex specimen processing and shipping to central laboratories. The Clinical Laboratory ensures that clinical research specimens are processed appropriately for both outpatient and inpatient research protocols and provide 24/7 coverage when needed based on the requirements of specific study protocols. Services are provided on a fee-for-service basis.

- Regulatory Support is critical for any clinical research, as each study requires rigorous institutional and federal regulatory review and documentation. USC and SC CTSI have therefore developed regulatory support services, including assistance with human subjects' protection by the IRB. The Regulatory Specialist provides the clinical research community at USC with support and information, as well as fee-for-services to coordinate regulatory affairs for clinical research studies and trails. Support includes preparation and submission of study protocol to Institutional Review Board (IRB); preparation and filing of IND/IDE initial submissions to the FDA as well as yearly reports; and completion of essential study regulatory documents.

  Recruiting for Clinical Studies: Recruitment specialists at USC and CHLA can assist investigators and study teams with maximizing participant recruitment and retention using traditional and digital methods, creating communications plans and strategies, and in-house design of study-specific print materials for a nominal fee.

Community Engagement: The SC CTSI has unique expertise in community engagement and has well-established channels to identify community health needs through annual community needs assessments. The CE group has a very strong track record of developing and supporting academic-community research partnerships that have real impact in our communities. CE has also pioneered integration of community health workers (e.g., *promotores* in Latinx communities and Community Health Workers in African American communities) into the research workforce, with strong results in both the conduct of research and dissemination of results. CE has expanded training opportunities by adding a module on clinical trials to the short course, Research 101, which educated community members on participation in research. CE offers more in-depth training on core competencies, leadership, and advocacy for development of Community Research Ambassadors and Advisory Boards.

Biostatistics: SC CTSI provides a variety of resources through our Biostatistics, Epidemiology and Research Design (BERD) core. SC CTSI BERD biostatisticians offer support to investigators in study design and formulating aims and hypothesis, safety outcomes, data collection, cleaning and management and data sharing. BERD also assists investigators with developing statistical analysis plans including development of research questions, identification of study variables to address the research question, and detailing statistical methods to be used to address the research question. For training and education, BERD offers seminars and individualized training and support on access and usages of the NIH-vetted Research Electronic Data Capture (REDCap) application, a free and secure, web-based tool designed to support data capture and surveys. The cloud-based database and calendar features are especially useful for coordinating multisite studies. Finally, BERD team also assist investigators with preparing publications related to biostatistics, study design and epidemiology.

Team Building: SC CTSI's team-building resources include an online search tool, USC Profiles, that automatically creates public profile pages for USC faculty and displays their PubMed publications. It currently includes 4,100 USC faculty in the health sciences. For researchers seeking external partnerships, the Community Engagement program facilitates the development of academic-community partnered research and also helps disseminate findings to promote uptake of effective interventions and the delivery of evidence-based, culturally competent, and relevant care in community settings.

Pilot Funding: SC CTSI's pilot grant program provides ~$400K per year to support early-stage clinical, community and healthcare research, as well as research to improve processes in clinical and translational research. Proposals as solicited once each year and reviewed using an NIH-style peer-review process. Past awardees have a strong track record of follow-on extramural research funding. Other support offered by SC CTSI for securing research funding include consultations on preparing funding proposals and coordination of

mock NIH-style reviews. Other SC CTSI awards provide pilot funds for team building, clinical research support, and healthcare delivery science.

Workforce Development: The SC CTSI develops, implements, and sustains a wide array of clinical and translational research training opportunities. SC CTSI offers for-credit courses in clinical and translational research, free workshops on digital scholarship and mentoring, research ethics forums, and short courses in clinical and translational research in urban populations. Topics in the Career Development Seminar Series have included Biostatistics, Communication, Community Engagement, Innovation, Leadership, Mentoring, Academic Advancement and Promotion, Regulatory Knowledge, Clinical Research Ethics, Research Methodology, and Team Science. A **fully equipped media studio and editing room** enables the recording of high-quality lectures for online delivery. The facility is designed as a green screen recording studio that allows users to present their lectures in any environment, from a classroom to a clinician's office or news desk. The studio is available as a service to anyone at USC and CHLA, as well as outside users. The SC CTSI **Education Resource Center** provides state-of-the-art learning initiatives and supports overall education program development, administration, and evaluation. The SC CTSI **Mentor Resource Center** promotes a culture of mentoring through competencies, training, matching, evaluation and practical tools to enhance the mentor-mentee experience. The three-year KL2 program provides junior faculty members at USC and CHLA with support for three years of protected time, didactic and experiential education and mentor-based career development. Program graduates have a very high rate of success in academic careers.

Healthcare Delivery Science: The Healthcare Delivery Science team within the SC CTSI advances health system innovations through research awards, training, and collaborations with LA County Department of Health Services and other partners. These partnerships provide opportunities to overcome healthcare silos and inefficiencies and address patients' and the health system's priorities. Researchers may request free consultations for help navigating the complex field of Healthcare Delivery Science, especially in the context of LA County safety-net hospitals.

Computing and Informatics Resources:

OnCore: USC's Clinical Trial Management System, OnCore, is a jointly sponsored, web-based software system for managing clinical trials. The CTMS is integrated with the KeckCare EHR (Keck Medicine of USC) and KIDS EHR (CHLA) to streamline the process of activating and managing clinical trials.

REDCap: Research Electronic Data Capture (REDCap) is a free, secure, web-based application designed for rapidly developing databases and surveys for research studies. The current instance of REDCap is HIPAA compliant. The system was developed by a multi-institutional consortium initiated at Vanderbilt University. It is currently being used across the nation on a broad spectrum of research studies.

Profiles: USC Health Science Profiles is a researcher networking and expertise mining tool. It helps users discover over 3,200 USC faculty, researchers at 30 biomedical institutions nationwide, and data on over 62,000 publications and more than 350 clinical trials

DataNexus: SC CTSI's DataNexus is a centralized system that integrates data from across the hubs' institutional and external databases, providing automated and efficient metrics reporting regarding service, productivity, and impact in support of Evaluation and Improvement activities. The metrics include NCATS Common Metrics, which are fully integrated into DataNexus and include pilot publications and grants, using data from PubMed and institutional grants and contracts (updated monthly); IRB duration, using data from our eIRB system (updated weekly); careers in CTR, using program data collected by our KL2 program (updated bi-annually); and interoperable clinical data availability and completeness, using EMR data obtained through TriNetX (updated bi-annually). DataNexus also includes data from OnCore, our clinical trials management system, to assess metrics such as trial activation time and accrual.

Cerner Health Facts®: The CERNER Health Facts® database captures and stores de-identified, longitudinal electronic health record (EHR) patient data, and then aggregates and organizes these data into consumable data sets to facilitate analysis and reporting. The data is derived from Cerner and non-Cerner participating contributing facilities and go back as far as 2000. Cerner Health Facts focuses on providing information on five health outcomes: clinical, economic, process, functional, and satisfaction. Specifically, the database includes data on patient demographics, encounters, diagnoses, prescriptions, procedures, laboratory tests, locations of services/patients (e.g., clinic, ED, ICU, etc.) and hospital information, and billing.

Keck i2b2: The Informatics for Integrating Biology & the Bedside (i2b2) system is web-based query tool that is used for cohort discovery. Data extracted from the Cerner EHR at Keck is transformed into OMOP data model to support various networks, such as PCORNet, and then harmonized and used to populate the Keck i2b2. Investigators can use this tool to query feasibility of projects, and find cohorts for recruitment into trials, and to derive data marts for studies.

TriNetX: TriNetX is the global health research network that optimizes clinical research and enables discoveries through the generation of real-world evidence. TriNetX combines real-time access to longitudinal clinical data with state-of-the-art analytics to answer complex research questions at the speed of thought.

ACT: The Accrual to Clinical Trials (ACT) Network is a real-time platform allowing researchers to explore and validate feasibility for clinical studies. The network contains de-identified data from over 100M patients from academic medical research centers in the Clinical and Translational Science Award (CTSA) network. ACT is secure, HIPAA-compliant, and IRB-approved.

OpenSpecimen: SC CTSI manages and hosts OpenSpecimen system, a comprehensive biospecimen laboratory information management system. This system tracks all types of biospecimens from collection to utilization for prospective biobanking, longitudinal collections, multi-site clinical studies, or non-human collections. The system manages biorepository efforts for COVID-19, Norris Cancer Center, and KSOM.

Service Core: SC CTSI coordinates research data services for researchers at USC and CHLA. In addition, DHS and SC CTSI have partnered to create an Informatics and Analytics core with SC CTSI staff members embedded in the DHS to facilitate research data access. DHS provides dedicated space for SC CTSI analysts.

Health Data Innovation Program:

USC has committed $45M to develop a Health Data Innovation Program (HDIP) composed of (a) a fully functional Enterprise Data Warehouse and Analytics Platform (EDW&AP), and (b) in-house analysts, developers, and support. This EDW&AP will be staffed by experts in data science, data management, and analytics. It will be architected for easy integration with cloud analytics to drive insights to better integrate clinical operations and translational research.

The HDIP is envisioned as a digital laboratory for innovations to transform medical care. It will create a health information ecosystem across USC's clinical and research enterprises to advance USC's position as a leading academic health center. Integration occurs in two primary dimensions: 1) clinical and human biomedical data from Keck Medicine, complemented by external datasets where appropriate, and 2) the IT, informatics, and data science tools and talent necessary to leverage those data. The HDIP comprises six major areas of infrastructure, innovation, and service.

1) *Infrastructure* includes a unified Enterprise Data Warehouse & Analytics Platform that serves as a platform with tools and resources upon which will be built the innovation. The EDW&AP is an agile, flexible, elastic cloud-based design.
2) *Innovation in Data Capture* will collect data from traditional health system sources such as EMR, imaging, and clinical notes. Beyond the EMR, it will capture data from novel sources such as Patient Generated Health Data, Real-World Data, and third-party dataset.
3) *Innovation in Data Management* will ensure that captured data conforms to the FAIR (Findable, Accessible, Interoperable, Reusable) standards. This will include making datasets easily discoverable, making it easy to understand the context of data and the data owners, enabling plug-and-play datasets and analytic pipelines, and cross-linking diverse datasets.
4) *Innovation in Applications* will enable real-time analytics and decision support through smart interfaces to the EMR. Specific use cases include extracted facts from NLP and GIS applications.
5) *Innovation in Advanced Analytics* will build reusable frameworks to push analytics from descriptive and diagnostic to predictive and prescriptive. It will develop plug-and-play pipelines to link analytics, to best exploit the datasets from the data capture and data management innovations. Some use cases include using machine learning to generate hypotheses and using image analysis and NLP to automatically annotate medical imaging.
6) *Service* means building a team of experts to power this digital laboratory. They will build, maintain, and operate the infrastructure; construct the innovation frameworks and pipelines; and guide and consult with researchers to make full use of the infrastructure and innovations.