**Institutional Information for Proposals**

**‘CHLA Facilities & Environment’**

**Q2 FY21 | Published December 10, 2020**

**Research Training and Education**

The Office of Training, Education, Career Planning and Development (TECPAD) serves the Children’s Hospital Los Angeles (CHLA) community of pediatric residents, clinical fellows, postdoctoral fellows, students, health professionals, and junior faculty who conduct pediatric research. CHLA aims to recruit the most talented and dedicated research trainees from diverse backgrounds, providing them resources to advance pediatric research and build successful and fulfilling independent research careers. TECPAD supports research trainees across various career stages and at different academic levels by creating forums for researchers to interact with and learn from one another in order to build community and share ideas. Additionally, TECPAD provides support to streamline administrative processes for research trainees.

*The George Donnell Society for Pediatric Scientists*

The George Donnell Society for Pediatric Scientists is dedicated to improving the health of children by training pediatric clinician-scientists to perform innovative and high-quality research. The Society, which provides mentorship, infrastructure, and a community for pediatric scientists in training, is an honorary society of pediatric resident physicians who are admitted to the program upon internal application submission and review. Donnell Scholars are supported with an individual development plan (IDP), support of research projects, including clinical data use projects, and receive educational and conference allowances. The Society aims to bridge candidates into fellowship, hopefully at CHLA.

*Weekly Research Seminar Series*

The Saban Research Institute hosts a weekly research seminar series during the academic year. The Research Seminar series hosts internal and external speakers and is intended to provide our scientists opportunities to learn about exciting new scientific developments important to our research community. Graduate students, research and clinical fellows as well as faculty members (MDs and PhDs) regularly attend our seminars, which makes the series unique. The topics are generally broad in scope in order to accommodate the heterogeneous research minded community at our institution.

*Annual Poster Session*

Every June, the Annual Poster Session provides the opportunity for our research community to come together and share our most recent observations and discoveries. For over two decades, this engaging poster session has fostered this translation by bringing pediatric investigators together to ask questions, to listen, and to offer new ideas, insights, and perspectives to one another.

*Research Success Teams*

TECPAD supports the successful development of early career faculty who seek to become independently funded investigators. Research Success Teams provides specialized support and resources to help junior investigators prepare and submit competitive proposals for career development awards or independent research awards by connecting them with services such as mentorship, mock grant reviews, professional grant writing support, and a repository of successfully funded proposals. The initiative also supports early career investigators with opportunities for peer support with regular “works in progress” feedback sessions, as well as a series of didactic sessions led by our more senior investigators.

*TSRI Annual Symposium*

Each year, The Saban Research Institute of Children’s Hospital Los Angeles (CHLA) and The University of Southern California (USC) host a research symposium that highlights an important area of study to advance our understanding of the developmental origins of health and disease. The day-long event highlights exciting strides researchers at CHLA, USC and from around the globe are making in understanding the developmental origins of health and disease. Each year, the theme of the symposium reflects a research priority area of TSRI and USC.

*Intramural Funding Program*

TSRI supports a broad intramural funding program designed to support investigators across all career stages. Supported intramural funding mechanisms include a training and travel award program, Cores Utilization Grants, Research Career Development Awards ($60K) for junior faculty, Health Professional Research Career Development Awards ($30K) for clinician junior researchers, Team Science Grants ($100K), Pre-Doctoral Support (stipend and health fees), Research Career Development Fellowships (salary and benefits support) for postdoctoral fellows and second R01 Pilot Projects ($50K) designed for faculty with one R01 to open a new line of research to submit a second R01.

*Merit Awards Program*

TSRI is committed to the recruitment and retention of transformative faculty and supports a program that recognizes external funding success through annual distribution of unrestricted funds calculated at a percentage of external funding. These funds are designed to further a faculty member’s research efforts.

*Responsible Conduct of Research Training*

This course is designed to meet the basic educational requirements in scientific integrity and the responsible conduct of research as per "NOT-OD-10-019" (Update on the Requirement for Instruction in the Responsible Conduct of Research, November 24, 2009, released by the National Institutes of Health). The NIH requires that all trainees, fellows, participants and scholars receiving support through any NIH training, career development award, research education grant or dissertation research grant must receive instruction in responsible conduct of research.

The Training, Education, Career Planning and Development (TECPAD) team at Children’s Hospital Los Angeles (CHLA) hosts the Responsible Conduct of Research course twice per year (Spring/Fall) for trainees and faculty at all levels. The training is convened over 8 weekly sessions and entails 8-12 hours of directed discussion among attendees and faculty facilitators.

The purpose of the course is to:

* Facilitate awareness and application of established professional norms and ethical principles in the performance of scientific research across the institution
* Comply with requirements for NIH funding
* Demonstrate CHLA’s commitment to ethical conduct in research activities across the institution

Content areas include:

* Introduction to responsible conduct in research and basic ethics
* Policies for human subjects
* Animal research and safe lab practices
* Research misconduct and conflicts of interest
* Responsible authorship, publication and peer review
* Data acquisition
* Collaborative research
* Contemporary ethical issues and responsibilities in biomedical research
* Attendance and completion of assigned tasks result in the award of a certificate of completion which stipulates that the individual has met all the federal requirements for such education.

Learn more by visiting [Training and Education](https://www.chla.org/research/training-education-career-planning-and-development-tecpad), or visit our internal [SharePoint Resource Hub](https://chla.sharepoint.com/teams/ResearchOperationsEducation2/SitePages/TECPAD%20Resource%20Hub.aspx). For questions or additional information about the course, please contact tecpad@chla.usc.edu.

**Research Core, Facilities and Equipment**

The Saban Research Institute provides scientific direction and the critical space to support a wide array of research activities at CHLA. The Institute supports a number of core facilities fully equipped with state-of-the-art instrumentation to facilitate research at CHLA. An overview of these core facilities and equipment is as follows:

***Animal Core***

The Animal Core consists of a main Animal Care Facility (ACF), an Acute Animal Care Facility (AACF) and an Animal Care Fish Facility (ACFF). The Animal Core provides state-of-the-art housing for research animals and support to investigators who utilize research animals. It is American Association for Accreditation of Laboratory Animal Care (AAALAC) accredited and maintains an Office of Laboratory Welfare (OLAW) Assurance that confirms animal research at CHLA is performed at the highest standards. Services include animal purchasing and housing, veterinary drug purchasing and provision, daily husbandry, including daily health observations, quarantine facilities, investigator training for proper performance of animal research, including survival surgery, and assistance with performing minor veterinary procedures.

**Capacity**

The 13,000 square foot Animal Core has 18 animal housing rooms, 8 dedicated procedure rooms, 3 BSL2 rooms, 3 quarantine rooms, support space for feed preparation, cage and tank maintenance, and environmental maintenance, plus storage space. The core also includes office space, restrooms/lockers, and a break area to support numerous staff members.

**Equipment**

* Balanced and constantly monitored HVAC and humidity systems
* Automated RO water supply system
* Static and ventilated micro isolator cages
* Tunnel washer and dryer
* Automatic bedding dispenser unit
* Pass-through rack washer and bulk autoclave
* Indicators for quality assurance of cage and rack maintenance
* Automatic watering valves
* Freezer/24 hour refrigerator
* Multiple aquatic systems
* Feed preparation systems
* Cs source irradiator
* Biosecurity and physical security systems

The Acute Animal Care Facility (AACF) provides housing for animals with special care requirements. The facility provides short-term or acute housing for laboratory animals; it is not intended for long-term housing or breeding colonies. The ACFF provides housing and both import and clean quarantine spaces. All facilities are monitored by CHLA’s Laboratory Science program, which establishes policies related to the use of the facilities and the Institutional Animal Care and Use Committee (IACUC), which reviews and approves protocols involving animal research.

***Biostatistics Core***

The Biostatistics Core is at CHLA is jointly supported by The Saban Research Institute and the Southern California Clinical and Translational Science Institute (CTSI). The Core is designed to support efficient and accurate data collection and analysis by providing a variety of consultation services, including research design, grant planning, data collection and consultation for presentations and publications for researchers. The Core has been built to reflect the institution’s growing research portfolio in the areas of basic, translational, clinical, health services, and community health research. Members of the Biostatistics Core offer assistance with:

* Study/experimental design
* Power/sample size
* Randomization schema
* Statistical analysis plans
* Analysis of results
* Data acquisition plans
* Data cleaning and management
* Data sharing plans

***Cellular Imaging Core***

The Cellular Imaging Core provides access to state-of-the-art equipment in light microscopy and digital imaging to investigators at CHLA. The primary focus of the Core is technology transfer and provision of facilities for acquisition and analysis of histological and cytological preparations. An important aspect of this technology transfer is to provide training in the use of digital imaging devices, as well as in the application of image analysis procedures for generation of quantitative data.

**Equipment**

**Confocal**

* Leica STELLARIS 5 point-scanning spectral, FLIM, superresolution, live imaging confocal microscope
* Zeiss LSM 710 point-scanning spectral confocal microscope
* Zeiss LSM 700 point-scanning confocal microscope

**Lightsheet**

* Miltenyi Biotec UltraMicroscope II fluorescence lightsheet microscope

**Live cell imaging**

* Zeiss Axio Observer 7 LED fluorescence live cell imaging microscope
* Zeiss Axiovert 200M spinning disk confocal live cell imaging microscope

**Fluorescence and transmitted light (brightfield, phase contrast, DIC)**

* Combined fluorescence/color transmitted light microscopes: Leica DMI6000B
* Nikon Eclipse Ti (SRT 309C), and Leica DM4000B
* Olympus IX73 inverted fluorescence microscope
* Zeiss Axioplan color brightfield light microscope

**Stereoscopy**

* Leica MZFLIII fluorescence stereo and Optical Projection Tomography (OPT) microscope

**Image processing and analysis**

* 3D image processing workstation with AMD Ryzen Threadripper 32-thread processor, 128 GB of RAM, NVIDIA graphics card with 11 GB of video memory and 3584 CUDA cores, fast 2 TB solid-state drive (SSD) for working storage, and 10 TB hard drive for archival storage; software installed: Arivis Vision 4D, ImageJ/FIJI, QuPath, Adobe Photoshop and microscope manufacturer software for efficient display of native file formats: Zeiss ZEN, Leica LAS X, Nikon Elements Viewer
* 2D image processing and dedicated deconvolution workstation with an Intel Core i7 processor, 32 GB of RAM, NVIDIA graphics card with 2 GB of video memory and 192 CUDA cores, fast 1 TB solid-state drive (SSD) for working storage, and 2 TB hard drive for archival storage; software installed: AutoQuant AutoDeblur deconvolution, Molecular Devices MetaMorph, ImageJ/FIJI, QuPath, Adobe Photoshop and microscope manufacturer software for efficient display of native file formats: Zeiss ZEN, Leica LAS X, Nikon Elements Viewer

***Extracellular Vesicle Core***

The ECV Core provides the research community with expertise, optimized tools and emerging technologies to support research in the rapidly evolving fields of extracellular vesicle (i.e. exosomes, microvesicles) and nanoparticle research. Extracellular Vesicle focused services include isolation by size exclusion chromatography and/or density ultracentrifugation, characterization by standard immunoblotting and/or fluorescent-based immunophenotyping, analysis of size and concentration by nanoparticle tracking analysis. Other services include the isolation and analysis of vesicular and cellular mRNAs or miRNAs by quantitative real-time PCR, and the generation of anionic lipopolyplex nanoparticles labeled with antibodies for targeting to specific cell types and tissues both *in vitro* and *in vivo*.

**Equipment**

* Nanosight NS-300
* ExoView R100
* BioRad fraction collectors (Model 2110) and chromatography econo-columns
* Bio-Rad Protean electrophoresis chambers and Trans-blot Turbo Transfer System
* Tangential Flow Filtration System: KrosFlo TFF by SpectrumLabs
* Ultracentrifuge: Beckman Coulter Optima XE-90K

***Flow Cytometry (FACS) Core***

The FACS Core provides technical expertise and access to equipment for CHLA investigators who use analytical and sorting flow cytometry. Data acquisition is achieved with specialized computer software directly interfaced with the cytometer. The following applications are supported by instrumentation at CHLA: Absolute Counts, Apoptosis, Calcium Flux, Protein Co-localization, Cytometric Bead Assay (CBA) for up to 30 soluble cytokines or proteins per sample, DNA Cell Cycle Analysis, Flow-FISH for telomere length, Immunophenotyping, Intracellular and Nuclear proteins analysis, Live cell sorting, PhosFlow, Rare Event Detection/Sorting, Reporter Molecules, Single-cell Cloning, Sizing, Spot Counting for viral load, Subcellular compartmentalization, Synapse activity, Translocation, and Viability.

**Equipment**

* The FACScan (BD) analyzer is a 488 nm (blue) one-laser instrument, capable of detecting a maximum of three colorsin addition to FSC and SCC. CellQuest Pro software drives this instrument.
* The FACSCalibur (BD) analyzer is a 488 nm (blue) and 635nm (red) two-laser instrument, capable of detecting a maximum of four colors in addition to FSC and SCC. CellQuest Pro software drives this instrument.
* The LSR-II (BD) analyzer incorporates four solid-state lasers: 488nm, (blue), 633nm (red), 405nm (violet), and 355nm (UV). It is suitable for the CBA assay and can detect up to sixteen colors in addition to FSC and SSC. DiVa software drives the LSR-II.
* The FACSAria-I (BD) instrument is a high-speed cell sorter that can deliver up tofour populations simultaneously to purity frequently in excess of 99% for tube sorting. The ACDU system offers the capability of sorting in to slides and multiwell cell culture plates.The 2nd floor instrument has four solid-state lasers 488nm (blue), 561nm (yellow green), 633nm (red), and 405nm (violet) while the 3rd floor instrument has three solid-state lasers—488nm, 633nm, and 405nm. DiVa software drives the instrument.
* The DiVa FACS Vantage SE (BD) has three lasers—a 488 nm Laser, a 635 nm, and the Innova I-302 tunable krypton laser—with UV, Violet, Green, Yellow, or Red line capability. The Vantage collects up to eight colors: four parameters (laser 1), two parameters (laser 2), and two parameters (laser 3). This is in addition to FSC and SSC. DiVa software drives the instrument.
* The ImageStream ISXMk II (Amnis) is a imaging flow cytometer. Loaded with three lasers—488nm, 633nm, and 405nm—it will capture six digital images (spatial resolution of up to: 0.9NA, 0.33μm pixel size at 60x magnification) of each cell with up to four parameters of fluorescence. The spectral decomposition element splits the cell imagery into six spectral bands, one for each CCD camera. The unique time-delay integration tracks the motion of the cells and increases the signal 1,000 fold before an image is recorded. Inspire software is used for data acquisition and IDEAS software is used for data analysis.
* Analysis Stations—Upon data acquisition, stations are available for free-of-charge data analysis. Software packages currently available include Cell Quest, FlowJo, VenturiOne, and Modfit.

***Human MRI Research Core***

The state-of-the-art Philips Achieva dStream 3.0T MRI system in the Human MRI Research Core offers investigators unique access to a 3.0T MR system dedicated to research (CHLA is one of only 3 free-standing Children’s Hospitals in the US with a dedicated research MR scanner), the Philips scanner is the nucleus of a mounting imaging research program here at CHLA. The research dedicated 3.0 T system provides an opportunity to develop, refine, test and implement novel MR protocols and greatly accelerate the implementation of these advanced protocols to the clinical care of patients here at CHLA. In addition, the research agreement with Philips gives the accessibility to research protocols for development and advancement of imaging protocols.

**Equipment**

The MRI Scanner is equipped with 32-channel head and 2 32-channel torso coils allowing for faster acquisition and higher resolution examinations of both the head (brain) and body. 16 channel MV, transmit-receive head, and flex coils are also available. In addition, the MRI suite is equipped with the VisuaStim a MR-compatible video-goggle and headphones system which may be used to present stimuli during functional imaging studies or child-friendly videos during structural scans, thereby reducing anxiety and boredom and allowing children as young as 4 years of age to participate in MR studies. A video camera has also been installed in the scanner room to monitor patient movement and enhance the safety of our pediatric patients during their MR scans. A Biopac physiological monitoring system is available as well (ECG, pulse-ox, respirations) that may be used to monitor patients and to carry out advanced imaging acquisitions that time the MR scans to the patient’s physiology (thereby removing artifacts generated by breathing or blood pulsing through arteries). Additionally, the core has a mock scanner equipped with a VisuaStim with goggles and headphones and motion sensor for MRI scanner simulation to prepare participants for scans and provide a MRI scanner-like experience.

***Neuropsychology Core***

The Neuropsychology Core provides collaboration on study design and grant proposals to determine the neurodevelopmental or neuropsychological assessment battery to address research questions. The Core provides data collection and interpretation of the results for participants, aged 3 months to 60 years, through neurodevelopmental evaluations (assessment of cognition, receptive and expressive language, fine and gross motor skills, social skills and adaptive functioning), autism spectrum evaluations (structured parent interview and child evaluation) and neuropsychological evaluations (assessment of attention, working memory, processing speed, executive functions, language, visuo-constructional skills, sensorimotor skills, verbal and non-verbal learning and memory, and intellectual functioning, as well as social, emotional, behavioral and adaptive functioning).

***Metabolic Core***

The Metabolic Core provides access to state-of-the-art technology and high-quality metabolic phenotyping services to basic science researchers studying diabetes to basic science researchers studying diabetes, obesity and metabolism. Phenotyping experiments are conducted at CHLA by highly trained and experienced core personnel using the most up-to-date, standardized techniques. The services include, body composition (NMR), indirect calorimetry, locomotor activity, food intake, glucose and insulin tolerance, pyruvate tolerance, leptin tolerance, glucose CLAMP, sample collection, hormone and lipid assay, core temperature, tissuelyser as well as consultation and training.

**Equipment**

* TSE Homecage System
* EchoMRI 700 NMR
* TissueLyser
* Olympus Microscope

***Small Animal Imaging Core***

The Small Animal Imaging Core provides investigators with access to state-of-the-art imaging equipment for research that involves small animals, primarily mice. The core is also able to house mice and perform stereotactic and open surgical procedures to facilitate imaging animal models of human disease. Assistance with protocol development is offered. Experiment design services and image post-processing services are also available. Staffed with a number of research specialists and research assistants, this Core provides images to investigators and facilitates image processing and interpretation via collaboration with the Radiology Department.

**Equipment**

* Bioluminescence/Fluorescence imaging
* Micro-CT for in-vitro imaging
* 11.7 Tesla small bore MRI for in-vivo mouse model imaging
* High-Res plain film X-ray

***Stem Cell Analytics Core***

The Stem Cell Analytics Core is a centralized support facility serving the entire Saban Research Institute community. The Core's primary mission is to facilitate stem cell research, innovation and interactions to enable successful funded research projects. To this end, investigators may rent shared, meticulously maintained, and fully equipped tissue culture facilities and utilize facility staff for tissue culture support, training, and supplies management (including ordering, inventorying, stocking). The Core also provides the following cell line validation services: mycoplasma and pluripotency testing and third party STR identification and genetic integrity testing (both karyotyping and qPCR based tests). We also provide access to shared equipment such as nucleofector, 96-well shuttle, fluorescence plate reader, real time PCR machines, fluorescence and dissection microscopes and freezers.

**Equipment**

* TS100 Fluorescent Inverted Microscope (Nikon)
* Dissection microscopes (Nikon, Leica)
* QuantStudio 7 Flex Real-Time PCR System (96-well, 384-well, array card) (Applied Biosystems)
* Cuvette-based Nucleofector (Amaxa/Lonza)
* 96-well shuttle (Amaxa/Lonza)
* UV fluorescence plate reader (Biotek)
* Freezers (-80C and LN2’s)

***Single Cell, Sequencing and CyTOF (SC2) Core***

The SC2 Core provides the research community with new, rapidly evolving technologies and instrumentation options for projects of any scale, from individual researchers to large international teams, spanning single cell genomic, mass cytometry (Cytof) and image mass cytometry (IMC), microbiome sequencing, gene expression profiling and high throughput RNA/ DNA sequencing and advanced data analysis. With a focus on rapid, accurate, reproducible high-throughput services and the bioinformatics support to interpret the results, the Core is committed to rigorous quality control standards to support the use of biological sciences for the advancement of biomedical research.

**Equipment**

* Fluidigm Helios System (CyTOF)
* Fluidigm Hyperion System (IMC)
* 10X Genomics Chromium System
* Illumina NextSeq 500
* Illumina MiSeq DX
* Agilent 4200 Tapestation
* Agilent 2100 Bioanalyzer
* Fluidigm Biomark HD
* Qiagen QiaCube
* Qiagen Qiagility

***Translational Biomedical Imaging Laboratory***

Using imaging technologies to observe the natural course of biology in action, within living organisms, will help accelerate development of new diagnostics and treatments. The Translational Biomedical Imaging Laboratory (TBIL) provides dynamic imaging equipment and technical expertise to accelerate the trajectory of scientific discovery from bench to bedside and is currently collaborating on studies that include intestinal stem cell propagation, neuroblastoma and heart regeneration. TBIL is designed as a research accelerator that brings clinicians together with researchers who are defining the basic mechanisms that build organs, so that they can design better therapies.

Bioimaging includes powerful, innovative tools for the study of biological processes—such as confocal microscopes that can image virtually any specimen on a slide or culture dish, live-cell imaging and in-vivo fluorescence imaging. Additionally, confocal laser scanning microscopy allows investigators to acquire in-focus images from selected depths, a process known as optical sectioning. Images are then acquired point by point and reconstructed with a computer, allowing three-dimensional reconstructions of topologically complex structures. All of these methods hold enormous potential for a wide variety of diagnostic and therapeutic applications.

**Instrumentation Capabilities**

* Live Imaging Lab – with a multi-spectral, multi-photon microscope for high-resolution imaging of living specimens
* High-Speed Microscopy Lab – offering high-speed, volumetric imaging
* Extended Volume Imaging Lab – providing an integrated microtome and laser-scanning microscope for imaging large specimens
* Quantitative Image Analysis and Visualization Suite – providing high resolution workstations for image processing and image analysis
* The “Collaboratory” is an interaction space with high resolution video and video conferencing capabilities

***Washing Core***

The Washing Core provides centralized support of glassware washing for investigators housed in the Saban Research Building and Smith Research Tower (SRT). Staffed by four full-time employees Monday through Friday. Services include collection of glassware and instruments from laboratories, washing, autoclaving, and return of clean glassware and instruments to laboratories. Saban Equipment—3 pass-thru autoclaves, 2 pass-thru washers and dryers, all state of the art. SRT Equipment – 2 autoclaves, 1 washer and 2 dryers.

**Clinical Research Support Office**

The Clinical Research Support Office (CRSO), in collaboration with the Southern California Clinical and Translational Science Institute, provides efficient and cost-effective research support to facilitate efficient, high-quality, and safe clinical research and trials throughout CHLA. CRSO staff are experts in implementing, conducting, and monitoring clinical research studies and trials from start-up to close-out, supporting both novice and experienced clinical investigators and study teams.

Research Navigation: Our Research Navigator connects investigators with the services and support needed to conduct efficient, safe and high-quality clinical research and trials at CHLA. 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 across the clinical divisions of CHLA. They are centrally managed and trained, SOCRA-certified and collectively provide a broad range of knowledge and expertise about conducting pediatric clinical research studies and trials here at the hospital. The CRCs are available on a fee-for-service basis to join study teams and help implement and conduct all aspects of a study from start-up to close-out.

*Research Nursing Pool*

Our dedicated research nurses facilitate clinical research by conducting protocol specific study activities. The nurses are able to travel to clinics or inpatients when needed to facilitate patient participation. All of our nurses are PALS certified, are trained to support specimen processing and shipping, and can assist with clinical research participant registration and CHLA 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 Clinical Trials Unit supports outpatient and inpatient clinical trials and research studies for research teams throughout CHLA. The unit is located on the first floor in the main hospital building, in a 1625 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.

*Research Regulatory Support*

Regulatory support is critical for any clinical research involving children. Each study requires rigorous institutional and federal regulatory review and documentation, including approval of human subject protection by the Institutional Review Board (IRB). Our Regulatory and IRB Support Specialist provides the clinical research community at CHLA with support and information, as well as fee-for-service activities to coordinate regulatory affairs for clinical research studies and trials. Support includes: preparation and submission of study protocol to Institutional Review Board (IRB); preparation and filing of Investigational New Drug/Investigational Device Exemption (IND/IDE) initial submissions to the Food and Drug Administration (FDA) as well as yearly reports; and completion of essential study regulatory documents.

**The Southern California Clinical and Translational Science Institute**

The Southern California Clinical and Translational Science Institute (SC CTSI) was established in 2008 to address one of the most important problems in the health sciences: the difficulty of translating basic research into real-world medical interventions. Leveraging generous institutional support from the University of Southern California (USC) and Children’s Hospital Los Angeles (CHLA) and a large Clinical and Translational Science Award from the National Institutes of Health, the SC CTSI has built an organization devoted entirely to improving the success of translational science with tools and programs that support researchers and their work.

The SC CTSI has emerged as a valuable, multi­faceted resource for pre-clinical, clinical and community-partnered translational research at USC, CHLA, and throughout Southern California. The SC CTSI has created unique institutional partnerships involving USC, CHLA, the Los Angeles County Departments of Health Services, Public Health, and Mental Health, and more than 40 community organizations with special interests in improving the health of our neighbors throughout Los Angeles and Southern California. The SC CTSI has supported more than 800 investigators in their quest to create and apply new diagnostic and therapeutic advances, medical procedures, and behavioral interventions to improve clinical care and the health of individuals and the public. This work has generated $62 million in new extramural grant funding, and has had great impact on the scientific community, as evidenced by over 350 peer-reviewed scientific publications from SC CTSI-supported projects.

Biostatistics and Bioinformatics Resources

The program offers individualized support across the lifecycle of clinical and translational research studies. Services include advice and assistance with developing study protocols, experimental designs, and analytical strategies; preparing data analysis plans, including interim efficacy and safety monitoring; creating and reviewing data acquisition plans, including collection and coding; responding to reviewer comments; and training on study design, data collection, and data analysis.

Clinical Research Informatics

The program creates and operates the information infrastructure to support clinical trials and a broad range of clinical research, focusing on large enterprise-wide informatics tools and systems within USC, across partner institutions, and with external collaborating organizations. This includes enabling the expansion and effective use of clinical data in conjunction with information technologies, as well as the broad, safe, and compliant discovery, reuse, and sharing of data through the development of a federated clinical data warehouse for research. The program also provides training in informatics tools and methods to conduct multidisciplinary research.

Clinical Translation/Clinical Trials Unit

The program supports human mechanistic studies and early phase clinical trials by providing the appropriate clinical research infrastructure (two Clinical Trials Units [CTUs] — one at the Keck Medical Center of USC and one at Children’s Hospital Los Angeles) and assisting investigators in the development and conduct of their studies. The CTUs provide a well-equipped physical space, well-trained and dedicated clinical research staff, and a laboratory for specimen handling and processing.

Community Engagement

The program bridges researchers and local communities, building sustained partnerships to ensure that research initiatives meet real community needs. Researchers benefit by focusing on timely, responsive, culturally relevant targets, while community members can directly influence research choices and academia-community relations. Services include training and technical assistance workshops for community-engaged research, individual consultations for faculty, partners and community members, and matchmaking between those constituencies.

Education, Career Development, and Ethics

The program plays an essential role in the training and career development of the next generation of clinical and translational researchers and offers in-depth training and career development for selected pre-doctoral trainees and early career clinical researchers through NIH-supported programs. Access to certificate and Master of Science programs and assistance with locating mentors and improving mentoring skills are available for a wider audience throughout USC and CHLA. In addition, the Research Ethics program provides education and training as well as consultations to help researchers and clinicians anticipate, identify, and respond to ethical issues.

Electronic Home and Digital Strategies for Clinical Research

The program promotes innovation in communications and technology to develop and disseminate highly accessible, web-based research tools, services, and information resources. Areas of focus include easy access and discoverability of knowledge resources, novel ways to enable research collaborations, and promotion of clinical studies. The program also develops technical solutions that improve operational efficiencies for planning, evaluation, and tracking. The program further coordinates SC CTSI communications and develops novel, measurable communications approaches to more effectively increase the visibility of research and engage partners.

Planning, Evaluation, and Tracking (PET)

With a focus on transparency and accountability, the PET program works to create a more strategic organization with greater alignment between program and institute-wide priorities and activities. It supports the development of goals, targets, and relevant metrics of success, assesses progress, and improves overall performance and management to build a data- and metrics-driven organization. SC CTSI measures its impact in various ways including efficiency of service delivery, transformative changes in how research is conducted, and new science generated.

Pre-Clinical Translation and Regulatory Support

The program serves as an accelerator for pre-clinical development of novel therapeutics, devices, and biomarkers. It catalyzes the advancement of projects towards commercial implementation and clinical practice by connecting investigators to experts and offering regulatory support services.

Research Development

The program fosters the establishment and development of interdisciplinary clinical and translational research teams, projects, and programs. It has awarded ~$1M annually in pilot grants to support research, team building, and career development across all phases of translational research. Activities include active team-building, support for interdisciplinary project development, pilot funds for project initiation, and assistance with strategies for securing sustainable funding.

**Additional Resources**

The Children’s Hospital Health Sciences Library provides resources and services to CHLA staff. In addition to its collection of 3,500 print books and 170+ current print journal subscriptions, the library supplies access to over 200 electronic books and 2000 electronic journals. Online access is available anywhere in the hospital or from remote computers that connect to the USC network.

In addition to books and journals, the library also provides local and remote access to various journal article databases including: Ovid MEDLINE, Ovid CIwwNAHL, PubMed, PsycINFO, Science Citation Index, and Journal Citation Reports. The library’s book and journal catalog, as well as that of the USC Norris Medical Library (with whom the CHLA library has reciprocal borrowing agreements), is searchable online as well.

Library services include mediated literature searching (searches conducted by a librarian), interlibrary loan borrowing (for obtaining materials that the CHLA library does not own), Ovid AutoAlerts (a current awareness service that delivers weekly citations that match a researcher’s predefined topic), and HouseCalls (one-one-one, time-of-need meetings where the librarian can instruct users on a variety of topics including database searching, PowerPoint, or EndNote).