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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 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 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, resources, career development, and a diverse and a supportive 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 career development, support of research projects, and receive educational and conference allowances.

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 TSRI Science Day

This event combined The Saban Research Institute Annual Symposium and the Annual Poster Session into a full day of learning, discussing, and socializing with colleagues. 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. The morning symposium portion features renowned internal and external speakers. The afternoon Poster Session in the Saban Courtyard features posters showcasing a variety of research topics.

Research Success Teams

TECPAD supports the successful development of early career investigators who seek to become independently funded. Research Success Teams (RST) 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. RST Work in Progress meetings are convened on a regular basis, during which participants discuss upcoming proposal submissions and share their draft specific aims with peers and senior faculty. The program also offers a didactic series, led by senior research faculty, which provides focused learning and discussion around specific topic related to grant preparation and submission.

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.

The Samuel's Family Latino/x and African American High School Internship Program (LA-HIP) LA-HIP is dedicated to increasing the number of underrepresented students in the field of Science, Technology, Engineering and Math (STEM). Under the mentorship of CHLA faculty, students perform cutting-edge biomedical research experiments at The Saban Research Institute of Children's Hospital Los Angeles during the summer before their senior year. LA-HIP offers a mentorship opportunity for CHLA faculty to participate in the development of the high school student's interest in lab-based research.

Responsible and Ethical Conduct of Research Training

The Training, Education, Career Planning and Development (TECPAD) team at Children's Hospital Los Angeles (CHLA) hosts the Responsible and Ethical Conduct of Research (RECR) course twice per year (Spring/Fall) for trainees and faculty at all levels. The training is convened over 9 weekly sessions and entails 13.5 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 (as per Notice Number NOT-OD-10-019)
- Demonstrate CHLA's commitment to ethical conduct in research activities across the institution

Additionally, the RECR course is an eligible Continuing Medical Education (CME) activity. Those who participate in the course will be eligible to receive 13.5 credit hours towards their CME requirements.

Content areas include:

- Introduction to responsible conduct in research and basic ethics
- Human subjects' protection
- Animal research
- Research misconduct and conflicts of interest
- Responsible authorship, publication, and peer review
- Data acquisition (management, sharing, and ownership)
- Collaborative research
- Genetics and Genomics

• Contemporary ethical issues and responsibilities

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 about research training and education programs and resources by visiting <u>Training and Education</u>, or visit our internal <u>SharePoint Resource Hub</u>. For questions or additional information about our programs, please contact <u>tecpad@chla.usc.edu</u>.

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 AAALAC accredited and maintains an federal 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. The facility is staffed by a full time Attending Veterinarian and a team of animal care technicians.

Capacity

The 16,000 square foot core has 19 animal housing rooms, 8 dedicated procedure rooms, 3 BSL2 rooms and 1 BSL1+ room, 5 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
- Controlled lighting systems
- Automated RO water supply system for both rodent & aquatic systems
- Static and ventilated micro isolator cages
- Tunnel washer and dryer
- Automatic bedding dispenser unit
- Pass-through rack washer and bulk autoclave
- Miele tank washers
- Indicators for quality assurance of cage and rack maintenance
- Automatic watering valves
- Freezer/24 hour refrigerator
- Multiple aquatic systems featuring automated water quality maintenance
- Feed preparation systems for aquatic species

- 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 by 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:

- Planning/Designing Study
 - Statistical Analysis Plan
 - Power/Sample Size Justification
 - REDCap Database Set-up
 - Randomization Schema
- Analysis of data that has been collected
 - Data Cleaning and Management
 - Preparing a Publication/Presentation
 - Responding to Reviewers
- Other
 - Data Acquisition Plans
 - 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
- Leica STELLARIS 5 deep imaging, spectral, superresolution confocal microscope
- Zeiss LSM 700 point-scanning confocal microscope

Two-photon

Zeiss LSM 780 inverted two-photon & confocal live imaging microscope

Lightsheet

Miltenyi Biotec UltraMicroscope II fluorescence lightsheet microscope

Live cell imaging

• Zeiss Axio Observer 7 LED fluorescence live cell imaging microscope

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

- Combined fluorescence/color transmitted light microscopes
 - Leica DMI6000B
 - Nikon Eclipse Ti-E
 - o Leica DM4000B
- Olympus IX73 inverted fluorescence microscope for tissue culture inspection

Stereoscopy

- Leica M205 FCA fluorescence stereo dissection microscope
- 3D image processing and analysis
- AMD workstationAMD Ryzen Threadripper 3.4 GHz 16-core (32-thread) processor
 - 128 GB of RAM
 - NVIDIA GeForce GTX 1080 Ti graphics card with 11 GB of video memory and 3584 CUDA cores
 - Storage:
 - 2 TB fast solid-state drive (SSD) working storage
 - 10 TB standard hard drive storage
 - Software:
 - Arivis Vision 4D
 - Bitplane Imaris Viewer
 - ImageJ/FIJI
 - QuPath
 - Adobe Photoshop
 - Microscope manufacturers: Zeiss ZEN, Leica LAS X, Nikon Elements Viewer
- Three Intel workstations
 - Intel Core i7 4.2 GHz 8-core processor
 - o 64 GB of RAM
 - Two NVIDIA TITAN Xp graphics cards with 12 GB of video memory and 3840 CUDA cores
 - 33 TB of storage
 - Software:
 - Bitplane Imaris
 - AutoQuant deconvolution (in Imaris)
 - Amira
 - Matlab
 - AnalyzeDirect Analyze 14
 - syGlass
 - ImageJ/FIJI
 - Zeiss ZEN lite
- Extracellular Vesicle Core

The EV 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 by fluorescent-based immunophenotyping with ExoView, analysis of size and concentration by nanoparticle tracking analysis. Other services include the isolation and analysis of vesicular and cellular mRNAs or miRNAs by TaqMan based 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*. The core also grants access to an ultracentrifuge, a tangential flow filtration system and a chromatography system for independent use by core users.

Equipment

- Nanosight NS-300 by Malvern Panalytical
- ExoView R100 by NanoView Biosciences
- 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
- Chromatography: ÄKTA Start by Cytiva

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: conventional multi-parameter analysis and cell sorting, spectral multi-parameter analysis and sorting, and proteomics analysis.

Equipment

- The FACSymphony (BD) is a conventional cuvette cell sorter with five lasers (355 nm, 405 nm, 488 nm, 561 nm, 633 nm) and 32 fluorescence detectors. It has the capability to resolve up to 30 colors in combination. The sorter is housed inside a Class II biosafety cabinet. It can sort up to six populations simultaneously in 5mL tubes, four populations in combination of 15mL tubes or two populations in combination with 50mL tubes. Other collection features include microscope slides and cell culture plates up to 384 wells. Acquisition is run on FACSDiVa v9 software.
- The Aurora (Cytek) is a full spectrum cell analyzer with five lasers (355 nm, 405 nm, 488 nm, 561 nm, 640 nm) and 64 fluorescence detectors. It has the capability to resolve up to 40 colors in combination. Acquisition is run on SpectroFlo software.
- The CytoFLEX LX (Beckman Coulter) is a conventional cell analyzer with 6 lasers (355nm, 405nm, 488 nm, 561 nm, 638 nm, 808 nm) and 21 fluorescence detectors. It has the capability to resolve up to 21 colors in combination. Acquisition is run on CytExpert software.
- The FACSCanto (BD) is a conventional cell analyzer with three lasers (488 nm, 633 nm, 405 nm) and 10 fluorescence detectors. It has the capability to resolve up to 8 colors in combination. Acquisition is run on FACSDiva v9 software.
- The LSR-II (BD) is a conventional cell analyzer with four lasers (355 nm, 405 nm, 488 nm, 633nm) and 18 fluorescence detectors. It has the capability to resolve up to 16 colors in combination. Acquisition is run on FACSDiva v6 software.

 Analysis Stations—Upon data acquisition, stations are available for free-of-charge data analysis. Software packages currently available include FACSDiva, Flow Jo-PC, and SpectroFlo.

Human Imaging Core

The state-of-the-art Philips Achieva dStream 3.0T MRI system in the Human Imagine 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

Research MRI Scanner: 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.

DXA Machine: The DXA Hologic Horizon A system is the latest in densitometry technology. Study acquisition capabilities include DXA of whole body, hips, lumbar spine, and extremities. Machine capabilities include detailed measurements of the body by looking at bone density, lean mass, and fat mass. In addition, system includes pediatric analysis for whole body, spine, femur, forearm, and infant spine DXA using pediatric/BMDCS reference data.

Neuropsychology Core

The Neuropsychology Core is directed by Sharon H. O'Neil, PhD, MHA, ABPP-CN, ABPdN, who is board certified in both clinical neuropsychology and pediatric neuropsychology and has twenty years post-licensure experience at CHLA. Dr. O'Neil is an Associate Professor of Clinical Neurology and Pediatrics with the USC Keck School of Medicine. She works closely with investigators on study design and grant proposals to determine the neurodevelopmental or neuropsychological assessment battery to best address research questions. Data collection, interpretation, and collaboration on presentations and manuscript writing is provided. Participants seen by the Neuropsychology Core range from 3 months of age to 60 years. Neurodevelopmental evaluations for infants and toddlers typically assess early cognition, receptive and expressive language, fine and gross motor skills, social skills, and adaptive functioning. Depending on the research question, neuropsychological evaluations for children ≥3 years of age may include assessment of attention, working memory,

processing speed, executive functions, language, visuo-constructional skills, sensorimotor skills, verbal and nonverbal learning and memory, and intellectual functioning, as well as social, emotional, behavioral, and adaptive functioning.

Nutrition and Metabolic Core

The Nutrition and 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.
- MRI CryoCoil for low noise mouse brain imaging.

Stem Cell Analytics Core

The Stem Cell Analytics Core is a centralized support facility whose primary mission is to facilitate pluripotent stem cell (PSC) research, innovation and interactions to enable successful funded research projects. To this end, the Core provides meticulously maintained, and fully equipped PSC tissue culture facilities; PSC tissue culture support, training, and supplies; iPSC production, validation, and maintenance; and PSC validation services including mycoplasma testing and undifferentiated state assay, third party STR identification and third-party genetic integrity testing via qPCR-based tests. The Core also provides access to shared equipment such as nucleofector, 96-well shuttle, real time qPCR machine, fluorescence and dissection microscopes.

Equipment

- 12 Baker Co Class II Biological Safety Cabinets-SteriGuard III Advance
- 6 Heracell 150 Copper CO2 Incubators

- 4 Heracell 150 Copper Tri-Gas Incubators
- 3 Nikon TS100 Inverted Tissue Culture Microscopes, two with cameras
- Nikon TS100 Inverted Fluorescent Tissue Culture Microscope,
- 4 Dissection microscopes (2 Nikon, 2 Leica)
- Applied Biosystems QuantStudio 7 Flex Real-Time PCR System (96-well, 384-well, array card)
- Amaxa/Lonza Cuvette-based Nucleofector
- Amaxa/Lonza 96-well shuttle
- Invitrogen Countess Automated Cell Counter
- Freezers (-80C and 2-LN2's, 5 -20C)
- 5 Refrigerators (4C)
- 2 Beckman Allegra X-22R Refrigerated Tabletop Centrifuges
- 2 Beckman Allegra X-15R Refrigerated Tabletop Centrifuges
- Heraeus Fresco 17 Refrigerated Microcentrifuge

Spatial Biology and Genomics Core (SBG).

The SBG core is located on the 9th floor of Smith Research Tower of CHLA's campus and was established to provide a broad suite of new technology services to investigators. The core provides expertise in the planning and conduct of 1) next generation sequencing (RNA/DNA, exome), 2) single-cell capture for variety of sequencing projects, 3) cell mass cytometry using Helios (Fluidigm), 4) tissue imaging mass cytometry using Hyperion (Fluidigm), 5) tissue spatial gene expression using the 10X Genomics Visium platform, 6) whole tissue spatial protein mapping on the Akoya platform. The core also provides full spectrum of clinical support for designing correlative studies for clinical studies and performs specimen processing that will be utilized for the supported technologies. The core further provides expert bioinformatics support and comprehensive analysis of microbiome, small genome sequencing, single cell (10X), gene expression sequencing (including RNAseq), spatial biology analysis and CyTOF-related experiments.

Equipment:

- Helios system 3rd generation CyTOF (Fluidigm) Located on 5th Floor of SRT
- Hyperion Image Mass Cytometry Module CyTOF-based module (Fluidigm) Located on 5th Floor of SRT
- 10X Genomics Chromium X Single Cell System (10X Genomics)
- 10X Genomics Chromium Single Cell system (10X Genomics)
- Akoya Phenocycler-Fusion System (formerly known as CODEX)
- MiSeq Dx Sequencer (Illumina)
- Two (2) C1 Touch Thermocyclers (Bio-Rad)
- Agilent 4200 Tapestation (RNA/DNA Quality/Quantity assessment)
- 2100 Bioanalyzer (Agilent)
- QlAgility robotic workstation for automated PCR reaction setup (Qiagen)
- Two (2) Qiacube Automated DNA/RNA/Protein purification (Qiagen)
- AirClean Systems PCR Workstation
- Two (2) Class II biosafety cabinets
- Qubit (Thermo Fisher) and NanoDrop Lite (Thermo Fisher) DNA/RNA quantitation

The SBG Core Facility also contains a full array of molecular and cell biology tools, including singleand multi-channel pipettors, refrigerated centrifuges, microcentrifuges, heat blocks and water bath, vortexers, a compound microscope, and analytical balances. In addition, 4 °C refrigerators, -20 °C and -80 °C freezers, and fume hoods are all available within the facility.

Computational Resources: The SBG Core is directly equipped with 2 custom-built Linux platforms:

- 2x 12-core AMD Opteron 6234 CPUs, 128GB DDR3 1600 RAM, 8TB RAID1 storage
- 1x 8-core AMD FX-8120 CPU, 32GB DDR3 1333 RAM, 8TB RAID1 storage
- Apple Mac Pro with 24 cores, 96 GB DDR4 RAM, 30TB of storage

The facility also has direct access to the clusters at the USC Center for High-Performance Computing (HPC). Altogether, Linux clusters at HPC provide ~3000 nodes, including large-memory nodes with 1TB of RAM, as well as more than 1.4 petabytes of disk storage. Scientific and specialized bioinformatics software are constantly maintained.

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 three 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 1 dryer.

Clinical Research Support Office

The Clinical Research Support Office (CRSO) 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.

Study Start-up

- Study design
- Scientific review
- Feasibility assessment
- Recruitment and accrual planning
- Identifying collaborators and community partners
- IRB applications
- Regulatory support (federal/industry/ investigator-initiated)

Study Operations

- Research coordination
- Research nursing
- Participant recruitment and retention
- Participant registration and billing
- Source and other study documentation
- Study drug accountability
- Regulatory binder maintenance
- Adverse event reporting
- Internal and external audit preparation
- Ancillary applications
- Amendments and continuing reviews
- Quality assurance

Study Closeout

- Sponsor and monitoring visits
- IRB and regulatory closeout
- Case report form storage
- Publication of study findings

NAVIGATING THE LIFECYCLE OF A CLINICAL TRIAL

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 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 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.

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, multi-faceted 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, training, and 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 increase the visibility of research and engage partners more effectively.

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 ClwwNAHL, 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).