Special Thanks

We would like to thank the following entities, at the University of Southern California (USC) and Children’s Hospital Los Angeles (CHLA), which provided resources that have been crucial to the success of the SC CTSI:

Office of the Provost,
USC

Office of the Vice President of Research,
USC

Office of the Dean,
Keck School of Medicine of USC

Office of the Dean,
USC School of Pharmacy

Office of the Dean,
USC Viterbi School of Engineering

Office of the Dean,
USC School of Social Work

Office of the Dean,
Herman Ostrow School of Dentistry of USC

Office of the CEO,
Keck Medicine of USC

Office of the CIO,
Keck Medicine of USC

Office of the President and CEO,
CHLA

Office of the CIO,
CHLA

The Saban Research Institute,
CHLA

Department of Pediatrics,
CHLA
Dear Colleagues,

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 research into real-world improvements in health care, health practices and health. Leveraging generous institutional support from the University of Southern California (USC) and Children’s Hospital Los Angeles (CHLA) and a Clinical and Translational Science Award (CTSA) from the National Institutes of Health (NIH), the SC CTSI team has built an organization devoted entirely to improving the success of translational science with tools and programs that support researchers and their work.

Today we are proud to report that 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.

In this report, you’ll read about the services and programs we’ve implemented and the impact they have had. You’ll also read about unique institutional partnerships involving USC; CHLA; the Los Angeles (LA) 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 LA and Southern California.

Together, we’ve generated $96 million in new extramural grant funding, demonstrating sustainability of the new programs we helped to start. We have had great impact on the scientific community, as evidenced by over 500 peer-reviewed scientific publications from SC CTSI-supported projects. Most importantly, we have begun to achieve our goal of creating real-world impact on health through translational science.

This report will highlight a few of the more than 800 researchers the SC CTSI has supported 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. Our SC CTSI Pilot Funding program, for example, supported groundbreaking pre-clinical research into the development of a fetal pacemaker to save lives of unborn babies with heart block. Our Clinical Trials Units have supported important first-in-human testing of new anti-cancer medications, providing medical facilities and nursing staff experienced with clinical research. The list goes on, as you will see.
We are particularly proud of our Community Engagement team’s initiatives to promote health in underserved populations and communities with demonstrated health disparities. The approaches that we have spearheaded forge close ties between researchers and the public, to the benefit of both. For example, a project to develop asthma education and deliver it to families in Long Beach, where children suffer disproportionately high rates of the condition, the Community Engagement team has made a real impact on health in our communities.

SC CTSI’s Education, Career Development, and Ethics program provides specialized training geared to the scientific and professional needs of translational researchers. This program is accelerating the careers of junior faculty members and graduate students from health science departments across USC and CHLA. Trainees get valuable guidance and experience in everything from team-based research and grant writing, to the business of leading and managing a laboratory. We continue to develop creative ways to assist more scholars and trainees, working with department heads such as Dr. Vaughn A. Starnes, professor of surgery and chair of the Department of Surgery at the Keck School of Medicine of USC, who partnered with us to support more surgeon-scientists in our training program.

In this report, you’ll read about the services and programs we’ve implemented and the impact they have had. You’ll also read about unique institutional partnerships involving USC; CHLA; the LA 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 LA and Southern California.

Thank you for taking the time to review this report on SC CTSI’s initial years. We invite everyone to join us as we continue our mission to improve translational research in years to come.
Our Purpose

The Southern California Clinical and Translational Science Institute (SC CTSI) has as its main goal the rapid translation of research to improve patient and community health, with a focus on diverse and underserved populations.

To achieve this goal, the SC CTSI provides infrastructure, services, funding, and training to support clinical and translational research.

Established in 2008 with the mission of “Translating Science into Solutions for Better Health,” the SC CTSI is part of a national consortium of Clinical and Translational Science Awards (CTSAs). The more than 60 consortium members are housed at leading research universities and medical centers throughout the United States.

CTSA Funding

CTSAs are funded by the National Center for Advancing Translational Sciences (NCATS), the newest center within the National Institutes of Health (NIH). In recognition of the particular difficulties and slow pace of translational science, NCATS was created to enhance and accelerate the transformation of research discoveries into medical therapies and applications. The SC CTSI and its partner CTSA organizations are the operational key to that mission’s success, working to improve the quality, efficiency, and safety of clinical research by developing and providing the research community with improved tools, operational models, and training.

Each CTSA institute functions as a living laboratory for the study of translational science, creating and sharing new knowledge, technologies, educational curricula, methods, and policies.

What is Translation?

Translation is the process of turning observations in the laboratory and clinic into interventions that improve the health of individuals and the public — from diagnostics and therapeutics to medical procedures and behavioral changes.

What is Translational Science?

Translational Science is the field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process. Translational science seeks to make translation easier, faster, more efficient and a more common result of biomedical research.
Contributing to National Consortium

The SC CTSI is part of a national CTSA consortium of more than 60 institutions — housed at research universities and medical centers throughout the United States.
Institute Leadership

Thomas A. Buchanan, MD  
Director, SC CTSI  
Vice Dean for Research  
Chief, Division of Endocrinology and Diabetes, Department of Medicine  
Professor of Medicine, Obstetrics and Gynecology, and Physiology and Biophysics  
Keck School of Medicine of USC

Dr. Buchanan is the founding director of the Southern California Clinical and Translational Science Institute (SC CTSI). Administratively, he brings to the SC CTSI more than 20 years of experience leading clinical and translational research programs.

Scientifically, Dr. Buchanan leads an interdisciplinary translational team whose groundbreaking research has helped define mechanisms and clinical approaches for prevention and treatment of gestational and type 2 diabetes in Latinos.

Dr. Buchanan’s honors include the Norbert Freinkel Award and a Distinguished Clinical Scientist Award from the American Diabetes Association, and election to the Association of American Physicians.

Dr. Buchanan received his medical degree from the University of Iowa, completed his internship and residency in internal medicine at Good Samaritan Hospital in Phoenix and at the University of Iowa, and did a combined clinical and research fellowship in endocrinology and metabolism at Northwestern University.

Michele D. Kipke, PhD  
Co-Director, SC CTSI  
Director of Community Engagement, SC CTSI  
Professor of Pediatrics and Preventive Medicine, Keck School of Medicine of USC  
Vice Chair of Research, Department of Pediatrics, CHLA  
Director of Clinical Research, The Saban Research Institute

Dr. Kipke received her PhD in Experimental/Health Psychology in 1990 from the Albert Einstein College of Medicine at Yeshiva University. A nationally known health researcher and policy expert, she is widely published on topics that examine individual, familial, peer, and social network influences on youth involvement in risky behaviors.

Dr. Kipke’s research interests include neuro-developmental disorders, including autism; disparities in health outcomes; social epidemiology and health status/outcomes of children, adolescents, and families; and community-based translational research.
Programs

Biostatistics

Wendy Mack, PhD
Director

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

Daniella Meeker, PhD
Director

Joshua Lee, MD
Director, 2012–2013

Carl Kesselman, PhD
Director, 2009–2012

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 the University of Southern California (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

Anthony El-Khoueiry, MD
Director

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 [CHLA]) 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

Michele D. Kipke, PhD
Director

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

Jonathan M. Samet, MD, MS
Director

Cecilia M. Patino-Sutton, MD, MEd, PhD
Director, Education

Stanley Azen, PhD
Director, KL2 program

Emil Bogenmann, PhD
Director, TL1 program

Alexander M. Capron, LLB
Director, 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 programs supported by the National Institutes of Health (NIH). Access to certificate programs and the Master of Science in Clinical, Biomedical and Translational Investigations as well as 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

Katja Reuter, PhD
Director

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’s communications and develops novel, measurable communications approaches to more effectively increase the visibility of research and engage partners.

Planning, Evaluation, and Tracking

Melanie Funes, PhD
Director

With a focus on transparency and accountability, the 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. The 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

Roberta Diaz Brinton, PhD  
**Director, 2008 – 2013**

Frances J. Richmond, PhD  
**Director, Regulatory Support, 2008 – 2013**

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

Research Development

Sarah Hamm-Alvarez, PhD  
**Director**

The program fosters the establishment and development of interdisciplinary clinical and translational research teams, projects, and programs. It 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.

External Advisory Board

The following individuals have donated their time to provide invaluable advice and guidance in the creation and operations of the SC CTSI:

**Mary L. (Nora) Disis, MD**  
Associate Dean for Translational Science, University of Washington, Medicine  
Director, Institute of Translational Health Sciences  
Director, Center of Translational Medicine in Women’s Health  
Athena Distinguished Professorship of Breast Cancer Research  
Professor of Medicine  
Adjunct Professor of Pathology and of Obstetrics and Gynecology

**Joe G. N. (Skip) Garcia, MD**  
Senior Vice President for Health Sciences, Arizona Health Sciences Center  
Merlin K. DuVal, MD Endowed Chair for Leadership and Innovation  
Professor of Medicine, University of Arizona

**Deborah Grady, MD, MPH**  
Associate Dean for Clinical and Translational Research, University of California, San Francisco (UCSF), Medicine and Nursing  
Co-Director, Clinical and Translational Science Institute (CTSI at UCSF)  
Director, UCSF Women’s Health Clinical Research Center  
Professor of Epidemiology and Biostatistics and of Medicine

**J. Mark Overhage, MD, PhD**  
Chief Medical Informatics Officer, Siemens Healthcare  
Fellow, American College of Medical Informatics  
and the American College of Physicians

**Steven Teutsch, MD, MPH**  
Chief Science Officer, Los Angeles County Department of Public Health  
Adjunct Professor, Fielding School of Public Health, University of California, Los Angeles  
Senior Fellow, Schaeffer Center, University of Southern California

**Laura Weisel, MBA**  
Executive Director, Harvard Catalyst, Clinical and Translational Science Institute, Harvard University

**Steven Goodman, MD, MHS, PhD**  
Associate Dean of Clinical and Translational Research, Stanford University  
Professor of Medicine and of Health Research and Policy

**Lisa Simpson, MB, BCh, MPH, FAAP**  
President and CEO, AcademyHealth

**William E. Smoyer, MD**  
Vice President and Director, Center for Clinical and Translational Research, The Research Institute, Nationwide Children’s Hospital  
Professor of Pediatrics, Ohio State University College of Medicine

**Hal F. Yee Jr., MD, PhD**  
Chief Medical Officer, Los Angeles County Department of Health Services  
Chief Deputy Director, Health Services, Clinical & Medical Affairs
Academic

USC University of Southern California

Clinical and Community

ABC School District
AIDS Project Los Angeles
American Diabetes Association
Autism Speaks, Autism Treatment Network
Boys and Girls Club
BREATHE California of Los Angeles County
Bridge Over Digital Divide
Clinica Oscar Romero
Community Health Councils
COPE Health Solutions
Didi Hirsch Community Mental Health Center
Eastern Los Angeles Regional Center
El Centro del Pueblo
Esperanza Community Housing Corporation
Exodus Recovery
Fiesta Educativa Inc.
Five Acres
Frank D. Lanterman Regional Center
HealthyCity.org
Hollywood Health and Society
Jewish Family Services
L.A. Care Health Plan
Los Angeles County Department of Children and Family Services
Los Angeles County Department of Health Services
Los Angeles County Department of Mental Health
Los Angeles County Department of Public Health
Los Angeles Gay and Lesbian Center
Magnolia Place Network
Mental Health America
National Multiple Sclerosis Society
Office of Samoan Affairs
Pacific Clinics
Partners In Care Foundation
Providence Center for Community Health Improvement
Queens Care Family Clinics
Samoan National Nurses Association
Search to Involve Pilipino Americans (SIPA)
Sickle Cell Disease Foundation of Southern California
South Central Los Angeles Regional Center
Special Needs Network
Special Services for Groups
St. John’s Well Child and Family Center
The California Endowment
USC – Government & Civic Engagement
Visión y Compromiso
Weingart East Los Angeles YMCA
West Los Angeles Regional Center
"Because successful translation requires teamwork, our SC CTSI is a collaboration among many schools at USC and with partners in the public, private, government, and nonprofit sectors."

THOMAS A. BUCHANAN, MD
DIRECTOR, SC CTSI
Services and Resources for Clinical and Translational Researchers

The Southern California Clinical and Translational Science Institute (SC CTSI) has provided a wide array of resources and services to assist investigators throughout the translational research process. In addition, we have developed and deployed tools that facilitate research and enable research collaborations to benefit the research community.

The SC CTSI homepage: sc-ctsi.org

The SC CTSI’s Accomplishments and Impact: 2008–2014

- 800+ Investigators Supported
- 500+ Publications
- $96M New Funding
- 80+ Patent Applications
Provided Funding

**Pilot Funding Program**

Annual Spring/Fall funding cycles offered individual awards up to $30,000 to support all aspects of translational research. Supported research areas include: academic-community partnerships, early-phase clinical trials, novel technologies, multi-disciplinary projects, mobile health research, and much more. 179 awards totaling $5.7M have been issued. Of these, 126 awards totaling $4M have been completed. The remaining are still in progress.

[sc-.ctsi.org/funding](http://sc-ctsi.org/funding)

Helped Find Collaborators and Clinical Trials Experts at USC

**USC Health Sciences Profiles**

The online search tool lets you find researchers at the University of Southern California (USC), their work, and professional networks such as co-authors. It automatically creates public profile pages for USC faculty members and displays their PubMed publications. It currently includes 3,000+ USC faculty members, postdoctoral scholars, and clinical research coordinators in the health sciences. Features include powerful search capability by research topic, name, school, department, and more. Users can view topic-specific research published by people at USC over time, both in a list format and in an activity timeline.

In an effort to highlight clinical trials expertise at USC, the SC CTSI has launched a new feature to our local expert finder tool: now it is easy to discover faculty members and postdoctoral scholars in the health sciences who are involved in active clinical trials.

[profiles.sc-ctsi.org](http://profiles.sc-ctsi.org)

---

"An invaluable expertise mining tool. I highly recommend it."

— Leslie Saxon, MD, professor of clinical medicine, Keck School of Medicine of USC; executive director and founder, The USC Center for Body Computing
Helped Design Studies

Consultation Services

Consultation Services, both free and fee-based, support efficient and accurate data collection and analysis and help researchers avoid translational research pitfalls. Support areas include biostatistics, study design, regulatory support, research ethics, human studies and trials, community-engaged research, statistical analysis and interpretation of results, data management strategy, manuscript preparation and review, and assistance in responding to reviewers, among others.

Request a consultation: sc-ctsi.org/consultation

HOURS PROVIDED

6,900+ Consultation hours provided to date

Made Resources More Accessible

Research Resource Finder

In partnership with the USC Office of Research, the SC CTSI developed a new, powerful e-tool, the Research Resource Finder, which makes it easy for researchers and external partners to find more than 500 resources at USC and Children’s Hospital Los Angeles (CHLA) — with ongoing new additions.

http://researchresourcefinder.usc.edu
Helped Develop New Skills

**Education, Career Development and Ethics (ECDE) Program**

Coursework and mentorship led by ECDE cover all aspects of translational science, with additional focus on team research, ethics, research in diverse populations, and community-engaged research. The program offers stipends and research support for junior faculty at USC and CHLA, as well as pre-doctoral trainees in science, medical and health-related science, and professional programs. Robust curricula include the TL1 and KL2 certificate programs and the Master of Science in Clinical, Biomedical and Translational Investigations.

[sc-ctsi.org/education](http://sc-ctsi.org/education)

**Research Training Finder**

In partnership with the USC Office of Research, the SC CTSI developed this tool to simplify the search for nearly 40 research compliance training opportunities at USC, sortable by roles and responsibilities as well as online or classroom formats.

[http://tinyurl.com/trainingfinder](http://tinyurl.com/trainingfinder)

Engaged the Community

**Community Engagement (CE) Program**

CE provides services for researchers interested in community-engaged research projects as well as services for community organizations seeking help to transform community needs into research projects. Further support includes community-based research training and technical assistance, workshops, match-making services to connect researchers at USC and CHLA with community partners, and dissemination of discoveries broadly in the community for implementation.

[sc-ctsi.org/community](http://sc-ctsi.org/community)
Helped Conduct Clinical Studies

Clinical Trials Unit (CTU) at USC

Clinical investigators can conduct research conveniently and efficiently. The CTU provides important clinical research services and facilities, with emphasis on high-intensity and high-risk human studies such as early-phase trials’ complex mechanistic studies. Facilities include inpatient and outpatient facilities, nursing services, sample collection and processing, research pharmacy, study coordinator services, bionutrition services, body composition and exercise labs, and more.

Helped Find Clinical Studies

USC Clinical Studies Directory

The SC CTSI partnered with Keck Medicine of USC and the USC Office of the Provost to launch USC’s Clinical Studies Directory (updated daily). The public website provides user-friendly access to about 500 active studies at USC in English, Spanish, and Mandarin Chinese searchable by disease, physician name, geographic location, and more.

http://clinicaltrials.keckmedicine.org/

Helped Manage Data

Research Electronic Data Capture (REDCap)

The SC CTSI provides training and access to REDCap, a free and secure, web-based tool vetted by the National Institutes of Health and designed to support data capture and surveys for any clinical or translational researcher. Built to allow researchers to go from database or survey concept to production in one day, REDCap is currently used by more than 1,000 institutions throughout the world.

REDCap.sc-ctsi.org

Clinical Research Support Office of The Saban Research Institute at CHLA

The support office is dedicated to facilitating and supporting investigators in the development and conduct of their clinical research protocols. It has expertise in implementing, conducting, and monitoring clinical research studies and provides a variety of services that benefit both novice and experienced clinical researchers: a clinical research coordinator pool, research regulatory support, biostatistics support, as well as research nursing and pediatric neuropsychology services through the CTU.

---

"Having a cloud-based database, calendar, and randomization scheme at a moment’s reach through REDCap is immensely helpful."

— Todd Chang, assistant professor of pediatrics, Keck School of Medicine of USC; associate fellowship director in pediatric emergency medicine, CHLA
Supported Research Successes

The following chapters highlight examples of research successes that the Southern California Clinical and Translational Science Institute (SC CTSI) supported between 2008 and 2014 in four areas: pre-clinical and clinical research, community, and training and career development.

These success stories are complemented by testimonials from our service users as well as outcome-related data points.

The icons that follow each story tell you more about the type of research conducted (in red) and specific services and resources that we provided (in blue). We additionally point out projects that pertain to child health, a national research priority (in gray).
Turning Research Discoveries into Therapeutics and Diagnostics for Human Testing

During its first five years the Southern California Clinical and Translational Science Institute (SC CTSI) provided broad resources for pre-clinical development of potential new diagnostics and therapeutics.

Because pre-clinical research is complex, costly, and burdened with a high failure rate, investigators desperately need access to varied forms of support for this portion of the translational research process. The SC CTSI provided project funding as well as a range of expert consulting resources to catalyze and support pre-clinical research efforts at the University of Southern California (USC) and Children’s Hospital Los Angeles (CHLA).

USC Coulter Translational Research Partnership Program

As part of an interdisciplinary team at the USC including the USC Viterbi School of Engineering and the USC Stevens Center for Innovation, the SC CTSI partnered with the Wallace H. Coulter Foundation to secure $5 million over five years in support of breakthrough innovations in biomedical engineering. The USC Coulter Translational Research Partnership program leverages SC CTSI and USC resources with nearly $1 million per year from the Wallace H. Coulter Foundation to support interdisciplinary, translational projects that focus on applying developed technologies to solve an unmet or underserved clinical need that will save, extend, and improve patients’ lives. In its first three years, the program’s projects have led to 30+ publications, 70+ patent advancements, and two new products on the market.

WOUND HEALING

Scientist Breaks Through the Body’s Intricate Healing Process

In a pilot investigation, Wei Li, PhD, professor of dermatology, Keck School of Medicine of USC, showed that heat shock protein 90alpha, found widely in cells throughout the human body, significantly improves healing when applied to skin ulcers in diabetic patients.

The research led to several USC patents for new drugs to be based on Hsp90alpha, which is currently being manufactured at 99% purity to meet clinical trial requirements.

Some $10 billion is spent annually to provide supportive wound treatment for diabetic patients. In diabetics, the elderly, or others with compromised health, wounds can remain open for months or years, requiring constant and expensive care to hold off infection. Li’s work may revolutionize treatment for these difficult wounds.

http://tinyurl.com/sc-ctsi-wei

NIH Funding

SC CTSI-supported research led to $2 million in NIH funding to advance the development of this wound healing treatment.
HEART HEALTH IN THE WOMB

Research Team Develops Pacemaker to Save the Lives of Unborn Babies

An interdisciplinary team of researchers developed a tiny pacemaker for unborn babies with a fatal heart problem called fetal heart block. Fetal heart block is a condition that causes an extremely slow heart rate, which may not be adequate to sustain the circulation. Babies with this condition normally don’t survive in the womb. The new pacemaker could save their lives.

With support and funds from the SC CTSI and the USC Coulter Translational Research Partnership program, Ramen Chmait, MD, assistant professor of clinical obstetrics and gynecology, pediatrics and surgery, Keck School of Medicine of USC; Yaniv Bar-Cohen, MD, associate professor of pediatrics, Keck School of Medicine of USC and director of cardiac rhythm devices, CHLA; and Gerald Loeb, MD, professor of biomedical engineering, USC Viterbi School of Engineering, were able to develop a functional prototype of a tiny implantable pacemaker and demonstrate that it works in sheep fetuses. A large grant from the National Institutes of Health (NIH) supported further development and with a humanitarian exemption by the U.S. Food and Drug Administration (FDA), the life-saving device is now ready for use in humans.

http://tinyurl.com/sc-ctsi-pacemaker

“The funding from the SC CTSI was critical for us to move our research forward.”
— Yaniv Bar-Cohen, MD, associate professor of pediatrics, Keck School of Medicine of USC; director of cardiac rhythm devices, CHLA
CHLA Researchers Demonstrate How Obesity Blocks Therapeutic Effects of Cancer Treatments

Clinicians at CHLA have noted that obese children with acute leukemia benefit less from chemotherapy than normal weight children. Steven Mittelman, MD, PhD, associate professor of pediatrics and physiology & biophysics, Keck School of Medicine of USC and colleagues at The Saban Research Institute of CHLA are working to find out why. With support from the SC CTSI, they showed that fat cells substantially impair the ability of a first-line chemotherapy agent to kill leukemia cells in the laboratory. Thus, the fat cells themselves may protect leukemia cells from chemotherapy. Mittelman has secured funding from the NIH to study how this happens. His long-term goal is to conduct clinical studies to see whether and how treating obesity can improve survival for children with leukemia. “This research shines a light on how cancer cells avoid chemotherapy and helps us better understand how to beat cancer in children,” said Brent Polk, MD, professor of pediatrics, Keck School of Medicine of USC and director of The Saban Research Institute.

Implantable Pump to Deliver Tumor-Fighting Drugs in the Brain

Many drugs cannot pass from the bloodstream into the brain and spinal cord. When patients have cancers that involve these sites, it may be difficult to get important chemotherapies in to fight the cancer. Ellis Meng, PhD, professor of biomedical engineering, USC Viterbi School of Engineering, is a leading expert in the development of mini-pump devices to deliver medications to hard-to-reach places. Meng teamed up with Hung Chi Tran, MD, assistant professor of clinical pediatrics, Keck School of Medicine of USC and physician at CHLA, to develop a mini-pump that can infuse chemotherapy directly into the fluid around the brain and spinal cord for children with cancer that involves these areas. The SC CTSI helped Meng and Tran obtain nearly $3 million in private and government funding to develop their small implantable “mini-pump.” The team’s technology, which is advancing toward clinical trials, addresses an important unmet clinical need and may help many other central nervous system conditions where sustained direct drug delivery into the cerebrospinal fluid can be beneficial.

Computer Speech Project to Boost Culturally Sensitive Doctor-Patient Interactions

The SC CTSI helped create a computerized speech translation system to be used in clinics and hospitals. SpeechLinks is designed to translate between English and Spanish in near real time. “This is the first study of its kind in the United States that deals with the Spanish-speaking population in a culturally relevant manner,” said Shrikanth Narayanan, PhD, professor of electrical engineering and computer science, USC Viterbi School of Engineering; professor of linguistics, psychology and neuroscience, USC Dana and David Dornsife College of Letters, Arts and Sciences; and professor of pediatrics, Keck School of Medicine of USC. Following SC CTSI support, the SpeechLinks team received a $3 million grant from the National Science Foundation and was mentioned in the MIT Technology Review. The project team further included researchers from the Keck School of Medicine of USC (Win May, MD, PhD; Lourdes Baezconde-Garbanati, PhD, MPH), from the Annenberg School for Communication and Journalism (Margaret McLaughlin, PhD), and from the USC Viterbi School of Engineering (Panayiotis Georgiou, PhD).

Computer Speech Project to Boost Culturally Sensitive Doctor-Patient Interactions

The SC CTSI helped create a computerized speech translation system to be used in clinics and hospitals. SpeechLinks is designed to translate between English and Spanish in near real time. “This is the first study of its kind in the United States that deals with the Spanish-speaking population in a culturally relevant manner,” said Shrikanth Narayanan, PhD, professor of electrical engineering and computer science, USC Viterbi School of Engineering; professor of linguistics, psychology and neuroscience, USC Dana and David Dornsife College of Letters, Arts and Sciences; and professor of pediatrics, Keck School of Medicine of USC. Following SC CTSI support, the SpeechLinks team received a $3 million grant from the National Science Foundation and was mentioned in the MIT Technology Review. The project team further included researchers from the Keck School of Medicine of USC (Win May, MD, PhD; Lourdes Baezconde-Garbanati, PhD, MPH), from the Annenberg School for Communication and Journalism (Margaret McLaughlin, PhD), and from the USC Viterbi School of Engineering (Panayiotis Georgiou, PhD).

http://tinyurl.com/sc-ctsi-block

http://tinyurl.com/sc-ctsi-speech
HUMAN IMMUNODEFICIENCY VIRUS

USC Researchers Develop Novel Approach to the Discovery of New Human Immunodeficiency Virus Drugs

A multidisciplinary team of researchers from the USC Dana and David Dornsife College of Letters, Arts and Sciences and the USC School of Pharmacy demonstrated a way to generate potential new Human Immunodeficiency Virus (HIV) drugs by inhibiting a crucial enzyme in the HIV replication cycle. New HIV medicines are critically needed because HIV mutates quickly into drug-resistant strains, rendering older medicines ineffective. The research team, led by Kyung Jung, PhD, associate professor of chemistry, USC Dana and David Dornsife College of Letters, Arts and Sciences, received pilot funds from the SC CTSI to investigate new HIV integrase inhibitors. They recently filed for patent approval and are now examining new clinical applications for their discovery.

http://tinyurl.com/sc-ctsi-enzyme

HEMOPHILIA

Researchers Identify Ethnic Genetic Differences in Hemophiliacs in Search of Improved Therapies

The SC CTSI funded research to identify ethnic variations in genetic mutations of factor VIII, a protein involved in blood clotting, which functions improperly in people with hemophilia A. Therapy for hemophilia involves infusing patients with replacement factor VIII protein, the structure of which varies across ethnicities. Past research has shown that use of factor VIII in non-white hemophiliacs can lead to immune reactions that block the effectiveness of the treatments. Studying Native American hemophilia patients, researchers in this project found a genetic locus that may modulate the immune response to factor VIII replacement therapy for hemophilia A. This finding may help predict who will get immune reactions with standard therapy and, thus, who will required a modified treatment approach. The research, which was recently featured in the Science-Business eXchange, was led by co-investigators Tom E. Howard, MD, PhD, of Veterans Affairs Greater Los Angeles Healthcare System and faculty volunteer at Keck School of Medicine of USC, and Howard A. Liebman, MD, professor of medicine, Keck School of Medicine of USC. It has also led to several publications in high-impact scientific journals, as well as Small Business Innovation Research grants from the NIH.

REGENERATIVE MEDICINE FOR NEWBORNS

Scaffolding Technology for Stem Cell-Induced Gut Tissue Regeneration

The SC CTSI helped researchers accelerate the development of a stem cell-based therapy that regenerates gut tissue lost to necrotizing enterocolitis, a complication that can affect prematurely born infants. Pediatric surgeon Tracy Grikscheit, MD, assistant professor of surgery, Keck School of Medicine of USC, and attending surgeon at CHLA, is currently working on scalability for therapeutic application in pediatric patients. The technique is applicable to other organs, including colon, liver, and pancreas. The SC CTSI helped the team identify regulatory consultants and manufacturing partners to move the project forward. The SC CTSI also allocated more than $100,000 in pilot funds to the project through the USC Coulter Translational Research Partnership program. Grikscheit and her team are currently in discussions with potential investors for support of clinical feasibility studies for this exciting technology.
New Treatment and Diagnostic Tests: What Works and What Doesn’t?

Clinical research identifies new disease mechanisms in humans and provides critical data about the efficacy and safety of potential new medications, medical devices, diagnostic products, and treatment regimens.

Clinical research is done with living, breathing human beings who volunteer to undergo testing to help identify new disease mechanisms and/or participate in clinical trials to determine if a new diagnostic or therapeutic approach really works. The process is complex and very resource-intensive. The Southern California Clinical and Translational Science Institute (SC CTSI) has supported a number of projects in this field.

“None of this new clinical research would have happened had it not been for the SC CTSI. We’ve seen that with some effort and creative financing we can pull together small amounts of money to fund early stages of research and then go after larger funding.”

— Daryl Davies, PhD, associate professor of clinical pharmacy, USC School of Pharmacy

ALCOHOL ABUSE

Drug Treatment for Alcohol Abuse Advances to Human Trials in Cross-Institutional Study

Alcohol use disorders affect 18 million people, cause 100,000 deaths annually, and cost society in excess of $235 billion annually in the United States, but current therapeutic approaches have had limited and short-lasting success in treating them.

Daryl Davies, PhD, associate professor of clinical pharmacy, USC School of Pharmacy, and his collaborators at the University of Southern California (USC) and Children’s Hospital Los Angeles (CHLA) discovered that ivermectin, a drug used to treat parasitic infections in millions of people and animals every year, may also be an effective treatment to reduce alcohol intake.

With pilot funding from the SC CTSI, his group demonstrated in mice that ivermectin significantly reduced overall alcohol intake and preference for alcohol compared to water. Because ivermectin is already approved for use in humans, they have been able to move directly to a clinical trial with collaborators at the University of California, Los Angeles to see if ivermectin can reduce alcohol intake in alcohol-dependent individuals. Results from an initial trial confirmed the safety of the drug. The research team is now planning a larger trial to test the efficacy of the compound.

“If what we saw in mice in the laboratory also happens in people, we may have a safe and effective way to help people with alcohol use disorders as it will reduce their urge to drink,” said Davies. The Davies group is also examining other compounds related to ivermectin to see if they might be even more effective at reducing alcohol intake.

http://tinyurl.com/sc-ctsi-davies
HEALTH POLICY

SC CTSI-Supported Research Drives Global Health Policy

Research by Jessica Maria Atrio, MD, former clinical fellow, Keck School of Medicine of USC, demonstrated that a safe but less-frequently prescribed birth control “mini-pill” is effective for women taking human immunodeficiency virus (HIV) medications.

Worldwide, HIV is the number one cause of death among women 18 to 45, according to the World Health Organization. The majority of women who have HIV live in countries, for example in sub-Saharan Africa, where their access to medical care is limited and where women and girls comprise a majority of people with HIV. Because of their serious and complex health concerns, HIV-positive women must take particular care with the decision to have children.

The SC CTSI provided several elements of support for Atrio, including the SC CTSI Clinical Trials Unit (CTU), regulatory support, consultations about study ethics and biostatistics, and advocacy for the research. Atrio, had never conducted a prospective study with human participants before.

http://tinyurl.com/sc-ctsi-mini-pill

“I couldn’t have conducted the study without the support of the SC CTSI. It was a tremendous undertaking for me at that point. I had only done retrospective research up to then, so this would be my first foray as a principal investigator in research that was more rigorous and translational in nature. It required a degree of sophistication I simply had no ability to do on my own.”

— Jessica Maria Atrio, MD, former clinical fellow, Keck School of Medicine of USC; assistant professor of obstetrics & gynecology and women’s health, Albert Einstein College of Medicine
HEART HEALTH

Cross-Institutional Study Looks within Arteries to Understand Effects of Cholesterol Medications

In a multi-year study, USC researchers are partnering with researchers from around the country to use magnetic resonance imaging (MRI) to understand the long-term effect of statin drugs on the arterial blockages associated with atherosclerosis, the world’s leading cause of death and disability.

Patrick Colletti, MD, professor of radiology, Keck School of Medicine of USC and chief of magnetic resonance imaging (MRI), Los Angeles County (LAC)+USC Medical Center, and his colleagues are imaging the carotid arteries of atherosclerosis patients to compare the impact of a variety of cholesterol medications on plaque deposits that narrow and block arteries.

Ultimately, the researchers hope to use this MRI approach to predict which patients will need more aggressive or different forms of therapy to reduce their risk of strokes and related problems. The SC CTSI made the study possible at USC with access to the SC CTSI CTU.

http://tinyurl.com/sc-ctsi-plaque

“‘It’s possible to conduct the research in the clinic, but it’s much harder. The SC CTSI Clinical Trials Unit provides a stable space for us to conduct this work efficiently.’”

— Patrick Colletti, MD, professor of radiology, Keck School of Medicine of USC; chief of magnetic resonance imaging, LAC+USC Medical Center
LIVER DISEASE

USC Pediatric Surgeon Leads Nationwide Study to Help Children with Liver Disease

To compare outcomes of two common surgical procedures for children with liver complications due to Alagille syndrome, researcher Kasper Wang, MD, associate professor of surgery, Keck School of Medicine of USC and pediatric surgeon, CHLA is driving a collaborative study with colleagues from 15 hospitals and research centers across the country.

Alagille syndrome is a congenital disorder that can interfere with the development of the liver’s bile ducts, leading to buildup of bile that can damage the liver and cause other complications.

“There are currently two surgical procedures being used to enable bile elimination, but there are no solid data to tell clinicians which procedure is better,” explained Wang. “This trial should sort that out and help surgeons provide better care for these children.”

http://tinyurl.com/sc-ctsi-child-liver

“Since the volume of cases is low, no single institution has sufficient experience to know which approach is preferable, or under what conditions one may be better than the other. A multi-center study is the only way we can gather enough data to compare the approaches.”

— Kasper Wang, MD, associate professor of surgery, Keck School of Medicine of USC; pediatric surgeon, CHLA

Fostering Multisite Data Collection

The SC CTSI supported the data collection for this project across 20 biomedical research sites through the Research Electronic Data Capture system, REDCap.
**ALZHEIMER’S DISEASE**

Research Team Evaluates Drug to Treat Alzheimer’s Disease and Improve Mild Cognitive Impairment

The SC CTSI provided support for research to study a drug that may ultimately restore cognitive function in patients with Alzheimer’s Disease (AD). The research by principal investigators Roberta Diaz Brinton, PhD, professor of pharmacology & pharmaceutical sciences, USC School of Pharmacy, and Lon S. Schneider, MD, professor of psychiatry, neurology, and gerontology, Keck School of Medicine of USC, led to $2.4 million in National Institutes of Health (NIH) funding to test the first regenerative therapeutic for the treatment of AD.

“Our grant from the National Institute of Aging, which is among the first to be funded under the National Plan to Address Alzheimer’s Disease, provides an extraordinary opportunity,” said Brinton. “We would not have gotten this grant without early support from the SC CTSI.”

The clinical trial, now in recruitment phase, will evaluate the safety and tolerability of allopregnanolone. This natural brain steroid may help in treating AD and mild cognitive impairment. To complement the clinical trial data, the research team plans to develop biomarkers and collect brain images with research collaborators at the Eli and Edythe Broad Center for Regenerative Medicine and Stem Cell Research at USC and the USC Mark and Mary Stevens Neuroimaging and Informatics Institute.

http://tinyurl.com/sc-ctsi-allo

**DIABETES & OBESITY**

Researchers Study Hormonal Function and Benefits of Bariatric Surgery for Weight Management and Glucose Control in Obese and Diabetic Patients

The SC CTSI connected investigator Elizabeth Beale, MD, assistant professor of clinical medicine, Keck School of Medicine of USC, with Travis J. Williams, PhD, associate professor of chemistry, USC Dana and David Dornsife College of Letters, Arts and Sciences, and helped them obtain seed funding to initiate clinical trials in obese diabetic patients. The researchers developed a method to non-invasively mimic the hormonal benefits of bariatric surgery and are preparing to initiate a second trial to show that the hormonal changes lead to improved weight management and glucose control over time. The team is working on an orally available version of their technology in the form of a nutritional supplement.

“SC CTSI’s funding in partnership with the USC Coulter Translational Research Partnership program enabled us to launch the study, but equally valuable was access to the SC CTSI Clinical Trials Unit, where we found excellent research facilities operated by a staff that was extremely experienced with clinical trials,” said Beale.

**DIABETES & OBESITY | CANCER**

Research Follows Multi-Ethnic Cohort to See How Obesity and Body Fat Distribution Affect Cancer Risk

Obesity is estimated to explain 15-20% of all cancer deaths in the United States. The SC CTSI supported a clinical trial by Kristine R. Monroe, PhD,
assistant professor of clinical preventive medicine, Keck School of Medicine of USC who recruited more than 800 research participants to evaluate body fat distribution patterns in U.S. ethnic and racial minorities and their association with cancer risks. “SC CTSI’s Clinical Trials Unit was vital for completing enrollment of our large study,” said Monroe. “The CTU team helped us provide a respectful environment, which is so important when you work with research participants. They also helped us ensure the quality of the data by adhering to protocols.”

Body fat distribution patterns — visceral or superficial — vary among different ethnic and racial groups and carry different risks of metabolic diseases. The study, unique in its scale and scope, is building signatures of fat distribution patterns based on nutritional, behavioral, biochemical, and genetic factors and high-resolution scans. When analyses are complete, Monroe and her team will use these signatures to predict breast and colorectal cancers, the two most common obesity-related cancers.

Body fat distribution patterns — visceral or superficial — vary among different ethnic and racial groups and carry different risks of metabolic diseases. The study, unique in its scale and scope, is building signatures of fat distribution patterns based on nutritional, behavioral, biochemical, and genetic factors and high-resolution scans. When analyses are complete, Monroe and her team will use these signatures to predict breast and colorectal cancers, the two most common obesity-related cancers.

SICKLE CELL DISEASE

CHLA Team Develops New Magnetic Resonance Imaging Technique for Assessing Stroke Risk in Sickle Cell Disease

Nearly 25% of sickle cell disease (SCD) patients will experience major strokes. Transcranial Doppler is the method currently used for estimating stroke risk in these patients. It may overestimate the risk by as much as 70%. As a result, many patients receive costly and sometimes risky blood transfusions to prevent strokes that they aren’t going to have in the first place. John Wood, MD, PhD, principal investigator, The Saban Research Institute of CHLA; professor of pediatrics and radiology, USC Viterbi School of Engineering; and associate professor of pediatrics, Keck School of Medicine of USC, is leading a team of researchers in developing an approach they believe will be more accurate in defining stroke risk in SCD. They are using functional MRI technology to assess brain blood flow patterns and metabolic rates, both potential markers for a future stroke. The SC CTSI provided pilot funding for studies that allowed Wood and his team to improve their method and identify abnormalities in blood flow and brain metabolism in children with SCD. The team used this information to win a prestigious $9.6 million NIH grant to fine-tune the MRI approach and then use it to test different treatments for stroke prevention in SCD. “Currently, we’re over-treating 70% of the SCD population,” said Wood. “Our goal is to help clinicians do much better so they can target the right treatments for stroke prevention to the right patients. The funding provided by the SC CTSI allowed us to get this project off the ground.”

SICKLE CELL DISEASE

Sickle Cell Disease Research by Cardiology Fellow Leads to Prestigious Award

Cardiovascular complications are common in patients with SCD and can cause illness, disability, or death, yet the mechanisms for this increased risk are not well understood. Jon Detterich, MD, assistant professor of pediatrics, Keck School of Medicine of USC and pediatric cardiologist, CHLA, was awarded an NIH Mentored Patient-Oriented Research Career Development (K23) Award to study red blood cell nitric oxide production and its relationship to vascular dysfunction in SCD. He credits SC CTSI’s Clinical Research Support Office of The Saban Research Institute at CHLA with providing critical support for his early work that led to the prestigious award. “I do not believe I would be successful at this point without the initial and ongoing support of the SC CTSI,” said Detterich.

NIH Funding

SC CTSI-supported research led to $9.6 million in NIH funding to predict the risk of stroke in patients with sickle cell disease.
Partnering to Address Health Needs in Los Angeles County

The Southern California Clinical and Translational Science Institute (SC CTSI) fosters robust community engagement by offering a wide range of services to researchers and community organizations interested in conducting collaborative projects that address real world health issues.

The SC CTSI has developed unique expertise in the process of community engagement as a discrete and critical skill within the translational research process. The most effective collaborations include representation from various sectors — clinicians, schools, academia, government, businesses, and the faith-based community. The partnerships we develop in support of researchers at the University of Southern California (USC) and Children’s Hospital Los Angeles (CHLA) strengthen the exchange of knowledge and insight from the community to academia and back.

“We establish greater trust between universities and the community, making translational research more efficient and relevant.”

Michele D. Kipke, PhD, co-director, SC CTSI

Transforming Community Partnerships

USC: 2500+ health science faculty / Hundreds of clinical trials annually

CHLA: Best pediatric hospital on the West Coast / 104,000+ children provided care annually

Los Angeles (LA) County Department of Health Services

LA County Department of Mental Health

L.A. Care Health Plan / Community Clinics

40+ Partner Organizations

55+ Mental Health Outreach Partners

2 advisory boards representing the diversity of LA

Clinical and Translational Science Awards (CTSA) Consortium: National network funded under the National Institutes of Health (NIH) mandate of “Translating Science into Solutions for Better Health”
Putting Food Smarts into Phones to Improve Nutrition and Reduce Obesity in Diverse Populations

Children in low-income families face particular risks for poor nutrition and obesity, problems often associated with diets low in fresh fruits and vegetables. Peter Clarke, PhD, professor of preventive medicine, Keck School of Medicine of USC and professor of communication, USC Annenberg School for Communication and Journalism, and Susan Evans, PhD, research scientist, USC Annenberg School for Communication and Journalism, collaborated with professional chefs and fine cooking schools to develop a culturally sensitive smartphone app that helps parents prepare kid-friendly dishes with the vegetables they receive from food banks and food-assistance agencies. Called “Quick!Help for Meals,” the app gives family cooks a tool to match the sometimes unfamiliar foods they receive from food banks with their family’s tastes, cultural food preferences, medical considerations, and their kitchen appliances. The app generates recipe books in English and Spanish customized for each family, as well as tips about food and nutrition. The app is designed to be used by parents and children together, a feature that promotes family conversations about healthy eating.

Clarke and Evans worked with SC CTSI’s Community Engagement and Biostatistics programs to determine the impact of Quick!Help in community settings. They identified study designs, outcome measures, and a community outreach plan to test the acceptability, usability, and effectiveness of Quick!Help in two local food banks. Baseline assessments ask participating children to what extent they are involved in making food choices and to what extent they want to be involved.

Kids across the board want to be involved in this area but generally are not. This app has allowed them to work with their parents to make healthy food choices.

A randomized controlled trial of the app is currently underway and will allow the team to assess changes in families’ food choices, the amount of fresh fruits and vegetables consumed, as well as changes in overall health such as weight and blood pressure.

http://tinyurl.com/sc-ctsi-reduce

“It’s not enough that our app is attractive and easy to navigate. It must also help people change their lives in measurable ways. SC CTSI’s expert support was invaluable so we could look at the impact of this health intervention and obtain subsequent funding.”

— Peter Clarke, PhD, professor of preventive medicine, Keck School of Medicine of USC; professor of communication, USC Annenberg School for Communication and Journalism
ACCESS TO CARE

Electronic Consultations Break Down Barriers for Medi-Cal Patients In Los Angeles County

Patients who receive health care in complex public health systems often encounter significant barriers and delays when they are referred from their primary providers to specialists. An electronic consultation system called eConsult was developed to address these barriers and delays. eConsult is an electronic referral program that allows primary care providers and specialists to securely share health information and discuss patient care.

The SC CTSI supported a formal evaluation to determine the impact of eConsult on access to specialty care among Medi-Cal managed care patients in small and solo physician practices. The findings demonstrated important benefits for the patient, primary care provider, and medical specialist. Patients could access specialty care faster, and they experienced better health outcomes with earlier specialist intervention. Patients also reported higher levels of satisfaction due to decreased wait times for subspecialty appointments. Primary care providers experienced enhanced communication with specialists and were able to expand the scope of their primary care practice, while specialists reported improved pre-visit work-ups, a decrease in unnecessary or inappropriate specialty referrals, and reduced “no-show” rates.

Based on these dramatic results, eConsult is being implemented by several Medi-Cal providers and across the public health clinics operated by the LA County Department of Health Services, where it is improving access to specialty care for thousands of low-income patients. This story is an outstanding example of how a modest investment in research on the part of the SC CTSI was translated into a major impact on health care for large communities of diverse and underserved patients.

http://tinyurl.com/sc-ctsi-access

“Specialists are turning around cases in three days, versus several weeks for referrals handled the traditional way.”

Sandy Atkins, VP, Institute for Change at Partners in Care

Funding

L.A. Care Health Plan invested $1.5 million to expand eConsult across LA County.

Findings and Impact at a Glance

<table>
<thead>
<tr>
<th>Increasing Access</th>
<th>Reducing Wait</th>
<th>Cutting Cost</th>
<th>Adoption Across LA County</th>
</tr>
</thead>
<tbody>
<tr>
<td>More Medicaid patients received specialist care (100% of study participants).</td>
<td>Referred cases were assisted in three days or less, versus several months.</td>
<td>71% reduction in face-to-face specialist appointments for some specialties. 55% of cases were resolved electronically; an electronic consultation with a specialist costs half of an in-person appointment.</td>
<td>Not-for-profit L.A. Care Health Plan provided $1.5 million to expand eConsult in LA County, called eConsult-LA. eConsult-LA program services more than 1,000 primary care providers and offers 10+ specialties. Within 18 months, over 45,000 electronic consults were exchanged between primary care providers and specialists.</td>
</tr>
</tbody>
</table>
HEART HEALTH

The SC CTSI Uses New “Promotora” Model to Improve Heart Health Among Latinos

Heart disease is the number one killer for all Americans, and stroke is the fourth leading cause of death. Hispanics and Latinos face a particularly high risk of these cardiovascular diseases because of high blood pressure, obesity, and diabetes. Monolingual Spanish speakers often face an additional language barrier in accessing preventive care that can save lives and money.

The SC CTSI has teamed up with researchers in the Keck School of Medicine of USC and a community organization, Visión y Compromiso, to study the impact of a promotora model for educating Latinos in two Southern California counties about cardiovascular health and ways to reduce their risk of heart disease.

Promotoras are community members trained to provide culturally and linguistically relevant health-oriented education to members of their community.

In an initial proof-of-concept study funded by the NIH’s National Heart, Lung, and Blood Institute (NHLBI), 25 promotoras were trained to deliver a heart health curriculum — Su Corazón su Vida, developed by the NHLBI. By the time the study was completed, promotoras had recruited and engaged a total of 730 residents in the two test counties.

Preliminary results show that participants significantly increased their knowledge about cardiovascular health, their desire and intent to change, and their involvement in physical activity and consumption of “heart healthy” foods. These changes were observed immediately after participation in the program, as well as at a 3-month follow-up assessment. The SC CTSI will also support the collection of one-year follow-up data to determine whether these changes were sustained over time.

“Many times people in the community wait to learn about health information until they’re already sick. That’s why it’s so important we get it to them.”

Promotora Maricela Sanchez, of Bakersfield, in Kern County, who conducted many of her workshops in schools and in churches
ASTHMA

The Most Powerful Weapon against Asthma Is Education

The Southern California city of Long Beach is home to America’s second largest port, a large municipal airport, and some of the busiest freeways in the country. As a result, Long Beach has some of the highest rates of both air pollution and asthma in the United States; 30% of its households have a child or adult living with asthma.

The SC CTSI partnered with BREATHE California of Los Angeles County and COPE Health Solutions to learn from residents what they understood about asthma, including what can increase the risk of an asthma attack and how to manage and prevent asthma. Based on what they found, they developed an NIH-funded, community-driven research project to adapt and tailor an extensive teaching curriculum about asthma and its management.

The project upgraded an existing curriculum with two new elements. One was designed to help kids with asthma engage safely in the physical activity that all kids need to stay healthy. The other element was about integrating a “buddy” system into classrooms to reduce the social isolation and limitation of activities that kids with asthma can experience at school. The buddy system enlists the help of friends who don’t have asthma and the buddy is taught to recognize signs of an attack and how to respond — by helping their friend stay calm, notifying an adult, reminding them to observe “pursed lip” breathing, and locating their inhaler. To date, the asthma prevention program has been implemented in 45 sites in Long Beach and LA. It reached more than 2,600 students in after-school programs last year. The program is also being shared with the Boys and Girls Club of Long Beach.

“A sustainable product of the work supported by the SC CTSI is a booklet, “What You Can Do about Your Child’s Asthma.” It provides information and guidelines to help parents work with physicians to manage their children’s respiratory health and achieve better health outcomes. 

http://tinyurl.com/sc-ctsi-asthma

Community Multiorganizational

Community Engagement

Child Health

200+ Participants

Children and parents worked with researchers to co-develop and implement the curriculum in schools.
AUTISM

Addressing Inequities in Care for Latino and African American Children with Autism

Latino and African American children are less likely to receive a timely autism diagnosis than their white counterparts. Delays in diagnosis lead to delayed treatment, which in turn decreases the chances of good long-term outcomes. So understanding and reducing disparities in the timely diagnosis of autism is an important health priority for Latino and African American communities.

To find out where the health care system stumbles, the SC CTSI partnered with the Autism Speaks Autism Treatment Network site at CHLA and the LA County Regional Centers (the local centers that diagnose and coordinate care for individuals with developmental delays). This team conducted focus groups with local families and providers to understand their experiences in the evaluation of children who ultimately proved to have autism. They also worked to identify potential areas for intervention to reduce disparities in the timely diagnosis of autism.

Results identified three primary areas for intervention: 1) increase knowledge about autism in community and clinic settings; 2) assist families in navigating the complicated health service systems; and 3) increase the advocacy skills of parents so they are better prepared to seek out appropriate services for their children.

The SC CTSI then supported the creation of a new curriculum to address these three areas. The curriculum was created with input from parents, local providers, promotoras, clinicians, and researchers. It is designed to be presented by promotoras in community settings, a novel approach to disseminating information about autism and helping families navigate complex service systems for this disease. The autism community has enthusiastically supported this endeavor. The SC CTSI is working with the Autism Treatment Network and other groups to assess the intervention’s effectiveness in helping parents and families obtain timely screening, diagnosis, and access to needed services for children with autism.

http://tinyurl.com/sc-ctsi-autism

CANCER

SC CTSI-Supported Cancer Education Film Receives Prestigious 2013 APHA Award

A multidisciplinary team from the Keck School of Medicine of USC and the USC School of Cinematic Arts produced a short film, “The Tamale Lesson,” and demonstrated the power of narrative storytelling to educate women from various cultural backgrounds about cervical cancer. Compared to the more traditional method of non-narrative health communication, the film led to a significant increase in cervical cancer screenings in the Mexican American and Korean women who viewed it. Thus, the narrative approach to communication helped to reduce the disparities in cancer screening that were found at baseline. The film received the American Public Health Association’s 2013 award for Health Education and Health Promotion and was a winner in the NIH Common Fund 10-Year Commemoration Video Contest.

The SC CTSI supported the production of a Spanish-language version of the film to help the research team reach more women and address additional health disparities. A total of 1,500 DVDs with both English and Spanish versions of the film were distributed to local women. The study team further received additional funding from the National Cancer Institute to continue studying the approach. Lourdes Baezconde-Garbanati, PhD, MPH, associate professor of
Preventive medicine, Keck School of Medicine of USC, and Sheila Murphy, PhD, professor, USC Annenberg School for Communication and Journalism, are spearheading the project.

http://tinyurl.com/sc-ctsi-film

**DIABETES & OBESITY**

**Text Messages Help Patients Better Manage their Diabetes**

USC researchers are exploring ways to use mobile phones and text-messaging to improve compliance with diabetes regimens for patients seen in the emergency department at LA County + USC Medical Center.

With support from the SC CTSI, Sanjay Arora, MD, associate professor of clinical emergency medicine, Keck School of Medicine of USC, and Elizabeth Burner, MD, MPH, former clinical research fellow, now assistant professor of clinical emergency medicine, Keck School of Medicine of USC, developed a mobile health intervention called TExT-MED to help low-income Latinos take concrete steps to manage their diabetes, such as taking medications as prescribed, keeping medical appointments, eating appropriate foods, and engaging in physical activity.

The TExT-MED program uses a platform where inspirational or instructional messages are sent to participants twice a day. Pilot data revealed improved medication adherence among those using the TExT-MED intervention compared to controls. In a subsequent feasibility trial, the study team found promising improvements in glycemic control, exercise and self-care behaviors. Participants assigned to TExT-MED were highly satisfied with the intervention and remarkably eager to recommend the program to friends and family. Thus, TExT-MED specifically and mHealth interventions more generally may be effective in engaging hard-to-reach patients such as low income, monolingual Spanish speakers.

http://tinyurl.com/sc-ctsi-text

**MENTAL HEALTH**

**Helping People with Mental Illness Get Medical Care**

Individuals with serious mental illness are less likely to get regular preventive health care and more likely to use the emergency rooms than are people without mental illness. As a result, people with serious mental illness generally report poorer health and more physical ailments than other individuals.

To address this disparity, the SC CTSI forged a new academic-community partnership. The academic side is led by John Brekke, PhD, Frances G. Larson professor of social work research and associate dean of research, USC School of Social Work. The community partner is Pacific Clinics, the largest...
behavioral and mental healthcare agency in Southern California. Together, they developed and tested the feasibility of a Peer Health Navigator model to help people with serious mental illness overcome barriers to critically needed health care.

Initial results indicate that patients assigned to the intervention experienced a significant improvement in physical health and a significant transition from using the emergency department to using outpatient clinics for their routine health care. As a result of this SC CTSI-supported feasibility study, the LA County Department of Mental Health is implementing peer health navigators in more than 50 community clinics. Simultaneously, Brekke has secured funding from the Patient Centered Outcomes Research Institute (PCORI) to conduct a larger randomized trial to formally evaluate the efficacy of the peer navigator approach in patients with chronic mental illness in two branches of Pacific Clinics in LA County.

http://tinyurl.com/sc-ctsi-mental

TRANSGENDER HEALTH

The Plight of Transgender People Seeking Basic Medical Care

Transgender individuals experience some of the greatest health disparities in our communities. While research investigating their health is limited, we do know that they experience challenges in accessing culturally appropriate care and have some of the highest rates of human immunodeficiency virus (HIV) worldwide.

To help physicians understand medical issues unique to transgender patients, the SC CTSI launched an observational study to collect data on markers of cardiovascular and metabolic health and attitudes toward health care from people who are receiving cross-sex hormone therapy. The study is a partnership between the SC CTSI and the LA Gay & Lesbian Center's director of Transgender Health, Maddie Deutsch, MD.

The pilot study found that barriers to care for transgender individuals include: lack of health insurance, anxiety about seeing a physician, lack of clarity about where to access care, and past negative experiences with a healthcare provider because of transgender identity. The study is the first of its kind to examine the effect of hormone therapy on the general physical health of transgender individuals. The results indicate that cross-sex hormone therapy in a young and generally healthy transgender population appears to have a protective effect on blood pressure in the short term. In addition, the data indicate that there was an increase in the prevalence of obesity seen in female-to-male individuals after the initiation of testosterone therapy.

The results revealed a stigma in the healthcare system associated with a patient's transgender identity. Moreover, the partnership between medical providers and transgender advocates/organizations are important to ensure access to care for this highly vulnerable population. The preliminary information on cardiovascular and metabolic health points to both risk and protective factors as a result of cross-sex hormone therapy. Multi-site, national trials are in discussion to further explore these issues.

http://tinyurl.com/sc-ctsi-trans
Preparing Future Generations of Clinical and Translational Researchers

The health needs of the nation call for a next generation of scientists and a research workforce trained in interdisciplinary, transformative clinical and translational research. The Education, Career Development, and Ethics (ECDE) program at the Southern California Clinical and Translational Science Institute (SC CTSI) has been focused on preparing the current and future research workforce for this challenge.

The program has built a robust curriculum as well as flexible hands-on training formats in various aspects of clinical and translational science and research in diverse urban populations, including clinical study design, grant writing, research ethics, multidisciplinary and team science, leadership, as well as a signature curriculum track.

The program targets PhD and professional degree students, as well as junior clinical faculty within the University of Southern California (USC) and Children’s Hospital Los Angeles (CHLA). The educational offerings draw on expertise throughout USC, including the USC Rossier School of Education, the Marshall School of Business, the USC Annenberg School for Communication and Journalism, and the Keck School of Medicine of USC.

“The teamwork has been one of my favorite aspects of the program. Because of my clinical training, I already feel very comfortable running an operating room, but I don’t feel as comfortable running a lab — it’s a whole other skill set. The coursework helped me develop that aspect of my work as a researcher.”

— Gabriel Zada, MD, assistant professor of clinical neurological surgery, Keck School of Medicine of USC; co-director, USC Pituitary Center, Keck Medicine of USC

Research Scholarship Awards

The SC CTSI provides two types of clinical research scholarship awards.

The KL2 program serves scholars and clinical junior faculty who already have MD or PhD degrees and seek careers as principal investigators. Each year, the SC CTSI funds early-career faculty and fellows from departments throughout USC to attend the three-year KL2 program.

The TL1 program admits medical and pre-doctoral PhD students from basic science and health-related departments throughout USC.
Team-Building Coursework Turns USC Clinician Researchers and PhD Candidates into Colleagues

With medical research becoming increasingly cross-disciplinary, education strategists at the SC CTSI developed a series of courses that brings together USC clinician researchers and PhD candidates to give them hands-on experience working with investigators from diverse backgrounds.

The new coursework proved successful when a four-person team consisting of two assistant professors and two graduate students collaborated to produce a comprehensive review of the scientific literature about emotional and behavioral impacts on children with a type of brain tumor called craniopharyngioma.

Team member Natalie Kintz, a fifth-year PhD candidate in the USC Neuroscience Graduate Program who studies neurodegenerative conditions such as Parkinson’s disease, said the opportunity to work with medical doctors gave her valuable additional insight for her areas of study.

“The KL2 Scholars brought a very different perspective than the people I’m normally surrounded by as a graduate student, both because they’re trained as clinicians, but also because they’re farther along in their careers. I wish more graduate students could take part in the program.”

— Natalie Kintz, PhD candidate, USC Neuroscience Graduate Program

“Our goal with these courses is to create a formal framework for teaching researchers how to work and produce high quality, transparent, and meaningful research findings as teams.”

— Cecilia M. Patino-Sutton, MD, MEd, PhD, director, SC CTSI Education, ECDE program
Practice Makes Perfect in Applying for Federal Grants

To coach newer scientists in the challenging task of applying for grants from the National Institutes of Health (NIH), SC CTSI’s ECDE program has teamed up with their counterparts at the North Carolina Translational and Clinical Sciences Institute (NC TraCS) to conduct dress rehearsals of the government’s rigorous proposal review process.

During mock review sessions, senior faculty scientists from both universities played the role of a panel of NIH reviewers. The panel, along with the SC CTSI educators, assessed research proposals before they were sent to the NIH, citing strengths and weaknesses and offering suggestions to improve the science and the written applications themselves.

“The mock reviews go a long way toward preparing newer researchers for the scrutiny that their ideas will receive during actual NIH peer review,” said Morris Weinberger, PhD, distinguished professor of health policy and management, Gillings School of Global Public Health, University of North Carolina and co-director of education, NC TraCS. “This approach helps desensitize them to criticism and helps them prepare stronger proposals.”

“The great benefit of this model is that it gives our scholars the opportunity to get feedback from experts in their fields who can look at the proposals with a fresh and outside perspective,” added Jonathan M. Samet, MD, director, SC CTSI ECDE program.

http://tinyurl.com/sc-ctsi-mock

“It is priceless to have access to a panel of senior scientists who can critique the application. Based on their ideas, I was able to improve my study design and make the grant a more cohesive package.”
— Mimi S. Kim, MD, MSc, assistant professor of clinical pediatrics, Keck School of Medicine of USC; co-director, Congenital Adrenal Hyperplasia Comprehensive Care Clinic, CHLA
Answering Questions that Start in the Operating Room

The Department of Surgery in the Keck School of Medicine of USC has set its sights on becoming a national force in surgical research. When Vaughn A. Starnes, MD, professor of surgery, Keck School of Medicine of USC was named chair of the department in December 2008, his top priority was to transform a department long recognized for its excellence in the operating room into one equally regarded for its leadership in research. “Our vision is to tackle an obvious clinical problem, take it to the bench and work on the science to solve it, and bring it to the clinical arena,” said Starnes.

The most recent step toward achieving that vision is a first-of-its-kind partnership with the SC CTSI, a partnership in which the department is providing the funding for one of its surgeons to take part in SC CTSI’s research career development (KL2) program.

“The KL2 program was created to enhance and accelerate the professional development of new clinical and translational researchers, so it’s critical for USC that we find ways to get the maximum number of scholars enrolled,” said Jonathan M. Samet, MD, MS, director, SC CTSI ECDE program.

The first researcher to be supported 100% by her own department in KL2 scholarship is Julie E. Lang, MD, FACS, associate professor of clinical surgery, Keck School of Medicine of USC. Lang is developing a laboratory-based research program to understand the role of circulating tumor cells in the biology and clinical care of patients with breast cancer. The support from her department allows Lang to devote a majority of her time to research at a crucial early stage in her career.

http://tinyurl.com/sc-ctsi-lang

“By sponsoring a KL2 Scholar, we may be an exception now, but I don’t think we should be. Not to take the fullest advantage of the incredible resource of the SC CTSI would be a lost opportunity.”

— Vaughn A. Starnes, MD, professor of surgery and chair, department of surgery, Keck School of Medicine of USC

“The decision by Dr. Starnes to protect time for one of his junior faculty members to participate in the KL2 program is a great model that we hope other departments and schools will use in the future.”

— Thomas A. Buchanan, MD, director, SC CTSI
“The studio allows us to create high quality educational content that can reach a broader audience interested in clinical and translational research, regardless of where they are. This approach allows our SC CTSI learners to access course materials in a way that matches their needs.”

— Jonathan M. Samet, MD, MS, director, SC CTSI ECDE program

Online Education for Clinical and Translational Research

The SC CTSI has created a video studio that makes it easy to create high-quality education and training videos 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 even from behind a news desk. The studio is available as a service to anyone at USC and CHLA, as well as outside users. In total, more than 500 educational videos have been produced using the studio’s resources.

http://tinyurl.com/sc-ctsi-studio

Video Series Created by SC CTSI Scholar Helps Graduate Students Apply for NIH Pre-Doctoral Grants

After successfully applying for a competitive NIH National Research Service Award (NRSA), Jamaica Rettberg, SC CTSI’s TL1 Trainee and PhD candidate in the USC Neuroscience Graduate Program, was encouraged by ECDE mentors to give her peers the benefit of her experience. Rettberg developed a multi-part video series to help other applicants complete the complex federal research application process for NRSA training grant support. Using her own successful application as an example, Rettberg took fellow students step-by-step through the application process, from major topics like writing effectively about research goals to small but important matters like formatting and font size. “I tried to give them the full background on what they need to prepare for a successful application,” said Rettberg. “They are all really smart in their research; I tried to add some practical pointers to help them assure success.”

http://tinyurl.com/sc-ctsi-video

“This video series is a wonderful resource for applicants. It is the first tutorial that I have ever seen focused on NRSAs from the perspective of someone who has been through that process. It was excellent.”

— Molly Wagster, PhD, NIH program officer
Successful Research by KL2 Scholars and TL1 Trainees

**CANCER**

**Using Circulating Tumor Cells to Assess a Patient's Response to Therapy in Real Time**

SC CTSI's KL2 Scholar Julie E. Lang, MD, FACS, associate professor of clinical surgery, Keck School of Medicine of USC, came to USC with a strong background in clinical surgery and bench science but said the KL2 program has provided valuable training in statistical methods for clinical research. She researches gene expression in circulating breast cancer cells, which are shed by tumors and travel through the bloodstream. Her lab collects the cells from research participants and uses sophisticated RNA sequencing techniques to determine what the circulating cells can reveal about their tumors of origin.

One of Lang’s projects is seeking to determine if capturing circulating tumor cells in the blood of stage four patients — those whose cancer has metastasized widely — can replace surgical biopsies when tumor location makes biopsies unpleasant or impossible. “The hope is to use circulating tumor cell biology to assess a patient’s response to therapy in real time,” said Lang. Since completing the program, she has received multiple foundation grants and a first-of-its kind contract with an international biotechnology company.

http://tinyurl.com/sc-ctsi-cells

**CANCER**

**Determining Genetic Factors of Tumor Invasiveness**

“The SC CTSI KL2 program has introduced me to the whole language of clinical research,” said SC CTSI KL2 Scholar Gabriel Zada, MD, neurosurgeon and assistant professor of clinical neurological surgery, Keck School of Medicine of USC. “So much of what we do is translational and multidisciplinary, and the more you can share that language with people from other specialties, the better your research will be.”

Zada sees research as a way to answer questions that come up in the operating room. “As surgeons, we interact with the body in a unique way and have the opportunity to see disease, such as tumors, in the body and to develop a grasp of the clinical barriers and issues,” he said.

His research focuses on pituitary adenomas, a tumor of the pituitary gland, and on the genetic factors that determine tumor invasiveness. Recently named co-director of the USC Pituitary Center at Keck Medicine of USC, Zada published pilot data from DNA methylation analyses and plans to leverage the data to secure future NIH funding.

http://tinyurl.com/sc-ctsi-tumors

“One of the most important skills in the KL2 training is grantsmanship — understanding how to convey the objectives of our research to reviewers who may specialize in different areas.”

— Julie E. Lang, MD, FACS, associate professor of clinical surgery, Keck School of Medicine of USC
CANCER
Understanding Chronic Swelling of Arms After Breast Cancer Surgery

“For most people reconstructive surgery is a full time job. But I wanted to also pursue research. SC CTSI’s KL2 program provided me with the protected time I needed to get my research career started.”

Alex K. Wong, MD, assistant professor of clinical surgery, Keck School of Medicine of USC, is now studying lymphedema, chronic swelling of the arms that often troubles patients who have had breast cancer surgery. He is investigating a molecule called 9-cis-retanoic acid for a new therapy designed to regenerate lymphatic vessels following surgery. He hopes his research will lead to better treatments that he and other surgeons can apply.

http://tinyurl.com/sc-ctsi-arms

CONCUSSION
New Concussion Guidelines for Young Athletes

Much of the public is aware that head injuries are a major problem for many athletes. USC neurosurgeon Gabriel Zada, MD, assistant professor of clinical neurological surgery, Keck School of Medicine of USC, is conducting studies about the effect of concussions on the brain. Zada points to new evidence showing the significance of a single hit to the brain. His work is contributing to the development of new guidelines designed to protect young athletes following head injury. Zada’s research career development was supported by SC CTSI’s KL2 program.

http://tinyurl.com/sc-ctsi-athletes

DIABETES & OBESITY
Viewing Images of High-Calorie Foods Brings on High-Calorie Cravings

USC diabetes researcher and KL2 program alumna Kathleen Page, MD, assistant professor of medicine, Keck School of Medicine of USC, uses state-of-the-art functional magnetic resonance imaging to study how different foods activate appetite and reward centers in the brain. These centers help to regulate food intake, which if excessive can lead to obesity. Her studies have shown that two sugars commonly found in our food supply, glucose and fructose, have different effects on the brain. Fructose, a main component of the “high-fructose corn syrup” that serves as a sweetener in many foods, activates brain reward centers better and suppresses appetite centers less well than glucose, the body’s main sugar.

“SC CTSI’s KL2 program provided a formal structure and dedicated time that I could never have created on my own. It has allowed me to connect with remarkable mentors and learn about study design, biostatistics, and other areas that have made me much more capable as a researcher.”

— Alex Wong, MD, assistant professor of clinical surgery, Keck School of Medicine of USC
Thus, fructose may promote overeating compared to glucose.

Her group also showed that when young adults viewed pictures of high-calorie foods, like a picture of chocolate cake, their brain appetite and reward centers were activated, and they reported greater hunger and desire to eat. These neural and behavioral responses to high-calorie food cues could stimulate food intake.

Page is currently conducting studies to determine brain and behavioral responses to dual stimulation by food images and sugar intake. These studies have important public health implications in a society that is inundated with high-sugar foods and tantalizing food stimuli.

Despite being relatively early in her career as a clinical researcher, Page has already received several awards for her research. Most recently, she received the prestigious Pathway Accelerator Award from the American Diabetes Association for her translational research project entitled, "Neural Mechanisms in Maternal-Fetal Programming for Obesity and Diabetes." The award will provide $1.6 million in support for five years.

Page’s work has been published in top journals such as *JAMA* and *PNAS*, it was the basis for an op-ed piece in the Sunday *New York Times*, and she has been featured by many national news services.

http://tinyurl.com/sc-ctsi-crave

Clinical

Biostatistics  Training and Career Development

Pilot Funding

MENTAL HEALTH

Developing Culturally Tailored Research and Health Solutions

SC CTSI's KL2 Scholar Joyce R. Javier, MD, MPH, assistant professor of clinical pediatrics, Keck School of Medicine of USC and primary care pediatrician, CHLA, focuses on the prevention of mental, emotional, and behavioral health issues among immigrant populations, particularly Filipino youth and families.

As part of her work, Javier gives workshops designed to help parents raise and interact with their kids in a less stressful and more productive way. Early results have shown that, for kids, the programs strengthened social skills, emotional regulation, and school readiness. “Most importantly, our initial results hold the potential to lead to larger studies to eliminate the health disparities that affect young people in these immigrant groups, as well as the behavioral issues that can get in the way of their development as they grow toward adulthood,” said Javier.
The mentorship and coursework provided by SC CTSI’s KL2 program helped Javier mount a community-based study and later apply successfully for an NIH research grant. In July of 2013, Javier was awarded a four-year K23 grant by the Eunice Kennedy Shriver National Institute of Child Health and Human Development. The focus of the K23 award is to develop and evaluate an innovative approach to overcome stigma associated with parenting programs in order to increase participation of Filipinos in evidence-based parenting interventions. Currently, Joyce and her team are moving toward implementation of the interventions in both community and primary care settings. Joyce is also sharing her findings more broadly as a regular panelist on a national talk show geared toward Filipino-American families.

“Without a program like the one offered by the SC CTSI that supports the mentors and organizes the coursework and seminars, there’s no guarantee you’ll get the best coaching and training for your research goals.”

— William J. Mack, MD, associate professor of neurological surgery, Keck School of Medicine of USC; director, The Neurointerventional Program at USC

STROKE

Investigating Inflammation in Search of New Treatments for Stroke Patients

While a scholar in SC CTSI’s KL2 program, William J. Mack, MD, associate professor of neurological surgery, Keck School of Medicine of USC and director of The Neurointerventional Program at USC, investigated how doctors could manipulate the body’s natural inflammation response to treat stroke and other blood flow disorders of the brain.

He used a mouse model to study a portion of the inflammation response called the C5 complement component. His research team found that by inhibiting the C5 receptors — and thus reducing inflammation — they could reduce the neurological damage after a stroke.

Mack credits SC CTSI’s KL2 program with helping him speed his development into an independent clinical researcher. “The program put me in a position to advance my research career much more quickly. Structured teaching like the KL2 program creates a formal pathway for more experienced researchers to guide newer researchers,” he said.
Mack’s work, supported through the SC CTSI, has led to multiple subsequent grants that are enabling him to further continue to investigate mechanisms of stroke. Currently, his R01 application is pending council review.

“The mentors in the SC CTSI and the KL2 program taught me how to think like a researcher,” he added. “This training affected the shape of my research in fundamental ways — they improved my skills in things like hypothesis generation, research design, and my formal knowledge of statistics and analysis of findings.”

http://tinyurl.com/sc-ctsi-stroke

THYROID DISORDERS

Using Novel Magnetic Resonance Imaging Application to Understand Thyroid Disorders in Children

SC CTSI’s KL2 Scholar Mimi S. Kim, MD, MSc, assistant professor of clinical pediatrics, Keck School of Medicine of USC and co-director, Congenital Adrenal Hyperplasia Comprehensive Care Clinic, CHLA, wondered if a novel application of magnetic resonance imaging (MRI) could be used to understand thyroid dysfunction in children.

Kim worked with a team of clinicians and radiologists to study a type of fat called brown adipose tissue — also known as brown fat. Brown fat is specifically evolved to generate heat. The team found that thyroid hormone deficiency led to an increase in brown fat, possibly the body’s attempt to increase heat production. Treatment with thyroid hormone reduced brown fat. Part of the work was featured as the front cover image for a recent issue of the leading endocrinology journal in the United States, the Journal of Clinical Endocrinology and Metabolism.

Kim said her research could not have succeeded without the teamwork and mentorship that SC CTSI’s KL2 program is structured to enable. “The group was more powerful than the sum of its parts,” she said.

http://tinyurl.com/sc-ctsi-thyroid

“It really takes a village to make a researcher. By protecting time in busy professional schedules for researchers to find mentorship and collaboration, as well as the coursework and seminars, the KL2 program has become a self-sustaining community that provides unique support to rising clinical researchers.”

— Mimi Kim, MD, MSc, assistant professor of clinical pediatrics, Keck School of Medicine of USC; co-director, Congenital Adrenal Hyperplasia Comprehensive Care Clinic, CHLA
The program put me in a position to advance my research career much more quickly. Structured teaching like the SC CTSI KL2 program creates a formal pathway for more experienced researchers to guide newer researchers.

WILLIAM J. MACK, MD
ASSOCIATE PROFESSOR OF NEUROLOGICAL SURGERY, KECK SCHOOL OF MEDICINE OF USC; DIRECTOR, THE NEUROINTERVENTIONAL PROGRAM AT USC
Look to the Future

We hope readers of this report will agree that the Southern California Clinical and Translational Science Institute (SC CTSI) has played a major role in creating a strong culture of clinical and translational research and strong programs to support that research.

We now face a major turning point. The National Institutes of Health (NIH) has created a new center, the National Center for Advancing Translational Sciences (NCATS), which serves as the organizational home for the Clinical and Translational Science Award (CTSA) program at NIH. With energetic and innovative leadership and important input from the research community, NCATS is taking the CTSA program in new directions. There will be an important focus on expanding capabilities to support high-quality, efficient clinical trials. Individual CTSAs will be encouraged to invest their resources to enhance their own unique strengths in order to benefit clinical research not only locally, but also regionally and nationally. Training of new investigators will continue to be an important role of the CTSAs. In parallel with these changes in the CTSA program, the University of Southern California (USC) and Children’s Hospital Los Angeles (CHLA) are expanding clinical and academic programs to establish themselves as world-class academic medical centers, with close integration of research, training, and clinical care. The time is right for the SC CTSI to lead the way in supporting outstanding clinical research that advances the health of our local populations, the reputations of our institutions, and national efforts to create an effective and efficient clinical research enterprise.

On this new landscape, the SC CTSI is embarking on an enterprise-wide transformation of clinical research and the infrastructure supporting it. We seek to simplify the clinical research process, to increase the efficiency with which clinical research can be conducted, and perhaps most importantly, to partner more effectively with our hospitals, clinics, and patients to support research that will benefit health. There will be many facets of this transformation, which is being undertaken in partnership with colleagues at USC and CHLA, Los Angeles (LA) County’s Department of Health Services, other local academic institutions, and people in our community. Below are descriptions of some of the things we are setting out to accomplish.

Clinical Trials Management System (CTMS)

Management of clinical trials requires information from a wide variety of systems and sources including budgeting, contracts, finance, scheduling, compliance, research, and clinical patient data. The CTMS will be deployed across USC and CHLA to bring together data from multiple sources to help streamline the initiation, management, and financial accounting of clinical studies. The SC CTSI is actively involved in assuring that the implementation leads to a highly functional and research-friendly CTMS. The SC CTSI is also working closely with the USC Office of the Vice President of Research and leadership at CHLA to assure that the business processes underlying clinical research are streamlined and as invisible to researchers as possible. Our ultimate goal is to create a digital home for clinical research that will provide research teams with a single point of access, backed by efficient systems, to facilitate the efficient, safe, and compliant conduct of clinical research across USC and CHLA.
Clinical Data Warehouse for Research

To strengthen the cross-institutional research, the SC CTSI is undertaking a major effort to aggregate enterprise-wide health records into a single repository that, with appropriate regulatory oversight, will allow the discovery, reuse, and sharing of clinical data for research. We call this initiative “Data Exploration, Warehousing, and Archiving for Researchers” (DEWARS). It is designed to provide a mirror of research-relevant components of electronic health records – demographics, diagnoses, medications, laboratory values, imaging results – that can be accessed to let researchers identify research cohorts, test hypotheses, and conduct powerful analyses that are only possible with a dataset of this scale.

To begin the DEWARS initiative, the SC CTSI is implementing new governance policies and leading compliance agreements that will provide a model to other collaborative ventures seeking to promote maximal inclusion of clinical data while still preserving patient confidentiality. As standards for the reuse of clinical data for research are evolving, the SC CTSI and its University compliance partners intend to remain at the forefront of ethical and compliant research conduct. Our long-term goal is to bring together other partners (e.g., the LA County Department of Health Services and other academic medical centers) to create a regional data warehouse that is federated to allow collaboration among researchers in major academic institutions and health systems in LA.

Biorepository

A very strong compliment to the clinical data that will become available through DEWARS will be access to biological specimens from patients whose data are in the research data warehouse. USC has begun the development of a biorepository to house such specimens. With generous support from the USC Office of the Provost, we are establishing a robotic freezer facility capable of housing more than 1.5 million biological samples. The next step is to begin the process of incorporating consent for sample collection into routine clinical care and then create the electronic systems that will, with appropriate regulatory approval, connect specimens in the biorepository to information in the clinical data warehouse. The ethical, technical, and informatics challenges in this endeavor are significant but not insurmountable. The end result will be a very rich resource for research than can identify new biomarkers for disease prevention and treatment and help the USC academic medical enterprise advance the field of personalized medicine.

We hope that those of you who have already experienced the value of the SC CTSI will continue with us on our journey to make translation an integral part of biomedical research. For those of you who have not yet accessed the SC CTSI, we look forward to the chance to open new opportunities that will help your research have a real impact on health.

— Thomas A. Buchanan and Michele D. Kipke
SC CTSI understands the meaning of discovery and takes a risk for you. The data we were able to generate with our SC CTSI pilot grant set the stage to convince the NIH to support our larger investigations."

WEI LI, PHD
PROFESSOR OF DERMATOLOGY,
KECK SCHOOL OF MEDICINE OF USC

This publication was supported by the National Center for Advancing Translational Sciences of the National Institutes of Health under Award Number UL1TR000130 (formerly by the National Center for Research Resources, Award Number UL1RR031986). The content is solely the responsibility of the SC CTSI and does not necessarily represent the official views of the National Institutes of Health.

CONCEPT DEVELOPMENT & EDITORS: Katja Reuter, PhD; Melanie Funes, PhD
WRITER: Paul Karon
CONTRIBUTORS: Thomas A. Buchanan, MD; Michele D. Kipke, PhD; Allison Orechwa, PhD
DATA COLLECTION & ANALYSIS: Eunbyul Evans, PhD; April Bagaporo; Aileen Dinkjian, MPH; Annie Hong
ACKNOWLEDGMENT: We wish to thank the SC CTSI program leadership and staff, and the researchers at USC and CHLA highlighted in this report for their contributions.
DESIGN: Laura Myers Design

© 2015 SC CTSI