

CTSC@connections

Building research teams of the future to improve human health • FALL 2011

DIRECTOR'S MESSAGE

Lars Berglund, M.D., Ph.D.

WELCOME TO THE FIRST ISSUE of *CTSC Connections*, a newsletter by faculty and staff at the UC Davis Clinical and Translational Science Center (CTSC). Published twice a year, the newsletter aims to raise awareness of the infrastructure, tools and support available for UC Davis investigators and their institutional and community partners to advance research, education and health.

The UC Davis CTSC was established in 2006 as one of 12 inaugural members of a national consortium led by the National Center for Research Resources at the National Institutes of Health (NIH). Members of the consortium, which now includes 60 academic research institutions, share a common vision to improve human health by transforming the research and training environment to enhance the efficiency and quality of clinical and translational research.

The UC Davis CTSC works to reduce the time it takes for laboratory discoveries to become treatments for patients, engage communities in clinical research and train the next generation of scientists who conduct high-

(Continued on page 2)

\$20 million grant helps CTSC set course for next five years

AN AWARD OF \$20 MILLION in renewed grant funding marks the fifth anniversary of the UC Davis Clinical and Translational Science Center (CTSC). The funding allocation by the National Center for Research Resources recognizes the center as an important contributor to medical research.

"UC Davis received funding at the requested grant level and scored among the top three centers applying for renewal," said Lars Berglund, CTSC director and associate dean for research in the UC Davis School of Medicine.

During the past five years the CTSC has fostered numerous advances in scientific understanding and essential training for scholars and students. Researchers working under the CTSC umbrella conduct on average more than 1,000 research studies annually. Some of the center's innovative collaborations include:

- partnerships with the College of Engineering to develop biological sensors that measure components in human breath to more accurately diagnose asthma and other diseases (*see story on page 3*);
- studies with the Betty Irene Moore School of Nursing to assess the effectiveness of using nurses as health coaches to improve diabetes self-management;
- a biomedical informatics program that consolidates multiple institu-



The CTSC focuses on team science, interdisciplinary curriculum and best practices across multiple training grants.

tional and national resources into a multifaceted resource for UC Davis investigators, including tools that enable investigators to securely access de-identified clinical data to analyze health trends and reposition pharmaceutical drugs for potential new uses;

- a dynamic research training environment that funded 64 pilot projects, resulting in 66 publications and 106 abstracts, 94 junior scientists working as team members and new research awards totaling \$23 million;
- a multicenter burn study and extensive child-health programs in

(Continued on page 2)

Next five years

Continued from page 1

partnership with Shriners Hospital for Children—Northern California;

- a robust Clinical Research Center that includes a mobile research unit with highly trained staff who conduct evaluations, offer laboratory support services and accommodate research study participants in their own environment.

“Initially the UC Davis CTSC served as an incubator of ideas and a catalyst for partnerships at UC Davis and beyond,” said Berglund. “Today, we offer a full-fledged toolbox of resources that faculty and staff across the spectrum of scientific research can use to improve health and health-care delivery.”

During the next five years, the CTSC expects to complete its comprehensive array of services, resources and tools to foster collaboration and advance research, training and health across the lifespan.

“By marshaling our collective brainpower toward a common goal,



CTSC graduate students shadow Assistant Professor of Cardiovascular Medicine Jeffrey Southard in the cardiac catheterization lab.

together we can ensure that the public more quickly benefits from discoveries in the laboratory,” Berglund said. “To get there, we must anchor our effort in teamwork.”

Specific goals of the UC Davis CTSC include:

- expanding information-technology tools for genetic and genomics research and education for all CTSC training programs;
- expanding training and resources for mentors and mentees at all career stages;
- increasing academic-community health-research partnerships and enhancing training curricula for programs on health services and health-policy research; and
- promoting translational research and facilitating collaborations among basic and clinical scientists.



DIRECTOR'S MESSAGE *Continued from page 1*

“The challenge is to take full advantage of resources and contribute to efforts that will result in improved detection, treatment and prevention of disease.”

~ Lars Berglund

impact research. Organized into eight programs, the UC Davis CTSC supports investigators and post-graduate students who are pursuing health sciences research (*see list on pages 6-7*).

At the national level the NIH is transitioning responsibility to a new entity, the National Center for Advancing Translational Sciences (NCATS). NCATS will re-engineer the process of developing drugs, diagnostics and devices by investing in science that creates powerful new tools and technologies that can be adopted widely by researchers in the public and private sectors. It will

oversee the Clinical and Translational Science Award consortium and other NIH programs, extending partnering efforts that will deliver on the promise of translational medicine and complement existing translational research efforts.

The challenge will be to take full advantage of resources and contribute to efforts that will result in improved detection, treatment and prevention of disease. Here at UC Davis, we accept this challenge and look forward to supporting scientists with education, training and research infrastructure.

A breath
of fresh air:
Working
together
across
disciplines



Cristina Davis and Nicholas Kenyon

THE CLINICAL AND TRANSLATIONAL SCIENCE CENTER enabled engineer Cristina Davis and pulmonologist Nicholas Kenyon to find common ground. Their goal is to demonstrate the practical application of a compact spectrometer capable of analyzing human breath to aid in disease diagnosis for patients with asthma and other respiratory disorders.

Their collaborative work began shortly after Davis left her position as a bioengineering group leader and principal member of the technical staff at a national laboratory in Boston to join UC Davis in November 2005.

“I told Cristina about my interest in exhaled biomarkers, and she told me about her sensor development and interest in measuring exhaled breath condensates and biomarkers,” said Kenyon, an associate professor of pulmonary and critical care medicine and expert in the diagnosis and treatment of severe asthma. Kenyon has been studying the mechanisms of airway inflammation, fibrosis and

airway hyperresponsiveness to find ways to improve patient care.

Davis, an associate professor of mechanical and aerospace engineering, directs the Bioinstrumentation and BioMEMS Laboratory. She received a Hartwell Individual Biomedical Research Award in 2010 for her research on miniature chemical sensors for childhood asthma, the result of CTSC project support. With her expertise in chemical and biological sensing applications, BioMEMS (microelectromechanical) devices, and bioinformatics interpretation of sensor output, she was an ideal collaborator for Kenyon’s asthma studies.

“The CTSC enabled us to meet and establish collaborations with UC Davis faculty from multiple disciplines,” Davis said. The CTSC also awarded seed money for several studies and provided support with study design, patient recruitment and clinical trials implementation.

“Our fruitful and productive collaboration demonstrates that working together across disciplinary boundaries enables scientists to achieve much more than they could by working alone,” Davis said. “The CTSC offers numerous resources to promote new partnerships. It’s the way science is moving forward.”

“Our fruitful and productive collaboration demonstrates that working together across disciplinary boundaries enables scientists to achieve much more than they could by working alone.”

~ Cristina Davis

Clinical Research Center without walls

CAREFULLY CONDUCTED clinical trials are the safest and fastest way to discover new treatments and approaches to care that improve health. The Clinical and Translational Science Center's Clinical Research Center (CCRC) is a specialized unit with facilities and experienced clinical staff who support the university's research mission. The center offers essential services for health researchers and study participants, from implementing study protocols to fostering enrollment and retention through a robust travel program.

The CCRC is a collaboration between UC Davis and the Veterans Affairs (VA) Northern California Healthcare System to advance state-of-the-art clinical research. The CCRC's main facility, located at the Sacramento VA Medical Center in Mather, Calif., occupies 8,000 square-feet of space. It contains a metabolic kitchen, core laboratory, body composition unit, patient day room, and nine patient beds for procedures that require extended outpatient or overnight stays. PET, MRI and standard radiology imaging is available on site along with blood sampling, investigational drug administration, monitoring, invasive procedure assistance, EKG or cardiac monitoring, and related procedures.

"The CCRC is a versatile facility that has hosted a wide range of clinical studies," said CCRC's medical director Ted Wun, who also is a professor of medicine and pathology and laboratory medicine and chief of the Division of Hematology and Oncology. "These include prolonged stays for complex metabolic studies, phase I studies of



Danise Gonzalez is one of 10 highly skilled RNs who provide care to participants enrolled in clinical research studies.

new therapies for sickle cell disease, hemophilia, cancer and Alzheimer's disease medications, as well as right heart catheterization for pulmonary hypertension studies and fat biopsies for metabolic studies."

"Our program fosters enrollment and retention by making it more convenient for community members to participate in research."

~ Nicole Mullen

The CCRC also has a satellite center in the Ticon I building on the UC Davis Sacramento campus, and an active travel program whereby members of the CCRC team visit study participants throughout the UC Davis campus and beyond to conduct evaluations, obtain blood samples and perform procedures on participants who find clinical facilities intimidating or have difficulty traveling.

"We regularly travel to Stanislaus, San Joaquin, Yolo and Bay Area

counties, visiting participants in their own homes, in Head Start facilities and farming areas, and via telehealth," said CCRC nurse manager Nicole Mullen. "Our program fosters enrollment and retention by making it more convenient for community members to participate in research."

The CCRC team includes nurses who have extensive training and experience in carrying out study protocols and adhering to university and government research policies and regulations; a nurse practitioner who offers a wide range of services such as physical assessments, biopsies and other invasive procedures, and bedside monitoring for participants receiving a higher-risk infusion; and a comprehensive support staff that includes an exercise physiologist, laboratory technician, research coordinators and a research dietitian.

CCRC services are available to all faculty members, residents, postgraduate fellows and medical and nursing students. Learn more by visiting healthsystem.ucdavis.edu/ctsc/areas/crc-facilities.html on the Web or by e-mail at nicole.mullen@ucdmc.ucdavis.edu.

Training future emergency medicine leaders

THE UC DAVIS Clinical and Translational Science Center (CTSC) supports investigators across the UC Davis campus and their efforts to pursue grants for research and training as part of its mission to advance translational research within and beyond UC Davis.

The CTSC recently supported the Department of Emergency Medicine's successful application for a major grant from NIH's National Heart, Lung, and Blood Institute. The \$3.3 million award will train faculty in collaborative, multicenter research to improve the care of critically ill and injured adults and children. UC Davis was one of only six institutions nationwide to receive the prestigious award.

“Our focus will be on conducting multicenter research, which is a powerful way to obtain sufficient sample sizes and definitive answers.”

~ Nathan Kuppermann

“The grant will enhance understanding and improve the care of acute traumatic injuries and emergent medical conditions, including cardiovascular, hematological and respiratory diseases,” said Nathan Kuppermann, professor and chair of the Department of Emergency Medicine. Kuppermann will lead the program with co-principal investigator James Holmes, professor of emergency medicine and director of the department's research fellowship training program.

“Our focus will be on conducting multicenter research, which is a powerful way to obtain sufficient

sample sizes and definitive answers,” said Kuppermann.

Kuppermann's work at UC Davis and as founding chair and a principal investigator of the Pediatric Emergency Care Applied Research Network (PECARN) has earned UC Davis an international reputation for excellence in academic emergency medicine. Through PECARN and other collaborations, he established a network of pediatric emergency departments nationwide that perform high-impact research.

The new grant funds the training of five junior faculty members over a two- to three-year period each. The trainees may come from the disciplines of emergency medicine, pediatric emergency medicine, internal medicine, pediatrics and surgery.

“Although the numbers are growing, there are not many emergency medicine and pediatric emergency medicine investigators with rigorous research training who are prepared to lead the next generation of research in our specialty,” he said. “Our goal is to find and prepare these researchers.”

CTSC Director Lars Berglund concurs. “This award recognizes a top-tier research program that offers tremendous prestige to the School of Medicine. Through their initiative and innovation, Dr. Kuppermann and his team have orchestrated the development of a research network of the highest caliber and, building on this, developed a first-rate education and mentoring program. I offer my warmest congratulations for this significant milestone, and I am happy that Dr. Kuppermann and his team have fully leveraged the offerings of the CTSC to achieve this national distinction.”

FEATURED SCHOLAR

AWARD-WINNING graduate student Collin L. Ellis credits the Clinical and Translational Science Center (CTSC) for helping him on his path toward a research career



in academic medicine. A Ph.D. candidate in the Graduate Group in Nutritional Biology, he is also pursuing a designated emphasis in both the Biotechnology and Biophotonics programs.

Ellis investigates the role of symbiotic microbes in health and disease. He has eight publications in peer-reviewed journals and 13 publications in conference proceedings.

He also has received numerous research honors and awards, including selection for a UC Davis “Professors for the Future” fellowship in 2009-10, and the Department of Internal Medicine's Graduate Student Trainee Research Award in 2011. His study of the gut microbiota of HIV-infected patients, published in the *Journal of AIDS*, also was named the highest-ranked paper in the graduate student/postdoctoral award category.

“I was able to use the skills the CTSC taught me from the beginning for my initial study in humans. More recently, I applied what I learned through the CTSC training programs to carry out my two main dissertation projects,” Ellis said. “I have had guidance from some of the best mentors you can find at UC Davis.”

SERVICES FOR INVESTIGATORS



The UC Davis CTSC includes the following programs that offer a wide range of services for investigators:

Research Education, Training and Career Development

A comprehensive clinical and translational research training and career-development program with six affiliated training programs and partnerships within and beyond UC Davis.

The program focuses on scholars who are advancing in career development, including graduate and medical students, postdoctoral fellows and junior faculty members.

Contact: jennifer.greenier@ucdmc.ucdavis.edu.

Biomedical Informatics

Provides database design support to develop HIPAA-compliant forms and databases that enable researchers to easily capture research data using protocol-specific information and appropriate coding standards and terminology; electronic medical record data retrieval support to extract Institutional Review Board (IRB)-approved clinical data in spreadsheet format for retrospective analysis and prospective follow up; terminology services to apply national and international ontology standards for biomedical informatics data-sharing activities; and data management consultation services for grant

submissions as well as existing and planned research projects.

Also offers monthly sessions for trainees and medical residents completing CTSC research rotations.

Contact: samuel.morleye@ucdmc.ucdavis.edu.

Clinical Research Center

Offers highly trained staff and facilities for research. The VA Medical Center has nine beds, a metabolic kitchen, laboratory, body composition unit and video recording equipment. Flexibly designed patient rooms accommodate inpatient and outpatient activities. The CCRC team furnishes resources wherever principal investigators need support, including community facilities, Ticon 1, UC Davis Medical Center and its clinics, and homes of study participants.

Staff includes a nurse practitioner, exercise physiologist, research dietitian, lab technician and research coordinators to conduct evaluations and gather research data.

Contact: nicole.mullen@ucdmc.ucdavis.edu.

Clinical Trials Resource Group

Facilitates compliance with IRB, Food and Drug Administration (FDA) and Medicare regulations for clinical research by: providing logistical support for clinical trials, including review of IRB materials, coding for clinical study protocols and analysis of and consultation for FDA

submissions; educational seminars and in-service training; and monitoring for investigator-initiated clinical studies.

The group facilitates efficiency by working closely with Compliance, Business Contracts, IRB, Finance, Patient Billing, Health Information Management and other research-related units at the health system.

Contact: kate.marusina@ucdmc.ucdavis.edu.

Community Engagement

Builds capacity and infrastructure for clinical and translational research among investigators, health-care providers and community-based organizations; offers consultation services for UC Davis investigators conducting practice-based research and for community members seeking academic research expertise; provides training in effective methods for conducting community-engaged research.

Provides training for clinical research coordinators, medical students, residents and researchers on community-engaged health research, including recruitment and retention, culturally and linguistically appropriate care, and fostering community-academic partnerships; sponsors health-related discussions and forums among UC Davis Health System faculty and staff and the community at large.

Contact: linda.ziegahn@ucdmc.ucdavis.edu.



Biostatistics and Clinical Research Ethics

Operated in conjunction with the School of Medicine’s Division of Biostatistics, the unit has more than 15 faculty, staff and graduate-student statisticians who assist researchers with design studies, determine sample size requirements, develop statistical analysis plans, write grant proposals, prepare manuscripts for publication and respond to reviewer comments about statistical aspects of studies. Also focuses on Responsible Conduct of Research instruction.

Services are available for students, scholars, fellows and faculty investigators from schools, centers and programs across the UC Davis campus.

Contact: Sandy Taylor, sltaylor@ucdavis.edu

Translational Technologies, Methodologies and Resources

Fosters innovative research campus-wide by encouraging investigators to form multidisciplinary partnerships and linking them with trainees, tools and resources locally and nationally to undertake novel studies and support career development; provides ready access to campus facilities, cores and resources through the searchable Facilities, Cores and Resources website (<http://ctscapps.ucdmc.ucdavis.edu/fcr/fcr.aspx>); organizes workshops and symposia to support team science; encourages local and national translational research initiatives.

Contact: Alice Tarantal, aftarantal@ucdavis.edu

Pilot Translational and Clinical Studies

Aims to spark innovative and collaborative scientific endeavors by supporting and facilitating robust new research paradigms, technologies and tools, and through partnerships that enhance team science. Serves as a critical resource to encourage collaborative studies representing new teams, and active solicitation of partnerships to leverage pilot funding through other campus programs.

Program announcements are frequently linked with collaborative workshops promoted through the Translational Technologies, Methodologies, and Resources program.

Contact: Alice Tarantal, aftarantal@ucdavis.edu

CTSC welcomes new administrative director

Meet Vincetta “Kitty” Lombardo, the new administrative director for the UC Davis Clinical and Translational Science Center (CTSC). Lombardo oversees personnel, finance, facilities, contracts, agreements and other aspects of the CTSC’s daily operations, as well as its areas of research support.

Lombardo has an extensive background in clinical research management and support, regulatory affairs and FDA approval processes. Before joining UC Davis in early May, Lombardo led clinical research for

Abbott Medical Optics in Milpitas, Calif., and directed regulatory affairs and clinical trials as a civilian contractor for the Navy Refractive Surgery Center in San Diego.

“Years of working in clinical trials have provided experience in the conduct of research, including understanding issues related to protection of human subjects and government regulations,” said Lombardo. “I have prepared and conducted multiple clinical trials governed by regulations in the U.S., Canada, Europe and Latin America, and was directly involved with the



Vincetta “Kitty” Lombardo

initial FDA approvals for the LASIK vision correction procedure. The UC Davis CTSC will enable me to focus on quality and compliance in a collaborative environment.”

**CLINICAL AND TRANSLATIONAL
SCIENCE CENTER**

2921 Stockton Blvd., Suite 1400
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ADDRESS SERVICE REQUESTED

CALENDAR OF SELECTED EVENTS

Career Development Seminars (Preregistration required)

- SEP 13** Introductory EndNote, 4 to 5 p.m., CTSC
- SEP 27** Advanced EndNote, 4 to 5 p.m., CTSC
- OCT 11** Cohort Discovery Tool Training, 4 to 5 p.m.,
Education Building
- OCT 25** Web-based EndNote, 4 to 5 p.m., CTSC
- NOV 8** Biostatistics and Biomedical Informatics, 4 to 5 p.m., CTSC
- DEC 13** Free and Low-cost Tools for Collaborative
Research Teams, 4 to 5 p.m., CTSC

CTSC Clinical Trials Brown Bag Seminar Series

- SEP 15** Clinical Trial Study Budget Negotiation, noon to 1 p.m., CTSC
- OCT 20** Biostatistics for Clinical Trials, noon to 1 p.m., CTSC
- NOV 17** Clinical Trial Study Designs and Study Subject Randomization,
noon to 1 p.m., CTSC
- DEC 15** Informed Consent, noon to 1 p.m., CTSC

Biostatistics Drop-in Workshops

- TUESDAYS** Hosted by Drs. Laurel Beckett and Sandy Taylor, noon to 1 p.m., CTSC

Health Informatics Seminar Series (Preregistration required)

- SEP 14** The Russian Invasion, noon to 1:15 p.m.,
Education Building
- NOV 9** Sepsis Process Improvement – An Informatics Perspective,
noon to 1:15 p.m., Education Building

Symposia

- NOV 16-18** 10th Annual Gene Therapy Symposium for Heart, Lung
and Blood Diseases, Sonoma, Calif.

Please note: The CTSC is located at 2921 Stockton Blvd. and the Education Building is at 4610 X St.
Both locations are in Sacramento.

For additional details regarding these and other events, visit the CTSC Event Calendar at
<http://ctscapps.ucdmc.ucdavis.edu/eventcalendar/calendar.aspx>, or ask to be added to
the announcements list serve at CTSCMail@ucdmc.ucdavis.edu.



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