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New Freidenrich Center to Accelerate Clinical Trials

Jill and John Freidenrich celebrate the groundbreaking of the Freidenrich Center for Translational Research on July 25. (Photo/Steve Castillo)

The Stanford School of Medicine marked the importance of translating scientific breakthroughs into better patient health on July 25 with the groundbreaking of the new Jill and John Freidenrich Center for Translational Research. This new three-story, 30,000 square-foot building will be a leading-edge facility for designing and conducting human-subject clinical trials.

Funded by longtime Stanford supporters Jill and John Freidenrich, the concept for the center was inspired by Jill Freidenrich's experience battling breast cancer. "This building will transform how we move the medical and scientific achievements here on campus from the research bench to patients," said John Freidenrich. "And the translational work in our building will enable the discoveries in the Lorry I. Lokey Stem Cell Research Building to be translated into cures for many diseases." Read more.

UNM Acquires State-of-the-Art Body Scanner

To better understand bone density, body fat composition and other variables that affect a wide range of health issues and disease, the University of New Mexico's (UNM) Clinical and Translational Science Center (CTSC) has acquired the state's only iDXA system, a new state-of-the-art body scanner.

The CTSC at the UNM Health Sciences Center is advancing scientific discovery into improved health outcome. The CTSC makes connections, finds best practices, bridges gaps, engages the community and builds on the HSC's foundation of medical research and education expertise. Read more.

UK Establishes Appalachian Translational Research Network

The Center for Clinical and Translational Science at the University of Kentucky is partnering with other Kentucky and regional institutions, local, state and national organizations, community groups, and interested community members to establish the Appalachian Translational Research Network dedicated to enhancing research collaborations and seeking new avenues to address the significant health challenges and health disparities in Appalachia. Read more.

TRIAD: The Translational Research Informatics and Data Management Grid

TRIAD is the middleware that addresses informatics challenges by enabling the creation of a scalable, secure, and knowledge-anchored data sharing environment, building upon the robust caGrid (the underlying service oriented infrastructure that supports caBIG) that was initially designed for the National Cancer Institute's caBIG (cancer Biomedical Informatics Grid) program. In the past decade, the field of informatics has undergone rapid change. New technologies such as grid computing and knowledge-anchored data, combined with major funding and growing community thrusts designed to break down institutional boundaries in order to create a richer research and clinical environment (e.g., caBIG, BIRN and CTSA), have led to new ways to combine data and services within and across institutional boundaries, resulting in increased speed, efficiency and outcome of clinical and
Double Damage: Partner Violence Affects Mental Health of Over Half-Million Californians

Victims who suffer violence at the hands of a spouse or other intimate partner not only are brutalized physically; they also suffer disproportionately higher rates of mental health distress, according to a new policy brief from the UCLA Center for Health Policy Research.

Using data from the 2009 California Health Interview Survey, researchers found that of the 3.5 million Californians who reported ever having been the victim of intimate partner violence, more than half a million — 594,000 — said they experienced recent symptoms of “serious psychological distress,” which includes the most serious kinds of diagnosable mental health disorders, such as anxiety and depression. Adult victims of IPV were more than three times as likely as unexposed adults to report serious psychological distress in the past year. 

Public-Private Partnerships Webinar Series

Academic health centers and universities will highlight examples of research partnerships that facilitate discoveries into treatments through a webinar series that began July 27 with Carolina KickStart, a core program of the University of North Carolina. See the webinar schedule.

Stanford Launches New Spectrum Website

The Stanford Center for Clinical and Translational Education and Research has launched a new Spectrum Clinical and Translational Research website, a unified gateway to Stanford research resources. The site is designed to assist researchers with all phases of running a translational or clinical study from design to close-out. This is an important milestone in Stanford's ongoing effort to streamline research processes across the university, and to make it easier for researchers to move their discoveries from the lab to health practice.

FUNDING

NIH Clinical Center FY 2012 Bench-To-Bedside Awards — New Cycle Announced

The NIH Bench-to-Bedside Program is soliciting proposals for the next funding cycle.

Once again, CTSAs, AIAMC (Alliance for Independent Academic Medical Centers) and NIH investigators will be able to initiate applications jointly for Bench-to-Bedside research projects. Up to $135K per year for two years is available to support these intramural/extramural partnerships in clinical research. As in prior years, intramural investigators in all Institutes/Centers are eligible to serve as project leaders on proposals.

Extramural principal investigators (PIs) with an existing NIH grant are invited to initiate proposals in one of two ways:

- Extramural investigators may seek an intramural partner at NIH who would function as the project leader and serve as the point of contact. To identify an intramural collaborator, extramural investigators can consult the NIH's intramural research database. Extramural investigators also may contact the Bench-to-Bedside Program Office for assistance in identifying an intramural partner.

- Extramural investigators may initiate proposals and serve as project leaders. In this role, extramural principal investigators will develop letters of intent and, if approved, may develop full proposals. In this scenario, extramural investigators are required to identify an intramural collaborator on the project. On behalf of the lead extramural PI, the intramural investigator will be responsible for submitting both the letter of intent and full proposal electronically using proposalCentral.

For the 2012 awards, a letter of intent must be submitted by September 28, 2011.

The NIH Bench-to-Bedside program was originally established in 1999 to integrate the work of basic and clinical intramural scientists. Since 2006, it has been open to partnerships between intramural and extramural programs.
Next CTSA FOA Delayed
The Funding Opportunity Announcement (RFA-RM-10-020) for new and renewal CTSA applications was postponed until June 2012 with an application submission date in December 2012. Please refer to:

- NOT-RM-11-021
- Questions & Answers Related to NOT-RM-11-021

Neuroscience Research Grand Challenge
The Blueprint Neurotherapeutics Group released the FY 2012 RFA, Neuroscience Research Grand Challenge: Developing Novel Drugs for Disorders of the Nervous System (U01). The Letter of Intent deadline is November 15, 2011. Learn more.

EVENTS

Webinar: Cardiovascular Imaging Informatics Platform — Prototype for CVRG Deployment, September 8, 2011, 1:00 p.m. ET
Johns Hopkins Institute for Computational Medicine invites you to join a webinar from the CardioVascular Research Grid. Cardiovascular imaging research requires quantitative, spatio-temporal imaging of the structure and function of the heart and vascular system. CVI research studies typically acquire complex sets of images typically from thousands of subjects located at multiple research centers and geographic regions. Learn more, including how to join the webinar.

IRB Options for Emergency Care Research, September 19 – 20, 2011
The Emergency Care Coordination Center at the Office of the Assistant Secretary for Preparedness and Response is holding a meeting on Institutional Review Board Options for Emergency Care Research. Meeting participants will explore alternative IRB models and other potential solutions to overcome the limitations, inefficiencies and challenges involved in using conventional IRB models in order to ensure the protection of human subjects in emergency care research. View the agenda. For more information, please contact Tabinda Burney.

Summer Institute for Comparative Effectiveness Research Training, September 19 – 23, 2011
The University of Washington Institute of Translational Health Sciences hosts this conference to guide researchers seeking to engage community and health care organizations as they identify CER questions, choose the best designs for studies and use comparative effectiveness results to improve health outcomes. Read more.

Advances in High-Throughput Screening for Drug Discovery, September 22, 1011, 8:30 a.m. – 5:00 p.m. ET
The University of Illinois at Chicago’s Center for Clinical and Translational Science is sponsoring a translational technology symposium on High-Throughput Screening (HTS) for drug discovery. Researchers will reflect on the use of HTS in developing therapeutics against infectious diseases, neurodegenerative diseases and cancer. Read more or register for this event.

Webinar: A New Paradigm for Pharmaceutical Innovation, September 28, 2011, 3:00 – 4:00 p.m. ET
Kenneth Kaitin of the Tufts Center for the Study of Drug Development will provide analysis on research and development trends and patent information on the top 10 companies and drugs.

- Join the webinar.
- Call in: 1-866-910-4857, Participant Code: 584064

Henrietta Lacks Memorial Lecture, October 1, 2011, 9:30 a.m. – 3:00 p.m. ET
The Johns Hopkins Institute for Clinical and Translational Research (ICTR) cordially invites you to attend the Henrietta Lacks Memorial Lecture: HeLa Reflected. The goal of this event is to describe the reach and complexity, both biomedically and ethically, of the story of Henrietta Lacks and HeLa cells as well as to provide some insight into the past, present and future methods of conducting of clinical research. Read more or register for this event.

Expanding the Boundaries of Health Care Value: Collaboration and Community Engagement in Practice-Based Research, October 6, 2011
Topics for this Rochester, Minn., conference include how to improve health care practices through research, how to secure funding and how to maintain a competitive edge while sharing results. Learn more.

Second Annual CTSA Comparative Effectiveness Research Key Function Committee Face-to-Face Meeting, October 11, 2011, 7:30 a.m. – 5:30 p.m. ET
NCRR will host the second annual CTSA Comparative Effectiveness Research (CER) Key Function Committee (KFC) Face-to-Face Meeting at the Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852. Dr. Joe Selby and Dr. Vicki Seyfert-Margolis will be the keynote speakers. The meeting will include concurrent mini workshops with discussions among multiple stakeholders, CER/Patient-Centered Outcomes Research presentations, and strategic planning of the KFC. Read more or register for this event.

Event participants can explore innovative approaches to bridge laboratory investigation and clinical research in disorders affecting blood vessels, including cancer, inflammatory disease and cardiovascular disease. The abstract submission deadline is August 31, 2011. Learn more.

Translational Strategies in Contemporary Science, October 18 – 19, 2011
Translational Strategies in Contemporary Science will focus on how organizational structures have matured to support translational research and to address the crisis in development of novel therapeutics. Topics will include how to exemplify excellence in the pursuit of translational research and the challenges and opportunities afforded by the availability of mega data. Register to attend in person or to participate via webstream.

Webinar: CTSA Public-Private Partnership Models for Translational Science, October 26, 2011, 2:00 — 3:00 p.m. ET
Anantha Shekhar of the Indiana University School of Medicine will discuss the Indiana model for partnerships with Purdue University, Notre Dame, and others across the state.

- Join the webinar.
- Call in: 1-866-910-4857, Participant Code: 584064

Webinar: Alabama Drug Discovery Alliance, November 23, 2011, 2:00 – 3:00 p.m. ET
Richard Whitley of The University of Alabama at Birmingham will explain the partnership between the university and the Southern Research Institute for drug discovery and development.

- Join the webinar.
- Call in: 1-866-910-4857, Participant Code: 584064

CTSA Committee Meetings and Activities
View the full CTSA Committee Meetings and Activities calendar on CTSAweb.org.
The University of Cincinnati (UC) Center for Clinical and Translational Science and Training (CCTST) and partners Cincinnati Children's Hospital Medical Center, Cincinnati Veterans Affairs Medical Center and UC Health coordinate a wide range of research support. Services include biostatistics, biomedical informatics, data management, inpatient and outpatient clinical services, and support for training community leaders.

CCTST received its CTSA in 2009. The award has helped support innovations that improve access to research support services, as well as training for community leaders. For example, the CCTST's Research Central online portal provides one-stop assistance with study design, methodology, biostatistics, biomedical informatics, intramural funding opportunities and other services to more than 700 investigators at all career stages. Service requests are triaged by trained staff who refer investigators directly to Research Central methodologists. New and ongoing cases are reviewed frequently to aid service coordination and strategy development. Thirty to 60 days after project assignment, investigators are sent a link to a service evaluation developed in REDCap, a secure Web application for building and managing online surveys and databases. A Research Central dashboard providing at-a-glance summaries of service usage and satisfaction is nearing completion.

CCTST's Community Leaders Institute (CLI), offers a six-week training program for representatives of community organizations, including those who work with children, adults and seniors as trusted agents of health services. Participants are trained by CCTST faculty in five specific competencies: grant writing, accessing public datasets, creating databases using REDCap and other software, quality improvement/evidence-based practice, and survey development. The Institute's first class graduated in 2010; it exemplifies the CCTST's promise to increase translational research by empowering community leaders. As a result of the CLI training, almost three-quarters of participants were successful in obtaining grant funding that totaled $1.8 million. In addition, graduates developed surveys, created databases and analyzed data. They also implemented quality improvement approaches or strengthened evidence-based practices. To learn more about the CLI, Research Central and other CCTST innovations, visit http://cctst.uc.edu.

Clinical Research Management KFC: Supporting Process Improvement

Adaptive trial design, alternative Institutional Review Board agreements, and process improvement are top priorities of the Clinical Research Management Key Function Committee.

The committee began the year with a webinar on adaptive trial design presented by Don Berry, head of the Division of Quantitative Sciences at The University of Texas MD Anderson Cancer Center in Houston. Berry provided practical tips for applying Bayesian analysis to improve the design of early phase trials. With careful planning, investigators may eliminate or add study arms based on accumulating data during a trial without biasing the results. The approach can minimize sample size and increase the likelihood of detecting a significant result.

To reduce duplicative review, many CTSA sites have developed alternative pathways to IRB approval by using a central IRB, signing agreements that permit ceding of review from one institution to another, or sharing membership in a common IRB. At the 2011 Annual Clinical Research Management Workshop (CRMW), CTSA institution representatives reported hundreds of
duplicative reviews that had been eliminated with alternative pathways.

New this year is a Clinical Research Management Process Excellence Group (CPEG), a group of CTSA members that plans to share educational materials, best practices, effective models and lessons learned. Formed in response to unanimous support from CRMW participants, the CPEG is intent on producing meaningful process improvement plans and publishing the results.

To learn more about the activities and accomplishments of this committee, visit the CRM KFC page of CTSAweb.org.

**BERD Watch: Vanderbilt Advances Comparative Effectiveness Trial**

Vanderbilt cardiologist David Maron, in cooperation with the Vanderbilt Institution for Clinical and Translational Research (VICTR) Design Biostatistics and Research Ethics (DBRE) program, designed, planned and implemented a survey to determine if a clinical trial strategy would be acceptable to practitioners and worthy of funding for an $84 million multicenter clinical trial.

It is unknown whether strongly held beliefs by cardiologists regarding the need for cardiac catheterization and revascularization (stenting or bypass surgery) in stable ischemic heart disease patients would prevent them from enrolling patients with abnormal stress tests to an initial conservative strategy without cardiac catheterization. In order to answer this question, the DBRE program helped Maron design and implement a multinational survey of cardiologists.

Survey development utilized most of the DBRE program's resources: clinics, studios, vouchers, REDCap expertise, and the expertise of many VICTR members and other Department of Biostatistics faculty. Dan Byrne, Terri Scott and Frank Harrell worked intensively with Maron to design a REDCap survey.

This online survey queried cardiologists to determine their willingness to enroll patients with frequent chest pain from coronary artery blockages and a moderately abnormal stress test into a randomized trial with a 50 percent chance of being managed conservatively without cardiac catheterization. Among 499 respondents, 57 percent were willing to enroll their patients. Among 207 cardiologists unwilling to enroll, 55 percent would do so if the policy excluded patients with stress tests that demonstrated very high risk, yielding a total of 80 percent willing to enroll.

These findings were part of the preliminary data submitted to the National Heart, Lung, and Blood Institute (NHLBI) in the grant application for the randomized controlled trial (ISCHEMIA: International Study of Comparative Health Effectiveness with Medical and Invasive Approaches). NHLBI awarded the grant to test, in patients with at least moderately abnormal stress tests, whether an invasive strategy is better than a conservative strategy to prevent serious cardiac events. Judith Hochman, NYU cardiologist and co-executive director of the NYU Clinical and Translational Science Institute is the study chair. David Maron is the principal investigator and study co-chair. Frank Harrell will head the Statistics Committee and the statistical analysis center for the Data and Safety Monitoring Board.

During the CTSA-sponsored collaboration, the team examined many aspects of study design. Margin of error, sequential safety monitoring, and modern clinical trial design were considered.

Read a success story on CTSPEDIA.org about the design of this survey.

**GENERAL INFORMATION**

**Updated Information on CTSAweb.org**

The CTSAweb.org home page, in keeping with the website's role of ensuring access to CTSA resources, enhancing communication and encouraging sharing, features:
• **CTSA Collaboration Opportunities** page listing CTSA collaboration opportunities
• Newly updated sections on the **Resources for Researchers** page enable targeted searches
• Updated CTSA **Governance Document** available at [CTSAweb.org](http://CTSAweb.org) “For the Consortium” menu on the left

The CTSA Web systems help desk e-mail is [help@CTSAweb.org](mailto:help@CTSAweb.org). Please contact the help desk if you have questions regarding the CTSA systems, including CTSA wiki and password questions.

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We hope you find this newsletter helpful and informative. If you have any questions or comments, or to unsubscribe, please contact [newsletter@CTSAweb.org](mailto:newsletter@CTSAweb.org).