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CTSA Clinical & Translational
Science Awards

Translating Discoveries to Medical Practice

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EVENTS:

NEW — The 2nd Conference on Clinical Research for Rare Diseases (CCRRD)

The Clinical & Translational Science Awards (CTSA) Rare Disease Workgroup and the Rare Disease Clinical Research Network (RDCRN) present The 2nd Conference on Clinical Research for Rare Diseases (CCRRD) on Tuesday, September 21 at the Bethesda North Marriott Hotel & Conference Center, Bethesda, Md. This unique conference will focus on methodology for conducting clinical research in rare diseases and should be of particular interest to new investigators, trainees, junior faculty and others interested in research in rare diseases. Topics will include study design and biostatistics relevant to small sample sizes, recruitment strategies for rare diseases, utilizing the resources of the CTSA program, regulatory pathways for developing orphan products, working with stakeholders including patient advocacy groups, industry, academia, and government, and career development in rare diseases research.

For more information about the conference, including details about the program, applying for travel awards, and conference logistics and registration, visit the [conference website](#).

NEW — UC Davis Clinical and Translational Science Center (CTSC) Hosts CTSA Social Network Analysis

Workshop

The UC Davis Clinical and Translational Science Center (CTSC) is pleased to announce the 2nd Annual CTSA Social Network Analysis Workshop to be held in Sacramento, Calif. on **September 23-24**, with an optional pre-workshop session on the evening of **September 22**.

The workshop is for participants from CTSA institutions who are interested in learning some of the tools and techniques of social network analysis for promoting and evaluating CTSA research, especially in community-engaged settings. The theme of the workshop is "Social Network Analysis and CTSA Community Engaged Research" and will include both instruction and CTSA-relevant research presentations.

There is no fee for the workshop, and meals will be provided during workshop hours; however, registration is required. Space is limited, and priority is given to participants from CTSA institutions.

[Register early](#) and no later than September 9, 2010.

For registration and hotel information, contact [Miyishia Slay](#), UC Davis.

For more information about the workshop, contact [Julie Rainwater](#), UC Davis.

Veterans Health Administration (VA) and CTSA Opportunities for Collaborative Clinical and Translational Science: Enhancing Clinical Phenotyping Meeting

On **September 28, 2010**, the Veterans Health Administration (VA) and CTSA will sponsor an [Opportunities for Collaborative Clinical and Translational Science: Enhancing Clinical Phenotyping Meeting](#) at the Natcher Conference Center at the NIH Main Campus in Bethesda, Md.

The meeting will focus on opportunities for enhanced collaboration among Department of Veterans Affairs and NIH's CTSA consortium. Topics will include electronic health records, genomic and observational research, Central Institutional Review Boards (IRBs), comparative effectiveness research (CER), and the synergies with training environment these provide.

A common goal of translational science is better understanding of disease susceptibilities and mechanisms. Evolving approaches utilize electronic health records, biorepositories and genotyping will create new opportunities for clinical phenotyping. Meeting presentations will describe resources such as a Central IRBs, informatics and a clinical research pharmacy that the VA has to support data-intensive studies.

Poster presentations are requested. Please submit poster abstracts by August 20, 2010.

[Registration](#) deadline is Friday, September 17, 2010.

For more information, contact [Jody Sachs](#), NCRR, [Anthony Hayward](#), NCRR, or [Alexander Ommaya](#), VA.

Save the Date — Evaluation Key Function Face-to-Face Meeting

The CTSA Evaluation Key Function Committee face-to-face meeting will be held **December 7-8, 2010**, at the Hilton Washington DC/Rockville Hotel and Executive Meeting Center in Rockville, Md.

For more information, contact [Lori Mulligan](#), NCRR, or [Meryl Sufian](#), NCRR.

CTSA Committee Meetings and Activities

View the full [CTSA Committee Meetings and Activities calendar](#) on CTSAweb.org.

NEWS AND ANNOUNCEMENTS:

NIH Clinical and Translational Science Consortium Expands to 55

On **July 14**, the NCRR announced the expansion of the CTSA Consortium to 55 member institutions. More information, including the list of new members, can be found in the [NIH News Release](#).

Atlanta Clinical & Translational Science Institute (ACTSI) Creates eBIRT — A Biomedical Interactive Resource Tool

The Translational Technologies & Resources (TTR) program of the Atlanta Clinical & Translational Science Institute (ACTSI) has created a tool to facilitate the use of shared resources and enhance opportunities for collaboration among translational investigators. [eBIRT](#) — the Biomedical Interactive Resource Tool — provides a central place to search for resources that are available at Emory University, Morehouse School of Medicine, Georgia Institute of Technology, and throughout Georgia. The new web-based application is used for research resource discovery. With support from Emory Health Sciences and Research IT and the ACTSI's Biomedical Informatics Program (BIP), TTR developed eBIRT to create a community of connected translational investigators who are able to easily share expertise and resources.



For researchers, eBIRT serves as a "one-stop virtual shop" for research resources, such as laboratory services, equipment, software, consultation services, training opportunities, and more. To search for resources in eBIRT, visit the [eBIRT website](#).

For resource providers, such as service centers and cores, eBIRT offers a platform to advertise research-related services and products. To share resources and make them more discoverable to the scientific community, or for more information about eBIRT, contact [eBIRT Support](#).

UTMB Institute for Translational Medicine to Help Create Statewide Resource for Cancer CER in Texas

The University of Texas, Medical Branch (UTMB) Institute for Translational Medicine (ITM) was recently awarded funding from The Cancer Prevention and Research Institute of Texas (CPRIT) to create a statewide resource for Comparative Effectiveness Research in Texas (CERIT) in the area of cancer. The CERIT project involves a multidisciplinary consortium which includes UTMB, MD Anderson Cancer Center, the University of Texas School of Public Health, Rice University, Baylor College of Medicine and the Texas Cancer Registry.

For more information, visit the [UTMB website](#) or contact [James Goodwin](#), UTMB CERIT PI, [Paul Meissner](#), CER KFC, Montefiore, or [Rosemarie Filart](#), CER KFC, NCRR.

NCRR to Host Web Demonstrations for the CTSA Wiki and CTSAweb.org

NCRR is offering two online demonstrations* of the CTSA web systems, CTSAweb.org and CTSA Wiki. Learn where key information is, how to navigate the sites, and basic editing in the Wiki.

- **Tuesday, August 24, 2010**, 3:00 – 4:00 p.m. ET
<https://webmeeting.nih.gov/demo0824201/>
- **Tuesday, September 14, 2010**, 4:00 – 5:00 p.m. ET
<https://webmeeting.nih.gov/demo09142010/>
- **Thursday, September 23, 2010**, 1:00 – 2:00 p.m. ET
<https://webmeeting.nih.gov/demo09232010/>

*Due to system limitations, when possible please plan to participate with others from a common room or location at your institution.

Recent Media Coverage

Read CTSA institutional and consortium news and media coverage at the [CTSAs in the News page](#) on [CTSAweb.org](#).

We want to post your CTSA institutional news items and open events in the CTSA e-Newsletter and on the CTSAweb.org [Events page](#). Please send submissions to newsletter@CTSAweb.org.

FUNDING OPPORTUNITIES:

Scientific Meetings for Creating Interdisciplinary Research Teams (R13)

This funding opportunity announcement ([PA-10-106](#)) encourages Research Conference Grant (R13) applications from institutions and organizations that propose to develop interdisciplinary research teams. Teams must include investigators from the social and/or behavioral sciences, and may include the life and/or physical sciences. The goal is to broaden the scope of investigation into scientific problems, yield fresh and possibly unexpected insights, and increase the sophistication of theoretical, methodological and analytical approaches by integrating the analytical strengths of two or more disparate scientific disciplines while addressing gaps in terminology, approach and methodology. This program will allow investigators from multiple disciplines to hold meetings to provide the foundation for developing interdisciplinary research projects. [View the announcement.](#)

FEATURES:

Washington University ICTS Funds New Cores through Competitive Process

At the [Washington University Institute of Clinical and Translational Sciences \(ICTS\)](#), new research cores are established through a competitive funding mechanism, requiring applicants to make the case for a new core and ensuring that the new core has been evaluated through a peer-review process. In this manner, three cores were funded in 2009 and two in 2010.

Human and Mouse-Linked Evaluation of Tumors (HAMLET) Core

Researchers have used human breast tissue xenografting techniques to propagate breast cancers *in vivo*, creating HAMLET mice. This new research core provides the infrastructure for distributing tumor lines and associated genomic, clinical and pathological data. The core aims to accelerate breast cancer research and increase knowledge about the drug sensitivity spectrum and genomic structure of tumor lines. The long-term goal of this effort is to better match treatment approaches with the genetic etiology of breast cancer. This approach has already led to exciting results, including a [recent paper in Nature](#) describing the genomic analyses of four DNA samples — the primary tumor, peripheral blood, a brain metastasis and a xenograft — derived from the primary tumor of a patient with basal-like breast cancer. A future aim is to extend the HAMLET approach to other tumor types.

Center for Administrative Data Research (CADR)

The CADR allows ICTS investigators to use existing administrative data for clinical epidemiologic, health services and comparative effectiveness research. The CADR assists investigators with selecting appropriate databases; obtaining, storing and using data; and providing tools, programs and other resources. Additionally, the CADR houses several databases, including the Chronic Condition Warehouse of the Center for Medicare & Medicaid Services (CMS), CMS Medicaid eXtract files, CMS Inpatient files, Surveillance Epidemiology and End Results — Medicare (breast and colon cancer) data, and Healthcare Cost and Utilization Project state and nationwide databases.

Dissemination and Implementation Research Core (DIRC)

The DIRC provides both methodological expertise for research and technical assistance on grants to ICTS investigators to help shape dissemination and implementation research aims. It also offers advice on developing and testing strategies to help implement evidence-based treatments in new settings of care.

Center for Economic Evaluation in Medicine

The Center conducts burden-of-illness studies, cost-benefit analyses and cost-effectiveness analyses to evaluate the economic aspects of disease prevention and treatment. These studies will inform decision-makers on the allocation of health care resources. The Center assists ICTS investigators with data analysis, data interpretation, model design, study design for grant applications and manuscript preparation.

Translational Cardiovascular Tissue Core

This core serves as a centralized facility for the acquisition, storage and distribution of human cardiovascular tissues. Phenotypic (electrophysiological, structural, molecular and biochemical) and genotypic (genomic and somatic) data will be integrated with archived (tissue and blood) samples and clinical information in a database that is queryable and accessible to the basic, translational and clinical cardiovascular research communities.

Annual Clinical Research Management Workshop Provides Early Data on Process Improvement

The Yale Center for Clinical Investigation, with support from an administrative supplement, Strategic Goal Committee One (SGC1) and the Clinical Research Management Key Function Committee (CRM KFC), sponsored the Third Annual Clinical Management Research Workshop in Bethesda, Md., June 21-22, 2010. The workshop provided participants from CTSA institutions a forum to discuss the implementation of process changes in clinical research management to increase efficiency, quality and output and, thus, shorten the time to enrollment for scientific studies and trials. All of the slide presentations from the meeting are available on the [CRM KFC page](#) of [CTSAweb.org](#).

The workshop emphasized the importance of collecting and analyzing data about the clinical research management process — for example, tracking the time required for each step in the process enables administrators and researchers to identify the changes most likely to improve processing time. Stephen J. Rosenfeld, M.D., M.B.A., president and chief executive officer of Western Institutional Review Board, noted that comparing the process flow across academic medical centers requires an understanding of the mechanisms for decreasing processing time. CTSA Principal Investigator (PI) Marc Drezner, M.D. (University of Wisconsin), said that returning institutional review board (IRB)-reviewed protocols for revision wasted time at his institution; he reduced processing time from a median of 79 days to 46 days by improving protocol preparation and eliminating IRB requests for revisions for many of them.

At the first Clinical Research Management Workshop, the CTSA consortium identified the time required to negotiate contracts and secure IRB approval as top priorities in improving efficiency in study startup and established groups to gather data on these processes. The priorities were confirmed in the consortium's strategic goals. Two pilot studies were conducted in 2009.

In analyzing the results of the IRB pilot study, the SGC1's Metrics, Analysis and Mapping group found that protocol and process variations made it difficult to compare sites based on the data they had collected. Dr. Drezner emphasized the need to further evaluate the review process at individual sites with a second IRB study.

Adam Rifkind, J.D. (University of Pennsylvania), and Libby Salberg, J.D., (Vanderbilt University), reported contracts negotiation pilot study data that showed the average time to negotiate and sign a contract was 38 days, with a broad range. Master agreements reduced the time, but contract research organizations did not; contract approval took longer for multi-site trials. Results of the study will be published in 2011. A second study is underway to provide more refined and meaningful data on contracts processing.

Issues related to enrollment are widely perceived as severe problems in clinical research management. Few sites track enrollment, measure feasibility or penalize investigators for failing to enroll studies according to projections. Rhonda Kost, M.D. (Rockefeller University), presented preliminary findings from the Regulatory Knowledge KFC's recruitment survey that identified potential opportunities for improving enrollment. Charles Rathmann (Washington University in St. Louis) described a dedicated core service that doubled enrollment at his institution in the first year it was implemented. The core uses strategic planning, pre-study efforts to increase awareness, teamwork involving the PI, and tracking of effectiveness of interventions to measure the success of each component of the program.

Participants identified a number of topics for discussion at next year's workshop, including training for research coordinators to improve the clinical management processes they oversee. Participants also suggested discussing successful strategies for increasing enrollment and decreasing the time to get studies up and running, such as using informatics to understand and streamline processes.

ARTICLES:

BERD Watch — Analysis of Unique Minority Population Database Reveals Important Findings

Minority health disparities are a major concern in the Lower Rio Grande Valley where The University of Texas Health Science Center at Houston (UTHSC-H) Center for Clinical and Translational Sciences (CTS) has established a Clinical Research Unit at The University of Texas School of Public Health, Brownsville Regional Campus (UTSPH-B). The Brownsville population is 96 percent Hispanic, low income, medically underserved and medically understudied. The community has high rates of obesity, diabetes and cervical cancer, and the underlying reasons for these rates are not known. To reduce these health disparities, researchers have employed the Biostatistics/Epidemiology/Research Design (BERD) component of the CTS to delve into medical research on the Texas-Mexico border.

Joseph McCormick, M.D., regional dean of UTSPH-B, turned to BERD to help his growing cadre of promising junior

research faculty develop, maintain and statistically analyze a unique clinical database — the Cameron County Hispanic Cohort — which chronicles the medical, socioeconomic and family histories of more than 2,000 local individuals. Dr. McCormick's Hispanic Health Research Center is funded by the NIH National Center for Minority Health Disparities. CCTS BERD Director Mohammad Rahbar, Ph.D., and faculty have helped the Brownsville group identify ways to share the Cameron County Hispanic Cohort data with other researchers and develop health promotion partnerships with community leaders. Investigators in cardiology, hepatology, infectious diseases, genetics and imaging sciences are collaborating with BERD and the Brownsville team to share research data to improve the health and health care of the Valley's population.

Dr. McCormick, former chief of the Special Pathogens branch of the Centers for Disease Control and Prevention, recognized immediately the benefits to be gained from collaborating with BERD. Although the two units are 300 miles apart, "Distance isn't an issue for us," said CCTS CTSA principal investigator David McPherson, M.D., who has championed the Houston group's work with Brownsville. "UTHSC-H primed the CCTS for long-distance collaboration by very generously giving us a state-of-the-art teleconferencing facility, and the Brownsville SPH has a similar facility supplied by the University of Texas system."

BERD support has already paid off in important scientific findings: Analysis of the cohort data revealed that patients with both tuberculosis and diabetes (both of which are common in the Valley) had a more severe course of tuberculosis and a poorer response to treatment for it. These results, which were partly funded by the National Institute of Allergy and Infectious Diseases, are being translated back to the laboratory for studies on possible immune-system causes and forward into the community to inform screening and treatment programs. The BERD and Brownsville collaborative efforts are perfectly poised for dissemination through the CCTS community engagement component that is building on NIH-funded public health programs already active in the region.

GENERAL INFORMATION:

Updated Information on CTSAweb.org

The **CTSAweb.org** home page, in keeping with the Web site's role of ensuring access to CTSA resources, enhancing communication and encouraging sharing, features:

- New 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](#) "For the Consortium" menu on the left

The CTSA Web systems help desk e-mail is 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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