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CTSA Clinical & Translational
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June 7, 2010

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EVENTS:

The Midwest Consortium: Rural Health and Health Disparities Research in the Heartland Meeting

Bringing new discoveries to underserved communities is a top priority for all of the participating institutions in the Midwest Consortium. The Midwest Consortium: Rural Health and Health Disparities Research in the Heartland meeting will be held **June 10–11, 2010**, at the University of Kansas Medical Center School of Nursing. The meeting will focus on sharing ideas and resources that can be used to foster health disparities research in both rural and underserved minority communities. The meeting will also highlight unique areas of health disparities research in Kansas, including highly successful practice-based rural research networks and community-based alliances for American Indian research and education. The meeting will also bring together experts in health disparities research from throughout the Midwest Consortium.

For more information and to register, visit the [2010 Midwest Consortium Web site](#).

The 3rd Annual Clinical Research Management Workshop

The 3rd Annual Clinical Research Management Workshop has been scheduled for **June 21–22, 2010** at the Bethesda North Marriott Hotel and Conference Center in Maryland. The Clinical Research Management Workshop serves as a dynamic venue for CTSA's and representatives from the private industry, NIH, Food and Drug Administration, and private research organizations to come together to discuss challenges and develop strategies that will improve clinical research management processes. The use of metrics to monitor process performance in the Institutional Review Board (IRB), grants and contract

management and budget development, and recruitment and retention strategies will be discussed at the workshop. Interested individuals from all sectors are welcome to attend the general sessions. Special breakout sections have been planned to emphasize specific interests of CTSA site specialists in contracts, IRB issues, electronic IRB software selection and implementation, and recruitment and retention. A face-to-face meeting of the Champions of Change for the CTSA Consortium will provide participants with specific tasks to help improve clinical research management at their sites.

For more information and to register, visit the [Clinical Research Management Workshop Web site](#).

Tufts CTSI Seminar on Comparative Effectiveness and Cost Effectiveness: Methods and Measurement

Tufts Clinical and Translational Science Institute (CTSI) will present The 2nd Annual Short Course on Comparative Effectiveness and Cost Effectiveness: Methods and Measurement on **June 24–25, 2010**, at the Museum of Science in Boston, Mass. This acclaimed two-day course provides participants with knowledge and hands-on experience in the nuts and bolts of the methods employed in evidence-based and value-based approaches—two essential components of comparative effectiveness research. Some background in comparative effectiveness research and cost effectiveness assessment is preferred.

More information, including the seminar schedule and a course brochure with a registration form, may be found at the [Tufts CTSI Calendar of Events page](#).

Save the Date—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 Opportunities for Collaborative Clinical and Translational Science-Enhancing Clinical Phenotyping Meeting will be held 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 1, 2010.

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

Save the Date—Evaluation Key Function Committee 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:

This funding opportunity announcement encourages Research Conference Grant (RCG) 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.

[Full announcement](#)

FEATURES:

Colorado CTSI Brings Together Academic, Private and Public Organizations Across the State

The Colorado Clinical and Translational Sciences Institute (CCTSI) is a statewide collaboration encompassing three campuses (University of Colorado [UC] Denver Anschutz Medical Campus, UC Denver Downtown and UC Boulder), six hospitals and health care organizations (UC Hospital, The Children's Hospital, National Jewish Health, Denver Health, Denver Veterans Affairs Medical Center and Kaiser Permanente) and more than 20 academic-community partnerships throughout the state. In 2009, the UC Denver Health Sciences Center and hospitals relocated in its entirety to the newly constructed, state-

participants of all ages, including preterm infants. Investigators are conducting studies of fetal and infant precursors of adult diseases in conjunction with the novel CCTSI Child-Maternal Health research program.

In 2009, the Colorado CTSA moved all of its operations to the new facilities at the University of Colorado Denver Anschutz Medical Campus.

Communicating with Communities

The Partnership of Academicians and Communities for Translation facilitates community-based participatory research, educates and connects investigators and communities, builds public trust in research and makes pilot funds available for community engagement and research. Eleven community liaisons have been placed in underserved areas to facilitate bidirectional communication and research studies. The novel Colorado Immersion Training in Community Engagement program places new researchers to live for one week in communities targeted by their research so they can learn about the medical needs and culture directly from the community.

Educating the Next Generation

Creating future successful investigators requires innovative training and strong mentoring. Among the many CCTSI educational programs is the novel Leadership Training in Innovative Team Sciences program, in which faculty leaders are trained in collaborative research team building through a series of retreats. The Summer Undergraduate Minority Mentoring in Translational Sciences program is training a group of Hispanic, Native American and Alaskan Native student scholars interested in biomedical research careers.

Facilitating Collaboration

Recognizing the vast constituency of the CCTSI, the [institute's Web site](#) has become the primary portal of entry for investigators, scientists, trainees, staff, community organizations, the private sector and the public. More than 1,550 people and organizations have become CCTSI members, providing access to CCTSI resources.

Regulatory Knowledge KFC To Present Findings at 2010 Clinical Research Management Workshop

The CTSA Consortium Steering Committee recently reinstated the Regulatory Knowledge (RK) Group to the status of key function committee (KFC). The RK KFC promotes the protection of human subjects and facilitates communication about shared regulatory compliance issues and improvements. It addresses clinical research regulation areas such as the provision of integrated training, services or tools for protocol and informed consent authoring and translation; adverse event reporting; and safety and regulatory management and compliance. The RK KFC has six taskforces. The following taskforces will present their recent work at the [3rd Annual Clinical Research Management Workshop, June 21–22, 2010](#), in Bethesda, Md. (More workshop information is listed in the [Announcement section](#) above).

- The IND/IDE Taskforce paper, "IND/IDE Support for Investigator-Initiated Clinical Research: The Clinical and Translational Science Award (CTSA) Experience," was accepted by *Academic Medicine* for publication on February 9, 2010, pending revision. The taskforce will present a poster that addresses tools and best practices and offers recommendations; the taskforce's Good Laboratory Practice (GLP) Subgroup plans to present a poster on GLP compliance.
- The Research Subject Advocacy Taskforce will present a preliminary analysis of the results from its survey on current practices in research subject advocacy at CTSA institutions.
- The Clinical Trial/Study Registration Tracking Taskforce will present a white paper summarizing the findings of its survey of approaches used by CTSA institutions to register trials on ClinicalTrials.gov and will make recommendations

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- The Clinical Trial/Study Registration Tracking Taskforce will present a white paper summarizing the findings of its survey of approaches used by CTSA institutions to register trials on ClinicalTrials.gov and will make recommendations on best practices for tracking registration.
- The Recruitment and Retention Taskforce will present preliminary results of its survey on recruitment and retention issues. Respondents had the option of completing a survey with either a shorter, high-level view or a more detailed, research-team-level view.
- The Clinical Research Coordinator Taskforce has divided into three subgroups: publications, education and training and job descriptions. The Job Descriptions Subgroup plans to share its findings.

Research Ethics and Regulatory Knowledge Core Competencies Proposed

The RK KFC Core Competencies Taskforce, in consultation with the Clinical Research Ethics KFC, drafted a set of joint research ethics and regulatory knowledge core competencies for inclusion within the recommendations of the Education and Career Development KFC. These competencies were forwarded to the Education and Career Development KFC in March.

Clinical Trials Tracking and Tools Management Taskforce Proposed

There is interest among consortium members in forming a new group across multiple KFCs to address clinical trials tracking and tools management, but the focus and deliverables of such a group have yet to be determined. The RK KFC is working with the Informatics KFC, the Clinical Research Management KFC and the CTSA Clinical Services Core Group to set up a meeting to discuss the proposal.

ARTICLES:

CTSA Consortium Gains New Opportunities for Collaboration Through iBridge Alliance

Users of the Web-based CTSA consortium intellectual property portal (CTSA-IP) can now connect with more than 100 other research institutions to collaborate and license their work, thanks to a new agreement with the iBridge Network, a program of the not-for-profit Kauffman Innovation Network.

"Both the CTSA consortium and the iBridge Network share the common goal of connecting researchers in order to make their innovations as useful and productive as possible," said Scott Steele, director of research alliances at the University of Rochester, who helps lead the initiative on behalf of the consortium's public-private partnerships committee. "With more than 3,700 innovations from CTSA member institutions already on the iBridge Network, we're garnering worldwide exposure for the breakthroughs our researchers are accomplishing, while moving toward the goal of improving human health through clinical and translational research."

[CTSA-IP](#) was founded as a means of collecting licensing and technology transfer information in an easily searchable format at a single Web site to encourage research collaborations and private partnerships throughout the consortium.

The new agreement offers consortium members and other portal users access to some 12,500 innovations posted on the [iBridge site](#), where universities, companies and entrepreneurs discover and share research findings and best practices across a variety of topic areas.

"CTSA shares our ambition of providing transparency and the opportunity for collaboration for researchers and innovation seekers across the country," said Lesa Mitchell, director of the iBridge Network. "They are already the most active community on the network, and we couldn't be happier to highlight the cutting-edge research that their members are conducting every day."

For more information about how consortium institutions can participate in the CTSA-IP portal, contact [Scott Steele](#) or [Mike Hazard](#), who have played a key role in developing and managing the site.

CTSA Imaging Working Group Developing Uniform Protocols for Imaging in Clinical Trials

Several factors may limit the value of imaging in clinical trials and clinical care, including lack of uniformity and standardization in the acquisition, post-processing, analysis and interpretation of imaging-derived data; technical differences among vendor platforms; machine drift over time; and changes introduced by service calls or system upgrades. To improve the reliability of imaging in clinical trials, the CTSA Imaging Working Group has drawn imaging scientists and clinical researchers from the imaging device and biopharmaceutical industries, federal agencies, imaging contract research organizations, academia and clinical imaging practices for the Uniform Protocols for Imaging in Clinical Trials (UPICT) effort.

UPICT to Create Searchable Library of Products

The CTSA Imaging Working Group has developed a [standardized template](#) to facilitate the authoring, comparison and use of imaging protocols for clinical trials. This template may be used to develop new protocols. Small workgroups are "extracting" or translating, existing protocols from both academic and industrial trials into the standardized template. The extracted protocols will go into a searchable library of imaging protocols along with consensus protocols under development. UPICT also provides a forum for clinical researchers and imaging scientists to collaborate.

"We welcome the input of interested imaging scientists and clinical trialists in the protocol extraction process, in the authoring of consensus protocols and in prioritizing needs for other UPICT protocols. This effort is a true partnership among academia, industry and federal agencies, and progress to date has been truly gratifying," said Gary S. Dorfman, M.D., chair of the CTSA Imaging Working Group Clinical Trials Committee that facilitates the UPICT process.

The UPICT effort is currently extracting these existing protocols into the standardized template:

- Oncologic fludeoxyglucose (FDG)—positron emission tomography (PET)/computed tomography (CT)
- Volumetric CT for use in oncologic pulmonary imaging
- PET/CT (FDG and Pittsburgh compound B) and magnetic resonance imaging for use in clinical trials in Alzheimer's disease.

The Working Group plans to expand the portfolio of protocols to include many devices and therapeutic areas.

Standardization Could Speed Research Results

Stakeholders recognize the need to harmonize imaging procedures, according to P. David Mozley, M.D., of the Pharma Imaging Group, a nonprofit alliance of professionals focused almost exclusively on medical imaging in support of for-profit therapeutic product development. Dr. Mosley noted that multiple sites—sometimes hundreds—contribute medical images to a single trial, and study subjects may have been imaged at more than one site.

"As a consequence, the biopharma industries need a mechanism for creating consensus on how to harmonize imaging procedures that are disease-by-device specific," said Dr. Mozley. "There are simply too many adverse consequences of trying to use one-product-only-specific procedures in multinational settings, all of which slow the delivery of new treatments to patients with unmet medical needs."

Just as interventions are translated from clinical trials to clinical care, these standardized imaging protocols will be translated from a supporting role in trials to clinical practice. UPICT's uniform imaging protocols could also improve the consistency of imaging performed during routine clinical care and increase the chance that pre-enrollment imaging could be used as the "baseline" study for clinical trials.

The Radiological Society of North America provides administrative support for the UPICT effort. The group's work can be viewed on the [UPICT wiki and Web site](#) and is open to any interested party. For more information, contact [UPICT](#).

BERD Watch—University of Rochester Biostatisticians Collaborate to Boost Human Health

Through the CTSA program, biostatisticians at the University of Rochester have developed novel statistical methodologies to enhance clinical and translational research capability. Their efforts are contributing to research in a variety of conditions that affect the health of people around the globe. These new methodologies, motivated by collaborations with clinical researchers, allow clinicians and biostatisticians to work in partnership to address key clinical and translational goals.

For example, biostatisticians created methods to clarify the findings from one of the world's longest-running studies of the effect of prenatal mercury exposure on children. Large quantities of data have been generated by measurements of numerous test outcomes on more than 600 children. Using data from the multiple test outcomes simultaneously, new methodology within a Bayesian linear mixed model framework was developed that can estimate, for instance, the overall effect of prenatal mercury exposure on cognition and compare it with the effect on memory in pre-teens.

In another project, scientists are working on a home-based technology to detect the onset of Alzheimer's disease earlier than is typically possible today. Using data from a system of motion sensors and wearable motion detectors, new methods allow nurses, doctors and even other family members to obtain a clearer picture of how an older person living alone is moving about in his or her own home. Such information is crucial for gauging the health of a patient, particularly one who may be suffering from the early stages of dementia and may not be able to report accurately how he or she spent the day. A person who paces back and forth for hours may be agitated, for instance, while someone lying in bed for hours could be depressed. The study creates vast amounts of data generated by our daily movements. Biostatisticians are working with the research team to develop new signal processing algorithms to determine whether continuous monitoring of a subject's movement at home can lead to a characterization of the onset of dementia.

Several additional projects are underway. One team has enhanced the capability of assessing the value of a diagnostic test to identify people with a health condition, such as depression. The setting considered is one where the test result is available for all people in the sample but information on the true diagnosis is missing in some people. This setting is commonly encountered when the "gold standard" evaluation of the diagnosis is costly or invasive, so only a highly select subset of people actually receives this evaluation. Another has developed a way to more accurately analyze the effectiveness of efforts to prevent the spread of HIV using information on the reliability of retrospective self-reports on risky sexual activities. In another project, biostatisticians have improved on methods to diagnose posttraumatic stress disorder, a crucial contribution in a nation where increasing numbers of soldiers are seeing active combat. In a broad set of studies, biostatisticians are helping cancer researchers assess huge quantities of genetic data in the search for genes involved in prostate cancer, leukemia and other forms of the disease.

University of Rochester investigators can take advantage of these new methodologies through collaboration with the university's biostatisticians. Many have found the approaches applicable to studies in other areas, and the announcement to the University of Rochester community of these novel methodologies has led to further planned collaboration between biostatisticians and clinicians from the following departments:

- Medicine
- Psychiatry
- Environmental Medicine
- Obstetrics & Gynecology
- Pediatrics
- Biomedical Genetics

- Neurology
- Cancer
- Heart Research
- Neurobiology & Anatomy

In addition, these methodologies are being used in collaborations between biostatisticians from the University of Rochester and researchers from the Department of Psychiatry & Behavioral Sciences at the University of Washington and the Department of Neuroscience at Georgetown University Medical Center.

The findings resulting from the development of novel statistical methodologies thanks to the CTSA program, have an impact far beyond the scope of a single research project focusing on one disease or condition. By addressing the methodological needs arising in clinical studies, novel statistical methods are helping to connect clinicians and statisticians in a useful partnership that holds great promise for addressing future research questions of importance to clinical and translational investigators.

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
- Streamlined search feature on [Resources for Researchers](#) page
- 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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