Director's Corner by Ronald J. Sokol, MD

This has been a very busy time for the CCTSI and the upcoming year will be even busier starting with two major events. On January 13 & 14, 2011 we will be hosting the 3rd meeting of the CCTSI External Advisory Committee (EAC) at the Anschutz Medical Campus. Our six external reviewers and NIH Project Officer will be coming to evaluate our program and provide us with important feedback and guidance as we look towards our CTSA grant resubmission in 2012. The EAC will also be attending a PACT Council meeting the first evening followed by a scientific poster session highlighting some of our pilot projects, ARRA supplemental grants, KL2 and TL1 funded investigators and our Progress Tracking System. Also on January 14, 2011 will be the CCTSI-sponsored Annual Winter Pediatrics Research Poster Session that will take place at Mt Princeton/Mt Yale rooms in the 2nd Floor Conference Center at The Children’s Hospital, highlighting child health research of all forms, including basic, clinical, translational, health outcomes, CER and public health. Those interested in presenting a poster should contact Rose Heineman at heineman.rose@tchden.org.

Please save the date for the quarterly CCTSI Grand Rounds which will take place on Thursday, February 3, 2011 from 12-1pm (lunch provided) with guest speaker Dan Masys, MD, Director of Biomedical Informatics at Vanderbilt University. Dan is one of the national leaders in creating and applying cutting-edge informatics technology and electronic medical records to enable and improve the performance of translational research. Dan is an exceptional speaker and scientist who will educate and inspire you.

In a very important development for UC Denver research, the CCTSI obtained final approval from the National Center for Research Resources for $2 million of funding towards the purchase of a research-dedicated PET–CT scanner that will be installed on campus in 2011 at the Brain Imaging Center. This will allow for expanded imaging research within the CCTSI-supported Colorado Translational Research Imaging Center (CTRIC). The CCTSI also obtained funding to help support purchase of a Next Generation Deep Sequencer that will be housed in the Microarray Core.

The CCTSI is also involved in the creation of a new regional CTSA consortium with University of New Mexico and University of Utah CTSAs, the Southwest/Mountain West CTSA Consortium. Programs are being developed to coordinate training, research and resource sharing among the three CTSAs and the Western IDEA state consortium.

Finally, a major change in the organization of NIH is in the works. The entire CTSA program will be moved from NCRR to a new institute/center that will be created in 2011, the National Center for Advancing Translational Sciences, or NCATS. For more details visit the National Consortium Update.

Upcoming Events & Important Dates

CCTSI Grand Rounds Series
The CCTSI Grand Rounds Series was launched spring 2010 with Barbara Ahling, MD from NCRR/NIH speaking at AMC. The series, which will highlight cutting-edge translational research or biotechnology, will take place three times a year (fall, winter & spring) from 12-1pm with lunch provided. Upcoming speaker dates are as follows:

Dan Masys, MD, Vanderbilt University, Director of Biomedicine Informatics — Thursday, February 3, 2011; 12-1pm at AMC room: Ed 2 North P28-2104 “The Translational Science of Genomes, Phenomes, and Personalized Healthcare”

Nanette Santoro, MD, UCD AMC Obstetrics & Gynecology Chair — Thursday, April 21, 2011; 12-1pm at AMC room: RC 2 P15-2100 Trivisible

CCTSI Informatics Seminar Series
Mark your calendars now and save the Third Thursday at Three-Thirty-Three. The Informatics Seminar Series schedule is as follows:

January 20, 2011 — Denver Health’s data warehouse and its use in quality improvement and clinical research
February 17, 2011 — HeartSmartKids: Minimally-Invasive Informatics for Addressing Childhood Cardiovascular Risks in Clinic and Community

All seminars will be in Teaching Lab 2 at the Health Sciences Library at the Anschutz Medical Campus. Please be certain to arrive early as refreshments will be served thirty minutes prior to the seminar start. If you are unable to attend in person, please note that all seminars are available via live video stream. For more information on the series or to view archived trainings, visit the Informatics Section of the CCTSI website at cctsi.ucdenver.edu.

CCTSI Nuts & Bolts Series

This series introduces the offerings of the CCTSI and clarifies how these resources can be leveraged to accelerate your research. Each session will provide an overview of the CCTSI Pillar Programs including: Discovery Translation, Community Translation, Translational Technologies and Novel Methods, Child and Maternal Health Research, Community Engagement and Research, Translational Informatics and Education, Training and Career Development. Several sessions are planned during the 2010-2011 academic year.

For more information contact Emily Warren ETCD Programs Manager as registration is required.

Wednesday, January 13th, 2010 — 4-5:30pm at Shore Family Forum, Nighthorse Campbell Building

The Translational Informatics group will discuss REDCap software, video lecture library and the "5 things you need to know in 5 minutes" (or 5x5) video series.

Wednesday, February 16th, 2011 — 4-5:30pm AO1 Boardroom, 7th Floor

This session outlines the educational opportunities available in Biostatistics and other BERD resources.

Thursday, March 10th, 2011 — 2-3:40pm AO1 Boardroom, 7th Floor

The Maternal & Child Health core will provide information on resources available including pilot grant awards.

Wednesday, April 6th, 2011 — 4-5pm Shore Family Forum, Nighthorse Campbell Building

Our Network of Translational Technologies (NeTT) component will outline the Novel Methods grant program as well as other core lab offerings including Medicinal Chemistry, Proteomics, Biobanking, Imaging, Gene Expression and Microarray analysis.

Wednesday, May 18th, 2011 — 4-5pm Shore Family Forum, Nighthorse Campbell

The Community Engagement core will discuss their pilot grant program and the importance of the PACT council in community based participatory research.

First Annual International SciTS (Team Science) Conference

The Annual International Science of Team Science (SciTS) Conference will be held April 11 – 14, 2011 in Chicago, Ill. The week-long SciTS Conference is an international, multi-agency forum dedicated to the empirical field of the science of team science (SciTS) and brings together thought leaders from a broad range of disciplines, including: translational research, evaluation, communications, social and behavioral sciences, complex systems, technology and management in an effort to enhance understanding of how best to engage in team science to meet society’s needs.

The event is sponsored by Research Team Support & Development (RTS&D) of the Northwestern University Clinical and Translational Sciences (NUCATS) Institute.

Registration, lodging, and poster abstract submission are expected to open on or about Monday, January 3, 2011. Learn more.

Recap of First Annual CCTSI Research Ethics Conference Focuses on Financial Conflict of Interest

At the First Annual CCTSI Research Ethics Conference, Jeremy Sugarman, MD, MPH, Professor of Bioethics and Medicine at the Johns Hopkins University, spoke about the spectrum of conflicts inherent in clinical and translation research, selected types of financial interests, and how data can inform policies about the disclosure of financial conflicts of interest to potential research subjects. Over 60 participants attended the meeting, held October 14, 2010, on the Anschutz Medical Campus.

Presentations by Teena Aiken, FDA Consumer Safety Officer, and Angela Wishon, JD, Asst. Vice Chancellor for Regulatory Compliance, UC Denver, gave participants a feel for the different policy requirements from various regulatory entities. A panel discussion included representatives from academic medicine, the pharmaceutical industry, the CCTSI Community Engagement program, and a retired minister. Some of the robust discussions focused on the broader definitions of conflict of interest, and the impact of conflict of interest in daily activities.

The CCTSI Ethics Core is committed to providing an opportunity to inform our academic community and initiate meaningful dialogues centered on salient issues which inform policies governing the ethical conduct of clinical and translational research with human participants. Future conferences will spotlight different hot topics in the research ethics arena.

For more information about the Research Ethics Consult Service, please send an email to ResearchEthics@ucdenver.edu or visit http://cctsi.ucdenver.edu/Research-Resources/Pages/Research-Ethics.aspx
Research Features

Aging In Community — Good for Your Health

Professor Ronica Rooks, PhD, UC-Denver’s Department of Health & Behavioral Sciences, is tackling one of the challenging aspects of our aging society. She has embarked on a community-academic partnership (funded by a CCTSI Community Engagement Pilot Grant award) with the non-profit Neighborhood Resource Center of Colorado (Sarah McCarthy, Executive Director) to develop evidence-based research on improving social capital and health among older adults in varied socio-economic status communities.

The decline of social capital (e.g., the informal, voluntary and reciprocal relationships that individuals develop over time, building social trust and mutual interdependence, and are enhanced through positive interactions and collaboration in shared interests and pursuits, Blanchard & Stambolian 2008) has been well-documented; however, how this decline impacts elders’ ability to stay in their home and connected to their communities is not well understood.

Most Americans would prefer to “age in place,” e.g., to continue living at home with supportive services if necessary, as an alternative to a nursing home. While many elders and families consider aging in place preferable to an institutional setting, others find it a hollow victory — particularly when it occurs in a home that poses physical and financial challenges and makes connection with family, friends, neighbors, and the community difficult or impossible. An increasing number of people now envision a third way for older adults to remain in their homes — “Aging in Community (AIC),” an emerging international grassroots movement, that looks to people being “darn good neighbors” to address gaps in aging services with the goal of creating innovative social capital building solutions to keep elders in their homes and connected to their communities.

Initial literature research funded by a CCTSI pilot-grant found few published, analytical studies documenting the relationship between social capital and elderly individual and community health outcomes, particularly at a population health level. It is also not yet clear which community building strategies increase social capital among the elderly or how social capital relates to their sense of health. While there is individual, anecdotal newspaper and website evidence on elderly and social capital supporting the positive health impact of AIC-type programs, this hypothesis has not been analyzed at a population-level. Thus, our community-based research program is examining whether social capital, expressed in a variety of ways: as a sense of community, social support within a community, reciprocity, and AIC-type programs, has a relationship with older adults’ health, and if this relationship varies by community socio-economic status. This study is intended to provide the evidence needed to move this important field of research forward.

The treatment Options for Type 2 Diabetes in Adolescents and Youth (TODAY) trial at the University of Colorado and The Children’s Hospital

Dr. Phil Zeitler is Professor of Pediatrics, is pioneering exciting studies into the growing problem of type 2 diabetes in the pediatric population. He is Study Chair of TODAY, a national, NIH-funded, multi-center trial examining treatment options for adolescents with type 2 diabetes, as well as the TODAY Genetics Study, a national effort to establish a DNA sample bank of individuals with onset of type 2 diabetes prior to age 18. The study is also supported locally by the CTRC at The Children’s Hospital and other resources of the CCTSI.

The incidence rate of type 2 diabetes (T2DM) in youth has increased 10-fold over the last decade. T2DM has been labeled a new epidemic disproportionately affecting minority youth. Systematic data are lacking on optimal methods to treat T2DM in children and adolescents. The TODAY study group, comprised of 15 clinical centers in the US, is nearing completion of a large prospective, randomized trial to evaluate treatment regimens and the clinical course of T2DM in youth. The trial compares the efficacy of 3 treatments in maintaining glycemic control among 700 participants over 2-5 years. The 3 treatment arms consist of standard diabetes education (SDE) plus three arms designed to compare standard therapy to the effects of more intensive intervention early in the course of T2DM: (i) metformin, (ii) metformin & rosiglitazone, and (iii) metformin & an intensive lifestyle program incorporating nutrition, physical activity, and behavior modification. The primary outcome is time to loss of glycemic control, with important secondary outcomes include measures of beta cell function and insulin resistance, body composition, nutrition, physical activity and aerobic fitness, cardiovascular risk factors, microvascular complications, quality of life, and psychological outcomes. The influence of individual and family behaviors on treatment response and the relative cost effectiveness of the three treatment arms are also being evaluated.

The TODAY study completed recruitment in February 2009 and will complete the initial intervention at the end of February 2011, with results available publicly later in the year. The NIH has decided to further support continued evaluation of the TODAY Cohort with a focus on long-term microvascular and macrovascular outcomes. Keep an eye out for the results of these ground breaking CCTSI-supported studies.

CCTSI Program Spotlight

CCTSI Research Navigator Resource

The newly created CCTSI Research Navigator Resource is providing guidance for clinical and translational researchers at all research stages, connecting CCTSI members with CCTSI resources, providing information on CCTSI funding opportunities, assisting investigators with COMIRB applications, and acting as a liaison between those looking to collaborate with clinical and translational investigators and the CCTSI research community. The two Navigator Resource team members (Sarah Stallings, PhD and Molly Van Rheen, MS) have diverse research backgrounds and areas of expertise, and they are able to cover a wide range of research support services from developing research strategies to securing funding, addressing COMIRB regulatory requirements, and communicating research results. The Research Navigators are available to assist investigators and staff on the AMC and at CCTSI affiliates, PACT Community Liaisons, and others who have questions about CCTSI resources or who have a community-based research need. For questions about this free resource contact the...
Biostats for Non-Statisticians

"Biostatistics for Non-Statisticians" seminar videos are available online. Feel free to visit cctsi.ucdenver.edu and click on "Biostatistics" in the left-hand menu. In the lower right-hand corner of the page, under the list of upcoming monthly seminars, is a link to over a dozen archived seminar videos.

These videos show the actual slides along with their narrated explanations. Each seminar lasts an hour and provides an overview of the topic covered. These talks do not replace actual coursework, but help investigators become more familiar with biostatistical concepts. This knowledge can then be applied to their own medical research as well as to a more informed review of journal articles.

This seminar series is sponsored by the Biostatistics, Epidemiology, and Research Design (BERD) core of the CCTSI.

Progress Tracking System (PTS) wins award

The progress tracking system (PTS) developed by The Evaluation Center to monitor progress for the Colorado Clinical and Translational Sciences Institute received runner-up status in a national technology competition, sponsored by ECM magazine. The Evaluation Center, based in the School of Education and Human Development at the University of Colorado Denver, was in competition with three other finalists in the category, SharePoint strategies. The PTS was nominated by 5280 Solutions, a technology consulting firm that provided the Center with programming assistance.

The system includes electronic reporting forms, summary reports, stakeholder briefs and performance dashboards. Standardized forms help ensure that progress with respect to aims and indicators is documented and reported on a regular basis. These and other system components not only help keep aims and indicators in the forefront, but also support evaluators' efforts to provide responsive formative feedback. Recent refinements to the system permit users to query archived data regarding the attainment of critical benchmarks for specific grant periods or timeframes designated “on the fly” to support progress monitoring and meet internal and external reporting requirements.

Perhaps the success of the system may best be measured by the outside interest it is generating. The CCTSI evaluation team has responded to a number of requests for demonstrations nationally. Last spring, the CCTSI evaluation team surveyed other Clinical Translational Science Award sites to gauge national interest in adopting the PTS. Of those surveyed, nearly half indicated that they would be “very interested” in adopting the system for use at their institutions. The CCTSI is currently working with NCRR to secure funding to allow the CCTSI to expand use of this system to other institutions.

CCTSI Welcomes New Personnel

As 2010 comes to a close we have hired two new key personnel in the Clinical Translational Research Centers (CTRC) Network that we’d like to formally introduce and welcome to our team: Joni McGuire, NP, DNP and Jeryl McGaw, MS, ND, RN.

Dr. McGuire, joins the CCTSI Team as the new Outpatient Manager in the CTRC Clinic at University of Colorado Hospital (UCH). She provides oversight to the clinic operations and is instrumental in launching the CTRC Mobile Research Team at UCH which we anticipate introducing in 2011.

Dr. McGuire joins us with vast experience in program design and development. She began her nursing career in a clinic in Nederland, Colorado then transitioned to Emergency Nursing in Boulder. She developed her nursing and management experience at Kaiser Permanente where she advanced from the Chronic Care Coordinator to the Nurse Practitioner at a baseline clinic. Within one year she became the Nurse Manager providing oversight to Kaiser’s Regional Clinics (19 clinics). She has developed management programs for patients with complex, chronic health problems such as DM, CHF, COPD, CA, HTN, CKD, Obesity, Hyperlipidemia, etc. She also developed the research design and implemented the programs for CRICC Medicaid and SPN Medicare. Her research has been in obesity.

Dr. McGuire joined our team on November 15, 2010. Since that time she has completed hospital orientation, orientation to the clinic, and orientation to our research operations. She will assume her responsibilities as Outpatient Manager in January 2011.

Dr. McGaw joins the the CCTSI Team as the new Manager of the CTRC Inpatient Unit at The Children’s Hospital (TCH). Dr. McGaw will provide oversight to the Inpatient Unit and direct the nursing care provided to the research participants as well as the TCH medical/surgical overflow patients.

Dr. McGaw began her executive nursing career as the Pediatric Clinical Research and Patient Education Director at National Jewish Health in Denver. She completed her Doctoral Residency as Education Director at The Children’s Hospital. She was the Director of Research Programs at the American Lung Association then transitioned to Kaiser Permanente as the Manager of Chronic Care Coordination. That role led her into the position of the Director of Case and Care Coordination.
Dr. McGaw joined our team on November 30, 2010. Since that time she has started hospital orientation, orientation to the inpatient unit, and orientation to our research operations. She will assume her responsibilities as the Inpatient Manager on the TCH CTRC in February, 2011. Please take the time and introduce yourself to and welcome Dr McGuire & Dr. McGaw as they are wonderful additions to our CTRC clinics.

The Clinical Science Graduate Program’s has also hired a new Program Administrator. Galit Mankin has accepted our offer to become one of the Program Administrators of the Clinical Science Program. Ms. Mankin replaces Lori Stepp, who has taken on a full time role at National Jewish Health. Ms. Mankin’s first day is January 3, 2011. As Program Administrator, Ms. Mankin will be responsible for the overall management of student progress in the Clinical Science Program. Ms. Mankin has over 12 years of experience in increasingly responsible roles within several departments at the University of Colorado including the Department of Biochemistry & Molecular Genetics and the Department of Physiology & Biophysics. In these roles, she gained significant experience in both operational and administrative management. Her experience is enhanced by her Master’s degree in Social Work. We welcome Ms. Mankin as a valuable team member and are excited for her to come on board.

Ms. Mankin’s office will be located in the Leprino Office Building, room 351. She can be reached at galit.mankin@ucdenver.edu and 720-848-6249.

CTSA National Consortium Update

On December 7, 2010, the National Institutes of Health (NIH) Scientific Management Review Board (SMRB) voted (12 - 1) to recommend the creation of a new center for translational research, called the National Center for Advancing Translational Sciences (NCATS). The plan calls for: 1) the creation of a new translational research center and 2) NIH to conduct a detailed analysis, to be presented at the next SMRB meeting, of the impact of the recommended reorganization on remaining National Center for Research Resources (NCRR) components and other programs across NIH.

The proposed Center would be formed initially by integrating selected translational research programs now located within the National Human Genome Research Institute (NHGRI), the National Center for Research Resources (NCRR), and the NIH Director’s Common Fund. These programs included RAID, TRND, the Molecular Libraries Program, the new Cures Acceleration Network (CAN) program, and the CTSA program. The CTSA program would be moved from NCRR to NCATS. Details are being worked out at NIH for this transition in late 2011. At the present time it does not look like this new home for the CTSA program will have any immediate impact on the CCTSI, but we are monitoring this closely.

For more information regarding the proposed National Center for Advancing Translational Sciences please visit: http://feedback.nih.gov/index.php/category/ncats/

Southwest Mountain West CTSA Consortium Created

The Clinical and Translational Science Award sites of the Universities of Colorado, New Mexico and Utah are forming a new regional collaboration, the Southwest/Mountain West CTSA Consortium. Its goal is to accelerate the progress of clinical and translational research in the region through increased collaboration and sharing. The three university medical centers also share special interest and expertise in the health of underserved populations such as Native Americans and the special challenges posed by frontier medicine. The regional consortium will collaborate with the Mountain West consortium of Institutional Development Awards (IDEA) centers to share core resources for joint projects, expertise for review of grant applications and educational tools. An example of such sharing will be the broadening of opportunities across all of the sites for summer research programs for undergraduates. More information will be released about this new Consortium as it is fully developed during 2011. We are very excited about this new opportunity to extend the reach and impact of the CCTSI and to build a bridge to these two outstanding academic centers that will benefit our faculty, staff and trainees and the citizens of all three states.

The principal investigators at the three institutions are: Richard Larson, New Mexico; Donald McClain, Utah; and Ronald J. Sokol, Colorado. For more information, contact Michael Briggs, New Mexico; Christine Chambreau, Utah; and Tim Lockie, Colorado.