Director’s Corner by Ronald J. Sokol, MD

It seems like it was just summer and we were waiting for the National Center for Advancing Translational Sciences (NCATS) to release the Funding Opportunity Announcement (FOA) as our CTSA grant is up for renewal. The FOA was released on July 6, 2012, and we have been moving at lightning speed ever since as the letter of intent is due December 10, 2012 and the application is due January 8, 2013.

I have been working with the CCTSI Executive Committee and Administrative Core personnel to strategize and operationalize the tasks that need to be done for this grant submission. In fact, on October 2 & 3, 2012 we held a review session of a “solid draft” of our application attended by 6 external reviewers. We’ve received their helpful feedback and are working on incorporating their comments into the application. If you or a co-worker is asked to help gather data or information which is related to the NCATS FOA, please respond as quickly as possible as this application impacts all of us. We are busy working on the budget and many other details in order to submit the best possible grant application in January, 2013.

In addition to working on the FOA, in mid-July we launched Colorado PROFILES, a new online resource for identifying researchers at the University of Colorado Denver | Anschutz Medical Campus, the other University of Colorado campuses and the affiliated hospitals. The “Colorado PROFILES” search engine provides a much needed mechanism to help investigators, staff, students and those external to UC Denver to quickly find experts, researchers, collaborators or mentors within the UC system, and view past and present research networking of our investigators. There will be many enhancements and upgrades to the system as they become available. Faculty and post-doctoral fellows are encouraged to begin exploration of their own profile and examine others. From that welcome site you can find a tutorial and a FAQ section. If you have specific questions about PROFILES, please email comments to profiles@ucdenver.edu.

As you walk across the Anschutz Medical Campus you will now notice banners promoting Colorado PROFILES and the CCTSI, as we try to make ourselves even more visible and accessible to researchers, students, staff and visitors to our campus. I would like to thank Natascha Palmer, our Communications Director, for assembling and getting approval to post these terrific banners. We encourage everyone to access cctsi.ucdenver.edu and profiles.ucdenver.edu for up-to-date information regarding the CCTSI.

Please visit the “Bulletin News” section below for additional updates within the CCTSI community.

Lastly, the NIH institute now directing the CTSA program is changed to NCATS, which requires us to change our grant number. Please remember to cite the CCTSI grant number UL1 TR000154 on all publications which received any support from any of the many CCTSI programs and cores. For publications supported by our TL1 program cite TL1 TR000155 and for KL2 publications cite KL2 TR000156.

Upcoming Events & Important Dates

CCTSI Training Opportunities

- October 31, 2012: Clinical Trials Basic Training, 1pm-5pm, Leprino Office Building, room 318, “Getting Started”, “Informed Consent Process”; “Hit, Wt, VS Competency Training”; and “UCH CTO/CTRC Tour and How-To”
- November 7, 2012: Responsible Conduct of Research, 12p-1p, Fulginiti Pavilion For Bioethics and Humanities, Gossard Forum “Mentor/Mentee Responsibilities and Collaborative Research”
Community-Based Participatory Research Seminar Series Developed by the PACT Training & Education Committee

A criticism of the current paradigm of clinical research is that the lag between the knowledge gained through research and the application and translation of that knowledge to benefit community members is too long, and often non-existent. As a result, successful research projects must meet the priorities or needs of communities and its members and must translate the knowledge gained through research so that communities may benefit. To prepare community members and researchers for successful research, a seminar series, “Research through Community-Academic Partnerships: Lessons Learned,” started in September 2012. This seminar series begins to provide the training and expertise necessary for these endeavors and highlights take-home messages and lessons learned from research performed in our communities. On the second Tuesday of each month, there will be a one hour seminar from 12pm-1pm, located at the UCD-Anschutz Medical Campus in Education 2 Building (13120 E. 19th Ave, Aurora), room P28-1103 — attendance open to the public.

- **November 13, 2012** - Seminar 3: Developing Partnerships II: Working with the Latino/a Community: Beyond Language - Speakers: Lorenzo, Ramirez, Rachel Cleaves, Mori Krantz
- **December 11, 2012** - Seminar 4: Partnership Infrastructure: Formalization of Roles, Responsibilities and Expectations - Speaker: Debbi Main
- **January 8, 2013** - Seminar 5: Making Meaning of Data and Disseminating Results - Speaker: To be determined
- **February 12, 2013** - Seminar 6: The Importance of Trust: Lessons from the Lesbian, Gay, Bisexual and Transgendered Population - Speaker: Leslie Wright
- **March 12, 2013** - Seminar 7: Unnatural Causes Video: Place Matters & Existing Health Disparities in Colorado - Speaker: Alyson Shupe
- **April 9, 2013** - Seminar 8: Practice-Based Research Networks: Working Together to Improve Practice and Address Health Disparities - Speakers: Marc Ringel, Linda Zittleman
- **May 14, 2012** - Seminar 9: The Role of a Community Advisory Board in Selecting and Prioritizing Health Disparities and Studies - Speakers: Jack Westfall, Maret Felzein

CCTSI Co-Brand Brown Bag

The CCTSI is hosting a brown bag session on Wednesday, November 14, 2012 from 12-1pm in Leprino Rm 318. This session will go over do's & don'ts of the CCTSI logo and CCTSI templates. All are encouraged to attend. Please RSVP so we can plan accordingly. For questions regarding this meeting please contact Natascha Palmer.

CCTSI K to R Transisition Program

This CCTSI program provides the opportunity for current NIH K or other Career Development grant awardees to submit their R type (or equivalent) grant proposals for internal review prior to NIH submission. The goal is to provide insight into the grant review process and help applicants improve the science and format of their proposals prior to submission to the funding agency.

Resources provided by the K to R Transition Program include the following:

- Attendance at mock study section on January 14, 2013 is required by applicants & mentor to increase impact of review and further understanding of study section process. Mentors will be asked to review other grant applications in the cycle.
- Ability to contact reviewers for further advice about proposal style, format and substance.

**STEP 1:** An online letter of intent due December 14, 2012 is required including: your name, department, mentors, grant type, agency, abstract and specific aims page for the proposal. Specific Aims are pre-reviewed before full proposal is submitted.

**STEP 2:** Full proposal is reviewed and discussed in mock study section attended by applicants, mentors and reviewers.

For questions contact KTR Program Director: Maggie Wieman, MD or ETCD Programs Manager, Emily Warren, MA

CCTSI Nutrition Core Holiday Closures

All investigators using the CCTSI Nutrition Core, please note that the Nutrition Core will be closed from December 24, 2012 – January 1, 2013. The first day for diet pick-ups will be January 3, 2013 as they need time to restock and prep proteins. If you have questions or concerns about the closure please contact Janine Higgins, PhD, Nutrition Research Director.

Also as winter is approaching, please re-familiarize yourself with the snow closure policy. You MUST remember to provide a pager or cell number where you can be reached whenever you have a diet pick-up or study visit scheduled. If there is a UCD closure, study staff are responsible for rescheduling their own subjects.
CCTSI Nutrition Core to Help Overhaul Cafeteria Menu at the Children's Hospital Colorado

The CCTSI Nutrition Core is partnering with the Children's Hospital Colorado Food Services Division and members of the Healthy Hospital Initiative to make more healthy options available at Children's cafeteria. The goal of the Healthy Hospital Initiative (HHI) is to improve the physical, mental, and emotional/spiritual wellbeing of patients, families, visitors, and staff. Janine Higgins, CCTSI Nutrition Research Director, is a member of the HHI task force and is providing nutrition expertise to help Children's cafeteria meet HHI nutrition goals. The Noodle station at the cafeteria was converted to the Healthy station (we are still searching for a better name so, if you have one, please let us know!). The Healthy station provides one complete meal each day which meets modified CDC guidelines of < 550 kcal, ≤ 30% fat, ≤ 10% saturated fat, and < 800mg sodium with an emphasis on providing lean protein and whole grains where possible.

Elizabeth Hibler, a CCTSI Nutrition Core intern, took on the mammoth task of obtaining and entering every cafeteria and catering recipe into state-of-the-art nutritional analysis software, Nutrient Data Systems for Research (NDS-R). This is the most accurate nutrient analysis software available as it has values for micronutrients, sodium, and fatty acid subtypes for many foods that are not available using other databases. Elizabeth spent over 3 weeks entering 367 recipes into NDS-R and then acting as a “secret shopper” to purchase and weigh back meals from every station at the cafeteria in order to compare recipe amounts with actual served amounts. Children’s Hospital Food Services provided $1,500 in funding for the purchase of meals and the CCTSI Nutrition Core provided all of the labor for the project.

In general, we found that proteins and starches were overserved whereas vegetables were selectively underserved at every station (Figure 1). This trend held true at the Healthy station except for certain meals where all components were overserved (Figure 2A). Overserving impairs our ability to meet HHI targets and makes Healthy meals economically unsustainable, particularly if the most expensive food components (proteins) are selectively overserved (Figure 2A). As shown in Figure 2A, the brown rice bowl meal, as designed, would utilize only $2.00 of food ingredients but, as served would cost $4.28. This meal sells for $5.75, leaving only $1.47 for consumables, labor (serving), preparation, waste, and disposal costs. $1.47 is much lower than the actual cost of these residuals so every portion of this Healthy meal loses money for the Food Services Division, a position which is unsustainable.

Figure 2B shows the impact of overserving on our ability to meet HHI targets. The brown rice bowl, for example, jumped from 473 kcal and 658 mg sodium to over 1,000 kcal and over 1,400 mg sodium which is actually worse than the caloric and sodium content of meals at other non-“Healthy” stations in the cafeteria and worse than a MacDonald’s Big Mac meal (Big Mac, fries, and Coke). So, by not adhering to recipe amounts, the Healthy station is not meeting HHI targets.

To remedy this situation, Janine Higgins conducted training at weekly Food Services staff meetings. In addition, the Food Services Division is trying to provide correctly sized serving tools and, in collaboration, we are looking into the size and shape of serving plates and providing weighed models of each meal as a visual aide when serving. The CCTSI Nutrition Core is gathering and entering new recipes that may be easier to serve accurately and provide more variety at the Healthy station. One problem with the initial Healthy station meals was that 33% were salads, despite the fact that there is a self-serve salad bar behind the Healthy station, 17% were pasta dishes, and no red meat was offered on any meal. The CCTSI Nutrition Core is adding lean red meat to the menus and showing how traditional “comfort foods” such as tacos, sloppy joes, and eggplant parmesan can meet HHI targets and be part of a healthy diet.

The CCTSI Nutrition Core wants to thank all members of the HHI task force and Children’s Hospital Food Service Department for their help and co-operation with this project. In particular, John Killeen and Bethany Luck from Food Service have provided funding, support, and immediate changes in the cafeteria in response to the data provided by the CCTSI.
CCTSI Program Spotlight

Effects of CCTSI Funding on Subsequent Research Productivity

The CCTSI Evaluation Core recently conducted a study to determine if the CCTSI career development and pilot award programs impact the research productivity of CCTSI-supported investigators. Grants and Contracts (G&C) data were collected for the first cohort of Child-Maternal Health (CMH) and Colorado Pilot and Collaborative Translational and Clinical Studies Program (CO-Pilot) awardees, as well as those who received CCTSI KL2 research scholar awards. The G&C data were compared to the next group of investigators who had applied to these CCTSI program, were not funded, but had the next best application scores.

The analysis examined differences in the number of grant proposals submitted and the number of grant dollars awarded between 2009 and 2011 (after the investigators had applied for their respective CCTSI awards). Results showed that CCTSI awardees submitted significantly more grant applications on average than their unfunded peers (4.14 vs. 1.81 per investigator). CCTSI awardees also brought in substantially more grant-dollars than non awardees ($137,327 vs. $49,485 per investigator). For additional details and to view graphs illustrating these results, feel free to contact Jeff Proctor in the CCTSI evaluation core.

Bulletin News

CCTSI Perinatal CTRC
Currently, the Perinatal CTRC is supporting 21 protocols in L&D, NICU and Newborn Nursery across three sites (University Hospital, Children’s Colorado Hospital and Exempla St. Joseph Hospital). Our newest protocols in the last 12 months include:

- Dr. Laura Brown’s study entitled “Mannose requirements in Pre-Term and Intrauterine Growth Restricted Neonates”. The Perinatal CTRC is recruiting patients from both University Hospital and Children’s Colorado Hospital’s Neonatal Intensive Care Units (NICU).
- Dr. John Kinsella is investigating “A Phase II Trial of Intravenous Sildenafil in Term Newborns with PPHN”. This is a randomized controlled trial occurring in Children’s Colorado Hospital NICU.
- Dr. Ronald Gibbs, Professor of Obstetrics and Gynecology, is the Principal Investigator for the Maternal Fetal Medicine Unit (MFMU) grant, awarded for the period 2011-16. Dr. Gibbs, Kathy Hale (Nurse Coordinator) and the MFMU team have implemented three protocols under this grant. The first protocol, “Antenatal Late Preterm Steroids (ALPS): Randomized Placebo-Controlled Trial” is studying the use of betamethasone in women who are likely to deliver between 34-36 6/7 weeks to determine if there is a decrease in neonatal respiratory morbidity. The second protocol, “A Randomized Trial of Fetal ECG ST Segment and T Wave Analysis as an Adjunct to Electronic Fetal Heart Rate Monitoring (STAN)” has completed the Pilot Training Study and has started recruitment into the RCT to determine if use of this additional technology decreases perinatal hypoxic/ischemic morbidity and decreasing operative deliveries. The third protocol, “A Randomized Trial to Prevent Congenital Cytomegalovirus Infection (CMV)”, is addressing whether the maternal administration of CMV hyperimmune globulin will lower the rate of congenital CMV infection in infants of women with a primary CMV infection during early pregnancy. In the next month, we will initiate “ALPS Ancillary – Genetics Study” to determine the relationship between fetal genotype and the development of neonatal respiratory morbidity and the “Observational Study of Hepatitis C Virus in Pregnancy (HCV)” to determine prevalence of HCV infection and identify risk factors for transmission of maternal HCV.

If you are considering a research study involving pregnant women, fetuses or neonates as subjects, the CCTSI’s Child and Maternal Health Core is here to help coordinate, facilitate and support such research. Please utilize the Perinatal Research Planning Checklist to begin the process and submit to either Leah Emerick or Christine Reed found on the CMH website: http://cctsi.ucdenver.edu/CMH/Pages/default.aspx. We hope this information will be helpful in avoiding potential pitfalls along the way.

CCTSI Staff Changes
As the CCTSI continues to grow and make changes over the years so does our staff. We would like to announce a few CCTSI administrative new hires as you might interact with these individuals at some point moving forward.

- Ade Benson is the new Protocol Coordinator for the CCTSI. Many of you may already know Ade as she comes to us from our affiliate, the University of Colorado Hospital. In her previous position, she worked closely with the CCTSI/
CTRC to provide clinical data reports and process billing reports. As the Protocol Coordinator, Ade will manage the preparation, submission, and maintenance of research protocols submitted to the Scientific Review and Advisory Committees (SARC) and coordinate actions throughout the approval process. She will also be responsible for research protocol record maintenance and data management. We sincerely thank Ade for helping us make the transition resulting from Nicole Arnold’s absence truly seamless. Ade can be reached at ade.benson@ucdenver.edu.

Glenda Crawford is the new Web Manager for the CCTSI. Glenda brings more than 11 years of experience in creating websites, project management, and instructional design to her role. In her most recent position, she was the Project Manager for the CITT at the University of Colorado. Her Masters of Art degree in Information and Learning Technologies, combined with her many years of experience, give her the current skills that will enhance the CCTSI website and all web activities. She can be reached at glenda.crawford@ucdenver.edu.

Mujeeb Zaidi is the new CCTSI Finance Manager. Mujeeb brings more than nine years of diversified experience in finance and accounting at several higher education establishments including the University of Colorado and Barry University. Mujeeb will be working with Tim Lockie to lead the financial accounting and reconciliation activities of the Institute. In addition to his many years of experience, he holds a Masters of Science Degree in Information Technology. He can be reached at mujeeb.zaidi@ucdenver.edu.

Amanda Whiting has joined the Clinical Science Graduate Program at the CCTSI as a Program Assistant. Amanda has extensive administrative experience and will be working part-time with Galit Mankin, Clinical Science Program Administrator, and the Clinical Science Faculty. Amanda will be assisting in events coordination, course management and database record keeping. She can be reached at amanda.g.whiting@ucdenver.edu.

Please welcome these individuals into their new roles as we hope their transitions will be as smooth and seamless as possible.

CTSA National Consortium Update

NIH Names New NCATS Director
Effective September 23, 2012, Christopher P. Austin, MD, was named director of the National Center for Advancing Translational Sciences (NCATS). Austin’s new NCATS role was announced by NIH Director Francis S. Collins, M.D., Ph.D., at the inaugural meetings of the NCATS Advisory Council and Cures Acceleration Network (CAN) Review Board. Austin will succeed NCATS Acting Director Thomas R. Insel, MD.

Austin has been serving as the director of the NCATS Division of Pre-Clinical Innovation since NCATS’ launch in December 2011. His experience and successes in virtually every stage of the translational research process will help to continue building on the momentum and achievements to date.

Austin came to the NIH in 2002 from Merck, where his work had focused on genome-based discovery of novel targets and drugs. He began his NIH career as the senior advisor to the director for translational research at the National Human Genome Research Institute, where he initiated the Knockout Mouse Project and the Molecular Libraries Roadmap Initiative. Other NIH roles have included serving as director of the Therapeutics for Rare and Neglected Diseases program as well as the NIH Chemical Genomics Center, and as scientific director of the NIH’s Center for Translational Therapeutics.

He earned a medical degree from Harvard Medical School and an undergraduate degree in biology from Princeton University. He also completed clinical training in internal medicine and neurology at Massachusetts General Hospital, and a fellowship in genetics at Harvard.


With the creation of NCATS and the dissolution of the National Center for Research Resources (NCRR), this change impacts how we reference our funding.

Please note that the CCTSI is supported in part by Colorado CTSA grant UL1TR000154 from NCATS/NIH.

Moving forward please omit references to NCRR/NIH and our previous grant numbers UL1RR025780, KL2RR025779 and TL1RR025778.

If you have questions please visit: http://cctsi.ucdenver.edu/CCTSI-About/Pages/FundingAcknowledgement.aspx.

As always, please remember to cite the Grant (UL1TR000154) in any publications related to usage of CCTSI resources and to register the publications with PubMed Central.