Vice Chancellor for Research: RJ Traystman

COLORADO MULTI INSTITUTIONAL REVIEW BOARD (COMIRB)

New GCP Training Requirements

The development of novel drugs, devices and interventions involves highly regulated processes and requires a well-prepared workforce of investigators and others with the skills and knowledge to advance translation of scientific discoveries. The National Center for Advancing Translational Sciences (NCATS) is helping to spearhead a national training initiative by articulating a minimum standard of practice and uniform approaches to Good Clinical Practice (GCP) training. GCP, an international quality standard, addresses the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials providing assurance that the study results are credible and accurate and the rights and safety of study participants are protected. This approach will also help reduce redundant training requirements and increase the pace at which clinical trial results impact health outcomes. Beginning on September 1, 2015, COMIRB will start gatekeeping GCP training. Any full-board protocol submitted with attachments C and/or D will require that the PI complete GCP training offered by CITI in addition to the Biomedical Group 1 CITI training. GCP training is good for three years, and will therefore need to be updated to prevent approval delays. A protocol cannot be approved until GCP training is completed. NIH defines a clinical trial as “a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health related biomedical or behavioral outcomes”.

DR. T’S CORNER

NIH Names Walter J. Koroshetz, MD Director of the National Institute of Neurological Disease and Stroke (NINDS)

NIH Director Francis Collins has named Walter J. Koroshetz, MD as Director of NINDS. Dr. Koroshetz has been serving as Acting Director of NINDS since October, 2014. Dr. Koroshetz is well-suited for the position as Director of NINDS having great experience in clinical neurology and basic neuroscience research. He will lead NINDS into the future and will fulfill the institute’s mission to seek fundamental knowledge about the brain and nervous system and to use that knowledge to reduce the burden of neurological disease. Dr. Koroshetz played a critical role in the creation of the StrokeNet, a national clinical trials network for research in stroke treatment, prevention and recovery. He has also played an important role in the Traumatic Brain Research Center of NIH. Dr. Koroshetz is Co-Chair of the NIH Brain Initiative and has participated in many other NIH research initiatives. As the new Director of NINDS, Dr. Koroshetz will oversee an annual budget of $1.6 billion and 1,141 scientists, physician-scientists and research administrators. The institute supports research in public and private institutions across the country, as well as by scientists working in its intramural laboratories. Dr. Koroshetz became the NINDS Deputy Director in 2007 and prior to that he was Professor of Neurology and Vice Chair of Neurology at Harvard and MGH. He was also Director of Stroke and NeuroIntensive Care. Dr. Koroshetz graduated from Georgetown and received his MD from the University of Chicago.

OFFICE OF REGULATORY COMPLIANCE - CONFLICT OF INTEREST

UCD 2015 Conflict Of Interest Disclosure Collection

The 2015 Conflict of Interest Disclosure collection period will commence on Monday, August 17, 2015. You can access the disclosure form at https://era.cu.edu. Detailed instructions for completion of your disclosure can be found on the COI website. For more information on these regulations, please see the Office of Regulatory Compliance-Conflict of Interest website at: http://ucdenver.edu/academics/research/AboutUs/regcomp/conflictofinterest/Pages/default.aspx

Please complete your 2015 COI disclosure as soon as possible. If you have a current COI disclosure on file, it will need to be updated on or after August 17, 2015 until you have updated your COI Disclosure for 2015, you will not be able to:

- Submit a PHS or NSF grant or receive approval of a PHS or NSF human subjects protocol
- Obtain approval for a new protocol or continuing review, when receiving minor modifications to renew your COI Disclosure.

Questions? Please contact the Office of Regulatory Compliance at COI@ucdenver.edu, (303) 724-0034.

REMINDER: Annual COI Disclosures must be submitted by October 31, 2015.
**RESEARCH CORNER**

Heather Lynn Johnson, Ph.D., is an Assistant Professor of Mathematics Education in the School of Education and Human Development. She earned her Ph.D. from The Pennsylvania State University in 2010. Forming and interpreting relationships between changing quantities (covariational reasoning)—a fundamental form of mathematical reasoning extends across mathematics, science, and social science. Despite covariational reasoning being essential for secondary students, little is known about its development.

In Johnson’s research, she has worked to address this problem. In particular, she has focused her investigation on students’ reasoning about quantities that covary, or change together. For example, imagine filling a water bottle from a filling station, such that the water is being dispensed at a constant rate. As a bottle fills with water, both the height and volume of the water in the bottle are changing. How might the height of the water in a tall, narrow bottle or a short, wide bottle change as the bottle fills with water? To make sense of this question, a student would need to conceive of the volume of water in the bottle as changing together with the height of the water in the bottle, or engage in covariational reasoning.

Johnson has found two distinct ways in which students form and interpret relationships between quantities—comparison and coordination. Students who compare amounts of change in quantities focus on how much change has occurred (e.g., there is “more” height than volume). In contrast, students who coordinate amounts of change in quantities can reason about quantities as continually changing (e.g., as the height increases, volume increases more slowly). It is coordination—not comparison—that fosters powerful covariational reasoning that can unlock doors for student success in gatekeeping courses such as algebra and calculus.

**OFFICE OF RESEARCH DEVELOPMENT AND EDUCATION (ORDE)**

Updated Pilot Project Funding E-Book

ORDE has updated our Pilot Project Funding E-Book, detailing both federal and private sponsor offerings for investigators seeking pilot project or seed grant funding. Opportunities covered represent many disciplines across the University. Information provided includes sponsor interests, eligibility criteria, maximum awards/award timeframes and links to sponsor websites. This new resource is available on the ORDE Funding webpage at http://www.ucdenver.edu/ACADEMICS/RESEARCH/ABOUTUS/ORDE/FUNDING/Pages/funding.aspx.

**CCTSI PILOT GRANT PROGRAM ANNOUNCEMENT**

The Colorado Clinical and Translational Sciences Institute (CCTSI) is proud to announce release of Request for Application (RFAs) for grants from the Colorado "CO-Pilot" Program, Center for NeuroScience "CNS-Pilot" Program, and Child and Maternal Health "CMH-Pilot" Program. These CCTSI Pilot Grant Programs will provide ~$1,000,000 in grants for translational research.

**Complete Program Information including RFAs, Resources and Application links can be accessed from the CCTSI Funding Opportunities website.**

**Key Dates:**

Online Mandatory Letter of Intent Submission: Jul 1, 2015 - Aug 17, 2015 5:00pm MDT

Online Application Submission: Aug 19, 2015 - Sept 14, 2015 5:00pm MDT

**Informational Call Dates:**

Applicants are encouraged to participate in a series of informational calls for the CO-Pilot and CNS-Pilot programs. Applicants may participate by calling 1-866-210-1669, passcode 8120669. Calls may end early if all questions are addressed.

- Call #1: Wednesday July 29th, 2-4pm
- Call #2: Thursday August 13th, 1-3pm
- Call #3: Wednesday September 2nd, 10-12noon

**Colorado "CO-Pilot" Program**

- CO-Pilot grants for clinical and translational research.
- Awards from $30,000-$100,000 made in Mentored, Junior, Independent, CSU/CU Collaboration, and Team Science categories.
- **CO-Pilot Program Contact:** Sandy Chalmers, 720-848-7797 or sandra.chalmers@ucdenver.edu

**Center for NeuroScience "CNS-Pilot" Program**

- CNS-Pilot grants from Center for NeuroScience (CNS) for translational neuroscience research.
- Awards from $30,000-$100,000 made in Translational Independent, Translational Team Science, Basic Research Independent, and Basic Research Team Science categories.
- **CNS-Pilot Program Contact:** Sandy Chalmers, 720-848-7797 or sandra.chalmers@ucdenver.edu

**Child and Maternal Health "CMH-Pilot" Program**

- CMH-Pilot grants for clinical and translational research focused on Child and Maternal Health.
- Awards of $20,000 made in Mentored and Junior categories.
- **CMH Pilot Program Contact:** Bonnie Savone, 303-724-1602 or bonnie.savone@ucdenver.edu