July 2014 Newsletter

Announcing the newest addition to the CTSC Regulatory Knowledge Support Core! The IND/IDE Regulatory Support Core

Through the CTSC, the IND/IDE Regulatory Support Core is an efficient, comprehensive, and standardized resource that exists to aid investigators during all phases of their protocol life cycle. By reaching sponsor-investigators early in the process of their FDA submission, sponsor-investigators will benefit from the comprehensive services available through the Core:

For more information, contact:
Jenna Stump, FDA Regulatory Specialist: (216) 286-0754
Carolyn Apperson-Hansen, CTSC Research Concierge: (216) 368-0035

Have FDA related Questions? Email the Core: ctsc-ind-ide-support-core@case.edu

News

Announcing the Appointment of Dr. Wilson Tang as the Director of the Cleveland Clinic Clinical Research Unit
W.H. Wilson Tang, MD is appointed as Director of the Cleveland Clinic CRU. Dr. Tang is a heart/failure transplant cardiologist at Heart and Vascular Institute and a physician-scientist at the Lerner Research Institute. He is also the co-Director of the CTSC Pilot Grant Program and the Chair of Cleveland Clinic’s Research Programs Committee.

Lara Jehi, MD is appointed as Associate Director of the Cleveland Clinic CRU. She is board-certified in neurology and clinical neurophysiology. She is currently leading efforts to broaden the spectrum of epilepsy management at the Cleveland Clinic Epilepsy Center to include social, psychological, and quality of life aspects.

Katherine Dell, MD is appointed as Associate Director of Pediatrics for the Cleveland Clinic CRU. She is certified in pediatrics and pediatric nephrology, with special focus on inherited kidney diseases, polycystic kidney disease, and congenital kidney malformations. She is currently appointed at the Cleveland Clinic Center for Pediatric Nephrology. Her role will be to expand the pediatric research studies within the CRU.

Ohio Clinical Trials Collaborative Launches at BIO2014, Accelerating Pharmaceutical Innovation in Ohio
Industry Gains Access to Ohio’s Medical Institutions through Single Point of Contact

The Ohio Clinical Trials Collaborative (OCTC) held its market launch at BIO2014 in San Diego, providing pharmaceutical and medical device companies centralized access to Ohio’s premier medical schools and affiliated entities for clinical trial development.

The OCTC streamlines the contracting, budgeting, approval of human subject use and patient recruitment/enrollment processes so medical discoveries can move to market faster. With financial support from the State of Ohio, its founding members are Case Western Reserve University, The Ohio State University and University of Cincinnati.

“"The OCTC will establish Ohio as one of the most efficient and effective states in which to develop new medicines and treatment strategies. Ohio is the only state that has three National Institutes of Health Clinical and Translational Science Awards centers. This concentration of excellence in a single state provides the opportunity to access an exceptionally strong research and clinical trials network to support the pharmaceutical, biotechnology and medical device industries’ development requirements," said James Chmiele, MD, Chief Executive and Director of the OCTC.”
John Peterson, PhD, Global Business Development Director of the OCTC, stated, “We are pleased to launch the OCTC onto the global stage at BIO2014. Biopharmaceutical companies and clinical research organizations now can access our statewide network of premier translational science centers, hospitals, clinical investigators and patient populations through a single contact point.”

Learn more about the OCTC.

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**Aziz to Chair Neuroscience Initiative for Ohio Clinical Trials Collaborative**

**Working Group Will Advance New Treatments for Patients Suffering From Neurological Disorders**

The Ohio Clinical Trials Collaborative (OCTC) announces the appointment of Dina Aziz, MSHS, CCRP, as Chair of its Neuroscience Working Group. Aziz is the Director of Research of the Neuroscience Program at The Ohio State University (OSU) Wexner Medical Center.

"The impact of neurological disorders is far-reaching, encompassing over 1,000 disorders of the brain and nervous system, and affecting over one billion individuals worldwide. New technologies and therapies are greatly needed to treat these disorders. I am honored to be given the opportunity to lead this statewide initiative in neuroscience clinical trials for the OCTC," said Aziz.

The OCTC provides centralized access to Ohio’s premier medical centers for clinical trial development. The pharmaceutical industry faces a challenging and expensive process for conduct of clinical trials. The OCTC streamlines the contracting, budgeting, approval of human subject use and patient recruitment/enrollment processes to move medical discoveries to market faster.

"The OCTC will establish Ohio as one of the most efficient and effective states in which to develop new medicines and treatment strategies. Neurosciences are a broad disease area of growing need where we look to support industry-sponsored clinical trials," said James Chmiel, MD, MPH, Chief Executive and Director of the OCTC.

Read this article on [Business Wire](https://www.businesswire.com).

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**NIH Public Access Policy**

**Watch for notifications on manuscripts published by Elsevier!**

The Cleveland Health Sciences Library is continuing to work with investigators and publishers to improve our institutional compliance with the National Institutes of Health (NIH) Public Access Policy.

NIH will delay processing of awards if publications arising from the grant are not in compliance with the policy. Currently, CWRU has 919 articles that are not fully compliant with the NIH Public Access Policy. Our institutional compliance rate is 86%.

Elsevier recently uploaded over 150 manuscripts to the NIH Manuscript Submission System (NIHMS) for CWRU researchers. The corresponding author should receive an email requesting that he/she login to NIHMS with the NIH/eRA Commons login to approve the initial submission. The PI of the project will also receive a notification.

Manuscripts submitted to NIHMS by publishers require two approvals by the PI or author. The first is approval of the submitted materials. The second is the approval of the final PubMed Central web version of the manuscript. There may be as much as a six to seven week interval between notifications that the approvals are required. Investigators will be sent notifications for each request for approval.

We encourage researchers to contact the representatives from the Cleveland Health Sciences Library with any questions about notifications you receive. Representatives are also available to conduct training sessions for departments or groups. For more information on training sessions or individual assistance, please contact Kathleen Blazar, MSLS, Interim Director, at (216) 368-1361 or kcb2@case.edu.

The [NIHMS System User’s Guide to Submitting a Manuscript](https://www.nihms.nih.gov) is also available online.

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**The PRCHN receives 5-year grant renewal from the CDC!**

Congratulations to the Prevention Research Center for Healthy Neighborhoods and its director,
Congratulations to the Prevention Research Center for Healthy Neighborhoods and its director, Elaine Borawski, PhD, for the 5-year grant renewal from the Centers for Disease Control!

The PRCHN is one of only 26 such centers competitively funded by the CDC across the country. The PRCHN’s research in nutritious food access, tobacco prevention and multi-level strategies for reducing childhood obesity have gained national attention. Their health data surveillance systems are just as impressive. The center is a proud example of how Cleveland partnerships enhance our ability to support local organizations and implement health prevention research strategies.

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**Congratulations to our April 2014 Pilot Awardees!**

Join us in congratulating the April 2014 CTSC Core Utilization Pilot Award recipients!

**Reshmi Parameswaran, PhD**
Case Western Reserve University School of Medicine
"Ex-vivo expansion of human Natural Killer cells for cancer therapy"

**Joseph Piktel, MD**
MetroHealth Medical Center
"Determining the effect of therapeutic hypothermia on connexin 43 phosphorylation during acute ischemia"

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**Research Highlights**

**Dr. Sangeeta Kashyap: NIDDK Award**

Congratulations to Sangeeta Kashyap, MD, a former KL2 Scholar from our first cohort of scholars, for receiving a subaward for a NIDDK U01 grant for her study, *Vitamin D for Type 2 Diabetes Prevention*. The total grant will be over $1.4 Million for 4 years.

The aim of the Vitamin D and type 2 diabetes (D2d) study is to define whether vitamin D supplementation is safe and effective in delaying the onset of type 2 diabetes in people at risk for the disease and to gain insight into how vitamin D affects glucose metabolism.

There are over 79 million Americans who are at increased risk for developing type 2 diabetes. Lifestyle changes, such as healthy eating, exercise and weight loss, can decrease the chances of developing diabetes. However, many people still develop diabetes despite efforts at changing their lifestyle. Therefore, there is a continued need for the identification of modifiable risk factors and interventions that are safe, inexpensive and easy to implement to prevent type 2 diabetes and decrease disease burden. Based on recently published studies, vitamin D has emerged as a potential determinant of type 2 diabetes risk as it regulates inflammation and glucose metabolism in animal modes. However, according to reports by the Institute of Medicine and the Endocrine Society, the evidence to support vitamin D supplementation for prevention of diabetes is inconclusive and there is a need for definite studies in this area, such as the D2d study.

The D2d study is a large multi-center clinical trial conducted in twenty cities around the United States. The D2d study will enroll approximately 2,400 participants who are at risk of developing type 2 diabetes. Participants are randomly assigned to receive either vitamin D or placebo and be followed for up to 4 years for development of diabetes. The D2d study is expected to define the role of vitamin D supplementation in modifying diabetes risk in people at risk for the disease. The Cleveland Clinic site is responsible for recruiting and following 100 subjects at risk for diabetes.

Please join us in congratulating Dr. Kashyap on her success.

**Anant Madabhushi and team awarded V Foundation Translational Research Grant**

Anant Madabhushi, associate professor of biomedical engineering, and his team were awarded a grant from The V Foundation for Cancer Research for $41,727. Their submission was titled "Use of PET and MR Imaging Biomarkers to Predict Response of Renal Cell Carcinoma to Tyrosine Kinase Inhibitor Therapy."

Madabhushi and his team will be developing computerized analytic tools to fuse PET and MRI to find image markers of early treatment response for renal cell cancers.

via The Daily

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**Events**

**PRCHN Seminar Series: Susan Flocke, PhD**
Wednesday, July 9th 2014, 12:00-1:15pm

How prepared are Ohio medical residents to address obesity, nutrition and physical activity counseling with patients?

Susan Flocke, PhD is an Associate Director at the PRCHN, and an Associate Professor in the Department of Family Medicine at CWRU School of Medicine. Her research interests include preventive service delivery in the primary care setting, doctor-patient communication of health behavior change and utilization of community resources to facilitate behavior change.

This presentation will highlight both the opportunities and challenges of addressing weight management in the primary care context. The talk will specifically discuss the findings from an Ohio-based survey of senior medical residents and an audit of 25 training programs regarding the preparation of the next generation of primary care clinicians to provide obesity counseling.

Find out more about this and future PRCHN Seminars.

Research Opportunities

KL2 Career Development Program 2015
Recruiting Period: July 1 - October 27, 2014

Congratulations to the following, who were selected from a highly competitive pool of applicants, as clinical scholars within the Clinical & Translational Science Collaborative (CTSC) KL2 career development program starting July 1, 2014:

Yong Chen, PhD (Radiology, CWRU)
Glen Taksler, PhD (Medicine, CCF)
Kathy Wright, PhD (Nursing, CWRU Frances Payne Bolton School of Nursing)
Jennifer Yu, MD, PhD (Radiation Oncology, Stem Cell Biology, CCF)

Applications are now being accepted for next year’s awardees, who would begin July 1, 2015.

Qualified candidates are being offered an opportunity to apply to an innovative career development program whose purpose is to train clinician investigators. The CTSC KL2 is designed to train the nation's future leaders in clinical and translational research, and is part of the NIH Roadmap aimed at "re-engineering the clinical research enterprise." Each scholar will embark on a 4 year program of intensive training in multidisciplinary team-based, patient-oriented clinical research, combining an innovative curriculum with mentored research experiences.

Qualified candidates:

- Hold an M.D., Ph.D., D.D.S., Pharm.D., Psy.D. or an equivalent degree
- Have demonstrated a keen interest in clinical research
- Need to hold a position in one of the CTSC partner Institutions on or before July 1, 2015
- Are U.S. citizens or have permanent resident status

Applications are encouraged from physicians, nurses, dentists, social and behavioral scientists, engineers, biostatisticians, epidemiologists, bioethicists and other professionals with expertise relevant to clinical research.

Successful applicants will receive a comprehensive package including:

- Salary and benefits commensurate with their qualifications supporting 75% effort
- Research stipend
- Tuition benefits for an innovative didactic program leading to a degree in clinical investigation (half of which will come from a Departmental cost-share)
- Travel funds
- Access to a multidisciplinary pool of highly accomplished mentors who will guide their research projects
- CWRU appointment

The competitive applicant will be at an early career stage, e.g. senior postdoctoral fellow, instructor, or entry level faculty member, and will need to explain through the application how the program will enable a successful career in clinical research.

We are especially seeking qualified applicants from under represented populations.

For questions or assistance, please contact Beth Spyke, MPA at spykeb@ccf.org or 216-
The Clinical and Translational Science Collaborative (CTSC) of Cleveland provides developmental, organizational, financial, and educational support to biomedical researchers as well as opportunities for community members to participate in meaningful and valuable research.

**CTSC KL2 Upcoming Informational Meetings (reservations requested):**

**Cleveland Clinic**
September 10, 2014  
2:00 p.m. - 3:00 p.m.  
Crile Building A8-800

**Case Western Reserve University**
September 11, 2014  
8:00 a.m. - 9:00 a.m.  
Wolstein Research Building, Room 1403

**MetroHealth Medical Center**
September 17, 2014  
3:00 p.m. - 4:00 p.m.  
Rammelkamp 219

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**National Institutes of Health (NIH)**

Faculty members who are working on a National Institutes of Health (NIH) Career Development K or R grant proposals and need additional support, are invited to apply for the 2014 Grant Writers Coaching Group for NIH Awards, being held September 5, 2014 in Vancouver. This one-day workshop (followed by three months of optional online sessions and support) is designed to provide practical knowledge, skills, and one-on-one guidance to submit a competitive proposal.

The application submission deadline is **July 10**.

For more information visit the [workshop website](#).

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**The Searle Scholars Program**

Key Deadlines: July 14, 2014, 5:00pm (CWRU internal application), September 26, 2014 (external application).

Case Western Reserve University is invited to submit applications for the 2015 Searle Scholar Program competition.

The Searle Scholars Program supports research of outstanding individuals who have recently begun their appointment at the assistant professor level, and whose appointment is their first tenure-track position at a participating academic or research institution. Today, 153 institutions are invited to participate in the Program.

The Program was established at The Chicago Community Trust in 1980 and has been administered by Kinship Foundation since 1996. The Program is funded from the estates of Mr. and Mrs. John G. Searle, Mr. Searle was the grandson of the founder of the world-wide pharmaceutical company, G.D. Searle & Company. It was Mr. Searle’s wish that certain funds be used to support "...research in medicine, chemistry, and the biological sciences."

Each year 15 new individuals are named Searle Scholars. Awards are currently set at $100,000 per year for three years. Since its inception, 527 Scholars have been named and over $111 million has been awarded.

Number of Applications Allowed: Two (see internal selection requirements below)

Amount of Funding: $100,000 per year for 3 years ($300,000 total)

For more information on this limited submission opportunity, visit the [Office of Research Administration website](#).

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**Patient-Centered Outcomes Research Institute (PCORI)**

PCORI has announced its' upcoming funding opportunities. The application system will open Wednesday, August 6 for the Fall 2014 PCORI Funding Announcements.

Visit the [PCORI website](#) for more information on the funding announcements.
The NCI is pleased to announce the Outstanding Investigator Award (OIA) funding opportunity announcement: PAR-14-267. The OIA will support investigators with outstanding records of productivity in cancer research with up to $600,000 in direct costs per year for 7 years to provide funding stability. NCI anticipates making about 50 awards annually.

The OIA will allow funded investigators the freedom to embark on long-term projects of unusual potential in cancer research; the opportunity to take greater risks and be more adventurous in their lines of inquiry; and sufficient time to develop new techniques.

Applications must be submitted by Institutions who have nominated a Program Director/Principal Investigator (PD/PI) with outstanding productivity in cancer research as a recipient of NCI grant(s) for at least the past 5 years. The PD/PI will be expected to commit at least 50% of his/her research activities to the OIA; the Institution will be expected to commit at least 20% salary support.

For more information, please see: PAR-14-267 on the NCI website.