In 2012, the NIH contracted with the Institute of Medicine (IOM) to conduct a study to assess and provide recommendations on appropriateness of the CTSA Program's mission and strategic goals and whether changes were needed. The study would also address the implementation of the program by the National Center for Advancing Translational Sciences (NCATS) while exploring the CTSA's contributions in the acceleration of the development of new therapeutics. A 13-member committee was established to head this task; the committee had collective expertise in community outreach and engagement, public health and health policy, bioethics, education and training, pharmaceutical research and development, program evaluation, clinical and biomedical research, and child health research.

This past June, the IOM issued a 179-page report that applauded the aims and outcomes of the CTSA program. "The CTSA Program has made some remarkable progress to date and has great potential to further advance clinical and translational science and improve human health," the review committee noted. "We look forward to seeing this potential fully realized in the coming years."

Launched in 2006, the CTSA program seeks to advance laboratory breakthroughs into solutions for patients. Institutional CTSA awards are its centerpiece, providing academic homes for translational sciences and supporting research resources needed to improve the quality and efficiency of all phases of translational research. Each institution that receives a grant determines how best to coordinate and collaborate to meet their respective goals.
The program has made awards to 61 academic health centers across the country, including our Clinical and Translational Science Collaborative (CTSC) in the School of Medicine at Case Western Reserve. Our CTSC was awarded in 2007; at the time, the $64 million award stood as the largest-ever in Northeast Ohio.

For the past six years, the medical school has worked with its partner institutions, which include Cleveland Clinic, MetroHealth System, University Hospitals Case Medical Center and Louis Stokes Cleveland VA Medical Center, under the CTSC of Cleveland. In 2012, the NIH renewed our grant, this time increasing the amount to $64.6 million.

Some of the most significant successes that contributed to the grant renewal were agreements among institutions that enable scientists and physicians to pursue research more easily across multiple hospitals and health care centers-enhancing the size and diversity of potential patient pools. Such cooperation also involved significant technological investments to enable systems at different sites to work together in more seamless ways. Finally, this spirit of teamwork extended to community organizations as well. The partners together launched nearly a dozen networks aimed at addressing key community health challenges, among them obesity, diabetes and hypertension. The award not only enabled neighborhood-based research, but also provided training to scientists, physicians and community leaders about ways they could work together more effectively to improve the health of residents.

In addition to praising the CTSA program, the IOM report made several recommendations for the program's governance and expansion. Some of the suggestions involve activities the medical school already pursues, such as an emphasis on child health and active community engagement.

The IOM's recommendations are particularly encouraging for our CTSC. One of the foundational beliefs at the School of Medicine is our desire to reach out to the community, and our pediatric research remains at the forefront of medical inquiry.

Click here to read the full analysis of The CTSA Program at NIH.

James F. Chmiel, MD, MPH
Meet the New Director and Chief Executive of the Ohio Clinical Trials Collaborative

We are pleased to announce the appointment of James Chmiel, M.D., as Medical Director and Chief Executive of Case Western Reserve University's Ohio Clinical Trials Collaborative (OCTC).

The OCTC is a new statewide model comprised of Ohio's 3-Clinical and Translational Science Awards (CTSA) - Clinical and Translational Science Collaborative (CTSC) of Cleveland, The Ohio State University Center for Clinical and Translational Science, and the University of Cincinnati Center for Clinical and Translational Science and Training - that initiated discussions to develop this concept statewide. In addition to the 3 CTSA sites, partners in the agreement include: Cincinnati Children's Hospital Medical Center, Cleveland Clinic, MetroHealth Medical Center, Nationwide Children's Hospital, and University Hospitals Case Medical Center.

This partnership with the State of Ohio will contribute to the success of the Governor's vision for a statewide Medical Corridor. The State of Ohio's nearly $2
A million investment will launch a new clinical trials initiative designed to capitalize on the strength of numbers. The program draws on the reach and expertise of the aforementioned academic institutions and medical centers. The OCTC offers economies of scale and unique capacity, leveraging expertise to facilitate clinical trial efforts across the state. The establishment of a robust clinical trials structure across Ohio will facilitate access to and accelerate performance of trials available through commercial Clinical Research Organizations, the pharmaceutical industry, and government agencies.

Dr. James F. Chmiel received his M.D. and M.P.H. in Epidemiology in 1991 from the University of Michigan. He worked as a resident in Pediatrics in Children’s Memorial Hospital in Chicago until 1994. Dr. Chmiel then joined the Pediatrics Pulmonology group at Case Western Reserve as a fellow from 1995-1998, and became an Instructor and then Assistant Professor of Pediatrics in 2001. In 2008, he was promoted to Associate Professor and served as Interim Chief of the Division of Pediatric Pulmonology and Allergy/Immunology and Director of the Leroy W. Matthews Cystic Fibrosis Center at Rainbow Babies and Children’s Hospital. He became Fellowship Program Director in 2001, the Associate Director of the LeRoy W. Matthews Cystic Fibrosis Center Center in 2004, and the Director of Clinical Affairs in 2007.

Jim Chmiel's research involves understanding the inflammatory response of the lung, particularly as it relates to asthma and cystic fibrosis and the impact of anti-inflammatory therapeutics upon this response. Dr. Chmiel participates in both basic science and clinical research projects. His basic science research focuses on studying the link between the mutant cystic fibrosis gene in bone-marrow-derived cells and the development of the pulmonary inflammatory response in cell culture and animal models. Dr. Chmiel participates in both independent and multi-center clinical trials. Dr. Chmiel is a Co-Investigator in the National Institute of Allergy and Infectious Diseases Inner City Asthma Consortium. In addition, Dr. Chmiel is currently interested in evaluating outcome measures for measuring the inflammatory response in CF patients. Studies are underway evaluating the utility of induced sputum, infant pulmonary function tests, and bronchoscopy with bronchoalveolar lavage as methods of characterizing the patient’s response to anti-inflammatory medications, such as ibuprofen and simvastatin. The ultimate goal of all of these studies is to develop safer, more effective anti-inflammatory therapeutics for the treatment of asthma and CF lung disease.

As an established clinician and researcher, Dr. Chmiel is no stranger to the challenges and requirements of research. He is a dedicated and enthusiastic doctor, as well as an active and experienced investigator who is well suited to lead the OCTC.

Please join us in welcoming Dr. Chmiel to this new role!

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CWRU and the Cleveland Clinic Partner on New Medical Education Building

Case Western School of Medicine would like to share news of an exciting collaboration between Case Western Reserve and the Cleveland Clinic. The boards of both organizations have voted unanimously to construct a state-of-the-art medical education building for students in the medical school's original university track and its Cleveland Clinic Lerner College of Medicine track.

The $80 million structure will be jointly owned and operated. Estimated to be about 165,000 square feet, it will be located on an 11-acre parcel between Euclid and Chester Avenues and 93rd and 100th Streets. It will include lecture halls, seminar rooms, simulation facilities, anatomy labs and extensive open common space.

The Cleveland Clinic is providing the land for the structure and paying all design and site preparation expenses. The Clinic also has agreed to match the dollars Case Western Reserve has raised for its medical education building to date, up to $25 million. Finally, these institutions will fundraise jointly for the project, and share costs of its construction and operation.

Last fall plans were announced for a building on the West Campus for the university track alone. The opportunity to partner with the Clinic on a structure that brings the two programs together provides extraordinary opportunities to exchange pedagogical ideas and explore potential synergies, and also allows us to achieve significant economies of scale. These advantages - coupled with the accompanying enhancements of our medical school and the way it is perceived nationwide - translate to a boon for both organizations and our partners across the region. Beyond its academic benefits, the building also is expected to contribute to the ongoing economic revival of the Upper Chester neighborhood.

The new building will provide students a unified location for the classroom and laboratory learning that takes place primarily during the first two years of medical school. Clinical rotations, where students spend several weeks at a time learning about different medical specialties, would continue as they do today at all of CWRU's hospital affiliates.

Case Western Reserve University President, Barbara R. Snyder, and Cleveland Clinic Chief Executive Officer, Toby M. Cosgrove, MD, jointly believe that this shared educational space will increase opportunities for students and faculty from both tracks to interact and learn from one another. While each track will continue to have its own individual identity and academic offerings, it is expected for both to borrow and adapt some of the best ideas they observe-and also to develop new initiatives through the conversations proximity encourages. In addition, this collaboration hopes to build on shared strengths in areas like international education and medical humanities.

Both Case Western Reserve and the Clinic have additional partnerships with one another and with other organizations, and these will continue. Case Western Reserve's primary affiliation with University Hospitals Case Medical Center also remains in place, as do cooperative arrangements with the Clinic, University Hospitals Health System, MetroHealth Medical Center and the Louis Stokes VA Medical Center. Ultimately it is believed that this will enhance medical education benefits for all of our partners, and the city as a whole. Cleveland already is recognized as a global hub for health care; this collaboration has the potential to make our region just as internationally renowned for medical education.
Case Western also emphasizes a commitment to developing the West Campus. Fundraising continues for The Milton and Tamar Maltz Performing Arts Center at The Temple Tifereth - Israel, and we are excited about conversations with the Cleveland Museum of Art regarding a potential pathway from our main campus to the performing arts center. The 14 acres of the West Campus remain’s CWRU's only significant area for expansion, and will receive intense focus as the campus master planning process is launched this fall.

Additional details of the project will be eagerly shared as they emerge. For now, please click here to learn more about the project and see two preliminary conceptual drawings.

KL2 Scholar Highlights & Successes

Melissa D. Pinto, R.N., Ph.D., (KL2 2009 Cohort), was invited to the White House to present her research at the Behavioral Health IT Innovations Conference in Substance Abuse and Mental Health Treatment. The Office of National Drug Control Policy (ONDCP) is collaborating with the Substance Abuse and Mental Health Services Administration (SAMHSA), the Office of the National Coordinator for Health IT (ONC) and the National Institutes of Health (NIH) to host a Technology Innovations for Substance Use and Mental Health Disorders Conference to be held September 16th, 2013 in Washington, D.C. The conference will promote the dissemination of innovative, evidence-based technologies to advance substance use disorder and mental health treatment and will include a panel on the future of Health IT for behavioral health. Congratulations, Melissa!

The CTSC Research Education & Training Reception was held on May 14, 2013 from 6:00-8:00pm at the Foundation House. This annual reception honors both the KL2 & TL1 programs. At the May 14th event, Dr. Rudick acknowledged both outgoing and incoming KL2 scholars, mentors and advisory board members and Dr. Harding welcomed the TL1 trainees. The reception is a great night for sharing successes, making connections and celebrating the CTSC Research Education & Training endeavors. Photos from the event are below.

Left to Right: Robert Bonomo, MD; Robin Jump, MD, PhD; Curtis Donskey, MD; Dave Aron, MD, MS; Patricia Higgins, RN, PhD, FGSA; Federico Perez, MD.
Recruitment for 2014 CTSC KL2 Scholars

A Message from Dr. Richard Rudick:
Clinical Research Career Development Opportunity

On behalf of the Clinical and Translational Science Collaborative (CTSC) KL2, a post-doctoral training program with an emphasis on multidisciplinary clinical and translational research, I am writing to invite you to identify outstanding candidates who would benefit from our program. 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."

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 an appointment in one of the Departments in the University or medical centers
• 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:

• CWRU appointment
• Salary and benefits commensurate with their qualifications supporting 75% effort (surgeons may commit 50%)
• 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

The CTSC KL2 has just welcomed its ninth cohort of scholars and is now seeking applications for the tenth cohort (Deadline: October 31, 2013). At this time, we expect to fill Clinical Research Scholar positions beginning the program in July 2014. 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. 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 the ways in which the program will lead to a successful career in clinical research.

We are especially seeking qualified applicants from underrepresented populations.

Please visit our website for more information.

For questions or assistance, please contact Beth Spyke, MPA at spykeb@ccf.org or call at 216-444-2702.

Ohio-led team takes on premature birth through March of Dimes Prematurity Research Center

Case Western Reserve University School of Medicine is leading a Northeast Ohio team that is part of a $10 million March of Dimes project to help prevent preterm births. Greater Cleveland's participants include University Hospitals MacDonald Women's Hospital and Rainbow Babies & Children's Hospital and MetroHealth Medical Center, with additional teams in Cincinnati and Columbus along with researchers across the country.

"The strength of the collaboration is that it brings together talented researchers with diverse expertise who share a common commitment," said Sam Mesiano, an associate professor of reproductive biology at Case Western Reserve University. Mesiano is the co-director of the research division at UH MacDonald's Women's Hospital and will be the site director the Northeast Ohio portion of the project.
"The promise of this work and the people involved are truly inspiring," he said. Initially, the Ohio Collaborative will focus on five investigatory aims:

- Evolution of human pregnancy
- Genetics of unique human populations
- The molecular developmental biology of pregnancy
- Progesterone signaling in pregnancy maintenance and preterm birth
- Sociobiology of racial disparities in preterm birth

For the past 75 years, March of Dimes' dedication to pregnancy, as well as infant and child health, has helped calm the fears of countless families. It has been a leading contributor to significant research that prevents birth defects, childhood mortality and premature birth. But, as expectant parents are quick to realize, not all risks are well known and not all problems have clear causes.

"March of Dimes Prematurity Research Center-Ohio Collaborative is a unique research enterprise," said Jennifer L. Howse, president of March of Dimes. "This new transdisciplinary, team-based research model will leverage the expertise of leading scientists here in Ohio to discover breakthroughs in our understanding of premature birth. Extraordinary research requires extraordinary funding, and we are very grateful to the leadership of the GE Foundation for awarding the program's first grant for $200,000."

In 2003, March of Dimes launched its Prematurity Campaign to prevent premature, or preterm, births-babies born before 37 weeks. Preterm birth is one of the leading causes of infant death around the world. It is extremely difficult to prevent and predict because half of them have no obvious cause.

Every year, 15 million babies are born prematurely across the world. Half a million of those births-the highest rate of any developed nation-occur in the United States. And in Ohio alone, premature births total more than 17,000 a year.

These babies often suffer from respiratory difficulties, underdeveloped organs, cerebral palsy, and developmental and learning disabilities. They have higher rates of infection, hospitalization, and long-term health problems than babies carried to full-term.

This project aims to identify causes of preterm birth and also develop multiple approaches to preventing it. Other Ohio participants include the University of Cincinnati College Of Medicine and Cincinnati Children's Hospital Medical Center and The Ohio State University Wexner Medical Center and Nationwide Children's Hospital, Columbus.

"This new research approach has assembled creative, accomplished and dedicated scientists to work together to generate innovative strategies to transform our understanding of causes of prematurity and use this knowledge to enhance obstetrical care and infant outcomes for Ohio and its residents," said Louis Muglia, co-director, Perinatal Institute, Cincinnati Children's Hospital Medical Center, and coordinating principal investigator for the new collaborative. "Too many babies, here in Ohio and throughout the United States, are born too soon, and this program will help prevent that."

Each participating facility brings its own strengths and expertise to the discussion. Teams and researchers will share ideas and information from diverse academic backgrounds to develop new ideas and evidence-based therapies and prevention. Mark Chance, the vice dean for research at the Case Western Reserve University School of Medicine, is also excited for the opportunity to participate in the
"Rather than all work in our contained silos," he explained, "we are collaborating on every step of the project . . . We talk a lot these days about 'team science' and this project exemplifies the very highest and best meaning of the phrase."

Also included in the collaborations are Vanderbilt University, Dartmouth College, the University of Iowa and Washington University in St. Louis. The various institutions will all be responsible for contributing to an explanation of the biology of birth timing and the hidden origins of preterm birth. By combining their efforts, March of Dimes Prematurity Research Center-Ohio Collaborative hopes to develop prevention for preterm birth and allow all pregnancies to advance full term.