Director’s Update
by Jasjit S. Ahlawalia, M.D., M.P.H., M.S.
Executive Director

I am pleased and excited to announce that during the week of November 26, the Office of Clinical Research (OCR) moved into its new space on the first and second floors of 717 Delaware St. S.E. Our 30,000 square feet of newly renovated space truly shows the University’s commitment to the clinical and translational research enterprise.

We have allocated 10,000 square feet of space on the first floor for Academic Health Center faculty and postdoctoral fellow offices, including the Medical School’s Program in Health Disparities Research, the Department of Medicine’s Applied Clinical Research Program, and several CAPS scholars. The west side of the second floor is a new 10,000 square foot outpatient clinical research facility outfitted with state-of-the-art equipment. The space includes 10 exam rooms; a child-friendly waiting room; metabolic kitchen and dining room; 6 procedure rooms; workspace for investigators, coordinators, and clinical trial monitors; and, conference room. The 10,000 square feet on the east end houses OCR operations and leadership staff, including Research Services Organization, the Biostatistics, Design, and Analysis Center (BDAC), and a number of General Clinical Research Center staff. Twenty parking spaces adjacent to the building have been allocated for research participants.

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The University’s clinical research enterprise is expanding its global reach through a strategic relationship with the Indian Council of Medical Research (ICMR), an organization similar to the NIH. In October, Senior Vice President for Health Sciences Frank Cerra led a University contingent to New Delhi, India to discuss potential areas of collaboration among U of M and Indian researchers. Presentations at this joint scientific symposium focused on cancer, diabetes, cardiovascular health, and infectious disease and immunology. These discussions resulted in a call for joint proposals for ICMR and University collaboration.

The ICMR seeks to enhance its international interactions, recognizing that improved health status will drive development efforts within the country, stated

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**NEWS**

**Call for applications: 2008 NIH Director’s Pioneer and New Innovator Award Programs**, which “support exceptionally creative scientists who take highly innovative—and often unconventional—approaches to major challenges in biomedical or behavioral research.” Pioneer Awards provide $2.5 million in direct costs over five years and are open to researchers at any stage of their careers; new investigators who have not received an NIH R01 or similar grant are eligible for New Innovator Awards, which provide $1.5 million in direct costs over five years. Pioneer Award applications will be accepted from December 16, 2007, to January 16, 2008. The New Innovator Award application period is from March 3 to 31, 2008. For more information on Pioneer Awards, go to: grants.nih.gov/grants/guide/rfa-files/RFA-RM-08-013.html and for information on New Innovator Awards, go to: grants.nih.gov/grants/guide/rfa-files/RFA-RM-08-014.html.

**Dec 26: Deadline for registering clinical trials with ClinicalTrials.gov.** A new law has been enacted to expand the scope of ClinicalTrials.gov, a registry of federally and privately supported clinical trials conducted in the United States and around the world. (continued at right)

**India, continued.**

ICMR Director General N.K. Ganguly. “Health is at the core of our ability to strengthen our economic future,” Ganguly said. “We’re seeking a strong relationship with U.S. universities that have translational research strengths for exchanges of faculty and students.”

Sr. Vice President Frank Cerra reviewed the presentations alongside Dr. Ganguly. “We need to find areas where we at the University can bring our strengths to bear on behalf of India,” Cerra said. “Our growing enterprise in clinical and translational sciences is clearly one of those areas along with our significant efforts in public and environmental health.”

University of Minnesota faculty who presented during the symposium included Jonathan Ravdin, Jay Cohn, William Toscano, Kumar Belani, Ranjit John, Inder Anand, and Sayeed Ikrumuddin. Deans John Finnegan (School of Public Health) and Connie Delaney (School of Nursing) also attended the symposium.

**News, continued.**

According to the NIH:

1) Trials initiated after 9/27/2007, or trials that are ongoing as of 12/26/2007 must be registered in full by: The later as of 12/26/2007 or 21 days after the first patient is enrolled.
2) Trials that were “ongoing” as of 9/27/2007 and do not involve a “serious or life threatening disease or condition,” must be registered by 9/27/2008.
3) Trials that were “ongoing” as of 9/27/2007, do involve a “serious or life threatening disease or condition,” and are completed (meaning, not “ongoing”) by 12/26/2007 are not subject to these requirements, though they may be subject to pre-existing registering requirements.

The sponsors of clinical trials and/or the principal investigators for clinical trials are responsible for meeting these expanded online registration requirements. Principal investigators are responsible for determining whether they are obligated to register their trials. For further information on these new requirements, go to grants.nih.gov/grants/guide/notice-files/NOT-OD-08-014.html or check the SPA website at www.ospa.umn.edu for updates.
University researchers are advancing how type 1 diabetes can be treated through innovative work using insulin-producing islet cells from pigs. It is already known that type 1 diabetes can be reversed by transplanting healthy human islet cells in patients. However, a shortage of donor organs limits availability of such cells. University researchers are hopeful that pig islet cells may be a safe and reliable source to make islet transplantation a viable solution for the tens of thousands of people with difficult-to-manage diabetes.

Recently, research led by Bernhard J. Hering, M.D., professor of surgery and scientific director of the University’s Diabetes Institute for Immunology and Transplantation, discovered that survival of pig islet transplants is possible with a novel immunosuppressive protocol. In the study, pig islet cells were transplanted into diabetic monkeys. Not only did the transplanted cells survive, the transplant resulted in long-term diabetes reversal in the monkeys.

“These results suggest it is feasible to use pig islet cells as a path to a far-reaching cure for diabetes,” says Hering. “Now that we have identified critical pathways involved in immune recognition and rejection of pig islet transplants, we can begin working on better and safer immunosuppressant therapies with the eventual goal of bringing the treatment to people.”

To conduct clinical trials, researchers will require “medical grade” pigs whose islet cells can be harvested. Spring Point Project, a non-profit corporation working in partnership with the University of Minnesota, recently opened a 21,000-square-foot biosecure barrier facility to raise high-health pigs for planned pig islet transplant trials in humans. The goal is to have suitable donor pigs available by the time the University has refined the immunosuppressive treatment to a point that makes it safe for clinical trials to begin.

Hering hopes to start clinical trials in humans in 2009. For more information on this and other work from the University’s Diabetes Institute for Immunology and Transplantation, please go to: www.diabetesinstitute.org/

**Director’s Update, continued.**

In addition to new space, we will be offering new and expanded services and resources to support clinical and translational science. Details are forthcoming, and will be announced in future issues of *Accelerate*.

On behalf of the clinical and translational research community I want to thank Drs. Cerra, Powell, and Paller for their outstanding leadership and commitment. Bringing together the many components of our research enterprise will only enhance our productivity and effectiveness.
CAPS Profile: David Boulware, M.D., M.P.H., D.T.H.&M.

Following his first year at Indiana University School of Medicine, David Boulware hiked the Appalachian Trail conducting a largely self-taught prospective cohort study of injuries and illness among backpackers. During his residency in internal medicine and pediatrics, his interests led to clinical trials for preventing mosquito bites and jellyfish stings, followed by clinical research in infectious diseases. Now assistant professor of medicine and beginning his first year as a CAPS scholar, Boulware is part of an international study on complications of HIV therapy in Sub-Saharan Africa. The Minnesota collaboration is investigating HIV immune reconstitution inflammatory syndrome (IRIS) which is a paradoxical response to HIV therapy. As the immune system recovers, some patients have an exaggerated inflammatory response to either previous treated infections or unmasking of new opportunistic infections. These IRIS events occur in approximately 10 percent of patients in the U.S. and are often a minor, temporary inconvenience. In Africa where people start HIV therapy much later in the HIV disease process, over one-third experience IRIS, and IRIS can prove rapidly fatal.

The unique ongoing collaborative study between U.S. and Ugandan researchers goes beyond descriptive epidemiology to translational research with a goal to understand the pathophysiology. From the bedside to the bench and back to the bedside, Minnesota researchers are investigating RNA expression to determine which genes are turned on and off over time in individuals with and without IRIS. The differences detected prior to starting HIV therapy should enable biomarkers to predict who will likely suffer IRIS. In understanding the pathophysiology and in having predictive tests, this will enable clinical trials in IRIS treatment and prophylaxis. As the roll out of HIV continues in resource-limited areas, Boulware’s research holds promise to improve patient care and quality of life for millions.

As a CAPS scholar, Boulware is allocated 75 percent protected research time. He will work with a multidisciplinary mentoring team including: Paul R. Bohjanen, M.D., Ph.D., associate professor, microbiology and medicine; Edward N. Janoff, M.D., professor, medicine at the University of Colorado; James D. Neaton, Ph.D., M.S., professor, biostatistics; and Tracy L. Bergemann, Ph.D., assistant professor, biostatistics. Dr. Boulware is particularly appreciative of the dedicated research time provided by the K12 program. “My research is in a new area with very little knowledge base,” he says. “The CAPS program is great as a junior faculty member interested in research which will improve the lives of people living with HIV.”