Mission

To expand our home for clinical and translational science that facilitates and promotes innovative research and training by bridging disciplines, institutions, and communities to advance knowledge and improve human health.

Message From the Executive Director

The Office of Clinical Research continues to grow and thrive under the strong commitment of the Academic Health Center. Over the past year, we have added a number of key staff to the office and continued to work toward integration with other clinical research service groups throughout the Academic Health Center. We have also provided additional support infrastructure and services to better serve the University’s clinical and translational researchers and our community partners.

For instance, we have created the Biostatistics, Design, and Analysis Center (BDAC) to provide full-service methodological assistance related to study design, data collection, data management, and analysis. BDAC currently includes five Ph.D.- and masters-level biostatisticians who collaborate with clinical and translational investigators through all stages of their research. Active searches for a director and three additional faculty/staff are underway.

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We continue to integrate the General Clinical Research Center and the Research Services Organization to provide “one-stop shopping” for clinical research services for investigators, staff, and the public. We are promoting a model in which research can be done anywhere at any time, based on the needs of the individual study.

We also continue to offer new opportunities for training and education related to clinical and translational research. Our NIH-funded K12 program, Career Advancement Program for Clinical Research Scholars (CAPS), is in its second year (page 9). The program, designed to further junior faculty members’ research careers, offers coursework and seminars and provides protected time and mentored support for research. In addition to CAPS, last summer we sponsored six predoctoral students to conduct mentored fellowships in clinical research and this summer, the program has grown to thirteen (page 13). We are excited about these future leaders of clinical and translational research.

We have also launched the “Building Bridges” initiative, bringing together faculty with similar interests from across the Academic Health and University (page 17). So far this has fostered new collaborations in biomedical genomics and nanomedicine through the Institute of Technology, and we plan to pursue similar partnerships with the social sciences, law, and business. Finally, we began our “Breakthrough Series” with LifeScience Alley, designed to forge new partnerships between investigators and the local biomedical industry (page 17).

We have strategically developed these initiatives in line with our vision to transform the University’s clinical and translational research enterprise. This vision is articulated in our resubmission for the NIH’s Institutional Clinical and Translational Science Award (CTSA) grant (page 6). While our first bid for this grant was unsuccessful, we have worked diligently over the past year to develop a stronger application that will be submitted in November 2007.

The future of clinical research at the University of Minnesota is bright. In November, we will move into our new location at 717 Delaware Street S.E., and we look forward to having our multidisciplinary team in one central home (page 7).

Our philosophy at the Office of Clinical Research is to “accelerate” the future through positive culture change, by creating an infrastructure that provides tools and removes barriers to research and scholarship. Our approach is team-based. And to all the faculty, staff, administrators, and students that I have the honor and pleasure of working with, I want to say thank you for everything you do! Together, we can help the University become a top three public research university.
JASJIT S. AHLUWALIA, M.D., M.P.H., M.S.
Dr. Ahluwalia joined the University in September 2005 as the Executive Director for the Office of Clinical Research, where he oversees clinical research throughout the Academic Health Center’s six schools and colleges: medicine, public health, dentistry, nursing, pharmacy, and veterinary medicine. Dr. Ahluwalia also serves as the Medical School’s associate dean for clinical research. A professor in the Department of Medicine, he conducts NIH-funded research working with ethnic minority populations and mentoring junior faculty and fellows. Prior to coming to the University of Minnesota, Dr. Ahluwalia was the Sosland Family Professor and chair of the Department of Preventive Medicine and Public Health and professor of Internal Medicine at the University of Kansas School of Medicine.

REBEECCA A. MOEN, M.B.A.
Ms. Moen is the associate director of the Office of Clinical Research, where she is focused on helping to build an efficient and streamlined clinical and translational research enterprise. She is responsible for aiding investigators on large institutional research grants and managing the integration of services of multiple clinical research units. Before joining the University, Ms. Moen spent eight years at Duke University focusing on increasing National Institutes of Health funding for the institution. She received her B.A. degree in communications from Augustana College and her M.B.A. from the University of North Carolina at Chapel Hill.

SUSAN JACKSON, B.S.
Ms. Jackson is the manager of the Office of Clinical Research, and is responsible for administering all operational, procedural, and practice aspects for the office. She has been at the University of Minnesota since 1976; she previously held administrative positions in the Office of the Vice President for Health Sciences, the Equal Opportunity and Affirmative Action Office, the AHC Human Resources Department, and the Medical School International Medical Education and Research Program Office.

BRENDA HUDSON, M.S.
Ms. Hudson is the science writing/communications manager in the Office of Clinical Research, where she works with investigators to provide writing support and mentoring, and oversees the communication needs of the office. Ms. Hudson has more than fifteen years of communications experience; she has an M.S. in journalism from Boston University and is a Ph.D. candidate in the University of Minnesota’s Rhetoric and Scientific Communication program.

NANCY J. JOHNSON, M.A.
Ms. Johnson is the education manager for the Office of Clinical Research. Ms. Johnson manages education and training initiatives for the office and works with OCR faculty and staff to ensure integration of educational programs with the strategic vision for clinical and translational research. She has fifteen years of teaching experience and earned an M.A. in public policy from the University of Minnesota’s Humphrey Institute of Public Affairs.

JOE MENTH, B.S.
Mr. Menth is the fiscal officer for the Office of Clinical Research. He has more than six years of experience in overseeing fiscal operations, including three years at the University of Minnesota. Mr. Menth received a B.S. in business administration from the University of Wisconsin-Stout in 2000.
Shawn Larson, B.A.
Mr. Larson is the webmaster for the Office of Clinical Research, where he designs and maintains the website, and manages electronic communications. Mr. Larson received his B.A. in psychology from the University of Minnesota in 2006.

Meredith Craven
Ms. Craven is a program associate in the Office of Clinical Research, where she assists with the communication needs of the office and provides administrative support to the executive director. She is enrolled in the School of Journalism and Mass Communication, and is working toward her B.A. in public relations.

Sara Hahne, B.S.
Ms. Hahne, executive office and administrative specialist, provides administrative support for Office of Clinical Research staff. She received her B.S. in human resources from Mankato State University in 2004.

Frank Lederle, M.D.
Dr. Lederle is a professor of medicine at the Veterans Administration Medical Center. He coordinates both the Clinical Research Conferences and the Distinguished Visiting Scholar Series for the Office of Clinical Research.

Russell Luepker, M.D., M.S.
As a member of the OCR’s Directors Committee, Dr. Luepker focuses on education, training, and career development. He serves as Principal Investigator for the NCRR-funded K12 program, Career Advancement Program for Clinical Research Scholars (CAPS). Dr. Luepker is a Mayo Professor of Public Health, professor of medicine, and director of graduate studies in clinical research.

Jeffrey S. Miller, M.D.
As a member of the OCR’s Directors Committee, Dr. Miller focuses on translational research. A professor of medicine, he is also director of the Translational Cell Therapy Core Laboratory in the University of Minnesota Cancer Center and is associate director of the Minnesota Molecular and Cellular Therapeutics facility.

Timothy S. Tracy, Ph.D.
As a member of the OCR’s Directors Committee, Dr. Tracy focuses on translational research and novel methodologies. He is appointed as professor and head of the Department of Experimental and Clinical Pharmacology in the College of Pharmacy.

Elizabeth R. Seaquist, M.D.
As a member of the OCR’s Directors Committee, Dr. Seaquist focuses on participant and clinical interactions. She is a professor in the Division of Endocrinology and Diabetes in the Medical School’s Department of Medicine and holds the Pennock Family Chair in Diabetes Research. Dr. Seaquist has served as the director of the NIH-funded General Clinical Research Center since 2002; she is also associate director of the Career Advancement Program for Clinical Research Scholars (CAPS).

Eileen Harwood, Ph.D.
Dr. Harwood is assistant professor of Epidemiology and Community Health and director of the Health Survey Research Center in the School of Public Health. As a member of OCR’s Directors Committee, she focuses on tracking and evaluation of programs.
Kelvin Lim, M.D.
Dr. Lim is professor and vice chair for research in the Department of Psychiatry, where he holds the Drs. T.J. and Ella M. Arneson Endowed Chair. As a member of OCR’s Directors Committee, he leads initiatives in biomedical informatics.

Jeff Kahn, M.D., Ph.D.
Dr. Khan is professor and Maas Family Endowed Chair in Bioethics in the Medical School, and directs the AHC Center for Bioethics. As a member of OCR’s Directors Committee, he focuses on clinical research ethics.

John Connett, Ph.D
Dr. Connett is professor and head of the Division of Biostatistics, and co-director of the Coordinating Centers for Biometric Research in the School of Public Health. As a member of OCR’s Directors Committee, he focuses on research design and biostatistics.

Mary Story, Ph.D.
Dr. Story is professor of Epidemiology and Community Health and director of the Center for Youth Health Promotion in the School of Public Health. As a member of OCR’s Directors Committee, she leads initiatives in community engagement.

Mark Paller, M.D., M.S.
Dr. Paller is the assistant vice president for research in the Academic Health Center, a professor of medicine, and a member of the OCR’s Directors Committee.

Hongfei Guo, Ph.D.
Dr. Guo is an assistant professor jointly appointed in the Biostatistics, Design, and Analysis Center (BDAC) in the Office of Clinical Research and the Division of Biostatistics in the School of Public Health, where he collaborates with and provides consulting services for AHC investigators. Dr. Guo’s research interests include theory and application of statistical methods for multiple outcomes data. Before joining BDAC in April 2007, he spent six years as a research assistant at Johns Hopkins Bloomberg School of Public Health.

Cynthia Davey, M.S.
Ms. Davey is a research fellow in BDAC, where she collaborates with and provides consulting services for AHC investigators. Ms. Davey is also an instructor in the School of Public Health Division of Biostatistics; she was previously a research fellow in this division. She received her M.S. from the University of Minnesota, School of Public Health, Division of Biostatistics in December 1998.

Philippe Gaillard, M.S., M.A.
Mr. Gaillard is a research fellow in BDAC, where he collaborates with and provides consulting services for AHC investigators. Before joining BDAC, he worked as a statistician for Allina Hospitals and Clinics, Best Buy, and the Department of Internal Medicine at the University of Nevada. He received his M.A. in research methodology from the University of Pittsburgh in 1993.

Scott Lunos, M.S.
Mr. Lunos is a research fellow in BDAC, where he collaborates with and provides consulting services for AHC investigators. He received his B.S. in Mathematics from the University of Minnesota, Duluth in 1999, and his M.S. in Biostatistics from the University of Minnesota in 2001. Before joining BDAC, Mr. Lunos spent five years at MGI Pharma, Inc., where he was the primary statistician on multiple Phase I-IV cancer clinical trials.
CTSA UPDATE
A critical goal of the Office of Clinical Research is to secure one of the National Institutes of Health’s Institutional Clinical and Translational Science Awards (CTSA). In 2006, the first year of the CTSA program, 12 grants were given to institutions that represent the “best of the best” in clinical research. We believe that the University of Minnesota belongs in this group of elite research institutions.

A large portion of our time during the past year was spent on the reformulation of our $66 million grant application, which we are submitting to the NIH for the November 2007 deadline. Involving faculty and staff from every college and school in the AHC, as well as other University schools and community partners, the CTSA planning group has met weekly to develop our strategies. With the receipt of this award, we will become the Institute for Clinical and Translational Research, with the following vision and goals.

INSTITUTE FOR CLINICAL AND TRANSLATIONAL RESEARCH VISION
The Institute for Clinical and Translational Research (ICTR) is a leader in transformative, collaborative research and education – integrating and accelerating innovative solutions to advance human health across the state of Minnesota and beyond. ICTR is an incubator for people and for ideas:
• Our faculty and students are leaders of multidisciplinary research.
• Our innovative methods accelerate the process of translating discovery into care.
• Our community partnerships are a national model for the integration of research and health care.

GOALS
• Leverage existing networks and collaborations to introduce new research and educational opportunities across Minnesota communities and the Upper Midwest.
• Increase the speed of translating research discoveries into prevention, treatment, and cures.
• Integrate our research resources into an easy-to-navigate, seamless infrastructure that fosters connections across disciplines, institutions, and communities.
• Train and mentor clinical and translational research leaders who value and conduct team science.

We are grateful for the hard work of everyone involved in this grant application and are certain that these efforts will be rewarded.
The Office of Clinical Research is, literally, on the move. In November, an additional 30,000 square feet of space will be available for clinical and translational research. This space is located on the first and second floors at 717 Delaware Street S.E., a building undergoing a $36.5 million renovation.

We have allocated 10,000 square feet on the first floor for clinical research faculty offices to foster multidisciplinary collaborations. On the second floor 10,000 square feet will house outpatient clinical research facilities, including 10 exam rooms; spacious waiting room with a child-friendly area; metabolic kitchen and dining room; 6 procedure rooms; workspace for investigators, coordinators, and clinical trial monitors; large conference room; and parking spaces dedicated for research participants. Another 10,000 square feet on the second floor will be available for Office of Clinical Research operations and leadership staff.

The General Clinical Research Center will be integrated into the new space, although its clinical research facilities will remain at the Masonic Building, where the research focus is high-intensity outpatient and inpatient clinical research visits.

This initiative truly shows the University’s commitment to grow and streamline the clinical research enterprise.

**Biostatistics, Design, and Analysis Center**

Over the past year, the Office of Clinical Research’s new Biostatistics, Design, and Analysis Center (BDAC) has made enormous advances. Four research fellows and one assistant professor have joined the center, and are actively collaborating with investigators on all aspects of study design, design innovation, data analysis, and results reporting. BDAC, designed as a full-service, one-stop shop for methodological assistance, offers statistical consulting and analysis for clinical trials and smaller-scale studies, and provides initial consultations to help investigators develop new ideas for review. Active searches for a director, a doctoral and a masters-level biostatistician, and a database programmer are underway.

BDAC members include Assistant Professor Hongfei Guo, Ph.D., and Research Fellows Cynthia Davey, M.S.; Philippe Gaillard, M.S., M.A.; and Scott Lunos, M.S.
WRITING SUPPORT
One of the many essential skills successful researchers and academics must master is writing, which can seem to many arcane and intimidating. Understanding the principles and writing fundamentals removes much of the mystery from the process and can help applicants develop both skills and confidence. The Office of Clinical Research sponsors two types of professional development series where faculty, research fellows, senior graduate students, and administrative research staff can learn the practical skills and conceptual approaches needed for shaping high-quality grant applications and successful journal articles.

The “Write Winning Grants” workshop was held on April 5, 2007 for 100 participants from the Academic Health Center. Evaluation comments were outstanding and participants urged that more training of this kind be made available. In response, beginning in September 2007, the Office of Clinical Research will sponsor two grant writing workshops each year by Grant Writers’ Seminars and Workshops, LLC. “Getting Started as a Successful Grant Writer and Academician,” aimed at new investigators, will be offered each fall and “Write Winning Grants,” designed for faculty members and others with some exposure to writing grant applications, will be the spring offering. Participants in these lively day-long workshops will learn strategies designed to help them achieve priority scores that will result in research funding for their investigations.

In April, we also introduced a Scientific Writing Development Series: a four-session series on writing for peer-reviewed journals, including tackling the writing process; anatomy of a manuscript; writing effective introductions and abstracts; and responding to reviewer comments. More than 100 faculty, staff, and students from the Twin Cities and Duluth campuses participated in the series, which will be developed and offered over subsequent semesters.

ACCELERATE
In September 2006, the Office of Clinical Research launched the inaugural issue of Accelerate, a monthly newsletter about clinical and translational research distributed to 1,600 subscribers. This newsletter provides information on a wide range of resources available to clinical and translational researchers, incorporating news from the Research Services Organization, the General Clinical Research Center, and the University’s NIH-funded K12 training program, the Career Advancement Program for Clinical Research Scholars (CAPS). Past issues of Accelerate have also included inserts on internal funding opportunities and external year-long pull-out training programs.
Career Advancement Program for Clinical Research Scholars (CAPS)

CAPS, the University of Minnesota’s mentored clinical research scholars program, is one of the K12 programs funded by the NIH, offering support and training for multidisciplinary scholars on clinical research paths. In its second year, CAPS offers courses and seminars, as well as protected time allowing scholars to focus on research over the course of three to five years. Each scholar also works with a multidisciplinary mentoring team of experienced clinical investigators, including a biostatistician. A deliberate goal of the program, which is funded through 2010, is to increase clinical and translational research across the disciplines.

In 2007, eight AHC junior faculty members were selected through a competitive application process to participate in the three-year program and receive mentoring and financial support. They are:

School of Dentistry

Donald Nixdorf, D.D.S., M.S. – Diagnostic & Biological Sciences

Project: Central processing of jaw muscle pain in temporo-mandibular disorders (TMD)

Mentors: Eric L. Schiffman, D.D.S., M.S., Associate Professor, Dentistry
David A. Bereiter, Ph.D., Professor, Dentistry
Kamil Ugurbil, Ph.D., Professor, Medicine
Noam Harel, Ph.D., Assistant Professor, Medicine
James S. Hodges, Ph.D., M.A., Associate Professor, Biostatistics

Medical School

David Boulware, M.D. – Infectious Diseases & International Medicine

Project: A prospective study to define the incidence and severity of HIV Immune Reconstitution Inflammatory Syndrome (IRIS) in an African cohort

Mentors: Paul R. Bohjanen, M.D., Ph.D., Associate Professor, Microbiology and Medicine
Edward N. Janoff, M.D., Professor, Medicine, University of Colorado
James D. Neaton, Ph.D., M.S., Professor, Biostatistics
Tracy L. Bergemann, Ph.D., Assistant Professor, Biostatistics

Adam Carpenter, M.D. – Neurology

Project: Neurodegeneration in multiple sclerosis: biomarkers and novel therapy

Mentors: Apostolos P. Georgopoulos, M.D., Ph.D., Professor, Neuroscience
Gareth J. Parry, M.D., Professor, Neurology
Kelvin O. Lim, M.D., Professor, Psychiatry
Lynn E. Eberly, Ph.D., Associate Professor, Biostatistics
Melissa Geller, M.D. – Obstetrics, Gynecology, and Women’s Health
**Project:** Neoadjuvant chemotherapy in ovarian cancer: predicting tumor response
**Mentors:** Amy P. N. Skubitz, Ph.D., Associate Professor, Laboratory Medicine and Pathology
Sundaram Ramakrishnan, Ph.D., Professor, Pharmacology
Douglas Yee, M.D., Professor, Medicine
Chap T. Le, Ph.D., Distinguished Professor, Biostatistics

Ken Kunisaki, M.D. – Pulmonary/Critical Care – VA Medical Center
**Project:** Micronutrients and the risk of COPD exacerbations
**Mentors:** Dennis E. Niewoehner, M.D., Professor, Medicine
Allen S. Levine, Ph.D., Professor and Dean, College of Food, Agricultural and Natural Resources Sciences
John E. Connett, Ph.D., Professor and Head, Division of Biostatistics

Jeffrey Wozniak, Ph.D., L.P. – Psychiatry
**Project:** Cognitive and behavioral consequences of prenatal alcohol exposure in patients with Fetal Alcohol Spectrum Disorders (FASD)
**Mentors:** Kelvin O. Lim, M.D., Professor, Psychiatry
Monica A. Luciana, Ph.D., Associate Professor, Psychology
Pi-Nian Chang, Ph.D., Associate Professor, Pediatrics and Psychiatry
Paul M. Thuras, Ph.D., Research Associate, Psychiatry

**SCHOOL OF NURSING**
Fang Yu, Ph.D., R.N. – Adult and Gerontological Health Co-operative Unit
**Project:** Promoting cognitive and functional independence in older adults with dementia through aerobic exercise
**Mentors:** Donna Z. Bliss, Ph.D., R.N., Professor, Nursing
Maurice W. Dysken, M.D., Professor, Medicine
Wei Pan, Ph.D., Associate Professor, Biostatistics

**COLLEGE OF PHARMACY**
L’Aurelle Johnson, Ph.D. – Experimental & Clinical Pharmacology
**Project:** Effect of childhood obesity on phase 1 and phase 2 drug metabolism enzymes
**Mentors:** Timothy S. Tracy, Ph.D., Professor, Pharmacy
Pamala A. Jacobson, Pharm.D., Associate Professor, Pharmacy
Julie A. Ross, Ph.D., Professor, Pediatrics
Antoinette M. Moran, M.D., Professor, Pediatrics
Melanie M. Wall, Ph.D., M.S., Associate Professor, Biostatistics
2006 CAPS Scholars continuing their research include:

**MEDICAL SCHOOL**

**Lisa Chow, M.D.** – Endocrinology  
**Project:** The influence of obesity, metabolic syndrome, and insulin resistance on cardiovascular risk factors in young adults  
**Mentors:** Elizabeth R. Seaquist, M.D., Professor, Medicine  
Michael Garwood, M.D., Professor, Radiology  
Lynn E. Eberly, Ph.D., Associate Professor, Biostatistics

**Sarah Cooley, M.D.** – Hematology  
**Project:** Translating state-of-the-art research in immunobiology and oncology into effective new immune-based therapies for cancer  
**Mentors:** Jeffrey S. Miller, M.D., Professor, Medicine  
Daniel J. Weisdorf, M.D., Professor, Medicine  
Chap T. Le, Ph.D., Distinguished Professor, Biostatistics

**Kamakshi Lakshminarayan, M.D., Ph.D.** – Neurology and Epidemiology & Community Health  
**Project:** Advancing and improving the clinical care of stroke patients at the individual and population levels  
**Mentors:** David C. Anderson, M.D., Professor, Neurology  
Russell V. Luepker, M.D., M.S., Mayo Professor of Public Health  
Beth A. Virnig, Ph.D., M.P.H., Associate Professor, Health Policy and Management  
David R. Jacobs, Jr., Ph.D., Professor, Division of Epidemiology & Community Health

**Peter Milev, M.D., Ph.D.** – Psychiatry  
**Project:** The anatomical and functional basis of deficits in perceptual organization in schizophrenia  
**Mentors:** Kelvin O. Lim, M.D., Professor, Psychiatry  
Angus W. MacDonald III, Ph.D., Assistant Professor, Psychology  
Susanne S. Lee, Ph.D., Assistant Professor and Statistician, Psychiatry

**Daniel A. Mulrooney, M.D., M.S.** – Pediatrics and Pediatric Hematology, Oncology, Blood & Marrow Transplantation  
**Project:** Pathophysiology of late effects of cancer therapy in children upon the cardiovascular system  
**Mentors:** Joseph P. Neglia, M.D., M.P.H., Professor and Interim Head, Pediatrics  
Robert P. Hebbel, M.D., Professor, Medicine  
James D. Neaton, Ph.D., Professor, Biostatistics
Marcie Tomblyn, M.D., M.S. – Hematology, Oncology & Transplantation
Project: Design and execution of local and multi-center trials to advance hematopoietic stem cell transplant patient care
Mentors: Daniel J. Weisdorf, M.D., Professor, Medicine
Mary M. Horowitz, M.D., Professor, Medicine, Medical College of WI
John P. Klein, Ph.D., Professor, Div. of Biostatistics, Medical College of WI
Brent R. Logan, Ph.D., Assistant Professor, Div. of Biostatistics, Medical College of WI

COLLEGE OF PHARMACY
Heather Vezina, Pharm.D. – Laboratory Medicine & Pathology and Experimental & Clinical Pharmacology
Project: Developing and sustaining an antiviral clinical pharmacology research program based on pharmacotherapy of HIV/AIDS and Epstein-Barr virus
Mentors: Henry H. Balfour, Jr., M.D., Professor, Lab Medicine and Pathology and Pediatrics
Richard Brundage, Pharm.D., Ph.D., Associate Professor, Pharmacy
William Thomas, Ph.D., Associate Professor, Biostatistics

In addition, the following are scholars from the AHC-sponsored Clinical Research Scholars program, a precursor to the CAPS program:

MEDICAL SCHOOL
Mukta Arora, M.D.
Project: New therapies for management of chronic graft-versus-host disease and methods to improve outcomes following transplantation therapy for multiple myeloma
Mentor: Daniel Weisdorf, M.D., Professor, Medicine

SCHOOL OF NURSING
Diane Treat-Jacobson, Ph.D., R.N.
Project: Mechanism of improvement in response to upper vs. lower extremity aerobic training in patients with claudication
Mentors: Jean Wyman, Ph.D., R.N., Professor, Nursing
Daniel Duprez, M.D., Ph.D., Professor, Medicine

COLLEGE OF PHARMACY
Mark Kirstein, Pharm.D.
Project: Population pharmacokinetics and pharmacogenetics of Gemcitabine in patients with solid tumors
Mentors: Robert Kratzke, M.D., Professor, Medicine
Richard C. Brundage, Pharm.D., Ph.D., Associate Professor, Pharmacy
Philip McGlave, M.D., Professor, Medicine

Michael Kotlyar, Pharm.D.
Project: Nicotine addiction and stress response
Mentor: Dorothy Hatsukami, Ph.D., Professor, Psychiatry
2007 Summer Predoctoral Fellowship in Clinical and Translational Research

The well-documented and growing shortage of clinical investigators in all health professions reflects the chasm between research opportunities and numbers of trained clinical researchers. Various programs provide sound training for postdoctoral fellows and young faculty, but few address critical pipeline issues of stimulating interest in and providing initial clinical research training to predoctoral students.

In response to this shortage, the Office of Clinical Research is bringing more young scholars into the research pipeline by sponsoring a Summer Predoctoral Fellowship program in Clinical and Translational Research. This 8- to 12-week paid fellowship gives each participating student an opportunity to work on an ongoing clinical or translational research project with an AHC faculty mentor who is an established investigator. Fellows also design and carry out small individual research projects and attend weekly group seminars. Thirteen new fellows selected to participate in 2007 represented all six AHC colleges and schools in the Twin Cities and Duluth. They are:

**SCHOOL OF DENTISTRY**
*Stephanie Wetzel* (Mentor: Scott Crow, M.D.)
Utilization of Dental Services of Patients Suffering from Bulimia Nervosa and Binge Eating Disorders

**MEDICAL SCHOOL**
*Sarah Barnes* (Mentor: Tracie Collins, M.D., M.P.H.)
Dietary Habits and Exercise Mediators in Patients at Risk for PAD

*Richard Beddingfield* (Mentor: Manoj Monga, M.D.)
Alfuzosin Hydrochloride to Relieve Uretral Stent Discomfort

*Justin Laube* (Mentor: Mary Jo Kreitzer, Ph.D., R.N.)
The Effects of Mindfulness-based Stress Reduction (MBSR) on Stress-related Biomarkers in Caregivers of Alzheimer’s Patients

*Sarah McAvoy* (Mentor: Mukta Arora, M.D.)
Comorbidity Index in Allograft Bone Marrow Transplants

*Barrie Miller* (Mentor: Kimberly Bohjanen, M.D.)
Recalcitrant Pruritus in Cutaneous T-cell Lymphoma
**SCHOOL OF NURSING**

**Darlene Bjorklund** (Mentor: Linda Chlan, R.N., M.S., Ph.D.)
Self-Management of Anxiety for the Mechanically Ventilated Patient

**COLLEGE OF PHARMACY DULUTH CAMPUS**

**Arinze Nkemdirim** (Mentor: Grant Anderson, Ph.D.)
Engineering the Blood Brain Barrier

**Stephanie Root** (Mentor: Michael Kotlyar, Pharm.D.)
Pharmacokinetics and Acceptability of Smokeless Tobacco Products

**COLLEGE OF PHARMACY TWIN CITIES CAMPUS**

**Dana Simonson** (Mentor: Henry Mann Pharm.D., F.A.S.H.P., F.C.C.P., F.C.C.M)
Spontaneous Awakening Trial (SAT)

**Ling Xu** (Mentor: James Cloyd, Pharm.D.)
Use of Topiramate for Neuroprotection in Newborns Undergoing Heart Surgery

**SCHOOL OF PUBLIC HEALTH**

**Mandy Stahre** (Mentor: Traci Toomey, Ph.D.)
Identifying Barriers to Implementing Programs in Local Public Health Agencies

**COLLEGE OF VETERINARY MEDICINE**

**Lisa Borgia** (Mentor: Stephanie Valberg, D.V.M, Ph.D.)
The Effect of Dietary Fructans in Forage on Horses with Polysaccharide Storage Myopathy

We expect to sponsor up to 20 summer predoctoral fellows in 2008.

**Philippe Gaillard, M.S., M.A.**

Biostatistics, Design, and Analysis Center

As research fellows in the Office of Clinical Research Biostatistics, Design, and Analysis Center (BDAC), Philippe Gaillard and his colleagues provide a wide range of statistical services, including study planning, form design, data management, statistical analysis, and results summarization. Gaillard collaborates with both internal and external clients; he is currently working with Amy Scheller, assistant education specialist in the School of Public Health, to evaluate a computer simulation game called “Disaster in Franklin County: A Public Health Simulation.” Dr. Scheller will compare test and survey data from the simulation for students who have had public health training vs. students who have not. “BDAC gives me the opportunity to be involved in every step of some truly innovative research,” Gaillard explains. “Working with the investigator to take a project from the planning stages into data analysis and results reporting is a rewarding process.”
Distinguished Visiting Scholar Series

Each month, the Distinguished Visiting Scholar Series (DVSS) brings an acknowledged leader in some aspect of clinical research to the University for a day. The visiting scholar presents a formal lecture on a topic that draws broadly on the speaker’s wisdom and experience, and also conducts a series of informal discussions with faculty, fellows, students, and staff. Visiting scholars in the past year have included:

August 24, 2006
“The Etiologist Versus the Phenomenologist Versus the Social Environmentalist and the Future of Health-Related Research”
Lewis Kuller, M.D., Dr.P.H., M.P.H.
University Professor of Public Health, University of Pittsburgh

September 21, 2006
“An Innovative, Dean’s Office-Based Approach Designed to Enhance Faculty Success”
Eugene Orringer, M.D.
Executive Associate Dean for Faculty Affairs
University of North Carolina at Chapel Hill

*October 3, 2006
“Wounded Spirits, Ailing Hearts: Trauma in American Indian Communities”
Spero Manson, Ph.D.
Division Head, American Indian and Alaska Native Programs
University of Colorado at Denver and Health Sciences Center

November 9, 2006
“When Results of Large Studies are Divergent: Hormone Therapy as a Case Study”
JoAnn Manson, M.D.
Chief, Division of Preventive Medicine, Brigham and Women’s Hospital; Professor of Medicine,
Harvard Medical School

December 5, 2006
“Developing a Successful CTSA Grant: The Oregon Experience”
Eric Orwoll, M.D.
Director, Oregon Clinical and Translational Research Institute (OCTRI)
Professor of Medicine, Oregon Health & Science University

January 25, 2007
“Towards Evidence-Based Implementation”
Jeremy Grimshaw, M.B.Ch.B., Ph.D.
Director and Senior Scientist, Clinical Epidemiology, Ottawa Health Research Institute
**March 6, 2007**
“Who wrote my paper?”
Drummond Rennie, M.D.
Professor of Medicine, University of California, San Francisco
Deputy Editor, *Journal of the American Medical Association*

**April 18, 2007**
“Oral and Systemic Disease: Crossing the Barriers of Interdisciplinary Research in Academic Health Centers”
Robert J. Genco, D.D.S., Ph.D.
Director, Buffalo Periodontal Disease Research Center
Department of Oral Biology, School of Dental Medicine
State University of New York at Buffalo

*May 9, 2007*
“Recruitment of Ethnic Minorities into Clinical Trials”
Mona Fouad, M.D., M.P.H.
Professor and Director, Minority Health and Research Center
University of Alabama at Birmingham

* Joint sponsorship with the Medical School’s Program in Health Disparities Research

**Clinical Research Conference**
The Clinical Research Conference, now in its third year, provides the Academic Health Center, Hennepin County Medical Center, Fairview Health Services, and V.A. Medical Center scholars, faculty, and staff a forum to present and discuss research methodology and findings, as well as topics of general clinical research interest.

The conference is held twice monthly, and is designed to support the career development of junior faculty. The open forum encourages investigators to develop independent research skills and gain experience in advanced methods. Attendance is open to all who are interested in clinical research.

**Debra Dykhuis, Research Services Organization**

Debra Dykhuis serves as the associate director of the Research Services Organization (RSO), a group dedicated to easing the administrative and logistical burdens of industry-sponsored research for faculty researchers. Since its inception, the RSO has been the contact point for nearly 900 industry protocols. “The RSO has maintained its commitment to service – meeting faculty research needs for completing project start-up activities and ongoing enrollment and data collection,” she says. “Integration with the Office of Clinical Research will give the RSO opportunities to provide assistance on all kinds of clinical research projects, regardless of funding source.”

The RSO, together with the Office of Clinical Research, will continue to provide timely, knowledgeable, and excellent service to clinical researchers throughout the Academic Health Center.
Collaboration

BUILDING BRIDGES
Fostering innovative collaborations among researchers is a main goal of the Office of Clinical Research, as today’s complex health problems are no longer best served by single investigators working in isolation. Yet, forming new productive and innovative collaborations can be challenging. Researchers are busy and, while knowledgeable in their own fields, may not be aware of others’ work in different disciplines and how that work might benefit their own areas of investigation. We call the disconnection between AHC and other researchers on campus the “Washington Avenue divide.”

To help bridge this gap and provide opportunities for faculty to share ideas for multidisciplinary research, the Office of Clinical Research began hosting “Building Bridges” sessions among researchers from the AHC and disciplines throughout the University. At these events, researchers introduce themselves and their work, break into small groups, briefly discuss potential research ideas, and then rotate tables. Tremendous energy, novel ideas, and collaboration among AHC and Institute of Technology researchers have come from the two events conducted to date: biomedical genomics and nanomedicine. Other planned topics include the social sciences (psychology, sociology, anthropology, American Indian studies, Latino studies, and African American studies), law, health policy, and business.

Tim Tracy, Ph.D., College of Pharmacy professor and head of the Department of Experimental and Clinical Pharmacology, who was instrumental in starting this initiative, says, “We too frequently assume we have to look to other universities for expertise in a given area, when that expertise already exists in our own backyard. It is amazing the number and quality of cutting-edge biomedical research projects being conducted by our colleagues in the Institute of Technology. We just need to look across the street to find our future collaborators.”

BREAKTHROUGH SERIES
LifeScience Alley, the trade association representing the biomedical industry in the Upper Midwest, has joined with the Office of Clinical Research in a new educational partnership designed to help advance our local medical technology edge and foster new academic-industry collaborations. Plans call for two events each year, in the early summer and late fall.

The first event was held on June 4-5, 2007 focusing on research into neuromodulation for the treatment of psychiatric and movement disorders. Twenty leading researchers and speakers from industry and the University spoke about the development and use of deep brain stimulation (DBS), vagus nerve stimulation (VNS) and other emerging modalities. The program was interactive and participants raised a host of intriguing issues around this new technology.

The second event in the series, slated for October 29, 2007 will focus on new research into the treatment of diabetes.
On September 18-19, 2007, a conference was held for clinical research professionals at the Minneapolis Convention Center, sponsored by the Office of Clinical Research and Mayo Clinical Trial Services. Since 2006, the University has partnered in this annual event that provides a comprehensive look at the responsibilities and processes of clinical research performance. Topics included individualized medicine, incidental findings in research, vulnerable subjects, recruitment of minority populations, budgeting, responsibilities of principal investigators and clinical research coordinators, and study design. There was also a presentation on the University of Minnesota and Mayo Clinic genomics collaboration. The conference provides an annual opportunity for learning and networking among clinical research professionals, including principal investigators, study coordinators, nurses, and other research professionals involved in managing and coordinating clinical research.

Nyra Wimmergren, R.N., General Clinical Research Center

As part of the General Clinical Research Center (GCRC) nursing staff, Nyra Wimmergren carries out the clinical portions and data collection of studies conducted in the center. “We see 30 to 40 patients each day from many different active trials,” she says. “This variety is what the GCRC staff really enjoy.” Wimmergren most likes interacting with trial participants and educating them about clinical research. “Monitoring patient tolerance to treatments and keeping participants informed throughout the process is essential. Our subjects are always the highest priority.” Wimmergren has been part of the GCRC staff for five years. “The combination of research and patient interaction makes this the most enjoyable job I’ve had in my nursing career.”
Health Disparities Research Grant Awards

Five community and University partnerships have been awarded planning grants for research in health disparities. The grants, a new program sponsored by the Office of Clinical Research and the Medical School’s Program in Health Disparities Research, aim to foster long-term collaborative research between community-based organizations and academic researchers to help address issues of importance to the community.

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<tr>
<th>Project Title</th>
<th>Population of Study</th>
<th>Org/University School</th>
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<tr>
<td>Translating Research to Action: Reducing Recreational Tobacco Use in the Urban American Indian Community</td>
<td>American Indian / Native American</td>
<td>American Indian Policy Center / School of Public Health</td>
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<tr>
<td>Community PI: John Poupart, M.P.A.</td>
<td>University PI: Jean Forster, Ph.D., M.P.H.</td>
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<td>Community Partnerships to Prepare for Pharmacogenomic Studies in the Hmong Community</td>
<td>Hmong</td>
<td>East Side Family Clinic, West Side Community Health Center / College of Pharmacy</td>
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<tr>
<td>Community PI: Kathleen Culhane-Pera, M.D., M.A.</td>
<td>University PI: Robert Strake, Pharm.D.</td>
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<td>Wise Kids Eat Well</td>
<td>African American</td>
<td>NorthPoint Health &amp; Wellness Center / Medical School</td>
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<td>Community PI: Pam Cosby, M.P.A.</td>
<td>University PI: Nancy Raymond, M.D.</td>
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<td>Using Photovoice to Document Perceived Routes of Pesticide Exposures and Health Concerns among Mothers from Minnesota’s Red River Valley</td>
<td>New Americans (Somalia, Liberia, Sudan, Kurdistan, Bosnia)</td>
<td>Northwest Regional Partnership / School of Public Health</td>
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<td>Community PI: Linda Kingery, M.S.</td>
<td>University PI: Patricia McGovern, Ph.D., M.P.H.</td>
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<td>The Family Education &amp; Diabetes Series (FEDS) Project: A Pilot Investigation</td>
<td>American Indian / Native American</td>
<td>St. Paul Area Council of Churches Department of Indian Work / Medical School</td>
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<td>Community PI: Sheila WhiteEagle</td>
<td>University PI: Tai Mendenhall, Ph.D.</td>
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Nancy Raymond, M.D., and Pam Cosby, M.P.A., co-principal investigators of “Wise Kids Eat Well”
Heather Vezina, Pharm.D.,
College of Pharmacy and Medical School

Dr. Heather Vezina oversees the antiviral pharmacology research laboratory in the Department of Laboratory Medicine and Pathology in the Medical School, where she is currently evaluating the use of the antiviral drug valacyclovir when used as an experimental treatment for primary Epstein-Barr Virus (EBV) infectious mononucleosis (IM).

“Data from these studies may provide clues into the management of more serious EBV infections that can occur in individuals with weakened immune systems, like those who have undergone transplantation,” explains Vezina. In 2002 she accepted a joint appointment in the College of Pharmacy and the Medical School. Vezina is applying a multidisciplinary approach to her research through the Career Advancement Program (CAPS), the University’s NIH-funded K12 program. “CAPS offers a unique opportunity to collaborate with other scholars and faculty from across the Academic Health Center.”
Dr. Kelvin Lim is a pioneer in the use of Diffusion Tensor Imaging (DTI) to examine disease expression and prognosis in schizophrenia patients. DTI is a magnetic resonance imaging technique that allows investigators to look beyond the gross anatomy of the brain and into the microstructural integrity of white matter, the tissue that passes messages through the nervous system. “White matter has, to some extent, been overlooked in previous psychiatric disorder research,” explains Lim, vice chair for research and professor in the Department of Psychiatry. “We believe that an abnormality in white matter may be a key to understanding disorders like schizophrenia.” In addition to his active research career, Lim spends much of his time mentoring junior investigators. “Leveraging our resources and expertise to train new researchers is one of the most important things we can do for clinical and translational research.”
The upcoming year will see many changes and new developments for the Office of Clinical Research.

In the fall, we will move into our new office location at 717 Delaware Street S.E., as well as open our ambulatory clinical research facility on the second floor. We are thrilled at having a true home for clinical research.

Our grant application for the Institutional Clinical and Translational Science Award (CTSA) will be submitted in November. We will not stand still while waiting for the outcome, but will continue working toward the vision that we have described in this grant proposal. This includes: 1) the development of processes and systems that make conducting clinical and translational research easier for all investigators; 2) the creation of new educational and training opportunities in clinical and translational research; and 3) the integration of research nursing staff from the General Clinical Research Center and the Research Services Organization.

The commitment that the Academic Health Center has made to the future of clinical and translational research here gives us confidence that the enterprise will continue to grow and flourish to promote health.