Our Mission

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

The purpose of the Office of Clinical Research is to:

- Provide researchers (faculty and non-faculty) at the University of Minnesota with training and support services for conducting clinical and translational research projects;
- Assist investigators in procuring sponsored research funding; and,
- Increase public awareness and advocacy for clinical and translational research.
MESSAGE FROM THE EXECUTIVE DIRECTOR

Clinical research is a crucial link in improving health. By applying new knowledge to the development of new prevention strategies, new diagnostics, and new treatments, clinical research helps people not only live longer, but also live better, healthier lives.

The University of Minnesota is committed to advancing medical knowledge and breakthroughs. Across the Academic Health Center (AHC), in medicine, nursing, pharmacy, public health, dentistry, and veterinary medicine, more than 1,400 researchers strive to improve health and health care in order to better prevent and treat diseases and disorders. To support the University’s wide range of clinical research, the AHC’s Office of Clinical Research was opened in September 2005.

What is clinical research?
The National Institutes of Health (NIH) defines clinical research as patient-oriented research conducted with human subjects, including mechanisms of human disease, therapeutic interventions, clinical trials, and development of new technologies. Clinical research also includes epidemiologic and behavioral studies, outcomes research, and health services research. Another important aspect is translational research—applying laboratory-based discoveries to the development of studies in humans to “translate” research findings to the patient bedside. A second component of translational research is implementing knowledge learned at the bedside and adopting best practices in the community.

Initiatives within the Office of Clinical Research
The purpose of the Office of Clinical Research is to: provide researchers with training and support services conducting clinical and translational research; assist investigators in procuring sponsored research funding; and, increase public awareness and advocacy for clinical and translational research. Our vision for creating an academic home for research is outlined in our response to the NIH’s Institutional Clinical and Translational Science Award (CTSA) grant (page 19).

We are particularly interested in partnering with community members and organizations to investigate relevant research questions and to implement findings for improved health. We are addressing health disparities across the state and region (page 14).

We are dedicated to training and educating current and future investigators and have developed a range of services to this end. Our Office hosts a monthly Distinguished Visiting Scholars Series for leaders in the field of clinical and translational research to share their expertise with University faculty, staff, and students (page 12); we offer a summer program for predoctoral students to build their interest and experience in clinical research (page 14); we assist researchers in learning from each other at bi-monthly clinical research conferences (page 16); and, we offer periodic seminars on important topics, such as grant writing (page 18).
Scientists searching for better epilepsy treatments and the mutations that cause this troubling disorder are turning to dogs for help. Veterinarian researcher Ned Patterson is an expert on canine epilepsy. He conducts research into the way epilepsy-causing gene mutations pass from one generation of dogs to the next and also treats epileptic dogs. His work is of great interest to those examining epilepsy in people, as dogs provide a near-perfect model for studying human epilepsy. About 70 to 80 percent of epilepsy in dogs is inherited, and often, a dog will suffer from a form of epilepsy that is virtually the same as that in a human. Once an epilepsy-causing gene mutation is found in a dog, it can shorten the search for similar mutations in humans. One of Patterson’s goals is to identify the epilepsy mutations in dogs so treatment can be targeted to the specific type of epilepsy. Patterson also is collaborating with colleagues in the College of Pharmacy to determine if a particular epilepsy drug can be safely and effectively delivered as an injection into a muscle, which acts more rapidly than the drug's current oral option and could be given during a seizure.
FACULTY AND STAFF

JASJIT S. AHLUWALIA, M.D., M.P.H., M.S.,
EXECUTIVE DIRECTOR

Dr. Ahluwalia joined the University in September 2005 as the Executive Director of 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 associate dean for Clinical Research and director for the Center of Clinical Research in the Medical School. He is a professor in the Department of Medicine, where he conducts NIH-funded research working with ethnic minority populations.

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. He also served as an associate director of Cancer Prevention, Control, and Population Sciences at the Kansas Masonic Cancer Research Institute. He was principal investigator of the NIH K30 program and achieved successful renewal before leaving the University of Kansas. He also led a NIH-funded research team of 25 that investigated nicotine addiction and other chronic disease risk factors in African Americans.

Dr. Ahluwalia received his B.A. degree at New York University followed by a combined M.D./M.P.H. program at the Tulane University Schools of Medicine and Public Health. At the University of North Carolina at Chapel Hill, he completed a three-year Internal Medicine residency followed by a two-year Harvard Medical School General Internal Medicine fellowship in clinical epidemiology and a M.S. in Health Policy at the Harvard School of Public Health in 1992.

REBECCA A. MOEN, M.B.A., ASSOCIATE DIRECTOR

Ms. Moen joined the University in October 2005 as 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.
Ms. Moen was at Duke University for eight years, where she worked at the Duke Clinical Research Institute and the Office of the Vice Dean for Research. In both of these positions, her main focus was on increasing research funding from the National Institutes of Health for the institution. She received her B.A. degree in Communications from Augustana College in Sioux Falls, South Dakota, and her M.A. in Business Administration 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 works to implement and publicize new programs, such as the Distinguished Visiting Scholar Series, the “Writing Winning Grants” seminar, the Clinical Research Conference, and the Pre-doctoral Fellows program. She coordinates meetings of the Clinical Research Advisory Board, and search committees, and serves as a key contributor for the overall planning, formulating, and revising of office administrative policies/procedures/practices. She has also assisted in 12 new hires for the Office of Clinical Research. She helps facilitate the preparation of grant proposals and budgets and prepares financial reports for faculty and staff.

Ms. Jackson has been at the University of Minnesota since 1976. She has previously held administrative positions in the Vice President for Health Science’s Office, 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, as well as overseeing the communication needs of the office. She has more than 15 years communications experience, including four years at the University of Minnesota’s Academic Health Center Office of Communications, where she worked in media relations and as a feature writer covering clinical research for the publication *Pictures of Health.*

Prior to that, she worked in national news for NBC in New York and London and the BBC World Service in London. She has a M.S. in journalism from Boston University and is currently enrolled as a Ph.D. student in the University of Minnesota’s Rhetoric and Scientific Communications program. Her research interests include issues of health disparities and communication aspects of translating clinical research into clinical practice and policy.

MEREDITH CRAVEN

Ms. Craven, executive office and administrative specialist, provides administrative support to the executive director of the office. Ms. Craven also works with Ms. Jackson to help coordinate programming and
events, such as the Distinguished Visiting Scholar Series and the Clinical Research Conference. She is enrolled in the School of Journalism and Mass Communication, and is working toward her B.A. degree in Journalism on the Strategic Communications and Public Relations track.

**SHAWN LARSON, B.A.**

Mr. Larson, executive office and administrative specialist, provides administrative support for the Office of Clinical Research. He maintains e-mail listserves for the Clinical Research Conference and Distinguished Visiting Scholar Series and is working to redesign and improve the Office of Clinical Research Web site. Mr. Larson recently received a B.A. degree in Psychology from the University of Minnesota.

**FRANK LEDERLE, M.D.**

Dr. Lederle has been a key contributor in the inaugural year of the Office of Clinical Research, coordinating both the Clinical Research Conferences and the Distinguished Visiting Scholar Series. He is a professor of Medicine at the Veterans’ Administration Medical Center. His academic activity focuses on abdominal aortic aneurysms and on clinical research methodology and training. He has extensive experience conducting epidemiological, diagnostic, and treatment studies, including observational and database studies, randomized trials, and meta-analyses. He has been awarded more than $35 million in federal clinical research grants and has designed, developed, and chaired four V.A. Cooperative Studies. Dr. Lederle also directs one of only two V.A. Clinical Research Centers of Excellence.

**RUSSELL LUEPKER, M.D., M.S.**

As a member of the Executive Committee for the Office of Clinical Research, Dr. Luepker focuses on education, training, and career development. Dr. Luepker is a Mayo professor of Public Health, professor of Medicine, and Director of Graduate Studies in Clinical Research. Trained in medicine (cardiology) and epidemiology, his experience in clinical research covers the spectrum from observational studies in large free-living and hospitalized populations to classical clinical trials and community trials. Dr. Luepker has been consistently supported throughout his career with more than $100 million in NIH funding. He serves as the steering committee chair for the NHLBI, CATCH, and REACT trials. He is chair of the Framingham Heart Study Advisory Board and the Honolulu Heart Study Advisory Board.

In 1997, he organized the Clinical Research Master of Science Program designed for clinicians wishing to pursue a career in clinical research. Dr. Luepker is the program director and teaches three of the semester-long courses. Dr. Luepker co-chaired the AHC Clinical Research Task Force that led to the creation of this office, and is currently the program director for the NCRR-funded K12 program, Career Advancement Program for Clinical Research Scholars (CAPS).
Jeffrey S. Miller, M.D.

As a member of the Executive Committee for the Office of Clinical Research, Dr. Miller focuses on translational research. A professor of Medicine, he is also the 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. He co-directs the Transplant Biology and Therapy Program at the University of Minnesota Comprehensive Cancer Center and is medical director of the Inpatient Adult Blood and Marrow Transplant Unit. He has more than 14 years of experience studying the biology of natural killer (NK) cells and other immune effector cells and their use in clinical immunotherapy. He is currently the principal investigator of a five-year, $11 million program project grant on the mechanisms of NK cell maturation to learn about the role of NK cells and unrelated bone marrow transplantation to improve transplant outcomes for patients with hematologic malignancies. Dr. Miller has served on the editorial boards of *Experimental Hematology*, the *Journal of Hematotherapy*, and *Stem Cell Research*.

Dr. Miller received a B.S. degree from Northwestern University in Evanston, Illinois, and received his M.D. from Northwestern University School of Medicine. He completed an internship and residency in internal medicine at the University of Iowa in Iowa City. After completing a post-doctoral fellowship in Hematology, Oncology, and Transplantation at the University of Minnesota, he joined the faculty in 1991.

Mark Paller, M.D.

Dr. Paller is the assistant vice president for Research in the Academic Health Center, a Professor of Medicine, and a member of the Executive Committee for the Office of Clinical Research. Dr. Paller has served in a leadership role at the University of Minnesota since 1997. He led the creation of the Research Services Organization, which focuses on providing regulatory support for clinical researchers. He has also stimulated clinical and translational research by founding the AHC Clinical Scholars Program, the Faculty Research Development grant program, the Seed Funding grant mechanism, and the Translational Research Grant program.

Dr. Paller received a B.S. degree from Northwestern University in Evanston, Illinois, and received his M.D. from Northwestern University School of Medicine. He received his M.S. in Administrative Medicine from the University of Wisconsin-Madison. He completed a residency in internal medicine at Case Western Reserve University and a nephrology fellowship at the University of Colorado. He joined the University of Minnesota in 1982.
ELIZABETH R. SEAQUIST, M.D.

As a member of the Executive Committee for the Office of Clinical Research, Dr. Seaquist focuses on participant and clinical interactions. She is a professor in the Division of Endocrinology and Diabetes in the Department of Medicine at the Medical School and holds the Pennock Family Chair in Diabetes Research. Since 2002, she has been the director of the General Clinical Research Center and has served as Associate program director between 1997 and 2002.

Dr. Seaquist has broad experience in clinical research ranging from hypothesis driven explanatory investigations to large multicenter clinical trials. As a medical student, she designed and performed the first investigation that demonstrated the familial clustering of diabetic nephropathy; this was subsequently published in the *New England Journal of Medicine*. Over the past ten years, Dr. Seaquist has been funded by the NIH to look at the effects of diabetes on brain glucose metabolism and function. Dr. Seaquist participates in the Action to Control Cardiovascular Risk in Diabetes (ACCORD) Trial as the principal investigator of the University of Minnesota site. Dr. Seaquist also serves as the associate director of the Career Advancement Program for Clinical Research Scholars (CAPS) at the University of Minnesota.

Dr. Seaquist received her M.D. from the University of Minnesota, where she also completed a residency in medicine and a fellowship at the Division of Endocrinology. She joined the University of Minnesota faculty in 1989.

VALERIE O’BRIEN AND KATHY MISCHKE, RESEARCH SERVICES ORGANIZATION

Valerie O’Brien and Kathy Mischke work behind the scenes to support clinical research. As monitors, they help researchers meet the Food and Drug Administration’s Good Clinical Practice, a standard for the design, conduct, performance, monitoring, recording, analysis, and reporting of clinical trials. O’Brien and Mischke do not have a policing role, but one of quality improvement and support. “We offer assistance that will support researchers in monitoring and reporting how they perform clinical trials, and documenting any concerns,” says O’Brien. This enables researchers to concentrate more on science and less on paperwork.
The Clinical Research Advisory Board meets monthly to provide advisory input to the Office of Clinical Research. It comprises research leaders from the six colleges and schools of the AHC, Fairview Health Services, the V.A. Medical Center, Hennepin County Medical Center, as well as from key clinical research partners in the Twin Cities.

Jasjit S. Ahluwalia, M.D., M.P.H., M.S., executive director, AHC Office of Clinical Research, and associate dean of Clinical Research, Medical School

Adrienne Baranauskas, B.S.N., R.N., director, Research Administration, Fairview Health Services

Donna Bliss, Ph.D., R.N., professor in Long-Term Care of Elders, and interim assistant dean for Research, School of Nursing

John E. Connett, Ph.D., professor and head, Division of Biostatistics, School of Public Health

Barbara Elliott, Ph.D., professor, Department of Family Medicine and Community Health, Medical School, and faculty associate, Center for Bioethics

Richard Grimm, M.D., Ph.D., professor of Medicine, and director of the Berman Center, Hennepin County Medical Center

Brenda Hudson, M.S., science writing/communications manager, AHC Office of Clinical Research

John H. Kersey, M.D., professor and Children’s Cancer Research Fund Land Grant Chair, Laboratory Medicine/Pathology, Pediatrics, Blood and Marrow Transplant Program, and director, University of Minnesota Cancer Center

Frank Lederle, M.D., professor of Medicine, Medical School, and director, Center for Epidemiological and Clinical Research

Russell V. Luepker, M.D., M.S., Mayo professor, Division of Epidemiology and Community Health, School of Public Health

Bryan Michalowicz, D.D.S., M.S., associate professor and the Erwin Schaffer Chair in Periodontal Research, Department of Developmental and Surgical Sciences, School of Dentistry

Rebecca Moen, M.B.A., associate director, AHC Office of Clinical Research

Charles F. Moldow, M.D., professor of Medicine, and associate dean, Research Programs and Operations, Medical School
Nursing professor and clinical research scholar Diane Treat-Jacobson is interested in how exercise can help people suffering from claudication – a painful, debilitating symptom of peripheral artery disease in which muscles in the legs cramp during activity. “The pain, like a vise, comes with exercise and goes away with rest,” she explains. Currently, there are few effective noninvasive interventions. Treadmill exercise is used to improve patients’ walking ability, but it’s very painful. After reading a study that indicated arm cycling also improved claudication symptoms, Treat-Jacobson thought “this should be confirmed.” If performing arm exercise, which isn’t painful to patients, causes changes throughout the body that lead to improved symptoms in the legs, Treat-Jacobson and mentor, Jean Wyman of the School of Nursing, believe this may help many sufferers of claudication by reversing the cycle of debilitation.
The Distinguished Visiting Scholar Series (DVSS) is one of a number of new initiatives by the Office of Clinical Research to begin the transformation of clinical and translational research in the Academic Health Center (AHC). Each month, the 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. Visiting scholars have included:

“Challenges and Opportunities in Future Clinical Research”
David L. DeMets, Ph.D., chair, Department of Biostatistics and Medical Informatics, professor of Statistics and Biostatistics, University of Wisconsin, Madison. January 9, 2006

Dr. DeMets, who received his Ph.D. from the University of Minnesota in 1970, is one of the world’s leading authorities in the analysis of clinical trials. He is best known for his role in developing the Lan-DeMets alpha spending function now used in many large clinical trials to allow for interim review of data. His contributions to general clinical research include the use of surrogate outcomes, the design of Phase II trials, data monitoring, and ethics. He is co-author of a leading text on clinical trials and one on monitoring in clinical trials.

“Strategies for Publishing in the Best Journals: Personal Reflections”
Jerome P. Kassirer, M.D., distinguished professor, Tufts University School of Medicine, and adjunct professor of Medicine and Bioethics, Case Western Reserve University, and former editor-in-chief of the New England Journal of Medicine. February 23, 2006

In editorials in the New England Journal of Medicine, and in multiple publications since, Dr. Kassirer has promoted professionalism, ethical scientific conduct, patient involvement in decision making, and reliable approaches to the assessment of the quality of health care. He has been highly critical of for-profit medicine, the abuses of managed care, political intrusions into medical decisions, and financial conflicts of interest.
MARCH 29, 2006

“The Road to Successful Clinical Research: A Case Study in Pittsburgh”

David J. Kupfer, M.D., a professor of Psychiatry at the University of Pittsburgh School of Medicine, is the Thomas Detre Professor and chairman of the Department of Psychiatry.

As the director of research at Western Psychiatric Institute and Clinic (WPIC), Dr. Kupfer oversees the coordination and expansion of investigations among the department’s 200-member faculty. Under Dr. Kupfer’s direction, WPIC has become one of the nation’s preeminent university-based psychiatric centers, illustrated by the quality and number of publications and the amount of peer-reviewed federal funding for mental health research. He has been a key figure in the University of Pittsburgh Health Sciences’ meteoric rise in NIH grants.

APRIL 18, 2006

“Academic Success vs. Making a Difference, Academic Success AND Making a Difference”

Robert H. Brook, M.D., Sc.D., is a professor of Medicine and Health Services, UCLA Center for Health Sciences, program director of the Robert Wood Johnson/UCLA Clinical Scholar Training Program, and vice president and director, RAND Health.

Dr. Brook led the Health Quality Group on the $80 million Health Insurance Experiment and was co-principal investigator on the Health Services Utilization Study. Most of the quality of care and health status measures being used today throughout the developed world were produced by Dr. Brook and his colleagues.

MAY 23, 2006

“Clinical Trials, Confusing Messages, and National Guidelines”

Marvin Moser, M.D., is clinical professor of Medicine at Yale University.

Dr. Moser has been a leader in the management of hypertension for more than 50 years and participated in research on almost every antihypertensive agent that became available during that time. He was the senior medical consultant to the NHLBI National High Blood Pressure Education Program since its inception and chaired the NHLBI’s First Joint National Committee on hypertension (JNC I) in 1976. For many years, his cogent analyses of new studies in light of the proven benefits of diuretics stood as a bulwark against unwarranted claims of superiority for newer antihypertensive agents, until his position was ultimately vindicated by the ALL-HAT findings.
The health and life expectancy of Minnesotans consistently rank number one in the nation. Yet, this standard is not equally shared across the state’s diverse populations. Ethnic and racial minorities including African Americans, Asians, Latinos, and American Indians continue to experience poorer health and disproportionately higher rates of illness, such as diabetes, cancer, and heart disease, as well as shorter life spans.

### Predoctoral Clinical Research Training Program

In the summer of 2006, the office launched the Predoctoral Clinical Research Training Program. Six fellows were selected in this inaugural year to participate in a mentored clinical research experience, focused on a diverse array of research topics, from examining a neurologic basis for visual impairment to the genetics of HIV/AIDS in Uganda. Each fellow will complete eight to ten weeks of mentored research as well as participate in weekly didactic learning opportunities focused on building the interest of professional school students to pursue careers in clinical or translational research. The following students were selected to participate this year:

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<tr>
<th>Fellow</th>
<th>Mentor</th>
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<tr>
<td>Annie Arens</td>
<td>Scott Sponheim, M.D.</td>
<td>&quot;Cognitive and brain-based abnormalities in schizophrenic patients and first degree relatives&quot;</td>
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<td>Medical School</td>
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<td>Julie Espel</td>
<td>Scott Crow, M.D.</td>
<td>&quot;Heart rate variability in patients with anorexia nervosa&quot;</td>
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<td>Medical School</td>
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<td>Sheiren Farag-el-Massah</td>
<td>Pamela Jacobson, Pharm.D.</td>
<td>&quot;Pharmacogenetics of busulfan in pediatric patients undergoing hematopoietic cell transplantation&quot;</td>
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<td>College of Pharmacy</td>
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<td>Benjamin Ho</td>
<td>Doug Yee, M.D.</td>
<td>&quot;Research in breast cancer, carcinogenesis/chemoprevention programs&quot;</td>
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<td>Medical School</td>
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<tr>
<td>Sarah Lee</td>
<td>Paul Bohjanen, M.D., Ph.D.</td>
<td>&quot;IRIS syndrome in HIV/AIDS patients in Uganda&quot;</td>
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<td>School of Public Health</td>
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<tr>
<td>Jane Serene</td>
<td>S. Charles Schulz, M.D., and</td>
<td>&quot;Research in anatomical and/or biological causes of psychiatric disorders&quot;</td>
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<td>Harvard Medical School</td>
<td>Joel Oberstar, M.D.</td>
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To address health disparities, the Office of Clinical Research supports multidisciplinary research in collaboration with community members and partners. More than 100 investigators at the University are working in a wide range of areas, including: end-of-life issues among the homeless in Minnesota; diabetes and obesity prevention in American Indian communities; the relationship between periodontal disease and preterm birth in underrepresented minority or low socioeconomic status women; smoking cessation in African Americans; access of care in rural and underprivileged communities; the role of ethnicity, race, and culture in the mental health and well-being of Asian immigrant, refugee, and adoptee populations; and suicide prevention in Somali populations—to name just a few. This work represents collaboration throughout the Academic Health Center’s six colleges and schools and with the Community-University Health Care Center, Fairview Health Services, Hennepin County Medical Center, the Veteran’s Administration Medical Center, and a number of community partners.

In addition, the University’s Medical School initiated the Program in Health Disparities Research through the recruitment of Kolawole S. Okuyemi, M.D., M.P.H. The mission of the Program in Health Disparities Research is to develop, coordinate, conduct, and disseminate interdisciplinary research, education, and community partnership initiatives aimed at reducing and ultimately eliminating health disparities among minority and other underrepresented populations. Focusing on the needs of special populations is also an important component of the University’s response to the NIH’s Institutional Clinical and Translational Science Awards (CTSA) grant (page 19).

Building on current relationships between the University and communities, the Office of Clinical Research has formed a working group of more than 150 members from the University and community. The goal is to form relationships across disciplines and communities where participants are able to learn from each other and collaborate on meaningful efforts to reduce health disparities. Meetings have been held in February and May, including approximately 50 attendees from the University, Hennepin County Medical Center, V.A. Medical Center, NorthPoint Health and Wellness Clinic, Minnesota International Health Volunteers, Regions Hospital, Park Nicollet, Minnesota Partnership for Action Against Tobacco, HealthPartners, and Blue Cross Blue Shield.

The Office of Clinical Research is also devoted to facilitating education of researchers, care providers, and community members on issues of health disparities. This includes improving diversity among faculty and researchers at the University, sharing culturally appropriate guidelines to care providers, and working with community groups and partners on their needs. The office is launching a new quarterly symposium, where outstanding scholars addressing health disparities will be invited to the University for two days of interaction with University researchers and community partners.
The Clinical Research Conference 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. Meeting twice monthly, the purpose of the program is to support the career development of junior faculty interested in clinical research and to encourage research-oriented clinicians to develop independent research skills and gain experience in advanced methods and experimental approaches needed to conduct patient-oriented research. Attendance is open to all who are interested in clinical research.

The 2005-2006 conferences included:

September 16, 2005
Introduction to the conference and presentation of “Writing a Research Article”
**Frank Lederle, M.D.**, professor, Department of Medicine, Medical School

September 30, 2005
“Developing Clinical Research at the Mayo Clinic”
**Sherine Gabriel, M.D., M.Sc.**, chair, Department of Health Sciences Research and Director, Clinical Research Training Program (K30 and Roadmap K12), Mayo Clinic

October 21, 2005
“A Proposal for a Randomized Trial of the ACE Inhibitor Minocycline to Effect Cardiac Remodeling”
**Y. Chandrashekhar, M.D.**, associate professor, Department of Medicine, Medical School, and V.A. scholar

November 4, 2005
“The Long-term Consequences of Acute Postoperative Changes in Serum Creatinine – a Work in Progress”
**Areef Ishani, M.D.**, assistant professor, Department of Medicine, Medical School, and V.A. scholar

November 18, 2005
“Randomized Clinical Trial of Induction and Maintenance Therapy of Chronic Graft vs. Host Disease”
**Mukta Arora, M.D., M.S.**, assistant professor, Department of Medicine, Medical School, and AHC scholar

December 2, 2005
“Population Pharmacokinetics and Pharmacogenetics of Gemcitabine”
**Mark Kirstein, Pharm.D.**, assistant professor, College of Pharmacy, and AHC scholar

December 16, 2005
“NIH Peer Review”
**Elizabeth Seaquist, M.D.**, professor of Medicine, Medical School

January 6, 2006
“Antidepressants, Smoking, and Response to Mental Stress”
**Michael Kotlyar, Pharm.D.**, assistant professor, College of Pharmacy, and AHC scholar
January 20, 2006
“Mechanisms of Improvement in Response to Aerobic Training in Patients with Claudication”
Diane Treat-Jacobson, Ph.D., assistant professor, School of Nursing, and AHC scholar

February 3, 2006
“Development and Testing of a Decision Aid for the Treatment of Malignant Polyps of the Colon”
Rocco Ricciardi, M.D., assistant professor, Department of Surgery, Medical School, and AHC scholar

February 17, 2006
“Usefulness of Exercise Heart Rate Profile for Predicting Sudden Cardiac Death in the Community”
Selcuk Adabag, M.D., assistant professor, Department of Medicine, Medical School, and V.A. scholar

March 3, 2006
“Opportunities in Clinical Research”
Anne Joseph, M.D., professor, Department of Medicine, Medical School

April 7, 2006
“A Multicentered Randomized Controlled Trial to Determine the Efficacy of Disease Management for Diabetes”
Areef Ishani, M.D., assistant professor, Department of Medicine, Medical School, and V.A. scholar

April 21, 2006
“Improving Efficacy of Allopurinol and Colchicin Use in Gout Patients”
Jasvinder Singh, M.D., assistant professor, Department of Medicine, Medical School, and V.A. scholar

May 5, 2006
“Colon Cancer in Persons Undergoing Serial Colonoscopy for Colon Cancer Surveillance”
Mandeep Sawhney, M.D., assistant professor, Department of Medicine, Medical School, and V.A. scholar

May 19, 2006
“Deciphering Summary Statements: K23 Award Applications”
Elizabeth Seaquist, M.D., professor, Department of Medicine, Medical School

June 2, 2006
“Access and Quality of Care for Youth with Chronic Conditions during the Transition to Adult Health Care: Recent Findings and Research Project Planning”
Peter Seal, M.D., M.P.H., Fellow in Health Services Research and Policy, and assistant professor, Department of Pediatrics, Medical School

June 16, 2006
“Group Peer Review of a Research Article in Preparation”
Anne Marie Weber-Main, Ph.D., assistant professor and associate director of Research, Department of Family Medicine and Community Health, Medical School
The mouth can provide important clues to health. Leading a multidisciplinary research study, Bryan Michalowicz, director of the School’s Oral Health Clinical Research Center, is working with obstetricians to determine whether periodontal disease causes a higher incidence of preterm births. If the study shows that treating periodontal disease reduces a woman’s chance of experiencing premature birth or another poor birth outcome, it could have “significant implications for developing public health policy as it relates to the delivery of routine prenatal care,” Michalowicz says. Preterm and low birth-weight births are major causes of sickness and death in newborns and result in tragic numbers of long-term health problems and disabilities in children. A causal connection would indicate that straightforward and relatively inexpensive periodontal therapy delivered during pregnancy could give babies a healthier start in life. It would also “help reduce the substantial societal and financial costs associated with prematurity,” Michalowicz says.

**Grant Writing Seminar**

Writing grants can be one of the most intimidating activities that researchers face. Particularly for new investigators, the process of putting together a grant application can be overwhelming. Therefore, in April 2006, the Office of Clinical Research sponsored a day-long grant writing seminar for faculty in the Academic Health Center. The seminar was conducted by David Morrison, Ph.D., of Grant Writers Inc., a nationally renowned group that consults with most of the major academic health centers in the country. The seminar was attended by more than 100 individuals representing all areas of the Academic Health Center. This program will be offered on a yearly basis for faculty and staff in the AHC. The seminar was widely valued, as shown in several comments by participants:

“Definitely a useful tool. I had already read the handbook; however, the seminar centered my knowledge of the Morrison and Russell strategy of grant writing. I feel very well prepared for writing grants now, and am glad that the University provided the service. I’m sure it will pay for itself in the long run.”

“This seminar was very informative and the speaker presented a lot of potentially tedious information in an interesting and helpful format. He helped us understand what reviewers look for, and how “little things” can have a significant impact on the success of grant applications. This was time very well spent. Thanks!”

“Very helpful, I wish I had attended this seminar prior to submitting my first K23 award – I will use this information when I need to resubmit!”

“Awesome! Material presented in such a way that audience very engaged! I attended this workshop five years ago and got my first submission of R03 accepted. Attending it again has reminded me of the importance of writing for the reviewer. Thanks!”

“Believe it or not, I’m actually excited to get back to my office and work on my grant proposals!”
Institutional Clinical and Translational Science Award

A major portion of our first year was dedicated to the development of a large institutional proposal in response to a request for applications from the National Institutes of Health (NIH). The Institutional Clinical and Translational Science Award represents one of the largest and most challenging solicitations ever put forth by the NIH.

It called for “…institutions to forge a uniquely transformative, novel, and integrative academic home for Clinical and Translational Science that has the consolidated resources to: 1) captivate, advance, and nurture a cadre of well-trained multi- and inter-disciplinary investigators and research teams; 2) create an incubator for innovative research tools and information technologies; and 3) synergize multi-disciplinary and inter-disciplinary clinical and translational research and researchers to catalyze the application of new knowledge and techniques to clinical practice at the front lines of patient care.”

Fortunately, the University of Minnesota had already begun the process of moving toward this vision with the creation of the Clinical Research Task Force in 2003. This task force’s strongest recommendation was the creation of a central office of clinical research, which occurred on September 1, 2005, with the formation of the Office of Clinical Research. We were also able to use the task force’s report, which described the strengths, weaknesses, opportunities, and threats related to clinical research at the University, as a starting point for the grant application.

On November 1, 2005, the office held a strategy meeting with approximately 50 research leaders from the AHC and partners to begin the planning process for the grant. Between then and the deadline of March 27, 2006, over many meetings, phone calls, e-mails, and cups of coffee, the application coalesced into a comprehensive vision for the clinical and translational research enterprise at the University of Minnesota. Ultimately, approximately 100 faculty members and staff were involved in the birth of the CTSA grant, which weighed 6 lbs. 6oz. The final grant was 554 pages long and included a $66.2 million budget over five years.
In May, the office began the first of 20 Office of Clinical Research/CTSA Road Shows across the University to communicate the vision of the Office of Clinical Research and describe the CTSA grant application. In its first year, the NIH will fund between five and seven institutions. Although the University will not receive funding on the first round, the “pink sheets” will be helpful to determine the next steps.

THE OFFICE OF CLINICAL RESEARCH IS ALSO SUPPORTING CLINICAL RESEARCH THROUGH SEVERAL RECENT INVESTMENTS:

GENERAL CLINICAL RESEARCH CENTER (GCRC)
The Office of Clinical Research recently committed to funding two research nurses and a certified medical assistant in the General Clinical Research Center. These individuals will be focused on conducting research in the context of clinical care (experimental therapeutics). In addition, the Office is providing funding for the recruitment of a body composition technician, a human performance technician, and other laboratory expenses.

GENOMICS AND GENOTYPING SEED MONEY
The Office of Clinical Research has provided $150,000 seed funding to the BioMedical Genomics Center (BMGC) to assist investigators interested in initiating or developing research programs that utilize genomics approaches and genotyping related technologies. The purpose of the program is to enable investigators to take advantage of technological advances in genomics and genotyping to obtain preliminary data for the development of extramurally funded programs or for the translation of pre-clinical discoveries into clinical applications with a focus on improving human health.

BIOSTATISTICAL DESIGN AND ANALYSIS CENTER
The Office of Clinical Research is funding a new center to advance biostatistical support for clinical and translational researchers. The Biostatistical Design and Analysis Center will be staffed by experienced biostatisticians who will guide researchers in study design, design innovation, data analysis, and results reporting. The center will offer statistical consulting and analysis for clinical trials and smaller-scale studies, as well as provide initial consultations to help investigators develop new ideas for review.
KOLAWOLE S. OKUYEMI, M.D., M.P.H.,
MEDICAL SCHOOL

As director of the Medical School’s Program in Health Disparities Research, Okuyemi leads a team of researchers specifically devoted to facilitating research with underrepresented populations, including children, women, minorities, the elderly, and the poor. Working with community partners is important, says Okuyemi, whose own clinical and research experience draws on collaborations to address health disparities. He adds: “It is also critical to better understand mechanisms underlying health-related disparities and develop interventions to reduce and ultimately eliminate these disparities.” Okuyemi conducts interdisciplinary research in nicotine addiction and smoking cessation among minority and other underserved populations. He is principal investigator in a number of research projects on African-American light smokers, smoking cessation in homeless populations, and neuroimaging and pharmacokinetic smoking studies in African Americans and Caucasians.
Timothy Tracy’s research career began in the pharmacy. As a practicing pharmacist, he saw many clinical questions that needed to be answered. He recalls working in a high risk pregnancy/neonatal intensive care unit where women in premature labor literally shook from medication prescribed to stop labor. “I remember thinking, ‘There must be a better way,’” he says. In fact, Tracy did identify a different drug that enables the uterus to relax without such negative side effects.

Tracy’s research continues to focus on the body’s response to drugs, known as pharmacokinetics and pharmacodynamics. Currently, Tracy studies drugs that do not follow expected patterns of behavior or are affected by a person’s genetics. He hopes to develop a new set of rules that will predict how these drugs will behave in the body. Ultimately, these rules will reduce—or potentially eliminate—the need to pull drugs from the market because of unforeseen drug interactions. The discoveries could also increase the number of new drugs brought to market because manufacturers will better understand the effects of genetics on the actions of drugs.

Elizabeth Seaquist, M.D., Medical School

Endocrinologist Elizabeth Seaquist directs the University’s General Clinical Research Center (GCRC), one of 70 centers nationwide funded by the NIH to support clinical investigations. “While our primary mission is to support NIH-funded researchers,” she says, “we also have a strong training mission for investigators just starting their research careers.” Seaquist had firsthand experience with GCRC as she began studying diabetes in the early 1980s. “I simply wouldn’t be doing my research now if it wasn’t for the GCRC,” she says. “One of the best things about the GCRC is that researchers like me can grow their work and develop their own team.” Seaquist discovered that some people have a genetic predisposition to diabetic complications.
What’s Ahead?

The future is bright for clinical and translational research at the University of Minnesota. We are thrilled about the support that the University and Academic Health Center leadership has expressed for the enterprise and to find the number of enthusiastic and skilled clinical and translational researchers here. The next year will hold much in store for the Office of Clinical Research.

We will continue to advance our investment in clinical and translational research. In this regard, the NIH’s “pink sheets” from our Clinical and Translational Science Award grant will provide useful feedback for our strategy’s direction.

Because the CTSA grant describes the ultimate vision for clinical and translational research at the University of Minnesota, we are beginning to implement several of the concepts described, regardless of external funding. We have begun searches for a number of key positions and will be recruiting heavily this year to begin to create the infrastructure needed to support the clinical research enterprise. All of the investigators involved in the application have committed to begin implementation of their ideas as well.

In addition, we will continue to carry out and build upon our existing programs. We plan to offer a “pull-out” year for predoctoral students to obtain their Master’s degree in clinical research. We will continue to bring world-class leaders in clinical and translational research issues to the University to share their knowledge. And we hope to make the Clinical Research Conference a “must-attend” event for all clinical researchers in the Twin Cities.

Finally, we will continue to learn about the research being conducted here and find ways to improve the enterprise for faculty, staff, and participants.