As Interim Director of the Office of Clinical Research, I would like to say how excited I am to further the aims of our service organization in supporting the outstanding clinical and translational research conducted at the University of Minnesota. We have come a long way since the OCR opened more than two years ago, thanks to Jas Ahluwalia’s leadership: our space at 717 Delaware Street includes a new ambulatory clinical research facility, and the office integrates the work of the Research Services Organization (RSO), Biostatistics, Design, and Analysis Center (BDAC), and the General Clinical Research Center (GCRC). Going forward, we will build on this strong base to provide services that facilitate research to improve health in the State of Minnesota.

I am committed to applying OCR resources to meet our mission: to support and promote the University’s clinical and translational research enterprise. The office provides a range of useful services aimed at helping investigators and staff in the process and development of conducting research. (For a listing, please see the feature in this issue.) I anticipate advancing these services in the year ahead.

Finally, I would like to add that your feedback is invaluable as we continue to shape the support to ensure efficient and safe clinical and translational research. The Office of Clinical Research is here to serve our customers—those conducting and those participating in research—and I welcome your ideas and comments on how we can improve our service. Please feel free to contact me by email, phone, or in person at any time. Thank you for all the important work you do.
Resources and Support, continued.

monitoring, collecting biological samples and other forms of data, and assisting with IRB and other oversight body applications, subject recruitment, case report forms, adverse events, project finances, protocol amendments, and final reports. Contact: Debra Dykhuis, dykhu001@umn.edu, (612) 624-9154 or Nancy Flemmons, flemm006@umn.edu, (612) 624-4628.

Research Facilities: We manage two research facilities: the Delaware Clinical Research Unit (D-CRU) for ambulatory clinical research located at 717 Delaware Street, and the Masonic Clinical Research Unit (M-CRU) for high-intensity projects for both in- and outpatients located in the Masonic Cancer building. Contact: Nancy Flemmons, flemm006@umn.edu, (612) 624-4628.

Regulatory Support: We assist investigators in determining whether an IND or IDE should be filed and the filing of appropriate regulatory documents. Contact: Harvey Arbit, arbit002@umn.edu, (612) 625-0930.

Writing Laboratory: We offer a range of writing and editing assistance to clinical and translational researchers including grant writing workshops and a four-session scientific writing development series that focuses on writing for peer-reviewed journals. Contact: Brenda Hudson, bhudson@umn.edu, (612) 624-3422.

Save the date: “Medical Device Commercialization: Getting Great Ideas to Market”
June 9, 8 a.m.-5 p.m., Continuing Education and Conference Center, St. Paul campus
This full-day program will address what it takes to be successful in medical device commercialization, with a focus on overcoming constraints with clear, practical knowledge. Limited guest enrollment (no fee) for the first 20 full-time University of Minnesota faculty and 30 full-time graduate students. To register, visit www.ahc.umn.edu/ocr/events/lifesciencealley/

Latest Updates on NIH Public Access Policy. The NIH Public Access Policy is now in effect. Manuscripts arising from NIH-funded research must be submitted to NIH’s PubMed Central repository upon acceptance for publication and made available to the public within 12 months. For further information, go to http://www.lib.umn.edu/scholcom/NIHaccess.phtml. Also available is a letter from Vice President Mulcahy that may be downloaded and submitted to publishers, to assist authors in meeting their NIH obligations. This letter is available at http://www.lib.umn.edu/scholcom/umn-ovpr.pdf.

Useful research resources from Fairview. Research Data Reports, to determine clinical trial feasibility and recruitment, are available to researchers. Fairview will search its patient database and identify the number of patients or patient visits with specific diagnoses or procedures. Searches may also be conducted based on clinical laboratory results. For instructions, go to: www.fairview.org/inc/downloads/c_255982.doc and to access the form, go to: www.fairview.org/inc/downloads/c_253029.doc Demographic information on the Central Metro’s patient population also is available at www.fairview.org/Research/Resources/c_324888.asp

Looking for boilerplate information for your grant applications? Check out OCR’s website at www.ahc.umn.edu/ocr/toolbox/write/resources/
Thirteen AHC pre-doctoral students have been selected to participate in the summer 2008 Fellowship in Clinical and Translational Research. The growing shortage of clinical investigators in all health professions is well documented and reflects the chasm between research opportunities and numbers of trained clinical researchers. Various programs provide sound training for post-doctoral fellows and young faculty, but few address critical pipeline issues of stimulating interest in and providing initial clinical research training to pre-doctoral students. Bryan Michalowicz, D.D.S., associate professor in the School of Dentistry, serves as fellowship director. “The fellowship provides an opportunity to engage students, early in their careers, in a meaningful dialogue across disciplines,” he explains. “For this program, we defined clinical and translational research broadly, and recruited students who were best able to articulate their passion for research and define their research goals.”

The newly selected scholars will soon begin the 8- to 12-week paid fellowship, during which time they will 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 and other activities. “This model truly immerses the fellows in research environments and helps them to focus their career paths while gaining a better overall understanding of the role of clinical and translational research in health care,” adds Michalowicz.

Mandy Stahre, a Ph.D. student in the School of Public Health, was a pre-doctoral fellow in summer 2007. She explains how the fellowship helped to both focus her research path and broaden her perspective. “The pre-doctoral program allowed me to make connections beyond the School of Public Health,” she says. “The fellowship has been invaluable as a connection to other schools, students, and areas of research, as well as resources like grant writing assistance and workshops.” Stahre continues her work in alcohol use, focusing on the effects of various types of tobacco interventions on alcohol use behaviors. The direction and continued energy behind her research career, she says, are due in large part to the networking and mentoring opportunities available during the summer fellowship. “For me, the Office of Clinical Research is really a gateway to interdisciplinary research.”

**Front Row, L-R:** Michael Oh Sang Woo (medicine), Justin Miles (medicine), Kathryn Brown (medicine), Carolyn Bramante (medicine), Lynn Choromanski (nursing), John Stendahl (medicine).

**Back Row, L-R:** Ryan Wolff (dentistry), Phil Barbosa (medicine), Kathleen Berg (medicine), Ashley Aaron (medicine), Wade Swenson (medicine), Arthur Johnson (medicine)

**Not present:** Ahmed Salem (pharmacy, UMD)
Scholar Profile: Carolyn M. Garcia, Ph.D., M.P.H.

Powell Center BIRCWH scholar Carolyn Garcia, Ph.D., M.P.H., is assistant professor in the Integrative, Global, and Public Health Cooperative within the School of Nursing. Her research is focused on clinical trials in the field of adolescent health, specifically Latino adolescent stress and coping. As a BIRCWH scholar, she will be testing a school-based coping intervention for Latino adolescent females and exploring the use of reactive cortisol as an objective measure of intervention effect.

This research builds on García’s previous community-based work that identified mental health as a concern faced by the immigrant youth population. Involving the community in all aspects of her research is crucial to García. “We strategized with health, social, religious, and educational agencies serving the Latino community and then went back with the results, saying ‘Here’s what the youth and their parents are saying. What do we want to do about this?’” The next step was important, says García. “I felt strongly, now that we know this information, let’s do something.”

With community support, García developed a school-based group intervention to improve coping and reduce stress for Latina adolescents. The intervention emphasizes connectedness to school and peers and development of healthy strategies to combat stress. “These are factors that we can help influence,” says García. While unable to directly address certain issues that may increase stress, such as lacking legal documentation as immigrants, García’s study focuses on aspects that adolescents can use to address the things they can’t change. For instance, even though an adolescent may not have documentation for citizenship, they can be supported in ways that help to reduce anxiety and to stay in school. “We want to teach tangible life skills,” says García.

Her research aims to demonstrate change in the way adolescents react to stress. For instance, is there coping improvement? Is it possible to prevent adolescents from dropping out of school or developing depression? She also hopes to determine whether cortisol as a biomarker for stress is a viable tool in longitudinal intervention research.

As a BIRCWH scholar, García is provided with 75 percent protected time to conduct research. As part of a collaborative team, García will be working with Renee Sieving, Ph.D., associate professor, Center for Adolescent Nursing, School of Nursing; Gerald August, Ph.D., professor, Department of Psychiatry, Medical School; and Wendy Hellerstedt, Ph.D., M.P.H., associate professor, Division of Epidemiology and Community Health, School of Public Health.

Upcoming Events

Clinical Research Conference
8 - 9 a.m. in A110 Mayo
May 5, Diane Treat-Jacobson, Ph.D., assistant professor, School of Nursing
“Exercise training to reduce claudication: arm ergometry versus treadmill walking. Revising and resubmitting an NIH application”

May 19, Mark Kirstein, Pharm.D., assistant professor, College of Pharmacy
“Reversal of aberrant translation: strategies for establishing novel anticancer regimens”

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