

ACCELERATE

CLINICAL AND TRANSLATIONAL RESEARCH NEWS
FROM THE AHC OFFICE OF CLINICAL RESEARCH

PRIVACY AND DATA SECURITY

How does HIPAA affect clinical and translational research? What is the best way to protect private data held on a mobile device? What should you do if you suspect a security infringement of protected health information? These are some of the questions faced daily by Ross Janssen, AHC privacy and security officer, as he works with investigators and others to ensure the security of private data at the University of Minnesota.

“Clinical and translational research often involves sensitive information, such as patient data,” says Janssen. “It’s absolutely vital that we are compliant with security measures required for handling private data protected under federal and state laws, as well as University policies.”

The following are common issues and where to go for help:

(Continued on page 2)

UNIVERSITY OF MINNESOTA

Academic Health Center

DIRECTOR'S UPDATE

by Jasjit S. Ahluwalia, M.D., M.P.H., M.S.
Executive Director



Writing resources

One of the functions of the Office of Clinical Research is to provide support services for University researchers conducting clinical and translational research projects. In this regard, I would like to highlight two writing resources that I know you will find useful.

First, on April 5th, OCR is sponsoring “**Write Winning Grants,**” a popular day-long workshop for AHC faculty and research staff engaged in clinical and translational research. This seminar, led by David Morrison, Ph.D., of Grant Writers’ Seminars and Workshops, a nationally renowned group that consults with most major academic health centers in the country, provides valuable advice on all aspects of grant writing, focusing on the NIH. Past AHC participants, including me, have found this workshop to be detailed, engaging, and very useful. There is a nominal \$35 registration fee. For further details and to register, go to: www.ahc.umn.edu/ocr/writewinninggrants/.

We are also offering a no-cost **Scientific Writing Development Series**, consisting of four one-hour sessions on consecutive Fridays from April 13 through May 4, from noon until 1 p.m. (with lunch provided). Topics will include: tackling the writing process (April 13); anatomy of a manuscript (April 20); writing effective introductions and abstracts (April 27); and responding to reviewer comments (May 4). AHC faculty and research staff are encouraged to attend as many of the sessions as they choose. Registration details will be available in the March issue of *Accelerate*. In the meantime, if you are interested please save these dates.

We hope you find these resources useful. As always, we welcome any suggestions at ahcocr@umn.edu.

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NEWS

SPA deadlines are as follows:

5-day deadline for all Grants.gov proposals: All proposals that must be submitted through Grants.gov must be submitted to SPA at least five (5) working days prior to the sponsor's official published submission deadline. See the SPA proposal deadline calendar at:

www.ospa.umn.edu/GrantGov/DeadlineCalculator.

24-hour deadline for all non-Grants.gov proposals: All proposals that do not require submission through Grants.gov must be submitted to SPA at least 24 hours before SPA must send the proposal to meet the sponsor's deadline. For frequently asked questions about SPA deadlines and a memo from the VP for Research, go to www.ospa.umn.edu/policiesandprocedures/deadlines/deadlineFAQs.html.

Seed grants: The Academic Health Center (AHC) is accepting applications for seed grants to fund faculty research. These funds will be distributed through a competitive peer review process. Fourteen awards will be funded. The maximum award per project is \$25,000. The deadline is April 6, 2007. For details, go to www.ahc.umn.edu/research/funding/seedgrants/home.html.

Privacy and Data Security, continued.

HIPAA authorizations: Unless the IRB provides a waiver, investigators must have a HIPAA authorization, separate from a consent form, stipulating that the patient approves the use of his/her health information for a particular study. For further information, go to: www.research.umn.edu/irb/guidance/hipaa/.

Secure systems: Private electronic health information must be kept on secure systems that meet University and AHC data security requirements. For instance, desktop and laptop computers must have anti-virus software or filters installed and updated daily. Computers and other devices must have an identified local data owner (such as the principal user of the data or the unit supervisor) who is responsible for the data and can act as a point of contact. For further information, go to: www1.umn.edu/oit/security/privatedata.html.

Encryption: For researchers storing private data on laptops or other mobile devices, encryption is required by the University's Securing Private Data Standard. Encryption translates data into a secret code; to read encrypted files, access to a secret key or password is required. For assistance, go to: www1.umn.edu/oit/security/Encrypting_Stored_Data.html.

Reporting violations: It's also important that the protocol for responding to a security problem is understood, Janssen adds. For examples of reportable violations and how to report them, go to: www.fpd.finop.umn.edu/groups/ppd/documents/procedure/rept_violations.cfm, call Janssen at 612 626-5844, or email janss006@umn.edu.



SPOTLIGHT

*Treat-Jacobson, center,
with study participant and
research assistant*

ARM EXERCISE FOR PAD

Progressive exercise training on a treadmill has been shown to reduce claudication, a debilitating symptom of peripheral arterial disease (PAD); however, walking is often difficult for these patients, as PAD restricts blood flow to the limbs, causing leg muscle fatigue, cramping, and pain. Now, researchers like AHC Clinical Scholar Diane Treat-Jacobson believe the benefits of walking may be obtained while staying seated. She is a participant in the AHC-sponsored Clinical Scholars program, a predecessor to the CAPS program, which provides mentoring and financial support to junior faculty pursuing clinical research.

Treat-Jacobson, Ph.D., an assistant professor in the School of Nursing, hopes to improve PAD symptoms through use of an arm ergometer (see photo). Unlike walking, aerobic arm exercise is not painful for patients with claudication. Her study, funded by the American Heart Association, compared arm ergometry training to the gold standard of treadmill training. She and her team measured how far 35 PAD patients could walk on a treadmill without leg pain, and how far they could continue to walk before pain forced them to stop. The participants were then randomly assigned to a control group (no exercise) or to one of three exercise groups: use of a treadmill only, use of an arm ergometer only, or use of both.

The results of Treat-Jacobson's study were reported at the 2006 American Heart Association Scientific Sessions. After three months of training, patients in all three exercise groups showed improvement (150-330 meters, or 2 to 3½ blocks) in the total distance they could walk. Patients in the treadmill group showed the most improvement, but those in the arm ergometry group also had significant benefits compared to those who did not exercise. Additionally, treadmill and arm exercisers showed similar improvement in the distance walked before pain started (more than 100 meters, or about 1½ blocks). "We were happy to discover that upper body aerobics can help patients with PAD increase the distance they can walk without pain," says Treat-Jacobson.

She now seeks participants for the second phase of her study, which will measure vascular and cardiorespiratory function to help determine if there are differing physiological responses between those who use arm training and those who use treadmill training. Eligibility criteria for this study include symptomatic PAD (claudication) and the ability to participate in a 12-week supervised exercise program. "Confirmation of the results of our pilot study would provide evidence that aerobic upper-body exercise is a pain-free alternative for patients with PAD who cannot or do not wish to perform treadmill exercises because of leg pain," she says.

For more information on this clinical trial, or to discuss enrollment, please contact Diane Treat-Jacobson at treat001@umn.edu.

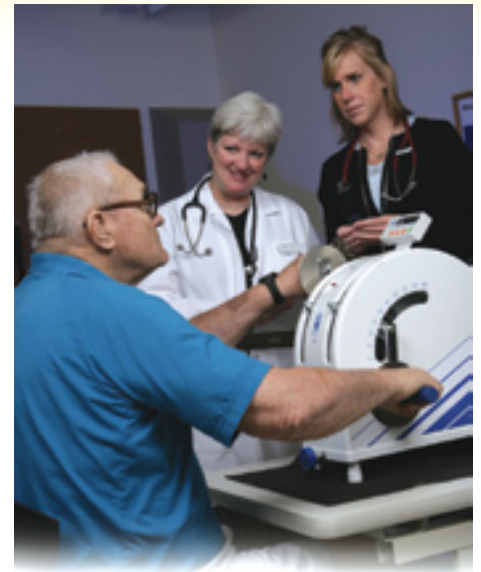


Photo by Tim Rummelhoff

UPCOMING EVENTS

"Write Winning Grants"

April 5, 8:30 a.m.-4:30 p.m.

Holiday Inn Metrodome, west bank campus

This popular seminar offers detailed guidance on all aspects of grant writing, focusing on the NIH.

Registration fee: \$35

Register online at: www.ahc.umn.edu/ocr/writewinninggrants/.

Scientific Writing Development Series

Save the dates for this no-cost series (see Director's Update, page 1)

12-1 p.m., 1-450G Moos Tower

April 13: Tackling the writing process

April 20: Anatomy of a manuscript

April 27: Writing effective introductions and abstracts

May 4: Responding to reviewer comments

Further details, including registration, will be available in March.



CAPS PROFILE: PETER MILEV, M.D., PH.D.

Variables that may predict outcomes in schizophrenia, a heterogeneous disorder with both behavioral and cognitive phenotypes, are the focus of the work of Peter Milev, M.D., Ph.D., with structural and functional imaging, and magnetic resonance spectroscopy. Milev hypothesizes that people with a particular subtype of disorganized schizophrenia may have regional changes in the concentrations of GABA, glutamate, and glutamine in their brains. Changes in these important neurotransmitters may also be related to deficits in perceptual organization; concentrations of these molecules may have a prognostic value, and people with disorganized schizophrenia may respond better to medications affecting GABA and glutamate in the brain.

A CAPS scholar and psychiatrist, Milev is interested in learning more about the pathogenesis of schizophrenia and whether new agents that affect the glutamatergic system and GABA may have benefit in the treatment of the disorder. "I have been interested in neuroscience since I did my Ph.D., moving from medicine to studies at the molecular/cellular level, and then to brain imaging," says Milev. "CAPS now gives me an opportunity to integrate all of these while working with great mentors and advanced imaging hardware and software."

Milev plans to continue his efforts in clinical schizophrenia research while developing as an expert in the assessment and treatment of people with psychotic disorders. He looks forward in particular to research on tasks of visual perception which will be carried out at the University's Center for Magnetic Resonance Research (CMRR) with mentor Kelvin Lim, M.D.

Following a research fellowship in an NIH-sponsored Clinical Research Center at the University of Iowa, Milev joined the Department of Psychiatry at the University of Minnesota as assistant professor. He earned his M.D. and a Ph.D. in Molecular and Cellular Genetics in Bulgaria and will complete a master's degree in clinical research as part of his CAPS program. He credits Lim, one of the leading experts in the use of MRI in psychiatric illness, and the expertise and support for schizophrenia research of Charles Schulz, M.D., head of the Department of Psychiatry, as major factors in his coming to Minnesota. Milev hopes that advanced mechanistic research will lead to improved understanding and treatment of schizophrenia in general.

As a CAPS scholar, Milev is allocated 75 percent protected time for research. He works closely with his three research mentors, Kelvin Lim, M.D., professor and vice chair for research, Department of Psychiatry; Angus MacDonald III, Ph.D., assistant professor, Department of Psychology; and Susanne Lee, Ph.D., assistant professor, Department of Psychiatry.

UPCOMING EVENTS

Distinguished Visiting Scholars Series in Health Disparities

Feb. 16, 12-1 p.m.

1-450G Moos Tower

Loretta Jemmott, Ph.D., R.N.,
F.A.A.N., Director, Center for
Health Disparities Research
University of Pennsylvania, School
of Nursing

***"Recruitment of ethnic minorities
into clinical trials"***

Clinical Research Conference

**8 - 9 a.m., 2-101 Nils Hasselmo
Hall**

Mar. 5, Peter Milev, M.D., Ph.D.,
assistant professor of psychiatry,
Medical School

***"Studies of visual perceptual
organization and thought disorder
in schizophrenia: functional
MRI and magnetic resonance
spectroscopy of glutamate and
GABA"***

Mar. 19, Michael Kotlyar,
Pharm.D., associate professor,
College of Pharmacy

***"Nicotine addiction and stress
response"***

**To subscribe or unsubscribe,
email us at ahcocr@umn.edu**

EXTERNAL FUNDING OPPORTUNITIES FOR CLINICAL AND TRANSLATIONAL RESEARCH TRAINING IN YEAR-LONG PULL-OUT PROGRAMS

For further information, including submission deadlines, please visit the Web sites listed for each program.

PROGRAM/FUNDING	SPONSOR/CONTACT	LAST APPLICATION DEADLINE/DESCRIPTION
<p>NIH Clinical Research Training Program (CRTP) Stipend of \$29,400, tuition and books, health insurance, computer allowance, domestic conference travel, travel and relocation expenses.</p>	<p>NIH www.training.nih.gov/crtp</p>	<p>January The CTRP, a public-private partnership supported jointly by the NIH and a grant from Pfizer, Inc., awards clinical research grants to 30 medical and dental students for a year of training at the NIH. The residential program includes a mentored clinical or translational research project, a seminar and journal club series and clinical teaching rounds. Applicants must have completed a year of clinical rotations.</p>
<p>NIH Pre-doctoral Intramural Research Training Award (IRTA) Research stipend depending on amount of education at time of award. Travel to first duty station and/or to scientific meetings may be available.</p>	<p>NIH www.training.nih.gov/student.Pre-IRTA/irtamannualinterim.asp</p>	<p>3 to 6 months prior to the desired start date IRTA fellowships are designed to augment the educational preparation and development of future scientists by supporting a period of research at the NIH. Applicants may delay matriculation if accepted into graduate school or medical school, or may be currently enrolled in either.</p>
<p>NIH Research Supplements for Underrepresented Minorities Research salary on an NIH research grant.</p>	<p>NIH grants.nih.gov/grants/guide/pa-files/PA-99-104.html</p>	<p>At least 8 weeks before the start date of the project This program allows faculty members who hold specific, commonly held types of NIH research grants to request additional money to fund an underrepresented minority student for a research experience that is an integral part of the parent grant. Any minority graduate student who is enrolled in a masters or doctoral degree program in biomedical or behavioral sciences, or a masters in nursing sciences or social work may be eligible.</p>
<p>Fogarty International Center/ Ellison Overseas Fellowships in Health and Clinical Research Stipend of \$18,000 - \$20,000 (adjusted to overseas cost of living), travel, insurance and educational materials.</p>	<p>NIH/AAMC www.aamc.org/students/medstudents/overseasfellowship/start.htm</p>	<p>December One-year fellowships for 25-30 medical or osteopathic students and doctoral students in public health, nursing or dentistry interested in pursuing careers in public health and clinical research. Mentored clinical research training provided at top-ranked NIH-funded research centers in developing countries. Applicants must have completed one year of clinical clerkship or coursework and qualifying exams for doctoral students.</p>
<p>"The CDC Experience: Applied Epidemiology Fellowship at CDC" Stipend of \$24,000, including an allowance for health insurance and relocation. Most students are able to have their loans deferred.</p>	<p>CDC www.cdcfoundation.org/fellowships/cdcexperience/index.aspx</p>	<p>December Funded by a grant from Pfizer, Inc., the fellowship provides 8 medical students with an applied hands-on training experience in epidemiology and public health at the CDC in Atlanta. With the guidance of experienced CDC epidemiologists, they carry out epidemiologic analyses and research.</p>
<p>American Australian Association Stipend of \$25,000, including travel.</p>	<p>www.americanaustralian.org/usa-australia.php</p>	<p>March Up to 4 U.S. graduate students are selected to conduct well-defined research projects in fields including medicine and life sciences. There will be particular interest in the field of stem cell research.</p>
<p>American Diabetes Association-- Medical Scholars Award Stipend of up to \$20,000 and tuition, lab expenses and grant-related travel of up to \$10,000.</p>	<p>ADA www.diabetes.org/diabetes-research/research-grant-application-forms/medical-scholars-awards-online-submission.jsp</p>	<p>January These awards are designed to produce leaders in the fields of diabetes research, teaching and patient care. Applicants must be medical students who have completed years two or three.</p>

PROGRAM/FUNDING	SPONSOR/CONTACT	LAST APPLICATION DEADLINE/DESCRIPTION
<p>American Heart Association Pre-doctoral Fellowship Stipend of \$21,000 plus \$1,000 for health insurance and up to \$4,000 in project support.</p>	<p>AHA www.americanheart.org/presenter.jhtml?identifier=9215#Predoc</p>	<p>January This fellowship is designed to help students initiate a career in cardiovascular research by providing mentored research assistance and training. Duration is up to two years. Applicants are postbaccalaureate, pre-doctoral MD, PhD, DO, DVM (or equivalent) students.</p>
<p>American Society of Nephrology Student Scholar Grant Stipend of \$20,800, \$5,200 to the PI's lab, up to \$1,500 to attend ASN meeting.</p>	<p>ASN www.asn-online.org/grants_and_funding/SSG-Grant.aspx</p>	<p>February This fellowship is for currently enrolled medical students without other sources of stipend support. The mentor must be an ASN member and must submit a program of study for the applicant. Support beyond 12 weeks requires evidence of productivity from the sponsor and student.</p>
<p>Doris Duke Clinical Research Fellowships Stipend of \$27,000 plus health insurance, funding to attend the annual Clinical Research Fellowship meeting and other research meetings, and supplementary research and training funds.</p>	<p>Doris Duke Charitable Foundation www.ddcf.org/page.asp?pageId=292</p>	<p>January A minimum of 50 fellows each year are sponsored for clinical research and didactic clinical research training at one of 10 outstanding medical schools. Students matriculated at any medical school in the U.S. are eligible to apply to any or all of the 10 designated schools.</p>
<p>Howard Hughes Medical Institute Scholars and Fellows (1) Research Scholars Program (The Cloisters) Stipend of \$25,000, paid health insurance and other coverage, moving expense reimbursement, and certain other costs. (2) Research Training Fellowships for Medical Students Stipend of \$25,000, \$5,500 institutional research allowance, \$5,500 institutional fellow's allowance.</p>	<p>Howard Hughes Medical Institute 1) www.hhmi.org/cloister/ 2) www.hhmi.org/grants/individuals/medfellows.html</p>	<p>The only yearlong program that offers tuition and support toward completion of a medical or dental degree or loan repayment of debt. Two program components. A large proportion of awardees remain engaged longterm in patient-related research. January 1) Run in partnership with NIH, this program brings 42 awardees to the HHMI campus each year to take classes and engage in research. January 2) This fellowship supports 60 students in mentored research at their home campus that probes basic biological processes or disease mechanisms.</p>
<p>Lindbergh Foundation Grants: Health and Biomedical Research Grants of up to \$10,580 to further the vision of a balance between the advance of technology and the preservation of the natural/human environment.</p>	<p>Charles A. and Anne Morrow Lindbergh Foundation www.lindberghfoundation.org/grants/index.html</p>	<p>June These grants (in a symbolic amount representing the cost of the "Spirit of St. Louis") are available to scholars whose individual initiative and work furthers the Lindberghs' vision. Health categories include biomedical research, health and population sciences, and adaptive technology.</p>
<p>Pharmaceutical Research & Manufacturers of American Foundation (PhRMA) Stipends and various expenses [see individual fellowship descriptions].</p>	<p>PhRMA www.phrmafoundation.org/</p>	<p>September or October [see individual fellowship descriptions] The PhRMA Foundation offers fellowships for medical, dental and pharmacy students in clinical pharmacology, health outcomes, pharmacology/toxicology, and pharmaceuticals. [Details can be found on the individual fellowship web pages.]</p>
<p>Sarnoff Endowment for Cardiovascular Sciences Stipend of \$25,000, travel expenses, moving expenses and certain other costs.</p>	<p>Sarnoff Endowment www.sarnoffendowment.org/fellowships.html</p>	<p>January The endowment offers up to 15 clinical research awards per year to medical students who conduct intensive work with a laboratory preceptor in a biomedical research lab at an institution other than their own. A unique feature is lifetime commitment to the fellow, including the Sarnoff Scholar Transition Award.</p>