REGISTERING CLINICAL TRIALS

Researchers may be aware that certain clinical trials must be registered with ClinicalTrials.gov (see page 2 in last month’s Accelerate). But where can a researcher go for help in determining if a particular clinical trial falls under that ruling, or for assistance in the registration process?

The answer is Harvey Arbit, Pharm.D., the University’s administrator for ClinicalTrials.gov. In addition to directing the IND/IDE Assistance Program, Arbit can help investigators determine whether their study requires registration. If so, he can establish individual accounts for the investigator and will review, approve, and release data for publication on the ClinicalTrials.gov site.

(continued on page 2)

Announcing the OCR Writing Laboratory

For any academic researcher, an important corollary to developing scientific knowledge and research expertise is the development of writing expertise. To help support faculty in the Academic Health Center, I am pleased to announce the launch of a new initiative in the Office of Clinical Research: the OCR Writing Laboratory. This initiative aims to provide a range of writing and editing assistance to clinical and translational researchers. Our first offering will be a Grant Writing Assistance service, initially available to AHC assistant professors working on NIH and other grant applications. While we are focusing on the assistant professor level at this point, we hope to expand the service in the future.

Assistant professors looking for help with RFA/PA review, detailed editing of the abstract and application, and/or a final read-through before submission can receive individual assistance, as our capacity allows. While our Writing Laboratory staff do not consult on scientific content, they are experienced at working with faculty to promote clarity, organization, and adherence to RFA/PA guidelines. We ask interested faculty to allow reasonable time for work before their grant deadline. Faculty wishing to use this service should contact Nancy Johnson at 612-625-1651 or nancyj@umn.edu.

In addition, in spring 2008, we will offer a four-session Scientific Writing Development Series, which will focus on aspects of manuscript writing. This, and other Writing Laboratory initiatives, will be announced in future issues of Accelerate.

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Arbit even recommends registering trials that are not required to do so. “It certainly can’t hurt. Even if a study doesn’t require registration from a regulatory point of view, registering may still benefit the investigator,” he says. Many peer-reviewed journals require that clinical trials be registered in order to accept publication of their results. While not all journals have this requirement, registering means an investigator has already covered the bases, Arbit explains.

Registering with ClinicalTrials.gov through Arbit provides other benefits too. As administrator, he is notified of errors in an investigator’s registration application. He can then fix the mistake or follow up with the investigator. “We also send out reminders for required updates, such as if a protocol is changed,” says Arbit. He also keeps abreast of new regulations and can alert investigators as necessary. For instance, he can assist with the FDA’s new form requiring that ClinicalTrials.gov information be submitted in the IND or IDE application.

For assistance, contact Harvey Arbit at 612-625-0930 or by email arbit002@umn.edu. For more information, please see the following: www.ahc.umn.edu/research/ind-ide/ and/or http://grants.nih.gov/grants/guide/notices/files/NOT-OD-08-014.html.

News

Academy for Excellence in Health Research: March 14 nominations deadline

Nominations are encouraged from all AHC colleges and departments for this award, the highest University recognition of research excellence. Up to four faculty members will be selected each year, receiving $10,000 annually for five consecutive years (which may augment their salary or support their research), and a lifetime membership in the academy. For more information, to go: http://www.ahc.umn.edu/research/academy.

2008 Summer Pre-doctoral Fellowship Program: applications are being accepted from pre-doctoral students in any of the AHC schools (D.D.S., D.V.M., M.D., Pharm.D., D.N.P. or Ph.D.). Up to eighteen students will be awarded 8- to 12-week paid fellowships to work with established investigators on an ongoing clinical or translational research project and will participate in weekly seminars. Application deadline is February 1; applicants will be notified by March 1. Applications and instructions are available at www.ahc.umn.edu/ocr.

Register now for a graduate course on clinical research. PubH 6305 - Introduction to Clinical Research for Health Professionals, taught by Russell Luepker, M.D., is designed for nurses, coordinators, and others working in or preparing to work in a clinical research setting. For more information on the course view the syllabus from Spring 2007 http://www.epi.umn.edu/students/syllabi.shtml, or to register, contact Kathryn Schwartz (schwa139@umn.edu).

NIH reduces temporary “error correction window” for electronic grant applications from five business days to two. The first phase of NIH’s plan to have error free/corrected applications in by the due date will begin with submission deadlines on or after January 8, 2008. NIH will reduce the “error correction window” (i.e. the time allowed after the submission deadline to address NIH system identified errors/warnings) from five (5) business days to two (2) business days for all electronic grant applications. There will no longer be grace periods after the deadline. The two business days provided to view the assembled application image in eRA Commons will remain unchanged. For more information please see the NIH Notice NOT-OD-08-018.

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

www.ahc.umn.edu/ocr
In May 2007, FEDS received a community-University planning grant in health disparities research, co-sponsored by the Office of Clinical Research and the Medical School’s Program in Health Disparities Research. WhiteEagle and Mendenhall are co-principal investigators. “We knew, anecdotally, that FEDS helped participants manage diabetes and improve their overall well-being. With the support of this grant, we are able to collect empirical data to evaluate the program,” explains Mendenhall. At each session, FEDS participants check and record blood sugar levels, weight, BMI, blood pressure, and conduct foot checks. Data analyzed so far are encouraging. Average blood pressure is trending down for both systolic and diastolic measures, average weight loss is approximately 10 pounds, and metabolic control has improved significantly; average values now are within treatment range. “The room erupted into cheers and applause when we shared these initial data with participants,” says Mendenhall.

This data will be incorporated into a field manual for the FEDS program, and the team is submitting an NIH R03 application to further evaluate the effectiveness of the Citizen Health Care Model, focusing on the Family Education and Diabetes Series.
Because pain is subjective, a quandary for investigators is how to measure it—an issue faced by CAPS scholar Donald Nixdorf, assistant professor in the School of Dentistry. Nixdorf investigates chronic orofacial pain, experienced by some patients with temporomandibular disorders (TMD) or following dental treatments such as root canal therapy. A standardized means to measure pain will help researchers classify it and assess treatment efficacy.

“When people feel pain, there is an underlying biological event within the brain,” says Nixdorf. “The challenge is to identify this signal and be able to quantify it.” To do this, Nixdorf plans to employ two approaches: psychophysics and functional magnetic resonance imaging (fMRI). Psychophysics aims to measure the relationship between physical magnitude and the corresponding perceived or subjective magnitude, while fMRI is used to determine how the brain responds to physical stimuli. “Using this approach we plan to measure those components of chronic pain disorders likely to indicate chronicity, hoping to apply this knowledge in clinical practice by relating outcomes to signs and symptoms,” says Nixdorf.

Nixdorf’s previous psychophysical investigations examined the tactile sensibility of subjects with TMD pain versus normal controls. He assessed pain response to three tactile stimuli, revealing that one stimulus was repeatable with good ability to classify subjects with TMD pain correctly and fair ability to classify subjects who did not have pain.

Working with faculty in the Center for Magnetic Resonance Research, as well as a graduate student in the Master of Science in Dentistry program and a physics engineer, Nixdorf is developing a method of administering a tactile stimulus within a subject’s mouth during functional imaging. Pain-free individuals feel this stimulus as touch but not pain, unlike individuals with chronic pain, who tend to experience the stimulus as painful. Nixdorf hopes this approach will allow him to observe non-invasively how brains of individuals with chronic pain function differently than those of people without pain.

As a CAPS scholar, Nixdorf is provided 75 percent protected time to conduct his research. “My research is in an exploratory phase,” he says, “and through the CAPS program, I have been able to develop a framework to start looking at my research questions and access cutting-edge technologies to help answer them.”

Nixdorf’s research and his mentoring team are multidisciplinary. The team includes School of Dentistry professors Eric Schiffman, D.D.S., M.S., and David Bereiter, Ph.D.; biostatistician Jim Hodges, Ph.D., M.A., associate professor, School of Public Health; Noam Harel, Ph.D., assistant professor of radiology, Medical School; and consultants Mike John, D.D.S., Ph.D., associate professor, School of Dentistry, and Ana Velly D.D.S., Ph.D., research associate, School of Dentistry.

### Upcoming Events

**Clinical Research Conference**
8 - 9 a.m. in 1-450G Moos Tower
Jan. 7, David Boulware, M.D., assistant professor, Medical School, Department of Medicine
“HIV Immune Reconstitution Syndrome in Sub-Saharan Africa”

**Distinguished Visiting Scholar Series**
12:05 – 1:05 p.m. in 2-690 Moos Tower
Jan. 10, Bruce Psaty, M.D., Ph.D. Professor, Medicine & Epidemiology University of Washington Cardiovascular Health Research Unit
“U.S. drug safety system and the FDA Amendments Act”