



The Bayview General Clinical Research Center

VOLUME 2, ISSUE 2

SUMMER/FALL 2005

INSIDE THIS ISSUE

- ⇒ An Update from the Program Director
- ⇒ The Introduction to Clinical Research Course
- ⇒ Nursing in the GCRC
- ⇒ New GAC Approved Protocols and CReFF Award
- ⇒ *In Focus:*
 - ◆ *Inside the Informatics Core*
 - ◆ *About the Research Subject Advocate*
- ⇒ *Of Statistical Significance*
- ⇒ *Staff Transitions*
- ⇒ *Kudos!*
- ⇒ *Important Dates and Resources for Investigators*

An Update from the Program Director: Pamela Ouyang, M.D.

It is just over six months since our renovation and much has changed! Along with the addition of nearly 15 new protocols, the Bayview GCRC now has a new Principal Investigator: Dr. Daniel E. Ford.

In late July, Dr. Ford was named the new Johns Hopkins School of Medicine Vice Dean for Clinical Investigation, a position that traditionally includes leadership of the two GCRCs at Hopkins.

We certainly anticipate sustained momentum at the Bayview GCRC and look forward

to working with Dr. Ford. At the same time, we thank Dr. Michael Klag for his expert guidance, support, and enthusiasm.

Naturally, we also wish Dr. Klag every success, as he takes the helm as Dean of the Johns Hopkins Bloomberg School of Public Health.

In this issue of the Newsletter, we focus on the research nurses at the Bayview GCRC, highlighting their indispensable role in the clinical studies conducted at the GCRC. Each nurse's, past and present, dedi-

cation is a testament to the missions of the Bayview GCRC and Johns Hopkins University: research, education, and patient care.

Finally, I want to invite formally new members of the research community at Hopkins to enroll in the Bayview GCRC's Introduction to Clinical Research Course. It is a unique opportunity and a valuable educational resource. Check the GCRC website and the information in this Newsletter for details. On behalf of the Course presenters, I hope to see you there!

The Introduction to Clinical Research Course

On September 12, 2005 the John Hopkins Bayview Medical Center's General Clinical Research Center GCRC will begin its 12th annual series of courses about important concepts in the design and conduct of patient oriented research.

This popular set of lectures is a traditional offering of the Bayview GCRC and is widely attended by investigators, research personnel, and students throughout the Johns Hopkins research community.

The interactive lectures are presented by GCRC faculty and research staff with broad experience in research. Specifically, the GCRC Program and Associate Program Directors, Informatics and Laboratory Core Directors, and additional staff representing nursing, biostatistics, dietary, administration, research subject advocacy, and the IRB will give presentations in their respective areas of knowledge and expertise.

Along with the principal lectures, there are three concurrent sessions. For three days the topics will be split between biostatistics and concepts related to research nursing and Bionutrition.

The series will run from Monday, September 12, 2005 through Wednesday, September 28, 2005. Specific information about the courses, lecture times and locations, and registration instructions are available on the Bayview GCRC website: <http://gcr.jhbmc.jhu.edu/course1.html>, or call the GCRC office at 0-1850 for more details. Registration forms may be faxed to the GCRC office (0-1227). There is a fee of \$50.00 per person, which includes a light breakfast beginning at 7:30 AM. The lectures run from 8:00 to 9:00 AM.

Each lecture is eligible for 1.2 Contact hours for Nursing. Also, Continuing Education Units (CEUs) for attending the entire series is available from the Maryland Nurses Association.

Research Nursing at the GCRC: On the front lines of progress

Everyday on the floor of the Bayview General Clinical Research Centers, research nurses carry out various study procedures with patients enrolled in the facility's many clinical trials. The expert performance of these responsibilities is critical to the success of the individual studies, as well as to the overall mission of the GCRC.

This mission is the provision of professional clinical support for any investigator conducting research at the Bayview GCRC.

The National Center for Research Resources specifically directs the GCRC research nurses to "...help investigators by facilitating the day-to-day research process and assisting the research patients in a supportive and efficient environment." The nursing staff accomplishes this mission, while often being assigned to several studies simultaneously!

With the busy schedules and high demands placed upon them, the nurses perform their respective duties with dedication, professionalism, integrity, and enthusiasm. In addition to the fast pace, the nurses recognize important benefits of conducting research at the GCRC. What do our nurses have to say about their time on the unit?

Cathy Eydeloth, RN, says, "What I find most interesting about research nursing is the diversity of the studies, and that these studies will make a positive impact on day-to-day health issues."

Donna Bihy, RN, adds "For me, our studies on the GCRC stand out for their work in expanding our knowledge of disease and treatments, which can positively impact current and future patients' quality of life, and eventually lead to improved therapies."

Confirming this spirit of nursing in the Bayview GCRC, Linda King, RN, states "With cutting edge technology, complex protocols, and an abiding team effort, the GCRC provides a challenging, dynamic, and unique environment for a nurse to grow in the dynamic field of research."

Stephanie Phillips, RN, says, "Opportunities with unlimited room to learn and teach are always part of our days in the GCRC. Being part of the TEAM has made me realize we can make a difference in peoples' lives through research."

Excitement, interesting studies and investigators, and clinical and scientific challenges are encountered daily at the GCRC. The nursing commitment not only sustains the GCRC's work, but also maintains the overall aim of Johns Hopkins University to promote the advancement of education, research, and patient care.

Barbara Spriggs, RN, summarizes the experience of the GCRC nurses: "I like being a GCRC Nurse, because of the variety of my work load; I enjoy the subjects and my peers, and there's never a dull moment."

Selected New Protocols Recently Approved by GAC 2005

Geoffrey Cundiff, M.D.	Ambulatory Treatments for Leakage Associated with Stress Incontinence: The ATLAS Trial
Una McCann, M.D.	PET Studies of the Dopamine Transporter in Adults
Pamela Ouyang, M.D.	A Randomized, Double-Blind, Multi-Centered, Study Comparing the Effects of Carvedilol Modified Release Formulation (CoregMR) and Atenolol in Combination with and Compared to ACE Inhibitor (Lisinopril) on LV Mass Regression in HTN Pts. With LVH
Susheel Patil, M.D.	Diet and Obesity Reduction Management In Obstructive Sleep Apnea
Philip Smith, M.D.	Study of Immune Effects on Sleep and HIV treatment on Apnea
John Stone, M.D.	Vasculitis Clinical Research Consortium (VCRC) Study of Giant Cell Arteritis
John Stone, M.D.	Vasculitis Clinical Research Consortium (VCRC) Study of Takayasu's Arteritis

As a reminder, please acknowledge the GCRC grant in publications resulting from support received from the GCRC: General Clinical Research Center, Grant Number 5M01RR02719 and provide a copy of each publication to our GCRC Office.

The 2005 CReFF Award Recipient

The Bayview GCRC congratulates **Anne Burke, M.D.** for being selected to receive the 2005 CReFF award. CReFF funding will be used to support her protocol:

"A Pilot Study of 6% Topical Gabapentin Cream for Vestibulodynia."

The Clinical Research Feasibility Fund (CReFF) is sponsored by the National Center for Research Resources. Each award is in the amount of \$20,000, in addition to GCRC resources, available free of charge. Applications are reviewed for scientific merit, feasibility, and expense. Projects that utilize Johns Hopkins Bayview GCRC resources are given priority.

About the Informatics Core

The role of the Informatics Core is to support investigators involved in GCRC approved protocols, specifically with the data management component of their studies.

These services include working with investigators and the biostatistician to develop effective strategies for data collection, entry, validation, storage, security, backup, analyses, and assembling data for posters, abstract, presentations, or manuscripts.

The Core also provides a number of educational activities that include teaching the investigative team (faculty, fellows, staff, and students), in addition to GCRC

nursing, nutrition, exercise, and administrative staff members, about the various computer hardware and software components of informatics.

Other services include instruction on how to access health statistics, conduct literature searches, and identify public databases on the Internet. The Core assists researchers with exporting and converting data to a digital form from a variety of laboratory instruments and analog sources. Also, scannable data-entry forms for expediting data acquisition and quality control can be created.

The Informatics Core maintains the GCRC website, which contains all the service descriptions and links to the GCRC applica-

tion, facility information, and external links to numerous web-based resources of critical interest to investigators.

For GCRC researchers, the Core has created a web-feature that permits on-line completion of the required annual update. At this time, efforts are underway to integrate the GCRC protocol application with the IRB's electronic application process: *eIRB*, which will be operational this fall.

If you have questions about the Informatics Core, or you would like utilize any of its diverse services, please contact the Informatics Core manager, Debbie Hill (410-550-7198), or the Informatics Core Director, Dr. Kerry Stewart (410-550-0870).

The Research Subject Advocate

The National Center for Research Resources (NCRR), which oversees the organization and operation of the GCRCs, is charged with assuring that subject safety in research is given the highest priority. Further, the NCRR requires oversight of the integrity of research conduct, and the strict adherence to and continuous compliance with all Federal, local, and institutional regulatory requirements.

For these responsibilities, the Research Subject Advocate (RSA) position was created.

In general, the RSA works with the GCRC program director, the GCRC Advisory Council (GAC), individual investiga-

tors, GCRC personnel, and, of course, the study subjects themselves.

Specifically, the RSA's job involves many responsibilities that are tailored for individual studies based on a study's complexity and level of risk to the subject. The following is a sample of these various duties:

- Serve as an unbiased observer during the consent process when requested by the either the subject or investigator.
- Provide study information to subjects (and occasionally a subject's partner or caregiver) participating in clinical trials.
- Assist investigators in developing data and safety monitoring plans.

- Assure that the GCRC studies are performed in accordance with the IRB-approved protocol and monitoring plan.

- Facilitate the reporting of Serious Adverse Events and Conflicts of Interest to appropriate committees and Federal agencies.

- Make certain that the GCRC investigators receive training on their regulatory and patient safety responsibilities, like "Good Clinical Practice" and HIPAA concepts.

For information about the RSA services at the JHBMC GCRC, please contact Frederick Luthardt at fluthard@jhmi.edu or call 410-550-1850.

Of Statistical Significance...

Dr. Nae-Yuh Wang

On behalf of the Bayview GCRC, I want to welcome Dhananjay Vaidya, MBBS, PhD, MPH to the Biostatistics Core.

Dr. Vaidya joined the staff of the Bayview GCRC in July 2005. He earned his medical degree in India in 1993, after which he pursued doctoral work in cardiac physiology at SUNY Upstate Medical University, Syracuse, New York.

He trained in epidemiology at the Johns Hopkins Bloomberg School of Public Health leading to an MPH degree. In July 2005, he joined the faculty of School of Medicine as an Assistant Professor in the Division of General Internal Medicine.

Dr Vaidya's research interest is the prevention of heart disease both before it takes root, and impeding its progress after it becomes established. His prior research experiences include studying risk factors that

cause atherosclerosis and conducting clinical trials on treatments that may slow disease progression.

Besides providing support within the Biostatistics core of the Bayview GCRC, Dr. Vaidya also serves as a co-investigator in the Johns Hopkins Sibling and Family Heart Study. He can be reached via email at dvaidya1@jhmi.edu. As always, contact the Core 410-550-1250 for more information about our services.

Nursing Opportunities in the Bayview GCRC! We Want YOU!

If you have an interest in Clinical Research and are an experienced nurse, the GCRC has two exciting full-time opportunities. The first position is for **Patient Care Manager** ("PCM"), which requires leadership and administrative skills to support the unit's research protocols and investigators. The PCM also ensures quality standards for the care of study participants, as well as develops and guides the nursing staff. This position requires a bachelor's degree in nursing with a master's degree in nursing preferred, along with administrative experience. The second position is for a full-time **Staff Nurse**. Current Maryland licensure and experience in direct patient care for each opening is essential. Find out more at the JHBMC website job-link: <http://www.healthcaresource.com/jhbmc/index-int.cfm>

Staff Transitions

Karen Gauss, BSN, RN, MS has joined the research team in the Vasculitis Center with Dr. John Stone. She brings with her several years of experience as a research nurse at the GCRC, as well as expertise in psychiatric nursing. We wish her all the best in her new position!

Kelly Divine, RN has started a new position with the Division of Pulmonary Medicine at Bayview. Kelly worked in the Bayview GCRC for over two years, and will be missed for all her hard work during the overnight shifts! Good luck!

Gretchen Weinsbach, BSN, RN has come to the GCRC as a Traveling Nurse. She received her nursing training and practiced in North Carolina. We hope she enjoys her stay!

We also would like to introduce **Robert Fisher, RN**, who joined the GCRC August 15, 2005 full time. He comes to the GCRC with 11 years of nursing experience in Bayview's Medicine/Surgery Floor, and the Short Stay Unit. With his skills and certifications in Trauma and IV Training, Robert will be a welcome addition to the staff.

Kudos!

Dr. Michael Klag, the JHU School of Medicine, Vice Dean of Clinical Investigation, has been appointed as the new Dean of the Johns Hopkins Bloomberg School of Public Health. In his capacity as the Vice Dean, Dr. Klag was the Principal Investigator for both the Bayview and East Baltimore GCRCs. During Dr. Klag's time, the GCRCs flourished and became a vital service to investigators, providing them with support that helps sustain the Institution image as the pre-eminent academic health care and research facility in the U.S.

Important Dates and Upcoming Events

September 12—28: The Introduction to Clinical Research

Course. Lectures are from 8:00 AM to 9:00AM. See the website for more details: <http://gcr.jhbmc.jhu.edu/course1.html>

September 16: Protocol submission deadline for October 21 GCRC utilization review.

October 14: Protocol submission deadline for November 18 GCRC utilization review.

October 21:* GCRC Advisory Council Meeting for Protocol Approval.

November 11: Protocol submission deadline for December 16 GCRC utilization review.

November 18:* GCRC Advisory Council Meeting for Protocol Approval.

December 16:* GCRC Advisory Council Meeting for Protocol Approval.

*All GAC meetings are in the Department of Medicine Conference Room or the Pavilion Conference Room, A Building.

GAC review is approximately 6 weeks after the protocol submission deadline.

Check the JHBMC GCRC website for further details on the application process and time tables.

Welcome!

Daniel E. Ford, M.D., M.P.H., has been named the new Vice Dean for Clinical Investigation and is now the Principal investigator for the Bayview GCRC. Dr. Ford has been at Johns Hopkins since 1988 and has been actively involved in his clinical practice in Internal Medicine and Psychiatry, as well as his endeavors in research associated with the interrelationships between mental disorders, particularly depression, and chronic medical conditions. The Bayview GCRC Administration and staff look forward to working with Dr. Ford and anticipate a progressive relationship.

This newsletter is published semi-annually.
Address comments and questions to:

General Clinical Research Center
4940 Eastern Ave., B3N
Baltimore, MD 21224
410-550-1850
410-550-1227 (FAX)

Editor: Frederick W. Luthardt, MA

Helpful Web Resources for Investigators:

<http://gcr.jhbmc.jhu.edu/index.cfm>

<http://irb.jhmi.edu/Guidelines/>

<http://www.ncrr.nih.gov/>

<http://www.os.dhhs.gov/>

<http://ohrp.osophs.dhhs.gov/>