



The Bayview General Clinical Research Center

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

The Bayview skyline is changing nearly every week, as construction on the exterior portion of the 500,000 square foot NIH building nears completion. It takes shape more and more almost daily. By early 2008, the "C Building", with its approximately 55,000 square feet of research and office space, will be turned over to the University.

Dr. David Hellman, Chairman of Bayview's Department of Medicine and Vice Dean of JHBMC, reminds investigators that the Medical Center and University are currently engaged in a process of drawing master plans for new construction at Bayview. Dr. Hellman advises that if you are interested in viewing these plans or contributing to them, you may contact Ms. Robin Brewster at (410) 550-4925.

The Bayview Medical Center GCRC is also expecting changes in the future. The GCRC is funded by a competitive award from the NCCR and NIH. The NIH Roadmap for Medical Research has started a new program of support called Clinical and Translational Science Awards (CTSA).

The purpose of the CTSA is to assist institutions to forge a uniquely transformative, novel, and integrative academic home for Clinical and Translational Science to advance. The new Institute will nurture and train multi- and inter-disciplinary investigators and research teams, while creating an incubator for innovative research tools and information technologies.

The goal is to encourage the development of multi-disciplinary and inter-disciplinary clinical and translational research with re-

searchers accelerating the translation of research from the bench to clinical studies and to clinical practice.

When an institution is granted a CTSA award, it will incorporate the institution's GCRCs into the award. Johns Hopkins University, led by Dr. Daniel Ford, Vice-Dean of Clinical Investigation, submitted an application in March 2006, the outcome of which will be known in late July, with funding to begin September 30, 2006.

For now, the Bayview GCRC functions will continue uninterrupted in the interim and when Hopkins obtains successful CTSA funding, we look forward to offering enhanced and expanded resources to investigators throughout the Johns Hopkins research community.

The Introduction to Clinical Research Course

Clear your calendar for the last three weeks in September! The time for the Bayview GCRC's popular annual seminar series is drawing near!

The 13th annual "Introduction to Clinical Research Course" is scheduled for this September 11-28, 2006. The courses run Monday - Thursday from 8:00am to 9:00am. A light breakfast is available beginning

at 7:30am.

As in the past, the Course will be comprised of 12 interactive sessions, to be held in Bayview Medical Center's Carroll Auditorium, with two parallel courses being offered in the Asthma and Allergy Center's Norman Library.

The classes provide a useful introduction to important considerations in the design, initiation,

and conduct of clinical trials.

The cost is \$50.00 for all the classes. The fee may be paid up to the first day of the class. Please visit the Bayview GCRC website (<http://jhbgcrc.jhu.edu/>) for updates and more information. Also, details will follow in the Fall/Winter Newsletter. If you have questions, please call the GCRC Administrative Office at 410-550-1850.

Selected 2006 Publications from Studies Utilizing the Bayview GCRC

- Ouyang P, Tardif JC, Herrington DM, Stewart KJ, Thompson PD, Walsh MN, Bennett SK, Heldman AW, Tayback MA, Wang NY. **Randomized trial of hormone therapy in women after coronary bypass surgery Evidence of differential effect of hormone therapy on angiographic progression of disease in saphenous vein grafts and native coronary arteries.** *Atherosclerosis*. 2006 Jan 23
- Young DR, Stewart KJ. **A church-based physical activity intervention for African American women.** *Fam Community Health*. 2006 Apr-Jun;29(2):103-17.
- Stewart KJ, Ouyang P, Bacher AC, Lima S, Shapiro EP. **Exercise effects on cardiac size and left ventricular diastolic function: relationships to changes in fitness, fatness, blood pressure and insulin resistance.** *Heart*. 2006 Jul;92(7):893-8.
- Pearson VE, Allen RP, Dean T, Gamaldo CE, Lesage SR, Earley CJ. **Cognitive deficits associated with restless legs syndrome (RLS).** *Sleep Med*. 2006 Jan;7(1):25-30.
- Golden DB. **Insect sting allergy and venom immunotherapy.** *Ann Allergy Asthma Immunol*. 2006 Feb;96(2 Suppl 1):S16-21.
- Jones HE, Suess P, Jasinski DR, Johnson RE. **Transferring methadone-stabilized pregnant patients to buprenorphine using an immediate release morphine transition: an open-label exploratory study.** *Am J Addict*. 2006 Jan-Feb;15(1):61-70.
- Polotsky VY, Rubin AE, Balbir A, Dean T, Smith PL, Schwartz AR, O'Donnell CP. **Intermittent hypoxia causes REM sleep deficits and decreases EEG delta power in NREM sleep in the C57BL/6J mouse.** *Sleep Med*. 2006 Jan;7(1):7-16.
- Velasco M, Alexander C, King J, Zhao Y, Garcia J, Rodriguez A. **Association of lower plasma estradiol levels and low expression of scavenger receptor class B, type I in infertile women.** *Fertil Steril*. 2006 May;85(5):1391-7.
- Walston J, Xue Q, Semba RD, Ferrucci L, Cappola AR, Ricks M, Guralnik J, Fried LP. **Serum antioxidants, inflammation, and total mortality in older women.** *Am J Epidemiol*. 2006 Jan 1;163(1):18-26.

Please remember to acknowledge the GCRC grant in publications resulting from any support received from the GCRC: General Clinical Research Center, Grant Number M01-RR-02719 and provide a copy of each publication to our GCRC Office.

Recent Protocols Approved by GAC (2006)

David Hellmann, MD	Development of a Survey Instrument for Measuring Quality of Life in Patients with Giant Cell Arteritis
Cheryl Koch, MD	The Effect of Telephone Intervention on Glycemic Control for Persons with Type 2 Diabetes
Pamela Ouyang, MD	Sleep-related Respiratory Physiology and Inflammation in Chronic Obstructive Pulmonary Disease
Pamela Ouyang, MD	Predictor of Advanced Sub-clinical Atherosclerosis
Naresh Punjabi, MD	The Sleep FM Study (Sleep Fragmentation and Metabolism)
Hamid Rabb, MD	Live Unrelated Kidney Donor and Sibling Follow-up Study
Annabelle Rodriguez, MD	The Role of the HDL Receptor, Scavenger Receptor Class B type I, in Human Female Infertility
Annabelle Rodriguez, MD	A Randomized, Double-Blind, Placebo-Controlled Study of 3, 5-Diiodothyropropionic acid (DITPA) in Combination with Standard Therapy to Attain NCEP ATP III Goal for LDL Cholesterol in Hypercholesterolemic Patients
John Stone, MD	Rare Diseases Clinical Research Network: VCRC Longitudinal Protocol for Polyarteritis Nodosa
John Stone, MD	Rare Diseases Clinical Research Network: VCRC Longitudinal Protocol for Wegener's Granulomatosis and Microscopic Polyangiitis
John Stone, MD	Rare Diseases Clinical Research Network: VCRC Longitudinal Protocol for Churg-Strauss Syndrome
Robert Wise, MD	Pilot Study in Impaired Glucose Tolerance Assessing Oxidative Stress and Effects of Alpha Lipoic Acid

ABOUT THE CORE LAB

The primary function of the JHBMC GCRC Core Laboratory is to provide technical support for sophisticated clinical research assays. The laboratory is a regional resource that supports clinical protocols at the JHBMC GCRC, the Johns Hopkins Hospital GCRC, the University of Maryland's GCRC and the Gerontology Research Center of the National Institute on Aging.

Within this context, the Core Laboratory supports GCRC approved protocols by providing facilities, technical experience and training for non-routine blood and urine biochemical analyses.

The Core Laboratory is staffed by a Director and three full-time technicians who have extensive experience

in the theory and practice of clinical laboratory assays, and in prioritizing access to laboratory resources.

The Core Laboratory technicians perform approximately 90 different immunoassays for the determination of proteins, peptides, hormones, and other biochemical markers.

Over 30,000 samples are analyzed yearly. Since 1993, the lab has employed a bar coding system for sample labeling and tracking. The Core Laboratory provides standardized sample handling that minimizes freeze/thaw cycles, low investigator cost and high quality control.

Quality control is maintained by including in each assay run kit manufacturer's controls as well as low, medium and high value in-house controls.

In addition, ED 80, 50 and 20 values as well as each standard curve is compared with historical values and "graveyard" curves. Control values are used to maintain a database of coefficients of variance for inter- and intra-assay variability.

The Laboratory is GLP and CLIA compliant. The laboratory participates in the AccuTest, Inc. (Westford, MA) Digital PT proficiency testing program for FDA-approved immunoassay kits or machine measurements and utilizes a consortium of national NCRR funded GCRC Core Laboratories for internal sample swapping and proficiency testing of immunoassay kits used for clinical research.

Contact Neal Fedarko, Ph.D. at 410-550-2632 for more information.

BIONUTRITION CORE SUPPORTS DIETARY INTERNSHIPS

Peggy Wroblewski, the GCRC's Bionutrition Manager announced the acceptance of 4 abstracts to be presented at the **2006 American Dietetic Association Annual Meeting** in Honolulu, Hawaii.

The presentations are the result of

research conducted by interns from the Clinical Nutrition and Foodservice Program at Bayview Medical Center, for which Peggy provided mentorship, designed the methodology, conducted the statistical analysis, wrote up the results section for their abstracts, and edited the

abstracts. Congratulations to a job well-done!

For details about the Clinical Nutrition service and internships, contact Peggy at 410-550-1768 or Cheryl Koch, Bayview's Director of Food Services and Clinical Nutrition at 410-550-1319.

Of Statistical Significance...

Nae-Yuh Wang, Ph.D.

There are few elements so misunderstood and yet so critical to the design of a clinical trial as the determination and justification of the **Sample Size**.

Sample size justification is a required component in IRB applications. There are at least 4 elements needed for the determination of required sample size: the type I (alpha) error, the type II (beta) error, which is 1 minus the statistical power, the size of the effect we wish to detect (e.g. the smallest difference between two group means that's clinically meaningful), and the magnitude of variability in the data (i.e. standard deviation, or SD).

Traditionally, the alpha error is

controlled at the level of 5% or less, and the beta error 20% or less (i.e. statistical power of 80% or more).

We will need larger sample size if we wish to keep one or both of these statistical errors to a lower level, or to have a higher statistical power. Ideally, the effect we set out to detect should be the smallest one that's clinically relevant. However, this may not always be feasible since the smaller the effect we wish to detect, the larger the sample size we would need.

Note that the relevant unit for the size of effect in a sample size calculation is not the absolute unit of the outcome measure, but the size in the unit of SD of the outcome. SD measures the variability of the outcome data and could be esti-

mated with pilot data or obtained from previously published data in the literature.

When looking up SD from the literature, pay attention to whether the number cited is SD or SEM (standard error to the mean). SEM is different from SD but can be used to calculate SD if the sample size of that study is known. When the size of the effect we wish to detect is set in the absolute unit of the outcome measure, the larger the outcome SD the larger the sample size we would need.

If you have questions regarding sample size determination or other statistical issues, the Biostatistics Core at Bayview GCRC would be happy to assist you. Please go to the GCRC website for more information on services we provide, or email me at naeyuh@jhmi.edu.

Opportunities for Staff Development

Giving a Research Talk

Date: 9/21/06 Time: 8:30am-4:00pm
Location: 1830 E. Monument St, 2-108
Cost: Faculty and Staff: \$750, Postdocs/fellows: \$375

Grant Writing

Date: 7/18-19/06
Time: 8:30 a.m. - 4:00 p.m. (7/18/06); 8:30 a.m. - 12:00 p.m. (7/19/06)
Location: Turner Building, Tilghman Auditorium
Cost: Faculty and Staff: \$1,250; Postdocs/fellows: \$625

Grant Writing

Date: 11/29-30/06
Time: 8:30 a.m. - 4:00 p.m. (11/29/06); 8:30 a.m. - 12:00 p.m. (11/30/06)
Location: Turner Building, Tilghman Auditorium
Cost: Faculty and Staff: \$1,250; Postdocs/fellows: \$625

To register for any of the courses, please contact Stacie Ranabhat at jhmipdo@jhmi.edu (payable w/tuition remission), (payable w/ M&S Form or check).

A Helpful Reminder:

Be certain to check the School of Medicine's "Research WebNotes" for information and current guidance assistance regarding Federal and Institutional regulatory requirements. Keep your finger on the pulse of research at Johns Hopkins University by visiting: <http://www.hopkinsmedicine.org/webnotes/>

Kudos Uno!

Mary Kay Willing, RN, BSN earned a designation as a Certified Clinical Research Coordinator (CCRC). The certificate is awarded by the Association for Clinical Research Professionals (ACRP) who pass an examination focusing on research regulations and Good Clinical Practice guidelines. Further, the recipient is distinguished for possessing the requisite skills to coordinate clinical trials. Mary is the GCRC's Patient Care Manager, as well as a Nurse Manager at Bayview's Clinical Studies Unit.

Kudos Dos!

Dhananjay (Jay) Vaidya, Ph.D., MPH, Assistant Professor, Department of Medicine, and statistician for the Bayview GCRC's Biostatistics Core, received the Trudy Bush Fellowship from the American Heart Association Council on Epidemiology and Prevention. Jay was awarded the fellowship for his paper entitled "*Endogenous Sex Hormone are Associated with Lipoprotein Subfraction Profile in Postmenopausal Women in the Multi-Ethnic Study of Atherosclerosis (MESA)*" It is truly a great honor and we congratulate Jay for his achievement.

Staff Transitions

Welcome! The Bayview GCRC welcomes our newest nurse: **Christine Pacitti, RN**. Christine comes to us from JHBMC Burton Pavilion Care Center, where she worked for three years on the Ventilator Unit. We're happy to have her join the team.

Farewell! **Melissa Scudder**, Administrative Secretary with the GCRC for nearly three years, will be leaving to join the administrative staff of Bayview's Department of Surgery. We regret her leaving, but we are excited for her new opportunity and wish her all the best for a future of continued success.

Important Dates and Upcoming Events

July 5: GCRC Utilization Application submission deadline for 8/18 GAC Meeting

July 21*: GCRC Advisory Council Meeting for Utilization Approval

August 9: GCRC Utilization Application submission deadline for 9/15 GAC Meeting

August 18: GCRC Advisory Council Meeting for Utilization Approval

September 15: GCRC Advisory Council Meeting for Utilization Approval

*GAC Meetings are 1:00 in the Dept. of Medicine Conference Room

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, MA, CCRP

Helpful Web Resources for Investigators:

<http://jhbgrc.jhu.edu/>

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

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

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

<http://www.hhs.gov/ohrp/>