



The Bayview General Clinical Research Center

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Greetings from the Program Director: Pamela Ouyang, M.D.

With this inaugural publication of the Johns Hopkins Bayview General Clinical Research Center newsletter, I would like to welcome our readers and briefly describe our service and its commitment to the investigative mission of Johns Hopkins Medicine.

The Bayview GCRC is in its 19th year of funding by the NIH National Center for Research Resources. It has continuously served as a centerpiece for clinical research on the Johns Hopkins Bayview campus, providing support to investigators conducting a wide variety of research projects.

A sample of these protocols include hormonal replacement studies (analyses of gonadal and growth hormones in older postmenopausal women and hypogonadal men, exendin-4 as a new therapy for diabetes, hormone re-

placement studies in women with established coronary disease); research in sleep disorders (including studies on the effect of bariatric surgery on sleep disordered breathing, obstructive sleep apnea, restless leg syndrome, sleep disorders in individuals with cardiomyopathy); investigations into lifestyle changes (studies on effects of weight loss and exercise on body composition, and exercise effects in mild hypertensives); studies on the effect of recreational drug use (including MDMA, nicotine withdrawal and marijuana); the effect of treatment for drug abuse on the newborns of drug using mothers; and studies on asthma in inner city children.

We consist of an inpatient unit adjacent to outpatient space on the 3rd floor of the B building. The unit is undergoing a complete renovation to be completed by Spring of 2005. This renovation will expand the space to make it more efficient

and user friendly for investigators and subjects.

The purpose of this biannual newsletter is to highlight resources that the Bayview GCRC can provide to clinical researchers, to alert investigators to educational or funding opportunities, and to showcase important research and publications. It will supplement the information currently available on our website (<http://gcr.jhbmc.jhu.edu>).

The mission of the GCRC is to support excellent clinical research. We welcome all clinical research investigators to contact us about the potential for research support. Successful funding of the GCRC by the NIH depends on the activity and productivity of our clinical investigators, and in particular publications that credit the support received from the GCRC Grant, M01-RR02719.

The 2004 CReFF Award Recipients

The Bayview GCRC congratulates the following investigators for their selection as CReFF awardees: Harry Silber, M.D., Ph.D., *Physiologic Response to External Counterpulsation (ECP)*; Sarbjit Saini, M.D., *Cellular Markers of Anaphylaxis*; Susheel Patil, M.D., *Effects of Adiposity in Sleep Apnea*; and Sean Leng, M.D., Ph.D., *Inflammation-Specific Gene Expression and Cytokine Production by Monocytes in the Frailty Syndrome*.

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.

Some Recent Publications by Bayview GCRC Investigators:

- Patil SP, Punjabi NM, Schneider H, O'Donnell CP, Smith PL, Schwartz AR. A Simplified method for measuring critical pressures during sleep in the clinical setting. *Am J Respir Crit Care Med.* 2004 Apr 7.
- Ouyang P, Sung J, Kelemen MD, Hees PS, DeRegis JR, Turner KL, Bacher AC, Stewart KJ. Relationship of insulin sensitivity with fatness and fitness and in older men and women. *Journal of Women's Health.* 13(2): 177-185, 2004.
- Sung J, Ouyang P, Silber HA, Bacher AC, Turner, KL, DeRegis JR, Hees PS, Shapiro EP, Stewart KJ. Exercise blood pressure response is related to left ventricular mass. *Journal of Human Hypertension.* 17:333-338, 2003.
- Stewart KJ, DeRegis JR, Turner KL, Bacher AC, Sung J, Hees PS, Shapiro EP, Tayback M, Ouyang P. Useful ness of anthropometrics and DXA for estimating abdominal obesity measured by MRI in older men and women. *Journal of Cardiopulmonary Rehabilitation.* 23 (2): 109-114, 2003.
- Stewart KJ, Sung J, Silber HA, Fleg JL, Kelemen MD, Turner KL, Bacher AC, Dobrosielski DA, DeRegis JR, Shapiro EP, Ouyang P. Exaggerated exercise blood pressure is related to impaired endothelial vasodilator function. *American Journal of Hypertension.* 17(4): 314-320, 2004.
- Houtsmuller EJ, Notes LD, Newton T, van Sluis N, Chiang N, Elkashef A, Bigelow GE. Transdermal selegiline and intravenous cocaine: safety and interactions. *Psychopharmacology (Berl).* 172 (1): 31-40, 2004.

Please remember to acknowledge the GCRC grant in publications resulting from 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.

New Protocols Approved by GAC for 2004

Sarbjit Saini, M.D.	"Cellular Markers of Anaphylaxis"
John Anderson, M.D.	"Physical Functions of Hemodialysis Patients"
Annabelle Rodriguez, M.D.	"Deficiency of the HDL Receptor, SR-BI, in Humans"
Annabelle Rodriguez, M.D.	"The Role of Rosiglitazone in Modulating HDL Cholesterol in Subjects with Type 2 Diabetes Mellitus"
Franklin Adkinson, M.D.	"Childhood Asthma Management Program - Continuation Study - Phase 2 (CAMP CS/2)"
Franklin Adkinson, M.D.	"Irreversible Airway Disease in Asthma: Exhaled Breath Condensates & Induced Sputum Studies"
Christopher Earley, M.D.	"Dopamine and Iron in Restless Leg Syndrome"
Christopher Earley, M.D.	"Systemic Iron Metabolism in Restless Legs Syndrome"
Joan Bathon, M.D.	"Evaluation of Subclinical Cardiovascular Disease and Predictors of Events in Rheumatoid Arthritis: the E.S.C.A.P.E – RA Trial"
Barbara J. de Lateur, M.D.	"Adipose Tissue Loss in Post-menopausal Females, at Least Thirty Percent or Greater Than Ideal Body Weight, Swimming in Cold/ Warm Water"
Sean Leng, M.D., Ph.D.	"Inflammation-Specific Gene Expression and Cytokine Production by Monocytes in the Frailty Syndrome"
Susheel Patil, M.D.	"Effects of Adiposity in Sleep Apnea"
Harry Silber, MD, PhD	"Physiologic Response to External Counterpulsation (ECP)"
Suzanne M. Jan de Beur, MD	"Endocrine Regulators of Normal Phosphate Homeostasis"
Jean Kim, MD, PhD	"Epithelial Cells and Chronic Rhinosinusitis"
Jeffrey Rade, M.D.	"Assessment of Risk Factors for Early Saphenous Vein Graft Failure Following Coronary Artery Bypass Surgery: Reduction in the Occlusion Rates (RIGOR) Study"

ABOUT THE SLEEP CORE

The Sleep Core laboratory of the Bayview GCRC is a four-bed facility that provides state-of-the-art polysomnographic testing for research protocols. It is currently utilized by investigators from the Departments of Neurology, Psychiatry and Medicine.

Sleep studies provide investigators information about sleep architecture and abnormal motor and breathing patterns during sleep. A broad range of protocols are currently utilizing the Sleep Core to examine (1) the inter-relationships between drugs, pain and sleep architecture, (2) underlying mecha-

nisms of restless legs and periodic leg movements during sleep and (3) the pathogenesis and metabolic and cardiovascular sequelae of obstructive sleep apnea. Investigators considering the use of Sleep Core testing are invited to discuss their protocols with its director, Alan Schwartz, M.D. at 550-0545.

INSIDE THE CARDIOLOGY CORE

The conventional measurement of the structure and function of the heart, the pulmonary vasculature, or of the systemic arterial tree, is performed in a clinical cardiovascular laboratory. However, for more sophisticated research purposes, the GCRC's Cardiovascular Imaging Core provides an advanced level of imaging. These methods include evaluation of

plaque in specific arterial territories prone to be involved by atherosclerosis, carotid wall thickness, and the functional aspects of the vascular tree.

Additional analyses include endothelial function testing that probe the vascular endothelium's ability to release relaxing factors in response to shear stress induced by ischemia or in response to pharmacologic

vasomotor modulation. Finally, arterial tree stiffness can also be assessed non-invasively.

The Core's cardiovascular tests can be integrated or performed separately, and may help assure protocol standardization and data reliability, as well as the development of novel imaging strategies. For questions about the core and its services, contact Pamela Ouyang, M.D. at 550-0853.

A Demographic Update

NIH policy on the Inclusion of Women and Minorities as Subjects in Clinical Research:

It is the policy of NIH that women and members of minority groups and their subpopulations must be included in all NIH-funded clinical research, unless a clear and compelling rationale and justification established to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances may be made by the Director, NIH, upon the NIH "Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research – Amended," recommendation of an Institute/Center Director based on a compelling rationale and justification.

Cost is not an acceptable reason for exclusion except when the study

would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This policy applies to research subjects of all ages in all NIH-supported clinical research studies.

The inclusion of women minority groups and their subpopulations must be addressed in developing a research design or contract proposal appropriate

to the scientific objectives of the study/contract.

The research plan/proposal should therefore describe the composition of the proposed study population in terms of sex/gender and racial/ethnic group, and provide a rationale for selection of such subjects. Such a plan/proposal should contain a description of the proposed outreach programs for recruiting women and minorities as participants.

Recent Population Estimates by Race and Area
Percent Population Within Each Geographic Area According to Race*

Area	Total	White	African American	Asian	Other
Maryland	100	66	28	4	2
Baltimore City	100	32	65	2	1
Baltimore County	100	76	22	3	--
Baltimore Region**	100	68	28	3	1

* July 1, 2002

** Also includes Anne Arundel, Carroll, Harford, Howard counties

Within the Baltimore Region, the population that is classified as Hispanic or Latino was estimated at 54,048 in 2002, i.e. approximately 2% of the total. It should be anticipated that the number has increased since 2002 and will increase in the immediate future.

Meet the GCRC Staff...



Front Row, Left to right: Dr. Kerry Stewart, Dr. Matthew Tayback, Dr. Suzanne Jan de Beur, Associate Program Director, Dr. Pam Ouyang, Program Director, Donna Boone. **Middle Row, Left to right:** Amy Li, Sandy Lima, Dick Gottlieb, Debbie Hill, Dr. Alan Schwartz, Pat Bishop, Linda King, Donna Bihi, Melissa Scudder. **Back Row, Left to right:** Peggy Wroblewski, Deb Grudzien, Fred Luthardt, Stephanie Phillips, and Cindi Williams.

Not pictured: Linda Weinberg, Dr. Neal Fedarko, Shannon Meise, Kelly Devine, Karen Gauss, Barbara Spriggs, Lawrence Jewell, Raisa Gelman, Catherine Eydeloth, Angela Taylor, Sara Evans, Shoshana Merzel, and Kiran Ayyanki.

Staff Transitions

The Bayview GCRC welcomes three new Administrative staff members: Administrative Manager **Debra Grudzien**, clinical dietitian **Peggy Wroblewski**, MPH, RD, LD and Research Subject Advocate **Frederick Luthardt**, MA, MA, CCRP.

Ms. Grudzien came to us from Anesthesiology and Critical Care Medicine at Johns Hopkins Hospital, where she was the Assistant Administrator. She has been with the University for 29 years.

Peggy is a registered dietitian and joins the dietary core as the Bionutrition Manager. Bringing to the GCRC experience in clinical, academic, and business endeavors, she currently serves as Adjunct Faculty at the George Washington University, teaching nutrition and health courses in the Department of Exercise Science.

Fred was recently with JHU's Division of Pain Medicine, where he managed clinical trials involving investigational drugs and devices for treating chronic pain. His educational background is in clinical bioethics, and he is presently adjunct faculty at the Maryland Institute College of Arts and lecturer at the Johns Hopkins University School of Nursing.

Coming up in the next issue:

- Details about the Exercise and Body Composition Core and the Dietary Core
- Recent additions to our nursing staff
- Progress of our facility renovations!

Important Dates and Upcoming Events

September 1: Protocol submission deadline for GCRC utilization consideration.

September 13-30: Introduction to Clinical Research Courses (Payment due first day of class. Contact GCRC office for more information: 410-550-1850.)

September 13: Seminars in Academic Medicine "Professional Development Opportunities for Faculty." Speaker: Wendy Sanders. John R. Burton Pavilion, 12–1 pm. Call 410-614-3385 for information.

October 4: Seminars in Academic Medicine "Using Resources of the General Clinical Research Center to Optimize Your Research." Speaker Pamela Ouyang, M.D. John R. Burton Pavilion, 12–1 pm. Call 410-614-3385 for information

October 5: Protocol submission deadline for GCRC utilization consideration.

November 2: Protocol submission deadline for GCRC utilization consideration.

Kudos!

Peggy Wroblewski, Bionutrition Manager, received the **PRIDE Award** in recognition of her "excellent service to the Clinical Nutrition Department in the areas of: Performance and Participation, Representation, Innovation, Diligence and Service Excellence."

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)

Editors: Matthew Tayback, Sc.D.
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/>