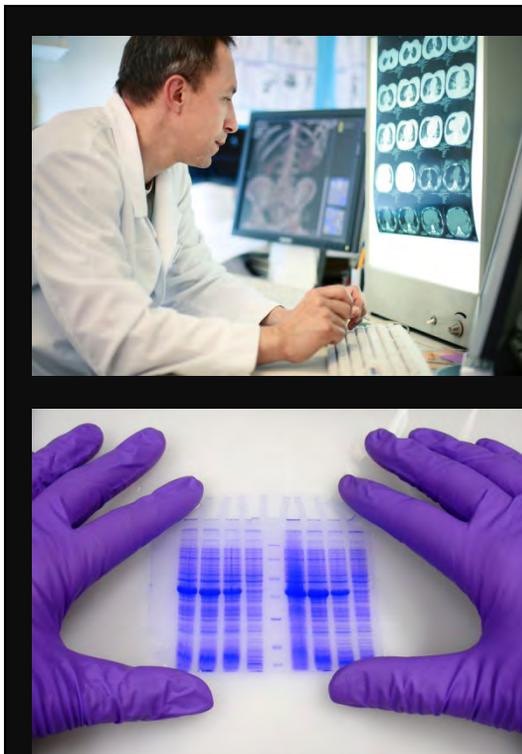


Research & Development

2009 Annual Report



Research and Development

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FOREWORD

Dear Colleagues and Friends:

Thank you for your interest in the Research and Development (R&D) Program at the VA Pittsburgh Healthcare System (VAPHS), and welcome to the inaugural edition of the VAPHS R&D Annual Report.

The R&D program at VA Pittsburgh is dedicated to the facility's mission of "advancing medical knowledge through research." We are a leader within the Veterans Integrated Service Network (VISN) 4, and one of the fastest-growing R&D programs in the VA -- much of which we can attribute to the ingenuity of our researchers, the tenacity of our research staff, the support we receive from our facility and VISN leadership and, most importantly, the dedication of our Veterans.

Our 2009 Annual Report highlights the accomplishments that have contributed to our success. In the past year, we have seen impressive growth in the funding our investigators receive, the types of research being conducted and the number of protocols under our purview. We also highlight the ambitious efforts made to improve the services we provide to our Research Community, VAPHS clinical staff and our Veterans. Please join us as we celebrate our achievements and make plans for continued success.



Ali F. Sonel, MD, FACC, FACP
Associate Chief of Staff for Research and Development

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OVERVIEW OF THE VAPHS RESEARCH PROGRAM

VAPHS has a significant research and development program designed to improve the lives of Veterans. Major research emphases include clinical trials, clinical science, health services, rehabilitation and related technologies, basic science and animal projects. Studies cover a variety of disciplines, such as endocrinology, liver transplantation, post-traumatic stress disorder (PTSD), cardiology, hematology/oncology, neurology, Alzheimer's disease, schizophrenia, orthopedics and health services disparities. At the end of 2009, our portfolio included more than 300 active research projects conducted by 127 investigators, representing an increase of approximately 17 percent in overall studies from 2008 (see Figure 1).

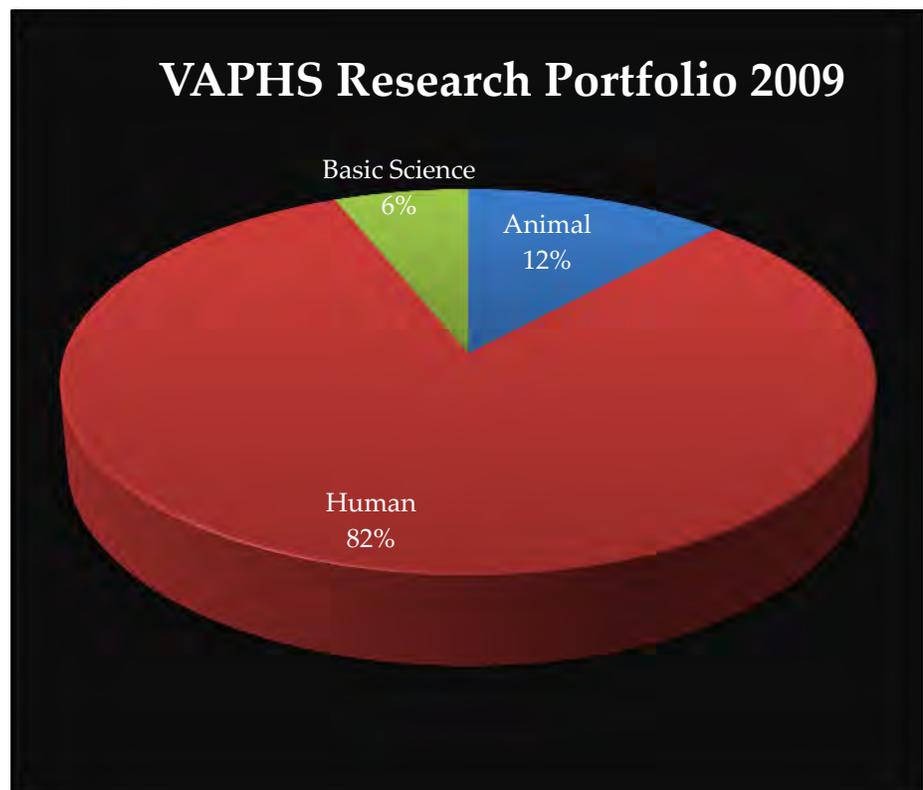


Figure 1: Breakdown of VAPHS Research Portfolio by Type as of 12/2009

The VAPHS Research Community is comprised of more than 600 individuals, including investigators and their research teams, committee members, research office staff and administration, as well as facility leadership. Both our human and animal research programs are fully accredited by the Association for the Accreditation of Human Research Protection Programs and the Assessment and Accreditation of Laboratory Animal Care, International. Figure 2 outlines the administrative structure of the VAPHS R&D program.

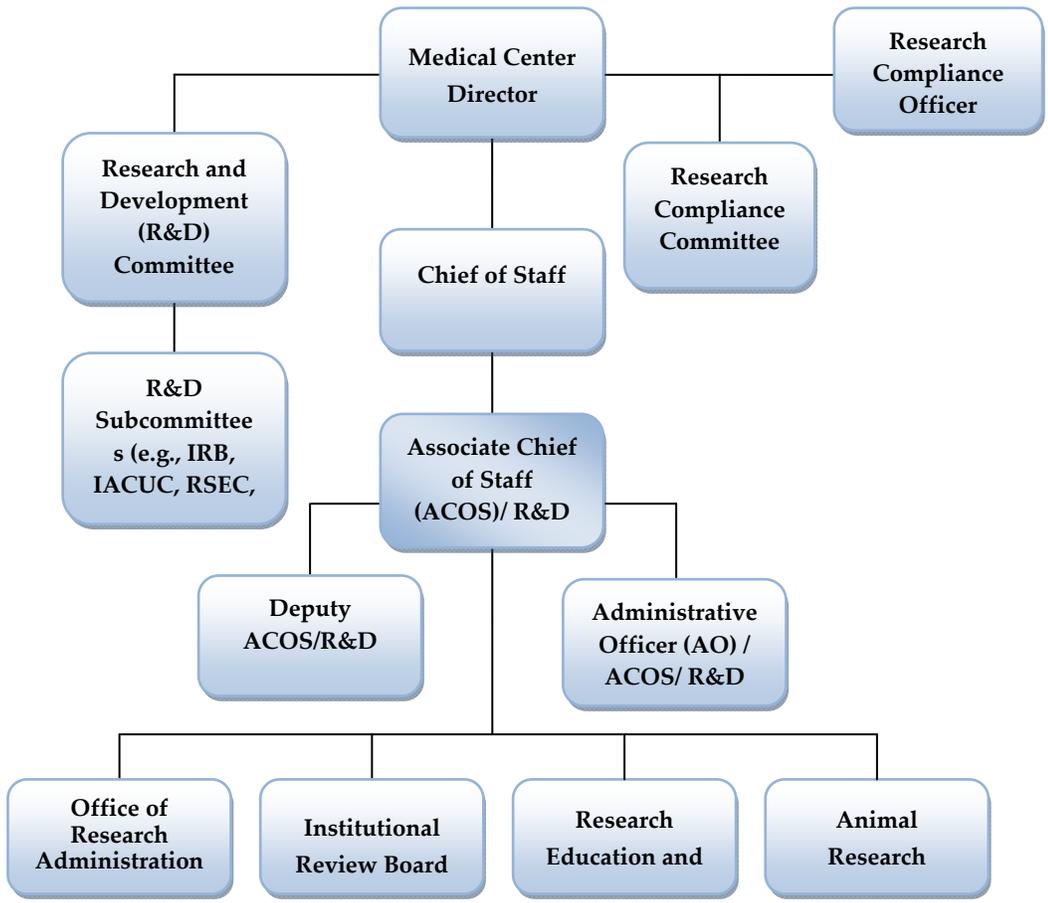


Figure 2. VAPHS Research Administrative Structure

Researchers within VAPHS represent various departments, services and centers, across the three divisions of VAPHS. Studies focus on issues affecting Veterans, ranging from traumatic brain injury and post-deployment stress disorder (PDSD) to developing technology to assist those with spinal cord injuries and amputation. Researchers have also worked diligently to bring studies to VAPHS that can evaluate the effectiveness of investigational drugs and devices for a variety of conditions, so that the Veterans who rely on the VAPHS for care are afforded better access to the types of studies seen in private health-care settings. Behind the scenes, but equally important, we have our basic scientists and animal researchers who work to identify mechanisms that cause disease and various conditions. Current topics of interest include drug addiction, schizophrenia and Parkinson's disease.

The VAPHS also has the distinction of being home to four VA Research Centers of Excellence. Center leaders are responsible for developing the direction of the Centers. Our four Centers are extremely productive, creative and a source of pride for VAPHS. A description of the Centers and their significant accomplishments in 2009 include:

- The mission of the **Center for Health Equity Research and Promotion (CHERP)** is to articulate the benefit of equity in health care, which is improved quality for all. CHERP's research continues to focus on vulnerable Veteran populations, including those that face potential discrimination because of race, ethnicity or social status, and those at risk for disparities in health or health care due to other physical and/or mental conditions. In FY 2009, CHERP investigators based in Pittsburgh and Philadelphia directed 16 Health Services Research and Development (HSR&D) Merit Review projects (up from 11 in FY08) and collaborated on another seven projects (up from four in FY08) at other VA Medical Centers. Core investigators published 167 peer-reviewed manuscripts, 20 other journal articles and six book chapters. They also made 120 presentations at national scientific meetings.

- The **Center for Wheelchairs and Associated Rehabilitation Engineering (WaRE)** has worked diligently to enhance community integration of veterans with non-progressive and progressive disabilities by understanding and implementing solutions for their assistive technology (AT) needs. This laboratory continues to evaluate emerging AT to ensure they truly benefit veterans; to improve the provision of wheelchairs and AT through education and clinical support in the local Pittsburgh VHA, the region (VISN 4) and nationally; and to build research capacity by training clinicians, scientists, engineers, graduate students and medical residents. One new project under way is Personal Mobility and Manipulation Appliance (PerMMA), an electric-powered wheelchair fitted with robotic arms. The device is being developed to help wheelchair users who have limited hand function. WaRE researchers also have begun to develop a modular wall system to help returning soldiers with traumatic brain injury. In 2009, the VA renewed the WaRE Center for the third time, granting a \$5 million award.
- The **Mental Illness Research, Education and Clinical Center (MIRECC)** serves as a resource to all of the medical centers in VISN 4, and to the network of medical centers at the national level, on issues related to the treatment and prevention of comorbid medical, mental health and/or substance-use disorders. The goal of the Center is to improve the mental and physical health, quality of life and outcomes of health-care services for veterans with mental illness. This is accomplished through: translational neuroscience, clinical research and health services research; education and training programs; clinical programs built on research findings; and involvement of the 10 VISN 4 Medical Centers. Recent MIRECC research projects include: *Assessing Readiness for Nurse Implementation of Alcohol Screening, Brief Intervention and Referral to Treatment [RN-SBIRT]*; *Treatment of OEF/OIF Neuropsychiatric Symptoms Following TBI*; *Comorbidity of Schizophrenia and Alcohol Dependence: Identifying Shared Brain Phenotypes*; *Use of the Telehealth System to Monitor Suicidality in Schizophrenia*; and the creation of a *MIRECC Comorbidity Research Registry*.

- The VAPHS **Geriatric Research, Education, and Clinical Center (GRECC)** serves as a resource for aging research, education and clinical care for VAPHS, VISN 4 and the VA system as a whole. Research areas include stroke, neuronal cell death, gene therapy, depression in the elderly, communication research, polypharmacy, end of life, barriers to delivery of care to the elderly, stroke-related quality-of-life measures and aphasia rehabilitation. During the 2009 fiscal year, GRECC faculty published 80 scientific, clinical and educational manuscripts in medical literature and conducted 66 research projects. The Pittsburgh GRECC developed a geriatric driving safety clinic and an outpatient residential aphasia treatment program as new clinical demonstration projects. GRECC investigators made several key findings in FY 2009 that have the potential to significantly improve care of elderly veterans, such as the establishment of consensus guidelines for the oral dosing of renally cleared medications in older adults, and determining that a palliative care team can reduce patient suffering and improve patient quality of life by reducing the use of inappropriate medications.

Another unique aspect of the VAPHS research program is the **Clinical Trials Center (CTC)**. Established in 2007, the CTC serves as a resource to clinicians seeking research support such as study coordination and regulatory support. CTC services are available through the VAPHS Research and Development Office and are funded by the Veterans Research Foundation of Pittsburgh (VRFP). The CTC is mainly expected to be used by junior clinicians interested serving as investigators on clinical trials, or by existing investigators who lack sufficient staffing to perform such research. In 2009, the CTC expanded its services to include an Ancillary Support Core to assist investigators with blood-specimen collection, and the processing and shipment of samples. To date, the CTC supports a total of 19 investigators and 34 studies. Staff includes an administrative officer, seven clinical research coordinators, two regulatory coordinators and one clinical support person.

RESEARCH OFFICE ACCOMPLISHMENTS

Throughout 2009, the R&D administration implemented a number of significant changes. Heavy emphasis was placed on several key aspects: 1) improving communication between the research administration and the research community; 2) expanding upon the quality of services we provide; 3) improving outreach activities for our Veterans and the greater community. A summary of our most noteworthy accomplishments is provided on the next two pages.

Reorganization of the Research Education and Compliance Program

The early part of 2009 brought significant changes to the Research Education and Compliance Program at VAPHS. Due to a VHA directive mandating that all research programs hire a research compliance officer, the VAPHS was no longer one of the few facilities with a compliance program. As a result, the Research Education and Compliance Program was reorganized to have the compliance aspect fall under the medical center director's supervision, and the new Research Education and Policy Office was formed. These changes have allowed for more focused efforts on auditing and identifying compliance issues, and for greater emphasis on education and policy/procedure development.

Expansion of the Education Program

The newly formed Education and Policy Office spent considerable time expanding the education program created for our human-subjects researchers and staff. A number of modifications were made to the program to include new topics and provide more reference materials. Efforts were also made to provide additional educational opportunities to our investigators and staff, beyond the monthly one-hour session. Greater focus was directed at addressing issues our institutional review board (IRB) members are faced with when conducting reviews. One of the most significant, and much-needed changes was the development of the orientation program for new investigators and coordinators, which was started in August, with very positive results.

Developing the Participant Outreach Program

Reaching out to the Veterans we serve was also a top priority for the VAPHS Research Program. In late February, the formal Participant Outreach Program was developed, and efforts to improve communication, as well as opportunities for Veterans to educate themselves about research, continued throughout the year. Steps initiated include: 1) developing a Veteran-directed research newsletter; 2) creating information cards for distribution at patient check-in, to inform Veterans of Research Week activities; 3) setting up informational tables for Veterans and their families; 4) putting together a PowerPoint presentation for those interested in learning more about research; and 5) distribution of the “Volunteering in Research” brochure to each potential participant.

Restructuring the R&D Committee

One of the most significant changes in 2009 was the restructuring of the R&D Committee. This change, which was spurred by the release of the revised VHA Handbook 1200.01, resulted in a completely new protocol review and approval process, taking the review of individual protocols out of the hands of the R&D Committee altogether. The R&D Committee is now the institutional body that assists the medical center director with the strategic planning and oversight of the Research Program.

Formation of the Research Scientific Evaluation Committee

Because the R&D Committee was no longer charged with reviewing individual protocols, the Research Scientific Evaluation Committee (RSEC) was formed in mid-2009. The RSEC, which is a formal subcommittee of the R&D, conducts initial and continuing review of VAPHS protocols designated as science-only or science-safety, as well as reviews of projects the IRB determines to meet the definition of exempt research. The RSEC is also charged with conducting reviews of peer-review grant applications.

Increasing Awareness outside the Research Community

Researchers at VAPHS conduct impressive studies, often with remarkable results. Very rarely do people outside the research community get opportunities to learn about that great work. Therefore, the VAPHS Research Program and the VISN have focused more on ensuring that our investigators' efforts are recognized. In 2009, we began collaborating with VA Pittsburgh's Office of Public Affairs to do just that. As a first step, we developed a video highlighting our program and the various types of research we do. This video was first shown during our 2009 Research Week kick-off event, and has since been featured on the VAPHS Web site and the televisions at the University Drive and Heinz facilities. The Education and Policy Office also has been working on ways to identify studies with high-impact results that have implications for front-line staff and that should be shared through press releases from Public Affairs.

Introduction of the Research Concierge Program

In the latter part of 2009, R&D introduced the customer-service-oriented Research Concierge Program, a pilot modeled after a hotel's concierge service that provides direct support to our "guests"-- investigators, coordinators and other research staff. The concierge is available to help staff with any research-related issues, ranging from a simple query about the status of a submission to a face-to-face meeting to review project submission requirements. We are fortunate to have a full-time staff member devoted to addressing our researchers' needs, and excited by the prospect of this program becoming a best practice among VA facilities.



TOTAL FUNDING

FY 2009 proved to be a prosperous year for investigators at VAPHS, with an increase of more than 30 percent in direct-support expenditure over FY 2008 -- resulting in VAPHS emerging as the top-funded program within the VISN (see Figures 3 and 4). The majority of this growth can be attributed to a considerable increase in non-VA federal support, as well as the burgeoning Clinical Trials Center and its ability to better support our investigators. Studies underway in 2009 received funding from a variety of sources, with the VA, National Institutes of Health (NIH) and private companies providing the most support (see Table 1).

Figure 3. Direct-support Expenditures FY09 vs. FY08

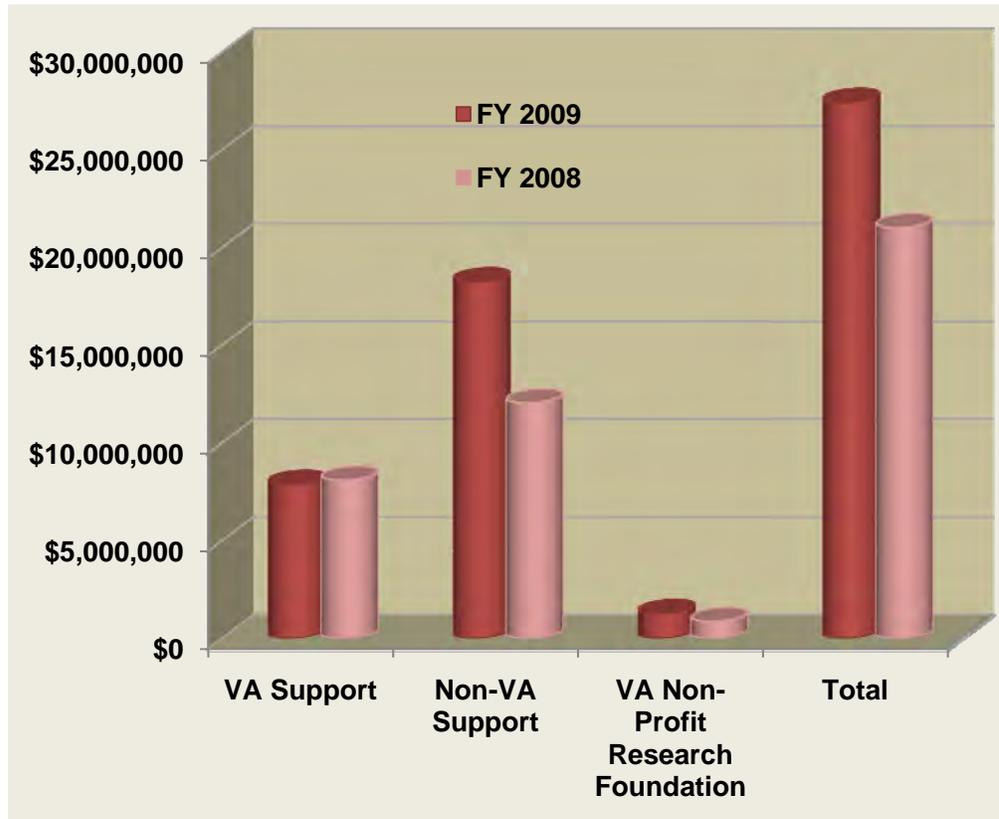


Figure 4. VISN 4 Direct Expenditure Comparison by Facility

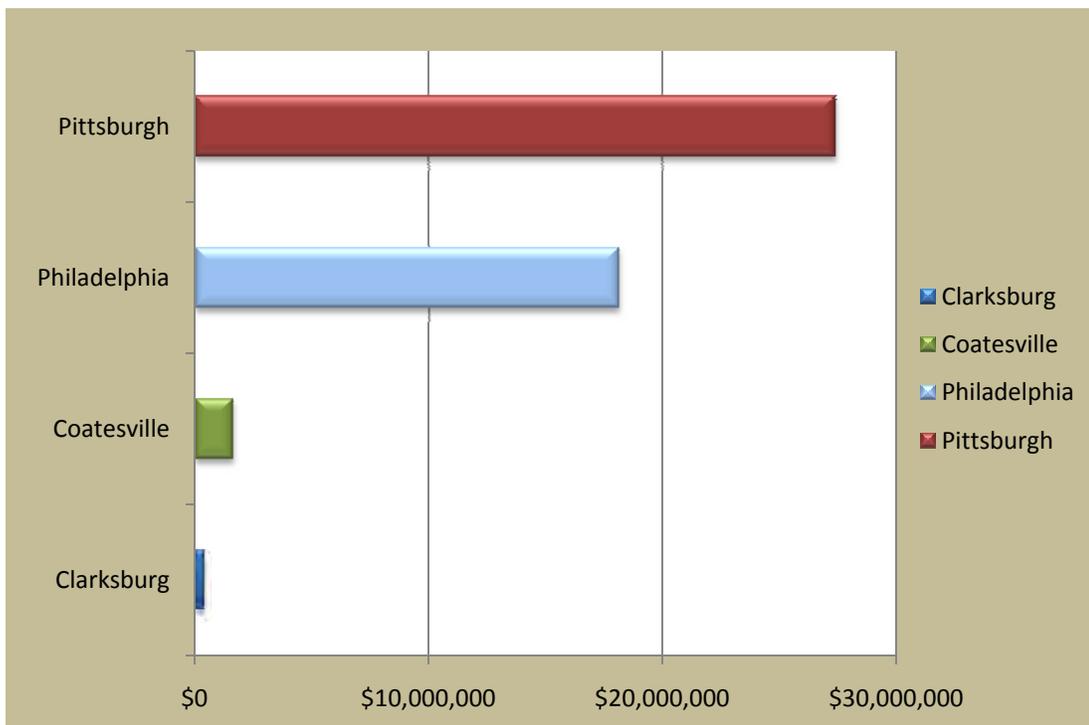


Table 1. Sources of Support for VAPHS Projects

Funding Source*	Number of Studies
Veterans Affairs (VA)	98
National Institutes of Health	43
Other Federal Government Agency	20
Other Government, Private Donor or Academic Institution	29
Private Company	46
Voluntary Agency/Foundation	9
No Funding	68

*Includes projects with more than one funding source

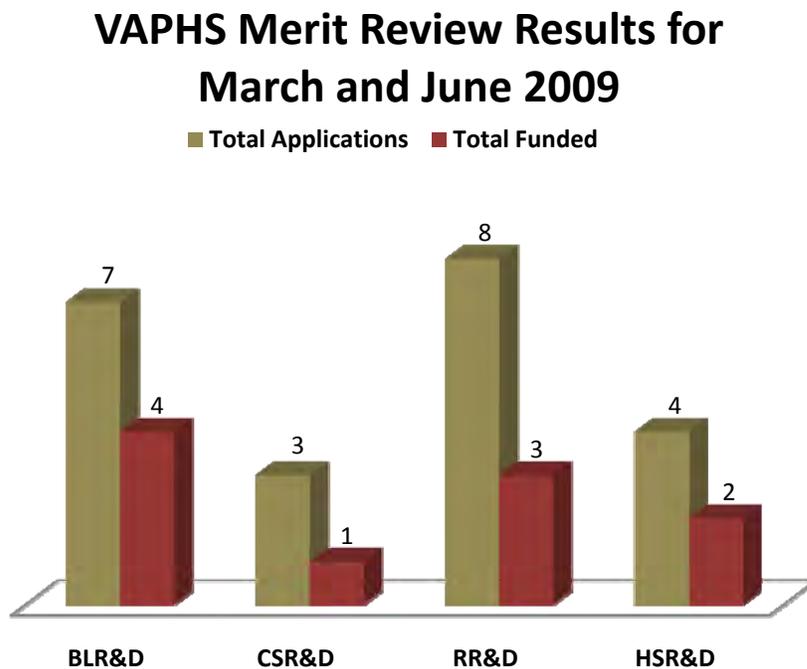
VA Funding

We continue to have an impressive number of VA-funded investigators. The Office of Research and Development (ORD) includes four research services: Biomedical Laboratory Research and Development (BLR&D); Clinical Science Research and Development (CSR&D), which also includes the VA Cooperative Studies Program (CSP); Health Services Research and Development (HSR&D); and Rehabilitation Research and Development (RR&D). Each service offers several funding opportunities, such as the Merit Review Award Program, which supports investigator-initiated research, and a career development program designed to attract talented VA researchers. At the VISN level, physicians and doctoral-level (Ph.D.) clinicians — or other clinicians and scientists interested in conducting noteworthy research — may apply for the Competitive Pilot Project Fund (CPPF) Program. CPPF provides initial funding for research projects to develop preliminary data so that an investigator can later apply successfully for competitive, external, peer-reviewed grant support. VAPHS also has one research career scientist and four senior research career scientists. Such distinctions are bestowed on non-clinician scientists in recognition of outstanding achievements and contributions to VA research. A comprehensive list of VA Pittsburgh investigators currently funded by one of these sources begins on page 16.



In 2009, VAPHS investigators from across the four programs submitted 35 Merit Review applications. Applications are submitted annually in March and September (for BLR&D and CSR&D) and June and December (for HSR&D and RR&D). Of those submitted in March and June, nearly 50 percent were eligible for funding (See Figure 5). The results for the applications from the latter part of 2009 were pending at the time of publication.

Figure 5: VAPHS Merit Review Information



VA-funded Investigators

Biomedical Laboratory Research and Development (BLR&D)

Harry C. Blair, MD	<i>Regulation of Bone Turnover by TNF-family Receptors</i>
Charles Bradberry, Ph.D.	<i>Cognitive Impact of Cocaine Cues and Agonist Treatment Approaches</i>
Edward Burton, MD, Ph.D.	<i>Alpha-synuclein RNAi in a Model of Sporadic Parkinson's Disease</i>
Jun Chen, MD	<i>Heat Shock Proteins and Neuroprotection in Cerebral Ischemia</i>
Cornelius J. Clancy, MD	<i>Regulation of Candida Albicans Histone Methylation</i>
Paula R. Clemens, MD	<i>Molecular Treatment of Muscle Atrophy</i>
Jie J.F. Fan, MD	<i>Role of TLR Crosstalk in Alveolar Macrophage Priming</i>
William F. Furey, Ph.D.	<i>Senior Research Career Scientist</i>
Chandrashekhar R. Gandhi, Ph.D.	<i>Augmenter of Liver Regeneration (ALR)</i>
Gerald Goldstein, Ph.D.	<i>Senior Research Career Scientist</i>
Steven H. Graham, MD, Ph.D.	<i>Fas-Mediated Cell Death in Cerebral Ischemia</i>
Garson D. Roodman, MD, Ph.D.	<i>Osteoblast Dysfunction in Multiple Myeloma</i>
Peter L. Strick, Ph.D.	<i>Senior Research Career Scientist</i>
	<i>Central Control Movement</i>
Robert Sweet, MD	<i>Cortical Synapses and Psychosis</i>
Edith Tzeng, MD	<i>Carbon Monoxide Mediated Inhibition of Intimal Hyperplasia</i>
Alan Wells, MD, Ph.D.	<i>Molecular Regulation of Prostate Cancer Progression</i>
Jeffrey K. Yao, Ph.D.	<i>Senior Research Career Scientist</i>
	<i>Application of Metabolomics in Psychosis and Therapeutic Monitoring</i>
Brian Zuckerbraun, MD	<i>Carbon Monoxide Therapy to Prevent Circulatory Collapse and Shock from Hemorrhage</i>

Clinical Sciences Research and Development (CSR&D)

Steven D. Forman MD, Ph.D.	<i>Do Smokers Exhibit Brain Error-Response Deficits?</i>
Jeffrey Yao, Ph.D.	<i>Phospholipid-Arachidonate-Eicosanoid Signaling in Schizophrenia</i>

VA Cooperative Studies Program

Linda Fried, MD, MPH	<i>CSP 565- VA Nephropathy in Diabetes Study (Study Co-Chair)</i>
Jeffrey Gingrich, MD	<i>Prospective Cohort of Early Stage Prostate Cancer</i>
Kent Kwoh, MD	<i>Rheumatoid Arthritis: Comparison of Active Therapies in Patients with Active Disease Despite Methotrexate Therapy</i>
Mohan Ramkumar, MD	<i>CSP 565- VA Nephropathy in Diabetes Study (Site Investigator)</i>
Mark A. Wilson, MD, Ph.D.	<i>Open Versus Endovascular Repair (OVER) Trial for Abdominal Aortic Aneurysm</i>

Rehabilitation Research and Development (RR&D)

Guodong Cao, Ph.D.	<i>Neurorecovery Effects of Novel Modified Erythropoetin on Ischemic Brain Injury</i>
Rory A. Cooper, Ph.D.	<i>Senior Research Career Scientist Center of Excellence for Wheelchairs and Associated Rehab Engineering Computer-based and Virtual Assessment of Power Wheelchair Mobility Powered-Seating Function Usage Among Veterans-Compliance and Coaching</i>
Patrick J. Doyle, Ph.D.	<i>Communicative Functioning in Neurogenic Speech-Language Disorders II</i>
Steven D. Forman, MD, Ph.D.	<i>Targeted Transcranial Magnetic Stimulation to Decrease Food Craving</i>
William D. Hula, Ph.D.	<i>Attention and Lexical Access in Aphasia and Apraxia of Speech</i>
Alicia M. Koontz, Ph.D.	<i>Longitudinal Study of Acute & Chronic Upper Limb Pathology Following SCI</i>

Rehabilitation Research and Development (RR&D) (continued)

Malcolm R. McNeil, Ph.D.	<i>Research Career Scientist</i>
Jonathan Pearlman, Ph.D.	<i>Assessing the Risk of Vibration Exposure during Wheelchair Propulsion</i> <i>Participatory Design of Improved Wheelchair Seating Systems (Career Development Award)</i>
Sheila Pratt, Ph.D.	<i>The Impact of Hearing Loss on Intra and Cross-Modal Context Effects</i>
Armando J. Rotondi, Ph.D.	<i>Accessible Website Design for Cognitive Impairment</i>
Debra K. Weiner, MD	<i>Efficacy of Periosteal Stimulation & Boosters for Advanced Knee OA Pain</i>

Health Services Research and Development (HSR&D)

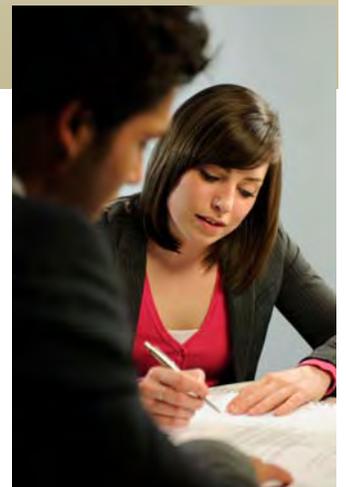
Megan Crowley-Matoka, Ph.D.	<i>Sociocultural Dimensions of Provider Decision-Making in Pain Management</i>
Michael J. Fine, MD	<i>Center for Health Equity Research Promotion</i>
Walid Gellad, MD	<i>Addressing Regional Variation in Drug Prescribing and Spending in the VA</i>
Adam J. Gordon, MD, MPH	<i>Primary Care Quality and Service Customization for the Homeless</i> <i>Determinants of Diabetes Control in Veterans with Serious Mental Illness</i>
Joseph T. Hanlon, MS, PharmD	<i>Inappropriate Drug Use for Seniors: Should VA Adopt New HEDIS Measures?</i>
Leslie Hausmann, RM, Ph.D.	<i>Identifying Mechanisms Linking Perceived Discrimination and Health (Career Development Award)</i>
Said Ibrahim, MD, MPH	<i>Knee Replacement Disparity: A Randomized, Controlled Intervention</i>
Bruce S. Ling, MD, MPH	<i>Improving Patient-Provider Communication for Colorectal Cancer Screening</i> <i>Impact of Plain Language Prostate Cancer Decision Aid on Decision Making</i> <i>Evaluating a Preference-Based Intervention for Increasing CRC Screening</i>

Health Services Research and Development (HSR&D) (continued)

Larissa Myaskovsky, Ph.D.	<i>Understanding and Reducing Racial Disparities in Renal Transplantation</i> <i>Understanding Race and Culture in Living Donor Kidney Transplantation</i>
Armando J. Rotondi, Ph.D.	<i>Treatment of OEF/OIF Veteran Neuropsychiatric Outcomes Following TBI</i>
Mary Ann Sevick, MS,RN,ScD	<i>Expert System-Based Feedback in Sedentary Overweight Veterans</i>
Stephen Weisbord, MD	<i>Pain, Sexual Dysfunction and Depression in Hemodialysis Patients</i>
Susan Zickmund, Ph.D.	<i>Barriers to Initiating Antiviral Therapy for Veterans with Hepatitis C</i> <i>Consortium for Healthcare Informatics Research: PTSD</i> <i>Evaluating the VA's Assessment of Military Sexual Trauma in Veterans</i>

VISN 4 Competitive Pilot Project Fund (CPPF)

Dimitri Gutkin, MD	<i>Dendritic Cell Homing and CXCL14 Chemokine Expression in Prostate Carcinoma</i>
Dan Hall, MD	<i>Describing Different Cultural Perspectives on Surgical Informed Consent</i>
Scott Kulich, MD, Ph.D.	<i>CTMP in Parkinsonian Neuronal Autophagy</i>
Justin LaFerrier	<i>Identification of Prosthetic Users Who Transition to Wheelchair Use for their Primary Means of Mobility</i>
Ronit Wollstein	<i>A Novel Split for Contractures of the Proximal Interphalangeal (PIP) Joint of the Hand</i>



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ACTIVE VAPHS INVESTIGATORS (as of December 2009)

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