Million Veteran Program: Partnering with Veterans to Revolutionize Health Care

The Bruce Carter Veterans Affairs Medical Center (VAMC) in Miami is one of 50 VAMCs selected across the nation to serve as an enrollment site for the Million Veteran Program (MVP), a research program that will help us better understand how genes affect veterans’ health and illness. The ultimate goal of the program is to transform health care.

MVP: A Partnership with veterans is a national, voluntary research program conducted by the Department of Veterans Affairs, Office of Research & Development. MVP aims to enroll as many as one million veterans over the next five to seven years. Participants will be asked to complete a one-time study visit (approximately 20 minutes in length) to provide a blood sample for genetic analysis. Participation also includes filling out health surveys, allowing ongoing access to medical records and agreeing to future contact. This research program will establish one of the largest databases of genes and health history. The results of MVP may lead to new ways of preventing and treating common illnesses.

Hermes Florez, MD, MPH, PhD is leading the Miami team efforts together with Silvina Levis, MD, Bruce Troen, MD, Carmen Guanipa, MD and Hector Villagran, MD and other research collaborators in the Miami Geriatrics Research, Education, and Clinical Center (GRECC). Nationwide, the MVP recently surpassed the milestone of 10,000 participants in the US and our local team completed in 5 months the enrollment of 500 veterans in South Florida. We aim to recruit 20,000 veterans in the next five to seven years. Our first Miami MVP participant is a VA employee, Mr. Antoine Garand.
Garand, AO in the Miami GRECC.

By participating in MVP, veterans will help contribute to the knowledge base that may result in developing personalized treatments for military-related illnesses, such as post-traumatic stress disorder (PTSD), as well as more common illnesses, like diabetes and heart disease. Results from MVP will help improve health care for veterans and all Americans. MVP has extensive safeguards in place to keep veterans’ personal information secure and confidential. Participation does not affect access to health care or benefits. Visit the website of the Million Veteran Program at www.research.va.gov/mvp or call toll-free 866-441-6075.

New Electronic Submission System Offers Convenience for Investigators

The Electronic Submission System is split into two parts; Credentialing and Project. Credentialing allows research teams to house their training, certifications, licenses, and basic information about themselves in one location. The Project allows the research teams to fill out required forms for their studies online in one central location with the ability to go back and make changes and/or updates when needed or requested by the Research Service. This allows research teams to submit projects for approval with a click of a button. With this new online system the Research Office will be able to find and verify all principal investigators and project information online without the need of paper forms or documents from the research teams. Use of the Credentialing Portal will begin within the next few weeks.

Research Highlights

Study on Ocular Surface Symptoms Aims to Improve Quality of Life of Miami VAMC Veterans

Anat Galor, MD, MSPH, Assistant Professor of Clinical Ophthalmology, presented the following abstract at the Association for Research in Vision and Ophthalmology meeting.

**Purpose:** To evaluate the impact of ocular surface symptoms on quality of life in a veteran population receiving eye care services.

**Design:** Cross-sectional, survey study.

**Methods:** **Setting:** Miami Veterans Affairs Medical Center (VAMC). **Patient population:** Patients seen at the eye clinic between June and August 2010 were asked to fill out the dry eye questionnaire 5 (DEQ5) and the Impact of Dry Eye on Everyday Life (IDEEL) questionnaire. **Main outcome measures:** To evaluate the correlation between ocular surface symptoms and functionality.
Results: Four hundred eighty-nine patients elected to fill out the DEQ5 questionnaire (36% response rate). The mean age of respondents was 66 years (standard deviation 12). Ninety-four percent were male; 62% were white and 37% were black. Using the DEQ5 as a surrogate measure of ocular surface symptoms, 65% of respondents reported at least mild ocular surface symptoms (DEQ5≥6) and 27% of them reported severe symptoms (DEQ5≥12). Blacks had a two-fold increased risk of severe symptoms compared to whites (odds ratio 2.06, 95% confidence interval 1.33-3.19). Several medications were associated with a significantly increased risk of severe symptoms including glaucoma medications (1.7 fold increase), anti-depressants (2.3 fold increase), and anti-histamines (2.1 fold increase). There was an inverse correlation between DEQ5 and IDEEL scores with regards to ability to perform activities of daily living (n=391, r=−0.54, p<0.001), emotional well-being(n=386, r=−0.63,p<0.001), and the ability to work (n=205, r=−0.57,p<0.001). Fifty percent of patients with severe symptoms had documentation that their symptoms were addressed during the visit.

Conclusion: Severe ocular surface symptoms reduce the quality of life of Miami VAMC veterans. Eye care professionals should be vigilant in eliciting ocular surface complaints from their patients.

Helping Amputees Gain Independence, FORE Center Team Consolidates Findings for Publication

The mission of the Functional Outcomes Research and Evaluation (FORE) Center at the Miami Veterans Affairs Healthcare System is to help veterans function as closely to normal as possible. The FORE Center is designed to help veterans with below-the-knee amputations improve their mobility and independence by analyzing problems they are having and customizing a rehabilitation program to improve them. To help improve care for other patients, the FORE center documents its activities, evaluates outcomes, and disseminates findings. This year the center published three manuscripts and is currently working on producing a Single Topic Issue for the Journal of Rehabilitation Research and Development (Veterans Affairs Journal for Rehab Research). This is a collaborative effort between the Armed Forces, DoD Military Treatment Facilities, Miami VAHS, and University of Miami, Miller School of Medicine. The issue will contain five guest editorials and nine manuscripts. In addition, several manuscripts will include the findings from the Center’s original Merit Review Grant (EBAR) and independently funded Ossur grant.
Congratulations to Dr. Ignacio Gaunard

Ignacio Gaunard, a Research Physical Therapist and Administrator of the Functional Outcomes Research and Evaluation Center at the Miami VAHS, successfully defended his PhD dissertation on November 7, 2011 at the University of Miami, Miller School of Medicine, Department of Physical Therapy. His dissertation was titled, The Comprehensive High-Level Activity Mobility Predictor (CHAMP): A Performance-Based Assessment Instrument of High-Level Mobility in Service Members with Traumatic Lower Limb Loss. The dissertation addressed the development of a new high-level mobility outcome measure for our Service Members with traumatic lower limb loss. It included establishing the CHAMP’s psychometric properties and determining the factors that predict CHAMP performance. Through his dissertation, he has had the privilege of working with our Service Members who have lost lower limbs in the recent conflicts in Iraq and Afghanistan. Future research efforts will focus on expanding the CHAMP outside the military and establishing community based interventions for those with lower limb loss.

Presentations

Carlton S. Gass, PhD is co-presenting four studies at the 31st Annual Meeting of the National Academy of Neuropsychology in Marco Island on November 17.

Case Study: A Patient with Agenesis of the Corpus Callosum with Minimal Associated Neuropsychological Impairment. Curiel, R., & Gass, C. S.


A Monte Carlo Study: Frequency of Normal Healthy Adults with Abnormal MMPI-2 Odland, A., Martin, P., Perle, J., Gass, C., Simco, E., & Mittenberg, W.

Carlton S. Gass, Ph.D., recently accepted an invitation to join the editorial boards of two journals - Psychological Assessment and the Archives of Assessment Psychology.

Herman S. Cheung, Ph.D. was invited to present two lectures at the Chinese University in Hong Kong - Advances and challenges of stem cell-based regenerative medicine on October 18 and Can entrepreneurship co-exist with academia research? on October 20, 2011.
Ivonne Schulman, MD presented two abstracts for poster presentations at the American Heart Association Basic Cardiovascular Sciences meeting in July 2011:


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**GRECC**

**Geriatric Research, Education, and Clinical Center**

Silvina Levis, MD attended the American Society for Bone and Mineral Research annual meeting in San Diego, CA, October 2011, where she presented a poster on her work entitled *Baseline Characteristics of Veterans Screened for VIVA-VA Study.* Authors on this study were Violet Lagari, DO, MPH, Orlando Gomez-Marín, PhD, and Silvina Levis, MD.

Damian Stanziano, PhD attended the Florida Alliance of Scholars meeting where he was named a 2011 Florida Alliance Scholar. He also presented his work in a talk entitled *Racial and Ethnic Disparities in Chronic Disease Risk Factors & Physical Performance Among Veterans Enrolled in an Organized Exercise Program in South Florida.*

Howard Guy, PhD was invited to present a lecture on *Stem Cells, Aging and Reparative Medicine* to the residents of the Miami VAMC Community Living Center on July 2011.

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**VA Endocrine, Polypeptide and Cancer Institute**

*Andrew V. Schally, PhD, MDhc, DSchc*

Dr. Andrew Schally was invited to present the ISCI Lecture Series entitled *Synthetic Analogues of Hypothalamic Hormone for Tumor Therapy – A Historical Perspective,* on November 18, 2011, at the University of Miami Miller School of Medicine

Dr. Schally also presented *Profiles of FSH responses to GnRH antagonist/agonists/VEGF* at the Ferring Scientific Advisory Committee Meeting on November 22, 2011 at the Fontainebleau Hotel in Miami Beach, FL.
Lawrence M. Fishman, MD is honored on the Miami VA Research Wall of Fame

Dr. Lawrence M. Fishman, former Associate Chief of Staff for Research & Development and Chairman, Board of Directors for the South Florida VA Foundation for Research & Education, Inc. (SFVAFRE) was honored on August 23, 2011 at the Miami VA Medical Center. Dr. Fishman was the third honoree to be inducted to the Research Wall of Fame. Many distinguished friends and colleagues were invited to attend this special occasion. Mr. Gustavo Godoy, former Administrative Office for Research, Executive Director of the SFVAFRE, and friend gave a heartfelt accolade to Dr. Fishman’s long and rewarding tenure at the VA and UM medical centers. Dr. Vincent DeGennaro, Chief of Staff VAMC, also gave a brief account of his impressive history with both institutions which dates back to 1967. After other friends and colleagues shared memorable stories about Dr. Fishman, everyone gathered at the Wall of Fame for the unveiling of the honorary plaques that include Dr. Fishman’s picture, biosketch, list of UM/VA UpJohn Visiting Professors and Department of Veterans Affairs Certificate of Commendation. Dr. Fishman joined Drs. Andrew V. Schally, David S. Howell and Robert J. Fitzgerald as VA Research Wall of Fame honorees. The Research Service Office would like to thank Gustavo Godoy, Luis Gonzalez, Isabel Perez and Dr. Jay Skyler for their contribution and participation in the event.

Herman S. Cheung, PhD, VA Senior Research Career Scientist and UM James L. Knight Professor of Biomedical Engineering, was named the 2011-2012 Distinguished Visiting Scholar (DVS) of Union College of Chinese University of Hong Kong as part of the 55th Anniversary of the founding of Chinese University of Hong Kong for his work on stem cell isolation and characterization in tissue repair.

Damian Stanziano, Ph.D., was nominated for the class of 2012 Presidential Management Fellows Program by the University of South Florida College of Public Health. Over 9,000 nominees vie for approximately 400 fellowships. Semi-finalists will be notified in November.

Dr. Stanziano was selected by a competitive process to participate in the National Institute on Aging (NIA) Grants Technical Assistance Workshop (TAW) held November 17-18, 2011 in Boston. Participants in this workshop have the opportunity to make podium presentations of current or planned research projects, receiving feedback from peers and NIA staff.
Guy Howard, PhD was invited to be trained as part of a Delegated Examining Unit for the national VA system. This unit provides guidance to Human Resource services throughout the VA system on the credentials of applicants for scientific positions. The training took place in Nashville, TN on September 19-21, 2011.

Grants Funded

Bal Lokeshwar, PhD was awarded the BLR&D Merit Review (Spring 2011) for the study Interaction of chemokine and growth factor receptors in prostate cancer progression in the amount of $927,575.

Dr. Lokeshwar scored a percentile ranking of 3.3 on his VA Merit Review renewal application; hence we are expecting the award to be funded for the period October 1, 2011-Sept 30, 2015.

Bruce R. Troen, M.D. and Co-Investigator, Manhui Pang, MD received the BLR&D Awarded MR for the study Differential Impact of Resveratrol and Resveratrol Mimetics upon Aging Bone. The amount awarded was $640,846.00 and was effective on April 1, 2011 to March 31, 2015.

Paul Schiller, Ph.D. was successful in renewing his VA Merit Review grant entitled Mechanisms of Marrow Stromal Stem Cell Self-Renewal and Aging. This award is for the period October 1, 2011 to September 30, 2015.

Hong Yu, MD received a Technology Transfer Feasibility (TTF) award from the Florida Department of Health, Biomedical Research Program to be funded for the period April 1, 2011 to March 31, 2012.

Herman S. Cheung, PhD received the BLR&D Awarded MR for the study Effect of Smoking on Adult Stem Cell Differentiation in the amount of $474,911.00. The expected award was effective on October 1, 2011 to September 30, 2014.
**Damian Stanziano, PhD** was awarded a 2011-2012 Public Health Traineeship Grant from the US Department of Health and Human Services, Health Resources & Services Administration (HSRA), Bureau of Health Professions.

### Publications

**Michael D. Norenberg, MD**


### Ivonne Schulman, MD

Schulman IH. *Wnt signalling: a mediator of the heart-bone marrow axis after myocardial infarction*. European Heart Journal. (in press)

Schulman IH. *The Role of Clinical Trials in Deciphering Mechanisms of Action of Cardiac Cell-Based Therapy*. Stem Cells Translational Medicine. (in press)

Dulce RA, Balkan W, Hare JM, Schulman IH. *Wnt signalling: a mediator of the heart-bone marrow axis after myocardial infarction?* European Heart Journal. 2011 (in press)


Curtis KM, Gomez LA, Schiller PC. Rac1b Regulates NT3-Stimulated Mek-Erk Signaling, Directing Marrow-Isolated Adult Multilineage Inducible (MIAMI) Cells Toward an Early Neuronal Phenotype. Mol Cell Neurosci 2011. Accepted for publication; DOI: 10.1016/j.mcn.2011.10.008


FORE Center Team


Gailey RS, Gaunaurd IA, Agrawal V, Finnieston A, O’Toole C, Tolchin R. Application of Self-Report and Performance-Based Outcome Measures to Determine Functional Differences between Four Categories of Prosthetic Feet. JRRD 2012 (Accepted for publication, date pending).

VA Endocrine, Polypeptide and Cancer Institute

Andrew V. Schally, PhD, MDhc, DShc

Peer Reviewed Journals:


In Press:


Submitted for Publication:


Buchholz S, Seitz S, Engel jB, Montero A, Ortmann O, Perez R, Block NL, and Schally AV. *Search for novel therapies for triple negative breast cancers (TNBC); analogs of luteinizing hormone-releasing hormone (LHRH) and growth hormone-releasing hormone (GHRH).* Hormone Molecular Biology and Clinical Investigation.


Abstract:


SFVAFRE Corner

EXECUTED

Sponsor: Agennix, Phase II CT CRADA
Project: Phase 2/3 Randomized, Double-blind, Placebo-controlled Study of the Safety and Efficacy of Talactoferrin Alfa in Patients with Severe Sepsis.
PI: Roland Schein, M.D.

Sponsor: Bristol-Myers Squibb Company Phase III CT CRADA
PI: Lennox Jeffers, M.D.

UNDER NEGOTIATION

Sponsor: Gilead Sciences, Inc., Phase II CT CRADA
Project: A Phase 2b, Randomized, Double-blind Placebo Controlled Trail Evaluating Response Guided Therapy with GS-5885 Alone or in Combination with GS-9451 with Peg-Interferon alfa 2a and Ribavirin in treatment Naive Subjects with Chronic Genotype 1 Hepatitis C Virus Infection
PI: Lennox Jeffers, M.D.

Sponsor: TyRx Pharma, Inc., Data Collection CRADA
Project: Citadel Registry - AIGISRx Anti-Bacterial Envelope for Prevention of Infection Following Cardiac Rhythm Management Device Replacement with an Implantable Cardioverter-Defibrillator (ICD)
Project: Centurion Registry - AIGISRx Anti-Bacterial Envelope for Prevention of Infection Following Cardiac Rhythm Management Device Replacement with a Cardiac Resynchronization Therapy Device (CRT)
PI: Gustavo Lopera, M.D.

Sponsor: Lilly USA, LLC., Phase III CT CRADA
Project: The Effect of LY2189265 on Major Cardiovascular Events in Patients with Type 2 Diabetes: Reducing Cardiovascular Events with a Weekly INcretin in Diabetes (REWIND)
PI: Jennifer Marks, M.D.

Sponsor: Celgene Corporation, Phase II CT CRADA
Project: A Phase 2, Pilot, Multicenter, Randomized, Placebo-Controlled, Sequential, Ascending Dose Study to Characterize the Safety, Tolerability, Pharmacokinetic and Pharmacodynamic Activity of CC-930 in Subjects with Recalcitrant Discoid Lupus Erythematosus (DLE)
PI: Javier Alonso, M.D.
The Annual Training for Chemical Hygiene and Biosafety, Fire, Natural Gas, and Biosecurity Workshop took place on October 21, 24 and 26, 2011. For those who missed this training, the Research Service now offers bio-safety training through CITI. Call the main Research Office for more information.

The Office of Research Oversight (ORO) will be conducting an Animal Care and Use Program (ACUP) and Research Safety and Security Program (RSSP) Routine Review from January 10 to 13, 2012.

The National Research Week for 2012 is scheduled for April 23-27. This year’s theme is VA Research: Caring for Veterans through Discovery, Innovation, and Health Care Advancement

The purpose of Research Week is to recognize veterans for their participation in research studies and to provide the opportunity for VA investigators and administrators to present their discoveries and innovation that have led to advancement in health care and the Nation’s medical knowledge. As noted in the theme VA Research: Caring for Veterans through Discovery, Innovation, and Health Care Advancement, our efforts directly benefit the care of Veterans and the quality of their lives.

For this year’s Research Week, the Miami VA will host events on April 24-25, 2012. In keeping with the theme, we want to highlight all of the champions in VA Research Caregivers, Investigators, Wounded Warriors, VSOs, and most importantly Veteran Research Volunteers themselves. We are in the early planning stages but plan on hosting the 4th annual poster session along with other activities. If you have any suggestions that can better highlight the theme, please e-mail Isabel Perez at iperez4@med.miami.edu. Your input is greatly appreciated.

The annual Animal Studies Workshop will be conducted on May 16, 18, and 20. This three day workshop is mandatory for VMU technicians/ husbandry staff, research technicians, investigators, and all others that perform procedures or manipulations on laboratory animals. For more information on attending these trainings, please contact the Research Administration Office at 305-575-3179.