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MEMORANDUM

To:

Donna E. Shalala, President

From:

Richard L. Williamson

Chair, Faculty Senate

Date:

August 29, 2013

Subject: Faculty Senate Legislation #2013-01(B) – Establish the Miller School of Medicine

Institute for Advanced Pain Management

The Faculty Senate, at its August 28, 2013 meeting, voted by majority with one negative vote to approve the establishment of the Miller School of Medicine Institute for Advanced Pain Management. The enclosure outlines the goal of this Institute to become a center of excellence for the treatment of pain related to chronic conditions and improve the quality of life for patients with pain. It will benefit patients, offer collaboration across numerous UM departments, and provide full-service sites for chronic pain patients to facilitate care, and conduct critical research, training, and community service. There is currently no other multidisciplinary pain center at the UMMSM.

The Institute, which had previously been granted provisional status under Faculty Manual Section C18.1.5, was authorized under the authority of B6.6.

The proposal is enclosed for your reference.

This legislation is now forwarded to you for your action.

RLW/rh

Enclosure

Thomas LeBlanc, Executive Vice President and Provost Pascal Goldschmidt, Senior Vice President and Dean, Miller School of Medicine Norman Altman, Professor, Miller School of Medicine

¹C18.2.2 Other NAMED or TITLED ACADEMIC UNITS established under Bylaw 6.6 may be approved by the Faculty Senate and the President. For each such approved unit, the Executive Vice-President and Provost shall consult with the dean of the host school at five year intervals to determine whether the unit remains active and shall report to the Faculty Senate the names of those that should be disestablished.

C18.2.3 Periodic five year reviews may be conducted on all programs, centers, institutes and similar academic units as deemed appropriate by the Faculty Senate or the Executive Vice-President and Provost.

APPROVED:

(President's Signature)

OFFICE OR INDIVIDUAL TO IMPLEMENT:

DEAN GOLDSCHMIDT

EFFECTIVE DATE OF LEGISLATION:

(if other than June 1 next following)

NOT APPROVED AND REFERRED TO:

REMARKS (IF NOT APPROVED):

CAPSULE: Faculty Senate Legislation #2013-01(B) – Establish the Miller School of

UNIVERSITY OF MIAMI MILLER SCHOOL of MEDICINE



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Executive Summary

- A. A dedicated well-planned easy-to-access clinic system is essential to attract patients while supporting and expanding our approach to revolutionize how we view the "pain state" of individuals and transform the care of chronic pain. This will benefit patients, training, and collaboration across numerous UM departments including: Anesthesiology, John P. Hussman Institute for Human Genomics (HIHG), Miami Project to Cure Paralysis, Psychiatry and Behavioral Sciences, Physical Therapy, Neurology, Neurosurgery, Physical Medicine and Rehabilitation, and Diabetes Research Institute, Internal Medicine, Pediatrics, Gynecology, other University of Miami experts by:
 - Providing full-service sites for chronic pain patients to facilitate care and conduct critical research, training, and community service.
 - 2. Developing objective and predictive measures of an individual's pain type.
 - 3. Developing novel treatment strategies, "ladders", and treatment protocols targeting chronic pain and maximizing functionality and quality of life.
 - 4. Conducting clinical studies using the latest chronic pain treatments in development while collecting pain populations and developing a Biorepository supporting genetic analyses of chronic pain and associated co-morbidities.
 - 5. Appreciating and treating the altered cognitive state, psychiatric co-morbidities (stress, anxiety and depression) and studying neurobiological changes linked with chronic pain and treatments.
 - Understanding mechanism of susceptibility and likelihood of treatment response using state-of-the-art genomic and epigenetic methods and bioinformatics, molecular biology, pharmacology, neurophysiology, noninvasive CNS imaging, and behavioral and clinical assessments as well as other methods.
 - 7. Creating and understanding preventive strategies and providing individualized treatments using various genetic methods in collaboration with the NIH, FDA and industry based on the above translational activities.
 - 8. Promotion of mobility and function in individuals with chronic pain, according to guidelines established by the International Classification of Function (ICF), a World Health Organization (WHO) document.
- B. The Sites will also facilitate regional and UM economic development by:
 - 1. Providing a home for the best full-service multidisciplinary pain referral system in South Florida supporting expanded clinical operations and revenues.
 - Creating an extraordinary environment to support leading mechanism-based research and the attainment of substantial additional Federal grants as well as attracting industry sponsored clinical trials of the latest diagnostic tests, devices, preventive and therapeutic strategies for chronic pain.

- Assisting the recruitment of additional well-funded (NIH) clinician-scientists supporting expanded state-of-the-art clinical care and research, as well as supporting training and mentoring of the future leaders of this specialty.
- Supporting the identification and clinical development and testing of genetic and epigenetic biomarkers predicting pain susceptibility and individualized treatment response.
- Facilitating the creation and testing of internally developed cutting-edge gene-based, cell-based, and mechanism-targeting chemical and biologic therapies for chronic pain in collaboration with the NIH, the FDA, and industry.
- Supporting intellectual property creation and licensing revenues through UM Innovations.

Mission

The goal of the Miller School of Medicine's Institute for Advance Pain Management (IAPM) is to become a center of excellence for the treatment of pain related to chronic conditions and improve the quality of life for patients with pain. The IAPM will create a comprehensive best practice clinical model to effectively evaluate and treat all areas of pain impacting patients. This will be accomplished by a multidisciplinary team of physicians, other health care professionals, and scientists representing six departments. Clinical, translational, and basic science research, educational activities, and clinical trials will be key components of the IAPM. The multiple Pain Management Sites will support promising research from the laboratory to the bedside, offering patients state-of-the art treatments and experimental techniques that may not be available elsewhere in Florida. The IAPM will continue to train medical students, Pain Management and Headache Medicine fellows, physicians, and allied health care professionals as it relates to the diagnosis, multidisciplinary treatment, and management of chronic pain conditions. The IAPM will also foster community service, via appropriate education, and raise increased awareness of acute and chronic pain problems.

Background

This proposal seeks to formally establish the Miller School of Medicine's Institute for Advanced Pain Management (IAPM) previously provisionally approved. This builds upon the clinical, research, and training excellence of the Miller School of Medicine's Department of Anesthesiology, Perioperative Medicine and Pain Management ("Department of Anesthesiology").

Other than the IAPM, there is currently no multidisciplinary Pain Center at the UMMSM. When Dr. Herbert Rosomoff was Chairman of Neurological Surgery, he developed a small Pain Center for his department. Dr. Rosomoff left the university in 2003 and moved the pain center to South Shore Hospital. The hospital closed down in 2006 and the pain center ceased to exist. There is a Pain Clinic at JMH that the Department of Anesthesiology operates for indigent patients. The strong

letters of support attest to the importance of the IAPM for our patients and the willingness of our physicians to provide comprehensive, multidisciplinary services.

There are numerous activities that have implemented under the interim status of the IAPM. An Advisory Committee has been established to develop a strategic plan to implement our clinical, research, and educational goals. This is critical to the success of the IPAM. This plan will involve clinic and patient scheduling, patient evaluations, submission of IRB protocols, joint research projects, and broadly based educational programs. Numerous multidisciplinary clinics have been established, IRB submissions have been increased, and we have expanded faculty interactions. An example of these activities is the multi-specialty grand rounds program that was created by the Department of Anesthesiology. This program – INSPIRE – is a well-attended forum by clinicians, other health care professionals, and researchers from across the campus to begin sharing and developing a team science approach. The strong letters of support attest to the commitment of the 6 departments that are part of the IAPM.

Chronic pain continues to be a major burden on patients and society in general. The Institute of Medicine of the National Academies issued a report in 2011 entitled "Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research." In this report they stated that acute and chronic pain affects large numbers of Americans with approximately 100 million adults burdened by chronic pain alone. Chronic pain is a condition that affects more people than heart disease, diabetes, and cancer combined. There are many causes of chronic pain including physical injury, numerous medical conditions, heredity, stress, depression, and many other causes. The report also recognizes that only a multidisciplinary approach will be successful to care for people with pain, and meet the Educational and Research Challenges.

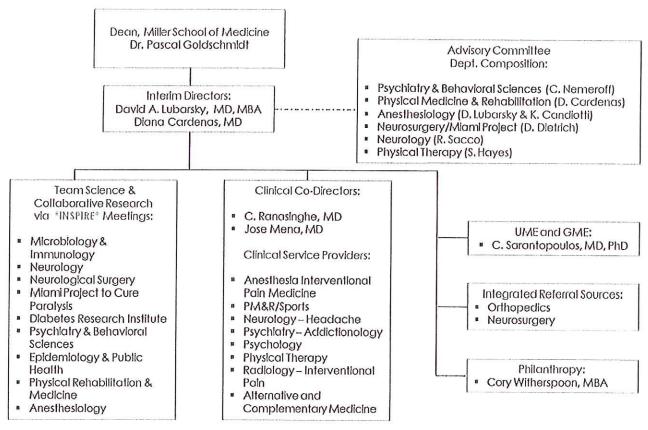
The Department of Anesthesiology Division of Pain Management, along with its clinical partners from the Departments of Physical Medicine and Rehabilitation, Neurology, Psychiatry, Physical Therapy, and Neurological Surgery, treat thousands of patients a year with chronic pain conditions. Lower back pain and related debilitating issues with various types of pain are the number one reason patients seek medical attention. Migraine alone is the 4th ranking cause among women and the 7th ranking cause of all disease-associated disability worldwide.

Faculty in the Department of Anesthesiology Division of Pain Management, and our departmental clinical partners, will conduct clinical and basic research in a variety of pain-focused areas through the IAPM. This will facilitate the integration of research projects and establish a collaborative structure of the various faculty specializing in specific areas of pain research, i.e., headache, back, oral-facial, cancer, post-operative, etc. This multidisciplinary model, for both clinical and research practices, will foster better clinical outcomes and measures which will ultimately enhance the design and efficacy of chronic pain treatment plans to further improve patient care and quality of life.

The IAPM will also benefit from involvement by many specialists within multiple departments/centers and our large diversity of ethnic groups and international patient populations.

We recognize that there are cultural differences in our patients and that multi-lingual communication skills are essential. The clinical expertise and diversity represented by our partnering departments is responsible for the large range in patients, and their diseases, that will be referred to the IAPM.

Current Organizational Chart: Institute for Advanced Pain Management



Clinical Sites of Operation: University of Miami Hospital • University of Miami Hospital & Clinics • Sylvester Comprehensive Cancer Center • Clinical Research Building • Jackson Memorial Hospital • Miami Veterans Administration Hospital

Advisory Committee Membership:

- Dr. Diana Cardenas, Chair of the Department of Rehabilitation Medicine
- Dr. Dalton Dietrich, Scientific Director, The Miami Project to Cure Paralysis
- Dr. Sherrill Hayes, Chair of the Department of Physical Therapy
- Dr. David Lubarsky, Chair of the Department of Anesthesiology, Perioperative Medicine, and Pain Management

- Dr. Charles Nemeroff, Chair of the Department of Psychiatry and Behavioral Sciences.
- Dr. Ralph Sacco, Chair of the Department of Neurology

The Advisory Committee will meet quarterly to review the activities of the IAPM and provide guidance on clinical, research, and educational activities.

Leadership

Interim Directors:

The IAPM is currently led by Dr. David Lubarsky (Anesthesiology) and Dr. Diana Cardenas (Rehabilitation Medicine) who are serving as co-Directors. The ultimate intention is to recruit an internationally recognized multidisciplinary pain expert who can guide the growth and development of the IAPM and its component sites. The appointed Director of the IAPM will also be expected to pursue external funding and promote the clinical, education and research components of the IAPM. We intend to recruit a senior faculty member with a national reputation in pain management to head the IAPM.

Diana D. Cardenas, M.D., M.H.A.

Dr. Cardenas has been Professor and Chair of the Department of Rehabilitation Medicine since 2006. Dr. Cardenas is also a professor of Neurological Surgery. She had extensive professional experience at Emory University and the University of Washington before relocating to Miami. Certifications include a Diplomate of the National Board of Medicine, American Board of Physical Medicine and Rehabilitation, and the American Board of Electro diagnostic Medicine. She has 121 publications in referred journals, numerous abstracts, book chapters and presentations. Dr. Cardenas has many funded research projects including serving as the P.I. on the South Florida SCI Model System grant (NIDRR, 10/01/2011-9/30/2016;). Dr. Cardenas has been an invited speaker nationally and internationally.

David A. Lubarsky, M.D., M.B.A.

Dr. Lubarsky is a Professor and Chair of the Department of Anesthesiology, Perioperative Medicine, and Pain Management. He also holds appointments as a professor in the School of Nursing and Health Sciences the School of Business. Dr. Lubarsky serves as the Chief Medical and Systems Integration Officer of UHealth. Certifications include the American Board of Anesthesiology and the American Academy of Pain Management. He has 89 publications in referred journals and numerous abstracts, book chapters and presentations. Dr. Lubarsky has been the P.I. on many funded research projects and clinical trials. He has been an invited professor at over 30 institutions nationally and internationally.

^{*} Financial Information Redacted

Clinical Services

The clinical activity is co-directed on an interim basis by Dr. Jose Mena (Rehabilitation Medicine) and Dr. Chaturani Ranasinghe (Anesthesiology). Each department within the program will also contribute a Medical Coordinator.

Jose Mena, M.D.

Dr. Mena is an Assistant Professor in the Department of Rehabilitation Medicine. He is certified by the American Board of Physical Medicine and Rehabilitation, with subspecialty certification in Pain Management. He is also currently a Board Examiner for the American Board of Physical Medicine and Rehabilitation. Dr. Mena has over 37 publications, abstracts, and presentations. He has been an invited speaker at local and national meetings.

Chaturani T. Ranasinghe, M.D.

Dr. Ranasinghe is an Assistant Professor in the Department of Anesthesiology. She is Board Certified in Anesthesiology and has completed a Fellowship in Pain Management at the New York University Medical Center. She is currently undergoing subspecialty certification in Pain Management. She directs the activities in pain management at the UMMSM Clinical Research Building. Dr. Ranasinghe is a member of the American Academy of Pain Medicine, the American Society of Interventional Pain Physicians, and The International Spine Intervention Society and has numerous publications and presentations on pain management.

Roy Clifford Levitt, M.D.

Dr. Levitt is a Professor in the Department of Anesthesiology and, he will coordinate the clinical and research services at the Veterans Administration Medical Center. Additionally, Dr. Levitt will play a key role in the IAPM research programs and his activities are listed in the next section. He is a Board Certified in Anesthesiology and currently undergoing subspecialty certification in Pain Management. He is a member of the American Academy of Pain Medicine, the International Association for the Study of Pain (IASP), Vice President of the Genetics and Pain IASP Special Interest Group, and The International Spine Intervention Society. His translational research focuses on mechanisms of acute to chronic pain transitions, neuropathic pain, and nociceptive pain, and specifically in the role of genetics of pain susceptibility. His clinical research focuses on the application of biologics including gene therapy for chronic pain conditions, and biomarkers of treatment response. His work has resulted in peer-reviewed articles in the areas of genetics/genomics of disease susceptibility. Dr. Levitt has published over 100 articles in scientific journals and books. He organized and presented lectures at local, national, and international meetings.

Dennis Patin, M. D.

Dr. Patin will assist in the coordination of clinical services at the University of Miami sites.

He received his M.D. in 1985 and is Board Certified in Anesthesiology and Pain Management. He is currently an Associate Professor and is Chief of Anesthesiology and Pain Management at the University of Miami Hospitals and Clinics and at the Sylvester Comprehensive Center. Dr. Patin is also Attending Physician, Anesthesia and Pain Service, at Jackson Memorial Medical Center. He has published works in both pain control and management. He has lectured locally and nationally on Obstacles to Pain Management in Cancer patients, and acute and chronic pain. Dr. Patin will coordinate the clinical service activities for the IAPM at the University of Miami sites.

Sandra Rojas, M.D.

Dr. Rojas is an Assistant Professor of Anesthesiology in the School of Medicine and the Veterans Administration Medical Center. She is Board Certified in Anesthesiology and Pain Medicine. Dr. Rojas has numerous publications and presentations on Comprehensive Intervention Pain Management. She has been an invited speaker locally and internationally on this subject. Dr. Rojas will see patients at the UM and VA sites.

Research

Constantine D. Sarantopoulos, M.D., Ph.D.

Dr. Sarantopoulos received his M.D. in 1985, a Ph.D. in Pharmacology in 1992 and is Board Certified in Anesthesiology and Pain Medicine. He is currently Professor and Chief, Department of Anesthesiology, Division of Pain Management. He has a robust clinical and research program. His basic research focuses in the pathophysiology and pharmacology of peripheral neuropathic pain and cancer pain, and specifically in the role of peripheral neuronal ion channels as mediators of neuropathic pain and neurodegeneration. His clinical research focuses in the transition from acute to chronic pain after surgery. Dr. Sarantopoulos has investigated ion channels in peripheral sensory neurons, and their role in pain following peripheral nerve injury, and developed novel techniques for studying ion channels in neurons. He has also developed clinical strategies limiting the transition from acute to chronic pain after surgery for cancer. His work has resulted in peer-reviewed articles in the areas of clinical and experimental neuropathic pain, several book chapters and international awards. To date, Dr. Sarantopoulos has published 60 articles in scientific journals and books. He has presented grand rounds and invited lectures at local, national, and international meetings.

Keith A. Candiotti, M.D.

Dr. Candiotti is a Professor in the Department of Anesthesiology, Perioperative Medicine &. Pain Management where he is also the Executive Vice Chair and Chief Operating Officer. Additionally, Dr. Candiotti is a professor in the Department of Internal Medicine. He is Board Certified in

Anesthesiology and Internal Medicine. His expertise in Anesthesiology and Pain Management are documented in his publication record of 13 book chapters, 72 referred articles, and 82 abstracts. He has been the Principal Investigator on 32 clinical trials and his funded research from 06/03/2013-02/18/2016 is \$6,436,886. He has won numerous honors and awards and has been an invited speaker nationally and internationally.

Roy Clifford Levitt, M.D.

Dr. Levitt is a Professor in the Department of Anesthesiology and actively practicing pain medicine at the Miami Veterans Affairs Healthcare System. He board certified in Anesthesiology and Internal Medicine, and has had extensive training in medical genetics. He has 12 years of pharmaceutical industry experience relevant to the mission of the IAPM including President and Chief Executive Officer of a NASDAQ biopharmaceuticals company. Since joining the University Of Miami Miller School Of Medicine in 2007, he has established and managed the pain research group as part of the Division of Translational Research in the Department of Anesthesiology. His clinical and basic research focuses on mechanisms of susceptibility to complex phenotypes including persistent pain, neuromuscular diseases. He has authored over 95 peer-reviewed publications, 12 clinical protocols (Phase I-IV), selected clinical, nonclinical, and CM&C sections of IND and NDA filings, and has been granted 22 patents. For the last five years, his focus has been on the genetics of pain. He is on the Vice President of the International Association for the Study of Pain (IASP) Genetics and Pain Special Interest Group (SIG). He also led a group that received an award from IASP in 2011 to organize and conduct the 10th IASP Research Symposium on Pain Genetics in February 2012. Ongoing studies are designed to identify and understand the genetic mechanism of susceptibility to the transition from acute to chronic pain. He has been Principal Investigator on numerous NIH awards and is NIH R01 funded (\$2,500,000 through 2017) and actively studying mechanisms in mouse models of novel susceptibility gene variants; and validating the roles of human functional DNA variants in these novel susceptibility genes; with a focus on developing better diagnostic methods and treatment strategies for chronic pain.

Services and Programs

Chronic pain conditions occur from a variety circumstances, accidents, illnesses, genetics, aging, surgery, etc., and can be extremely painful and debilitating. Studies have shown that patients suffering from these conditions have a diminished quality of life and a high rate of disability, often impacting employment, relationships, daily functioning and psychological balance. The IAPM is uniquely positioned to diagnose and treat chronic pain effectively with the goal of improving patient outcomes through the services and programs described below.

Clinical Services

Pain Management Specialists: There are three Board Certified pain physicians who will spearhead this area along with other pain specialist at the multiple clinical sites:

- University of Miami Hospital and Clinics
- University of Miami Hospital
- University of Miami Clinical Research Building
- Sylvester Comprehensive Cancer Center
- Jackson Memorial Hospital
- Miami Veterans Administration Healthcare System
- Pending Sites: Plantation and Kendall

Approximately 25% of chronic pain patients have pain related to cancer. The Sylvester Comprehensive Cancer Center Pain Site will be dedicated to treating these patients and provide care to both adult and pediatric patients.

ARNP and Nurse Specialists: These intermediate level providers will assist with targeted assessments, facilitate clinical care, offer education and develop a nurturing relationship with patients to address their needs while at the sites to treat Pain and to maintain the continuity of care when they return home. This is critical to insure compliance with medications and supporting services such as physical therapy and psychological support.

Multidisciplinary Clinical Services: This particular aspect of the IAPM is unique and will set it apart from other pain treatment centers in the region. The comprehensive nature of the IAPM will permit immediate consults with various specialties and allow the coordination of assessments, symptom management, and various therapeutic treatments. In one visit, patients will be able to have multiple diagnostic assessments, targeted treatments and personalized interventions as needed to maximize the patient visit.

Integrative Medicine Support: Dr. Diana Cardenas, Chair of the Department of Rehabilitation Medicine, is also the Project Director for the South Florida Spinal Cord Injury Model System and will bring unique expertise and experience to the IAPM. In addition to Dr. Mena, her team has five physiatrists, psychologists, and other health care specialists. Physical Therapy services will be coordinated with Dr. Sherrill Hayes, Chair of the Department of Physical Therapy. Dr. Ashwin Mehta, Department of Medicine, Medical Director of Integrative Medicine, will bring expertise in complementary techniques and positive health behaviors. The expertise listed above will be augmented by numerous other specialists who will offer consultations and recommend treatment plans utilizing various alternative therapies targeted to assist with pain relief such as: acupuncture, bio-feedback, nutrition counseling, massage, and exercise physiology, which are part of a comprehensive patient-centered approach. Specialized Headache Clinic: Dr. Monteith, Director of the Headache Division of the Department of Neurology, will establish a highly specialized headache clinic for patients with a variety of headache conditions from acute to chronic. Dr. Monteith is of a

few UCNS-board certified headache specialists in South Florida; the development of the UCNS headache clinic will attract regional, national and international referrals to the IAPM as well as stimulate multidisciplinary and coordinated care within the IAPM and the UHealth system. The establishment of the UCNS headache medicine fellowship, one of two in Florida, will encourage an academic environment and mentored research aimed to investigate headache related knowledge gaps identified across federal funding agencies and national societies. The outpatient headache program is supported by an infusion center and inpatient program. Patients receive evidence based treatment guidance with a personalized approach. As migraine is a common cause of workforce disability, the clinic would also serve to support both student and employee wellness within the UHealth system.

Physical Therapy: The Department of Physical Therapy maintains an active out-patient physical therapy clinic within the Institute at the Medical Wellness Center/Clinical Research Building. Because chronic pain affects physical strength, mobility and function, our trained specialists provide comprehensive therapy aimed at decreasing pain, and increasing strength and functional mobility, through the use of therapeutic modalities, exercise, aquatic therapy, and other activities. All are provided in a collaborative effort with other medical specialties aimed at looking at the patient in a holistic manner, addressing all of their needs.

Psychological Support: Psychological support will be coordinated with Dr. Charles Nemeroff, Chair of the Department of Psychiatry and Behavioral Sciences. Because chronic pain affects all aspects of a patient's life and depression correlates with decreased function and activity, psychologists specially trained to deal with chronic pain will provide counseling and behavioral therapy to patients and their families to support them in developing effective coping strategies to be used in conjunction with other clinical interventions. Highly trained individuals are present in many departments/centers, but the IAPM will offer venues for sharing best practices, novel research approaches, and educational opportunities.

Patient and Family Education: It is important to note that chronic pain not only affects patients but the family setting. Addressing quality of life issues are critical to excellent patient outcomes. A variety of resources devoted to patient and family education will be available, including brochures and computers with links to pain management websites, as well as televised educational videos located in the lobby waiting areas. The educational materials will be provided in English, Spanish, and Creole to reflect our multicultural patient population.

Research

Basic Science Research:

The IAPM's basic science research is focused on various projects of high importance, with an emphasis on genetic interactions and pathways that underlie susceptibility to the syndrome of chronic pain. This mechanistic approach will help develop treatments that attack the cause of chronic pain rather than only treat symptoms. The importance of this work was underscored on June 29, 2011, when the Department of Health and Human Services enlisted the Institute of Medicine in examining pain as a public health problem. Through the National Institutes of Health, state-of-the art pain research, care, and education are being evaluated in an effort to advance the field. To understand pain as a public health challenge, areas of critical importance in research have been identified such as: the impact of pain on the quality of life; subpopulations at risk; understanding the characteristics of acute and chronic pain; and developing new mechanism-based approaches for treatment. The results of the research being conducted in the IAPM will affect the lives of people suffering from a variety of severe painful conditions, including pain related to diabetes and cancer.

Clinical and Translational Research:

The current areas of focus related to pain research in the Department of Anesthesiology, Division of Translational Research, include persistent pain, genetic propensity to pain (acute and chronic) and susceptibility and the pursuit of the preclinical development of non-opiate based analgesic treatments for persistent pain.

Clinical Trials:

Although chronic pain is caused by a variety of common conditions, including genetic and environmental factors, there are a lack of studies of large populations designed to better identify optimum treatment plans. Current therapies may reduce symptoms, and even bring about long-term comfort in some cases; however, there is no particular treatment that works for most chronic pain and current medications can carry substantial risks. The localized multidisciplinary clinical services described above will allow for a wide variety of large clinical trials – both investigator-initiated and pharmaceutically-sponsored – for patients suffering from persistent pain syndromes.

Researchers in the IAPM are also preparing to implement a major database initiative to conduct research focusing on clinical outcome management and translational applications for "best practice" pain management treatment plans. Outcomes include the ability to track health care expenses and

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perform comparative effectiveness research that will analyze the differences in costs for hospitalizations, surgery, and medical therapy before and after the implementation of a multidisciplinary clinical model. Data will also be drawn from health care claims databases to benchmark the IAPM's performance compared with the rest of Florida and the nation, particularly as it relates to large self-insured public and private companies, including worker's compensation, employee assistance programs, commercial insurance payers and other vested entities where health care has been the largest increase in the percent of their expenses.

Current Funding of Institute Leadership, Funded Projects in Pain, and IRB Protocols

Listing of active grants from key personnel of IAPM.

Listing of active grants from key personnel of IAPM. Sponsor Grantille Description Inc.				
Grant Title	Department	IRIS		
BOSTON SCIENTIFIC FELLOWSHIP GRANT	ANESTHESIOLOGY	Patin, Dennis		
AND PERSONALIZING ANALGESIA IN CHILDREN	ANESTHESIOLOGY	Candiotti, Keith		
DOUBLE-BLIND, PARALLEL-GROUP, PLACEBO-CONTROL	ANESTHESIOLOGY	Candiotti, Keith		
PROTOCOL CPI-CL-015: A MULTI-CENTER, OPEN-LABEL, SURVEILLANCE TRIAL TO EVALUATE THE SAFETY	ANESTHESIOLOGY	Candiotti, Keith		
A MULTI-CENTER, OPEN-LABEL, SURGICAL SURVEILLANCE TRIAL TOEVALUATE THE SAFETY AND EFFICACY	ANESTHESIOLOGY	Candiotti, Keith		
LABEL, SINGLE-DOSE STUDY TO ASSESS THE PH	ANESTHESIOLOGY	Candiotti, Keith		
USE OF DEXMEDETOMIDINE IN PEDIATRIC SUBJ	ANESTHESIOLOGY	Candiotti, Keith		
A DOUBLE-BLIND, RANDOMIZED, MULTICENTER, DOSE- RANGING STUDYTO EVALUATE THE SAFETY AND EFF	ANESTHESIOLOGY	Candiotti, Keith		
A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLEDTRIAL TO EVALUATE THE EFFICACY	ANESTHESIOLOGY	Candiotti, Keith		
OPEN-LABEL, PARALLEL, ACTIVE-COMPARATOR,	ANESTHESIOLOGY	Candiotti, Keith		
TRIAL UTILIZING THE INFILTRATION OF A LONG	ANESTHESIOLOGY	Candiotti, Keith		
TRIAL UTILIZING THE INFILTRATION OF A LONG	ANESTHESIOLOGY	Candiotti, Keith		
ADVERSE CARDIOVASCULAR ANDCEREBROVASCULA	ANESTHESIOLOGY	Candiotti, Keith		
PROTOCOL PALO 1014: A MULTICENTER, DOUBLE-BLIND, DOUBLE-DUMMY, RANDOMIZED, PARALLEL GROUP,	ANESTHESIOLOGY	Candiotti, Keith		
PERIOPERATIVE ISCHEMIC EVALUATION-2 TRIAL	ANESTHESIOLOGY	Candiotti, Keith		
CA8 VARIANTS: NEW MECHANISMS UNDERLYING TRANSITIONS TO PERSISTENT PAIN SYNDROMES.	ANESTHESIOLOGY	Levitt, Roy		
	BOSTON SCIENTIFIC FELLOWSHIP GRANT PREDICTING PERIOPERATIVE OPIOID ADVERSE EFFECTS AND PERSONALIZING ANALGESIA IN CHILDREN PROTOCOL 402-C-323: A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PARALLEL-GROUP, PLACEBO-CONTROL PROTOCOL CPI-CL-015: A MULTI-CENTER, OPEN-LABEL, SURVEILLANCE TRIAL TO EVALUATE THE SAFETY A MULTI-CENTER, OPEN-LABEL, SURGICAL SURVEILLANCE TRIAL TOEVALUATE THE SAFETY AND EFFICACY PROTOCOL CXL-PK-04: A PHASE 1, MULTICENTER, OPEN-LABEL, SINGLE-DOSE STUDY TO ASSESS THE PH PHASE IV, OPEN-LABEL, SAFETY STUDY EVALUATING THE USE OF DEXMEDETOMIDINE IN PEDIATRIC SUBJ A DOUBLE-BLIND, RANDOMIZED, MULTICENTER, DOSE-RANGING STUDYTO EVALUATE THE SAFETY AND EFF A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLEDTRIAL TO EVALUATE THE EFFICACY PROTOCOL CPI-CL-012: A MULTI-CENTER, RANDOMIZED, OPEN-LABEL, PARALLEL, ACTIVE-COMPARATOR, PROTOCOL MA402S23B302: AN EXTENDED PAIN RELIEF TRIAL UTILIZING THE INFILTRATION OF A LONG PROTOCOL MA402S23B602: AN EXTENDED PAIN RELIEF TRIAL UTILIZING THE INFILTRATION OF A LONG THE EFFECT OF ACADESINE ON CLINICALLY SIGNIFICANT ADVERSE CARDIOVASCULAR ANDCEREBROVASCULA PROTOCOL PALO 1014: A MULTICENTER, DOUBLE-BLIND, DOUBLE-DUMMY, RANDOMIZED, PARALLEL GROUP, PERIOPERATIVE ISCHEMIC EVALUATION-2 TRIAL CAS VARIANTS: NEW MECHANISMS UNDERLYING	BOSTON SCIENTIFIC FELLOWSHIP GRANT PREDICTING PERIOPERATIVE OPIOID ADVERSE EFFECTS AND PERSONALIZING ANALGESIA IN CHILDREN PROTOCOL 402-C-323: A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PARALLEL-GROUP, PLACEBO-CONTROL PROTOCOL CPI-CL-015: A MULTI-CENTER, OPEN-LABEL, SURVEILLANCE TRIAL TO EVALUATE THE SAFETY A MULTI-CENTER, OPEN-LABEL, SURGICAL SURVEILLANCE TRIAL TOEVALUATE THE SAFETY AND EFFICACY PROTOCOL CXL-PK-04: A PHASE 1, MULTICENTER, OPEN- LABEL, SINGLE-DOSE STUDY TO ASSESS THE PH PHASE IV, OPEN-LABEL, SAFETY STUDY EVALUATING THE USE OF DEXMEDETOMIDINE IN PEDIATRIC SUBJ A DOUBLE-BLIND, RANDOMIZED, MULTICENTER, DOSE- RANGING STUDYTO EVALUATE THE SAFETY AND EFF A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLEDTRIAL TO EVALUATE THE EFFICACY PROTOCOL CPI-CL-012: A MULTI-CENTER, RANDOMIZED, OPEN-LABEL, PARALLEL, ACTIVE-COMPARATOR, PROTOCOL MA402S23B302: AN EXTENDED PAIN RELIEF TRIAL UTILIZING THE INFILTRATION OF A LONG PROTOCOL MA402S23B602: AN EXTENDED PAIN RELIEF TRIAL UTILIZING THE INFILTRATION OF A LONG THE EFFECT OF ACADESINE ON CLINICALLY SIGNIFICANT ADVERSE CARDIOVASCULAR ANDCEREBROVASCULA PROTOCOL PALO 1014: A MULTICENTER, DOUBLE-BLIND, DOUBLE-DUMMY, RANDOMIZED, PARALLEL GROUP, PERIOPERATIVE ISCHEMIC EVALUATION-2 TRIAL ANESTHESIOLOGY ANESTHESIOLOGY		

Sponsored funding with "pain" in the title

Sponsor	Tiltle	Department	IRI
DUKE UNIVERSITY	PROSPECTIVE MULTICENTER IMAGING STUDY FOR EVALUATION OF CHEST PAIN (PROMISE STUDY)	MEDICINE	Hendel, Robert
CRAIG H NEILSEN FOUNDATION	UTILIZING DESIGNER GENES TO ALLEVIATE CHRONIC SCI PAIN	MIAMI PROJECT	Sagen, Jacqueline
CRAIG H NEILSEN FOUNDATION	RECOMBINANT STEM CELL THERAPY FOR SPINAL CORD INJURY PAIN	MIAMI PROJECT	Sagen, Jacqueline
NATL INST OF DENTAL & CRANIOFACIAL RESEARCH	CA8 VARIANTS: NEW MECHANISMS UNDERLYING TRANSITIONS TO PERSISTENT PAIN SYNDROMES.	ANESTHESIOLOGY	Levitt, Roy
NATL INST ON DRUG ABUSE	CARBONIC ANHYDRASE 8 AND SUSCEPTIBILITY TO THE ACUTE TO CHRONIC PAIN TRANSITION	ANESTHESIOLOGY	Fu, Eugene
NATL INST OF HEALTH	POTENT ANALGESIC CONOPEPTIDES FOR TREATMENT OF CHRONIC SPINAL CORD INJURY PAIN	MIAMI PROJECT	Sagen, Jacqueline
NATL INST OF NEUROLOGICAL	HIV AND NRT'S-INDUCED PAINFUL PATHOGENIC	ANESTHESIOLOGY	Hao, Shuanglin

Sponsor	Title	Department	iai
DISORDERS & STROKE	MECHANISMS AND GENE THERAPY		
PACIRA PHARMACEUTICALS INC	PROTOCOL MA402S23B302: AN EXTENDED PAIN RELIEF TRIAL UTILIZING THE INFILTRATION OF A LONG	ANESTHESIOLOGY	Candiotti, Keith
PACIRA PHARMACEUTICALS INC	PROTOCOL MA402S23B602: AN EXTENDED PAIN RELIEF TRIAL UTILIZING THE INFILTRATION OF A LONG	ANESTHESIOLOGY	Candiotti, Keith
DERMWORX INC	AN OPEN-LABEL TOPICAL LIDOCAINE STUDY TO ASSESS PERCEPTIONSOF PAIN AT SPECIFIC RANDOMIZED	DERMATOLOGY COSMETIC CENTER	Baumann, Leslie
DIABETES RES & EDU FND	THE MECHANISM APPROACH OF THE THERAPY FOR DIABETIC NEUROPATHIC PAIN	ANESTHESIOLOGY	Zhang, Yan Ping
AMER CANCER SOCIETY - NATL	MOLECULAR DISSECTION OF PAIN SIGNALS IN C. ELEGANS	PHYSIOLOGY & BIOPHYSICS	Bianchi, Laura
U S ARMY MED RESEARCH ACQUISITION ACT	EXPERIENCES OF LIVING WITH PAIN AFTER A SPINAL CORD INJURY	MIAMI PROJECT	Widerstrom- Noga, Eva
U S ARMY MED RESEARCH ACQUISITION ACT	TREATMENT OF PAIN AND AUTONOMIC DYSREFLEXIA IN SPINAL CORD INJURY WITH DEEP BRAIN STIMULAT	MIAMI PROJECT	Jagid, Jonathan
WINGS FOR LIFE SPINAL CORD RESEARCH FND	AGRIN MECHANISMS IN SPINAL CORD INJURY INDUCED NEUROPATHIC PAIN	ANESTHESIOLOGY	Cul, Jian Guo

Pain-Related NIH Funding

(Project Title	ProjectNumber	Gontact IRI // Project Leader	IFY
CA8 VARIANTS: NEW MECHANISMS UNDERLYING	1R01DE022903-	LEVITT, ROY	
TRANSITIONS TO PERSISTENT PAIN SYNDROMES	01	CLIFFORD	2012
VOLUMETRIC MRSI EVALUATION OF TRAUMATIC	5R01NS055107-	MAUDSLEY, ANDREW	
BRAIN INJURY	07	Α.	2012
CHEMOSENSORY TRANSDUCTION IN TASTE	5R01DC000374-		
CELLS .	22	ROPER, STEPHEN D.	2012
POTENT ANALGESIC CONOPERTIDES FOR	500		
TREATMENT OF CHRONIC SPINAL CORD INJURY	5R21NS072769-		
PAIN	02	SAGEN, JACQUELINE	2012
	5R01NS070969-		
GLIA IN TOUCH SENSATION	03	BIANCHI, LAURA	2013
HIV AND NRTI'S-INDUCED PAINFUL PATHOGENIC	5R01NS066792-		
MECHANISMS AND GENE THERAPY	05	HAO, SHUANGLIN	2013





Autive IRB Protocols Related to Pain	RIILastiNamo	RUfffrettName	PHDepartment
A Randomized, Placebo Controlled, Multi-Center Study of the			
Efficacy, Pharmacokinetics (PK) and Pharmacodynamics (PD) of			
Intravenous (IV) Acetaminophen for the Treatment of Acute Pain in			
Pediatric Patients	Candiotti	Keith	Anesthesiology
A Pain Relief Trial Utilizing the Infiltration of a Multivesicular			
Liposome Formulation Of BupiVacaine, EXPAREL®: A Phase 4			
Health Economic Trial in Adult Patients Undergoing Laparoscopic			
Colectomy (IMPROVE – Lap Colectomy)	Candiotti	Keith	Anesthesiology
The effects of polymorphisms of the COX-2 promoter, interleukins			
and opioid metabolizers on pain modulation, opioid consumption			
and clinical outcomes in patients undergoing major urological or			
orthopedic procedures.	Candiotti	Keith	Anesthesiology

Active IRB Protocols Related to Pain	PHLast Name	RUBirst Name	RIIDepartment
An Open-label, Multicenter Study of the Safety of Twice Daily Oxycodone Hydrochloride Controlled-release Tablets in Opioid Experienced Children from Ages 6 to 16 Years Old, Inclusive, with Moderate to Severe Malignant and/or Nonmalignant Pain Requiring Opioid Analgesics		Ralf	Anesthesiology
An Open-label, Multicenter Study of the Safety, Pharmacokinetics, and Efficacy of Buprenorphine Transdermal System (BTDS) in Children From 7 to 16 Years of Age, Inclusive, Who Require Continuous Opioid Analgesia for Moderate to Severe Pain A Randomized, Double-blind, Double-dummy, Placebo-controlled,	Gebhard	Ralf	Anesthesiology
A Kandomized, Bouble-Billd, Bouble-duminy, Placebo-controlled, Active-controlled, Parallel-group, Multicenter Trial of Oxycodone/Naloxone Controlled-release Tablets (OXN) to Assess the Analgesic Efficacy (Compared to Placebo) and the Management of Opioid-induced Constipation (Compared to Oxycodone Controlled-release Tablets (OXY)) in Opioid-experienced Subjects with Moderate to Severe Chronic Low Back Pain and a History of Opioid-induced Constipation who Require Around-the-clock Opioid			
Therapy	Gebhard	Ralf	Anesthesiology
Prospective Multicenter Imaging Study for Evaluation of Chest Pain	Hendel	Robert	Medicine
Treatment of Pain and Autonomic Dysreflexia in Spinal Cord Injury with Deep Brain Stimulation	Jagid	Jonathan	Neurological Surgery
Bone Marrow Stem Cell Grafts for Neurogenic Pain	Sagen	Jacqueline	Neurological Surgery
International Spinal Cord Injury Basic Pain Data Set survey for Self-Report Measures.	Widerstrom- Noga	Eva	Neurological Surgery
Experiences of living with persistent pain after a spinal cord injury	Widerstrom- Noga	Eva	Neurological Surgery
Use of Marijuana Treatment of Pain and Spasticity	Sharma	Khema	Neurology
Comparison of Postoperative Pain with Two Different Types of Local Anesthesia in Surgery for a Drooping Eyelid	Lee	Wendy	Ophthalmology
Retrospective Review of Pain Episodes in Children with Sickle Cell Anemia Treated with Opolids with and without the Addition of Ketorolac	Alvarez	Ofelia	Pediatrics
Does pain catastrophizing predict pain intensity and self-reported	uru	S.G.III	Physical
disability?	Wong	Marlon	Therapy
The effect of acculturation on pain appraisal and physical therapy outcomes	Wong	Marlon	Physical Therapy
Can application of a topical vapocoolant spray decrease perceived pain from initial anesthetic intradermal injection during imageguided breast procedures?	Collado-Mesa	Fernando	Radiology
Prospective, Randomized Controlled Trial for Shoulder Pathology and Pain in Chronic SCI.	Cardenas	Diana	Rehabilitation Medicine

Antive IRB Protocols Related to Patin	IAIITessy/penie	BHHrst Name	RIDepartment
Pain, mood, and perceived exertion in relation to inpatient/outpatient rehabilitation	Dalal	Kevin	Rehabilitation Medicine
Chronic Pain Comorbidity Prevalence	Johnson- Greene	Douglas	Rehabilitation Medicine
Effect of Vibration on Pain Level During Rehabilitation Therapy of Burn Patients			
	Pizano	Louis ·	Surgery

Medical Education

A major focus of the IAPM will be to provide educational opportunities to multiple levels of health care professionals. Currently, the Department of Anesthesiology has five residents who rotate through Pain Management Sites. This is a required rotation as part of the residency training program in Anesthesiology. The IAPM will provide a well-organized training experience for the five residents ranging in rank from first year to senior resident. In addition to residents, the IAPM will provide experience for Pain Management Fellows. The Department of Anesthesiology has three fellows from various subspecialties, with diverse and comprehensive patient exposure. Educational opportunities are also provided to medical students and allied health care practitioners. The IAMP will also serve as a resource for chronic pain specialists nationally and internationally. Dr. Dennis Patin currently conducts an international training program for implantable pain devices for physicians from South and Central America.

Philanthropy

* Financial Information Redacted

Miller School of Medicine Pain Management Site (s) Budget Projections

* Financial Information Redacted

Conclusions

As detailed in this proposal, multidisciplinary pain management is critical to successful treatment outcomes for the patients, their families, and quality of life issues. There are Pain Management clinics in South Florida; however, there is no dedicated multidisciplinary academic based chronic pain center in Florida and few nationally that combine comprehensive treatment plans. Having a bench-to-bedside program will enable the IAPM to bring state-of-the-art and innovative treatment opportunities for patients with chronic pain. The multidisciplinary services through the IAPM clinic visits will complement single visit options such as, physical therapy, acupuncture, nutritional and exercise counseling, psychological support, headache medicine, and medication interventions. The IAPM educational programs will span patients, families, medical students, residents, fellows, and many other health care professionals.



MILLER SCHOOL of MEDICINE

July 31, 2013

Professor Richard Williamson Chair, Faculty Senate University of Miami

Dear Professor Williamson,

This is to inform the Faculty Senate that the Medical School Faculty Council met on July 30th, 2013 to review and vote on the Miller School of Medicine Institute for Advanced Paln Management.

This institute will benefit patients, training, and collaboration across numerous UM departments including: Anesthesiology, John P. Hussman Institute for Human Genomics (HIHG), Miami Project to Cure Paralysis, Psychiatry and Behavioral Sciences, Physical Therapy, Neurology, Neurosurgery, Physical Medicine and Rehabilitation, and other University of Miami experts.

This proposal seeks to formally establish the Miller School of Medicine's Institute for Advanced Pain Management (IAPM) previously provisionally approved. This builds upon the clinical, research, and training excellence of the Miller School of Medicine's Department of Anesthesiology, Perioperative Medicine and Pain Management ("Department of Anesthesiology").

The IAPM is currently led by Dr. David Lubarsky (Anesthesiology) and Dr. Diana Cardenas (Rehabilitation Medicine) who are serving as the *co-Interim Directors*. The ultimate intention is to recruit an internationally recognized multidisciplinary pain expert who can guide the growth and development of the IAPM and its component sites.

The Council members voted to approve the Miller School of Medicine Institute for Advanced Pain Management.

Respectfully Submitted,

Carl Schulman, M.D., Ph.D.

Speaker, Medical School Faculty Council

"MSOM Institute for Advanced Pain Management' 8/28/13 FS agenda Page 20 of 27



UNIVERSITY OF MIAME OF MEDICINE

Pascol J. Guldschmidt, M.D. Senter Vita Prubbert for Staked Affelir ved Devr Clif lixeathe Office, Unhanity of Mari Haddi Synter

July 22, 2013

Richard Williamson, J.D. Chair, Faculty Senate Ashe Building, Sulte #325 1252 Memorial Drive Coral Gables, Florida 33146

Re: Institute for Advanced Pain Management (IAPM)

Dear Professor Williamson:

This letter is in support of the proposal to establish the Institute for Advanced Pain Management at the University of Miami Leonard M. Miller School of Medicine, which I am certain will emerge as the premier South Florida Center for the treatment of chronic and pain-related conditions. The Institute will improve the quality and scope of life for many of our patients - specifically those who require collaborative care from our renowned specialists in the fields of anesthesiology, psychlatry, physical therapy, rehabilitation as well as neurology and neurosurgery. Moreover, the integration of clinical services (aeross multiple specialites) will ensure that our clinical, translational and basic science research will be merged and strengthened.

Educational activities, combined with multidisciplinary research programs, will promote an interchange of ideas that will no doubt lead to team science grants — benefiting all involved. In addition, the IAPM will also standardize clinical approaches, develop standard care pathways and monitor outcomes related to optimization of treatment plans for pain management.

I am in full support of our multidisciplinary team of physicians, healthcare providers and scientists who will engage in a coordinated effort to improve the quality of life of our patients and, it is with great enthusiasm that I endorse the Institute.

Sincerely,

Pascal Goldschmidt, M.D.

Senior Vice President for Medical Affairs and Dean

Paul J-915 - 6-1

Chief Executive Officer, University of Miami Health System





Diama D. Cardemas, M.D., M.H.A. Professor and Chair Chief of Service for Rehabilitation Medicine and Director of Jackson Memorial Rehabilitation Hospital

July 1, 2013

Richard Williamson, J.D. Chair, Paculty Senate Ashe Building, Rm. #325 1252 Memorial Drive Coral Gables, FL 33146

Dear Dr. Williamson:

This letter is in support of the proposal to establish the Institute for Advanced Pain Management (IAPM). My department has been actively participating in the care and treatment of patients with pain who are seen in the current multidisciplinary pain clinic on the ninth floor of the Wellness Center. Five physiatrists from my department and one of our psychologists are providers there. In addition, Dr. José Mena, Assistant Professor and a physiatrist, along with Dr. Chaturani Ranasinghe, Assistant Professor and an anesthesiology are co-medical directors who together help run the day-to-day operation of the clinic. The providers all support each other as a team. The establishment of the IAPM will ensure that the clinical research translational and basic science research of all related parties will be merged and strengthened under a single umbrella institute. The educational activities will also be strengthened by the IAPM. Trainces and students will benefit greatly.

My department is enthusiastic and supportive of this multidisciplinary team of physicians, other health cure professionals, and scientists who have become engaged in the vital endeavor to improve the function and quality of life of patients who suffer from neute, subscute, and chronic pain.

Sincerely,

Mana D. Cardenas, MD, MHA

Professor and Chair

Department of Rehabilitation Medicino

DDC:

Department of Rehabilitation Medicine P.O. Box 010960 (G-206) | Miami, FL 33101 Phone: 305-243-9616 | Pax: 305-243-4660

"MSOM Institute for Advanced Pain Management' 8/28/13 FS agenda Page 22 of 27



THE MIAML PROJECT TO CURE PARALYSIS AN INTERNATIONAL CENTER FOR PRINCIP CORD INJURY RESEARCH

W. Dalton Dietrich, Ph.D. Scientific Divetor

April 16, 2013

Dr. David Lubarsky Professor and Chairman Department of Anesthesiology Leonard M. Mitter School of Medicine University of Miami Health System C 300B JMH Central Miami, FL 33136

Re: Pain Management Institute

Dear Dr. Lubarsky, 1 4... 1

This is a strong letter of support for your proposed Institute for Advanced Pain Management at the University of Miami Miller School of Medicine. The outstanding group of scientists and elinicians that you have brought together to target pain is very exciting and timely to the field. I know that your program is multi-departmental as well as multi-disciplinary in your attempt to investigate the pathophysiology of pain mechanisms as well as develop new clinical treatment strategies. I and other members of The Miami Project and the Neuroscience community support your program. If I can be of any additional help regarding this important subject, feel free to contact me

Sincerely,

1 Mid

W. Dalton Dietrich, Ph.D.
Scientific Director, The Miumi Project to Cure Paralysis
Kingtle Concepts Distinguished Chair in Neurosurgery
Senior Associate Dean for Discovery Science
Professor of Neurological Surgery, Neurology and
Cell Biology and Auntomy



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UNIVERSITY OF MIAMI OF MEDICINE

July 26, 2013

Richard Williamson, JD Chair, Faculty Senate Ashe Building, Room II 325 1252 Memorial Drive Coral Gables, FL 33146

Dear Dr. Williamson:

This letter is in support of the proposal to formally establish the institute for Advanced Pain Management (IAPM). The Department of Physical Therapy has been a founding supporting department for this initiative for several years. We have a clinical team that is actively engaged in the institute, providing physical therapy care for patients with chronic pain, 5 days a week. We have many clinicians involved in treating patients with chronic pain and painful conditions, including low back pain (which usually accounts for more than 50% of all patients treated in physical therapy out-patient clinics), painful neuropathy, joint pain from degenerative joint disease or rheumatoki arthritis, spinal stenosis, cancer pain, and many more. This physical therapy clinical site at the Medical Wellness Center has grown to over 300 patient visits per month, and serves as a clinical practice site for our department, and a place of educational training in the form of a clinical internship for our Doctor of Physical Therapy (DPT) students.

Until this institute was founded here at UM, there was no integrated, comprehensive, interdisciplinary center for the treatment of chronic pain in all of South Florida. Since pain is multifocal, complicated, and truly requires a dedicated *Team approach*, there is no location or center that is better equipped than the Miller School of Medicine to bring many players together for the successful treatment of chronic pain, with the primary purpose and mission of better patient care.

The formal establishment of this institute, bringing together cutting edge developments in genetics, neurology and neurosurgery, interventional treatments from both Physical Medicine as well as Anesthesiology, physical therapy, and psychological support and counseling is truly a model of best practice for the clinical treatment of chronic pain, but also for very fundable clinical research in both the basic sciences as well as the translational sciences, or "bench to bedside," so vital in our future health care arena.

Our department is very enthusiastic and supportive of this endeavor, and of the very nature of a multi- and interdisciplinary team approach to improve the well-being and function of individuals with chronic pain.

Sincerely,

Sherrill H. Hayes, PhD, PT Professor and Chair

Department of Physical Therapy

House & Not day

Department of Physical Therapy 59 IS Ponco de Leon Boulevard, 5th Floor | Corol Gables, FL 33146-2406 Ph: 305-284-4535 | Fox: 305-284-6128 www.pt.med.mlamt.edu





July 2, 2013

Richard Williamson, J.D. Chair, Faculty Senate Ashe Bullding, Suite #325 1252 Memorial Drive Coral Gables, Florida 33146

Re: Institute for Advanced Pain Management (IAPM)

Dear Dr. Williamson:

As the Chairman of the Department of Anesthesiology, Perioperative Medicine and Pain Management, I can only enthusiastically support an Institute whose goal is to create synergies from the multi-faceted programs already ongoing on the campus. There already exists basic neuroscience research in collaboration with the Miami Project, grants to help our wounded veterans recover from painful injuries, and translational research aimed at developing novel therapies for the acute to chronic pain transition.

Under the interim status of the Institute, a multi-specialty grand rounds program has been created by members of my department — INSPIRE — and is a well-attended forum for researchers from across the campus to begin sharing and developing a team science approach. The very non-parochial nature of an institute umbrella is necessary to create the environment to allow free flowing ideas that will lead to team science grants. We have been less successful transforming the educational offerings now mandated by LCME, and which should be mandated by the ACOME (and will soon) for enhanced training and education in pain management.

An Institute such as the IAPM under strong non-parochial leadership has the opportunity to craft an optimal multi-specialty orientation to pain management that will serve our current patients and all the patients our students and trainees will eventually touch. This requires a level of coordination and commitment that only an Institute Director could bring. As for clinical work, our interventional pain physicians work alongside multiple other specialties at our profitable IAPM clinic in the CRB. We already convene to discuss care pathway but have not made sufficient inroads to transform how patients are treated here at UM; we are a multi-specialty clinic with multiple separate departmental executions. A dedicated Institute leadership, which will only be recruited with a clear University commitment to such an Institute, will allow us to

Department of Anesthesiology Perioperative Wedicine and Pain Management P.O. 80x 016370 (R-370) | Miami, FL 33101 Phone: (305) 585-7037 | Fax: (305) 545-6501 standardize clinical approaches, develop standard care pathways, and track and report on the outcomes related to optimizing treatment plans for pain management. With at least 100 million Americans suffering from some sort of chronic pain each year, this should be UM's most important initiative.

Sincerely,

David A. Lubarsky, M.D., MBA Chief Medical and Systems Integration Officer University of Miami Health System

Emanuel M. Papper Professor and Chair Department of Anesthesiology, Perioperative Medicine and Pain Management

/gle



UNIVERSITY OF MIAMI MILLER SCHOOL of MEDICINE

Charles B. Nemeroff, M.D., Ph.D. Leonard M. Miller Professor and Chaliman

July 5, 2013

Faculty Senate University of Miami Coral Gables, Florida

To whom It may concern:

It is with great enthusiasm that I write this letter in support of the establishment of the University of Miami Miller School of Medicine Institute for Advanced Pain Management.

My support for this concept is based on three fundamental factors. First, there will be a marked improvement in the quality of patient care associated with the creation of a multidisciplinary institute for Advanced Pain Management. Indeed, patients with chronic pain require collaborative care from specialists in anesthesiology, psychiatry, physical therapy, rehabilitation, as well as neurology and neurosurgery. These patients often have other complicated medical conditions that may require other specialists, as well. If one thinks about what is best for the patient, there is no doubt that a single site providing comprehensive diagnostic assessment and treatment planning for patients with chronic pain will be a boom to the patient community in South Florida. This is in sharp contrast to the number of "blockshops" and so-called pain clinics that dispense narcotic analgesics in excess in our community.

In addition to patient care, another major advantage of this institute will be in training. Specialists in a variety of medical disciplines ranging from neurologists and psychiatrists to anesthesiologists and oncologists, and other specialists need to be trained in caring for patients with pain. The institute for Advanced Pain Management will provide an optimal training environment to attract the very best young trainees in the field to the University of Miami.

Finally, and not insignificantly, is the tremendous research potential that this institute will provide. With the inclusion of basic neuroscience investigators from The Miami Project, and the basic science departments ranging from Pharmacology to Biochemistry and Molecular Biology, we should be able to capitalize on "big ticket" research grants from the NIH in this much needed research area. The opportunity for basic research, translational research, and clinical trials, with the establishment of this institute will be a much needed sea change that will help the University of Miami Miller School of Medicine be competitive for NIH and other extramural sources of funding at this very difficult time in external funding history.

In summary, the Department of Psychiatry and Behavioral Sciences stands firmly behind the establishment of the Institute for Advanced Pain Management.

If you require any further information from me, please do not hesitate to let me know.

Sincerely,

Charles B. Nemeroff, M.D., Ph.D.

Leonard M. Miller Professor and Chairman-

Director, Center on Aging

Department of Psychlatry & Behavioral Sciences
Clinical Research Building | 1120 NW 14th Street, Room 1455 (D-28) | Miamil, FL 33136
Ph: 305-243-6400 | Fox: 305-243-1619
cnemerof@rned.miamil.edu



OLWEDICINE MITTER ECHOOP MINESPLAND

RALPHL. SACCO, MD, MS, FAHA, FAAN
Chairman, Department of Neurology
Clemberg Family Cheir in Neurological Disorders
Miller Professor of Neurology, Public Health Sciences,
Human Genetics & Neurosurgery
University of Mismi Leonard M. Miller School of Medicine
Executive Director, Evolyn F. McKnight Brain Institute
Chief of Neurology Service, Jackson Memorial Hospital

July 15, 2013

Professor Richard Williamson Chair, Faculty Senate

Re: Endorsement of the Institute for Advanced Pain Management

Dear Professor Williamson,

I am writing as Chairman of Neurology and Executive Director of the McKnight Brain Institute to support the application to formally create the Miller School of Mcdicine Institute for Advanced Pain Management (IAPM). The Department of Neurology has been a founding supporting department for this initiative for several years. The overall goals of the IAPM are to become a center of excellence for the treatment of pain related to chronic conditions and improve the quality of life for patients with pain and integrate clinical research, translational and basic science research, educational activities, and clinical trials involving pain.

The Department of Neurology has faculty who treat-many patients with chronic pain including headache, migraine, back pain, neuropathy, and central pain syndromes. Moreover, we are developing research programs in migraine under the direction of Tesha Monteith who has funding from a NINDS Minority Investigator Devolopment Award. Tesha has participated in multidisciplinary pain research meetings and evaluated patients with intractable migraine. She has also received approval from the United Council for Neurologic Subspecialties to create a followship program for headache. We also have had other neurologists who have completed pain followships under the direction of the Department of Anesthesia after their neurology residencies. There are multiple neurology faculty who could benefit from interactions with the IAPM.

As Chairman of Neurology I am enthusiastically supportive of multidisciplinary initiatives to tackle difficult clinical and research problems facing our patients. Treating chronic pain patients is complicated and requires a team approach. By integrating efforts across multiple departments we can harness the talent at UM MSOM and develop multidisciplinary research programs to address chronic pain. I am willing to serve on the Advisory Committee to review the activities of the IAPM and provide guidance on clinical, research, and educational activities. I fully support this application for institute status at UM.

Sincerety

Ralph L. Sacco, MD, MS, FAHA, PAAN

Chairman & Professor

Department of Neurology 1120 INV 14th Steet, Claket Research Backlang, State 1352 [Marm, Ft 33136 Fn: 305-243-7519 [Fax: 305-243-7031 15340811ed.inlam.edu