



**MEMORANDUM**

**To:** Donna E. Shalala, President

**From:** Richard L. Williamson  
Chair, Faculty Senate

A handwritten signature in blue ink, appearing to read 'Richard L. Williamson'.

**Date:** September 30, 2011

**Subject:** Faculty Senate Legislation #2011-06(B) – Establishment of the Crohn’s and Colitis Center at the University of Miami Miller School of Medicine

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At its September 21, 2011 meeting, the Faculty Senate unanimously approved the proposal to establish the Crohn’s and Colitis Center at the University of Miami Miller School of Medicine for five years and any extensions thereafter.<sup>1</sup>

The supporting materials are enclosed for your reference.

This legislation is now forwarded to you for your action.

RW/rh

Enclosure

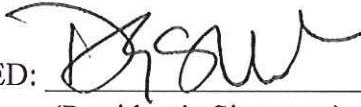
cc: Thomas LeBlanc, Executive Vice President and Provost  
Pascal Goldschmidt, Senior Vice President and Dean, Miller School of Medicine  
Jennifer McCafferty-Cepero, Presenter, Miller School of Medicine  
Maria Abreu, Director, Crohn’s and Colitis Center, Professor, Miller School of Medicine

<sup>1</sup> C18.2.2 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.

CAPSULE: Faculty Senate #2011-06(B) – Establishment of the Crohn’s and Colitis Center at the University of Miami Miller School of Medicine

PRESIDENT’S RESPONSE

APPROVED:  DATE: 10/4/2011  
(President’s Signature)

OFFICE OR INDIVIDUAL TO IMPLEMENT: Pascal Goldschmidt

EFFECTIVE DATE OF LEGISLATION: IMMEDIATELY  
(if other than June 1 next following)

NOT APPROVED AND REFERRED TO: \_\_\_\_\_

REMARKS (IF NOT APPROVED): \_\_\_\_\_



## Proposal to Establish the Crohn's and Colitis Center at the University of Miami Miller School of Medicine

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### **Mission**

The goal of the Crohn's and Colitis Center is to improve the quality of life for patients with inflammatory diseases of the bowel through state-of-the-art, evidence-based care. The Center will create a seamless process to treat both intestinal (inflammation, strictures, and perforations) and extra-intestinal symptoms (bone loss, depression, and growth failure). Additionally, the Center will expedite promising research from the laboratory to the bedside, educate fellows and visiting gastroenterologists, and help referring gastroenterologists who need help managing these complex patients.



## **Background**

This proposal seeks to formally establish a Crohn's and Colitis Center (Center) at the University of Miami Leonard M. Miller School of Medicine. The Center, provisionally approved in July 2010, will build upon the clinical care and research acumen of the Division of Gastroenterology in the Department of Medicine and add nutritional and psychological services, as well as support staff to ensure continuity of care, including scheduling regular appointments, following-up with laboratory and pathology results, and educating patients. Through the Center, patients will be closely monitored to avoid rather than treat flare-ups as they occur.

The Division treats hundreds of patients with ulcerative colitis (UC) or Crohn's disease; approximately 1.5 million Americans suffer from these two most common forms of inflammatory diseases of the bowel, and approximately 80,000 are Floridians.

Faculty in the Division conduct research in inflammatory bowel diseases and the immunology of the gastrointestinal tract and are also experts in irritable bowel syndrome, gastrointestinal cancer, pancreatic diseases, diagnostic and therapeutic gastrointestinal endoscopy, esophageal disorders, and diverticulitis. Providers administer a broad array of diagnostic tests and therapeutic procedures, and when patients require surgery or transplants, the gastroenterologists work closely with the surgeons to ensure that patients receive the best care.

The disciplines within the Department are responsible for nearly every major organ and physiological support system in the human body and they have recently hired more than 100 new faculty. Patients often develop osteoporosis and liver diseases that require the expertise of the faculty in various disciplines within the Department. The Center will also benefit from access to many other specialists within the Miller School and an international patient population.

## **Services and Programs**


Chronic inflammation of the digestive tract can be painful and debilitating and studies have shown that patients suffering from these conditions have a diminished quality of life and a high rate of disability. The Crohn's and Colitis Center is uniquely positioned to improve patient outcomes through the services and programs described below.

### **Clinical Care**

**Inflammatory Bowel Specialists:** Gastroenterologists and colorectal and laparoscopic surgeons will hold office hours in conjunction with each other.

**Nurse Specialists** will provide education and develop a nurturing relationship with patients to address their needs.

**Localized Clinical Services** will centralize medication, symptom management, and therapeutic treatments. In one visit, patients will be able to have blood drawn for regular testing, bone density scans



to screen for low bone mass (a particular problem in inflammatory bowel diseases), and a hydrogen breath test to measure the overgrowth of bacteria in the small intestine or lactose intolerance. Patients will also be able to receive medication through intravenous infusion. Those who require subcutaneous injection will receive one-on-one training on how to administer the medication. More invasive diagnostic tests, such as endoscopies, will continue to be performed at hospital-based endoscopy units on the Miller School campus.

**Nutritional Support:** Since the most frequently asked questions by patients with inflammatory bowel diseases are related to diet, a consult with the on-site dietician will be included with every patient's first visit to the Center. Especially in the case of Crohn's disease, patients may be malnourished, vitamin deficient, and require care by dietitians trained to handle patients suffering from inflammatory bowel diseases. We plan to evaluate the efficacy of nutritional interventions, which will facilitate much-needed clinical research studies on diet and management of inflammatory bowel diseases.

**Psychological Support:** Because inflammatory bowel diseases affect all aspects of a patient's life and depression correlates with increased disease activity, we will house an on-site psychologist to provide counseling and behavioral therapy to patients and their families, helping them cope with the diagnosis.

**Walk-In Services** will enable patients who are experiencing a change in their baseline symptoms to be evaluated by an appropriate inflammatory bowel diseases specialist that day, rather than waiting until the next scheduled visit.

**Patient and Family Education:** A variety of resources devoted to patient and family education will be available, including brochures, computers with links to websites with information on the various inflammatory bowel diseases, and a television with educational videos. The computers will also link to our privacy-protected database where patients could enter their health history for our medical professionals.

## **Research**

### **Basic Science Research**

The Center's basic science research includes examining how bacteria are recognized by the gut to cause inflammation and colon cancer using a germ free facility, the innate immune system in inflammatory diseases of the bowel, and the genetics of inflammatory diseases of the bowel. Biochemical and proteomic approaches are being used to identify novel bacterial proteins that lead to inflammation and may be used to prognosticate the course of inflammatory bowel diseases. Members of the faculty in the Department of Microbiology and Immunology and the Department of Biochemistry and Molecular Biology, as well as discovery scientists within the University of Miami Sylvester Comprehensive Cancer Center, are active in these projects and programs.



## **Clinical and Translational Research**

### ***Personalized Medicine and Database/Biobank***

The Center will support a novel personalized medicine program, transforming the traditional "one-size-fits-all" model by applying individual gene-based information to improve disease prevention and treatment. We are collaborating with the John P. Hussman Institute for Human Genomics at the University of Miami to analyze DNA samples to better understand individual genetic variation in patients suffering from inflammatory diseases of the bowel and how one may react to specific treatments. In addition, we manage a database and biobank and have collected over 500 samples of DNA and tissue. The database and biobank are a unique resource because of our diverse patient population and since little is known about the emergence of inflammatory diseases of the bowel in recent immigrants from Latin America. A rising number of Hispanics are afflicted with inflammatory diseases of the bowel; half of our patients are Hispanics from the Caribbean and Latin America or American-born Hispanics.

### ***Clinical Trials and Comparative Effectiveness Research (CER)***

Although the immune response and certain genetic and environmental factors play a role, no one knows exactly what causes inflammatory diseases of the bowel. Therapies may dramatically reduce signs and symptoms and even bring about a long-term remission, but there is no cure and the medications carry substantial risks. The localized clinical services described above will also be used for multiple clinical trials – both investigator-initiated and pharmaceutically-sponsored – for patients who have failed conventional therapy and are seeking other options.

Formally establishing the Crohn's and Colitis Center will enable us to track health care expenses and perform comparative effectiveness research (CER) that will analyze the difference in costs for hospitalizations, surgery, and medical therapy before and after the development of the Center. We will also draw from health care claims databases to benchmark our performance compared with the rest of Florida.

## **Medical Education**

The Center will be an active partner in the Miller School's education and training mission. Current and planned activities include providing gastroenterology fellows with focused training, serving as a resource for gastroenterologists from Latin America who can apply for a month-long sabbatical with the Division of Gastroenterology, and providing an opportunity for translational/clinical research experience for trainees in Cancer Biology and Microbiology and Immunology.

## **Organization**

### **Leadership**

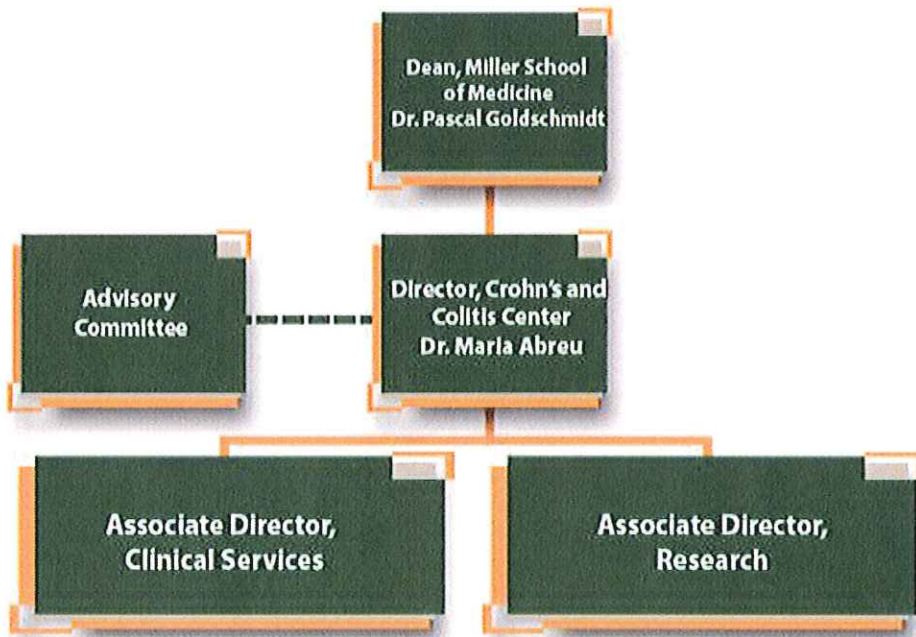
The Crohn's and Colitis Center will be led by a Director who will report to the Dean of the Miller School and represent the Center in the Miller School and the University. He/she articulates the Center vision and enhances the synergism and cross-fertilization of its programs by promoting common clinical, research,

education and community outreach activities. The Director will work to integrate the Center within the structure and mission of the Miller School and UHealth system by promoting and nurturing interactions with academic departments and other Centers and Institutes. There will be two Associate Directors who will report to the Director – one focused on the clinical services and the other managing the Center’s research initiatives and collaborations.

The proposed Director is Dr. Maria Abreu, M.D.; Chief, Division of Gastroenterology and Martin H. Kalser Chair; Professor of Medicine; and Professor of Microbiology and Immunology. An alumna of the University of Miami, Dr. Abreu has served as Director of the Inflammatory Bowel Disease Center at the Mount Sinai School of Medicine in New York. She holds key positions in several professional societies and recently received the Hope Award from the Florida chapter of the Crohn’s and Colitis Foundation of America (CCFA). Dr. Abreu’s research focuses on the role of intestinal bacteria in colitis and colon cancer and her laboratory has received numerous grants from the National Institutes of Health and the CCFA.


The Center will be organized as per this chart:

#### Organizational Chart



#### Advisory Committee

An Advisory Committee will meet quarterly to advise the Director on the management, operations, and governance of the Center including project prioritization and allocation of resources. The Committee will be chaired by the Center Director and will include University of Miami faculty who are demonstrated



experts in Crohn's and Colitis. The faculty members will be determined by a majority vote of the Committee and will serve for three year terms, which will be renewable at the discretion of the Committee.

The Committee will reflect the multidisciplinary nature of the Center and include two external specialists in inflammatory bowel diseases, the Chair of the Department of Medicine, two basic scientists, and two clinicians (an adult and a pediatric gastroenterologist). The Committee may allow other members of the University community to attend the meetings.

### **Professional Staff**

Committed to empowering and supporting patients and families of those with inflammatory diseases of the bowel, the Center will be staffed with clinical and research faculty (gastroenterologists and colorectal and laparoscopic surgeons), gastroenterology fellows, a registered nurse, a senior registered nurse, a phlebotomist, a dietician, a psychologist, a genetic counselor, a senior patient access representative, and a secretary. The staff will emphasize a team approach to treating, training, evaluating and following-up with patients.

### **Membership**

The Center openly seeks and supports research and activities related to its mission and does not have formal members. Per University of Miami policy, all faculty and voluntary physicians are required to have an appointment through a Miller School department. University faculty interested in affiliating with the Center can contact Dr. Abreu.

### **Space**

Currently, patients must travel between many different buildings on the medical campus for doctor's visits and procedures. The Center plans to house all inflammatory bowel disease-related services in the new space being built as an annex to UM/Sylvester, including rooms for exams, infusions, phlebotomy, nutrition, psychology, nurses, patient/family education, and conferences.

### **Funding Sources and Budget Projections**

The costs of the Center, estimated to be \$5 million, include the personnel required for its success and the remodeling of space. The Center will be funded through philanthropy and clinical revenues. As the Center's activities are an expansion of services currently provided to Crohn's disease and UC patients and their families, it is anticipated that the cost of Center operations will change in parallel with clinical revenues (as clinical revenues increase, required services increase). Annual operating costs are expected to be \$750,000. The budget projections are as follows:



Budget information redacted from on-line version of this legislation.

Pascal J. Goldschmidt, M.D.  
*Senior Vice President for Medical Affairs and Dean  
Chief Executive Officer, University of Miami Health System*

## Memorandum

**To:** Robyn Hardeman  
Secretary of the Faculty Senate

**From:** Pascal J. Goldschmidt, M.D.  
Senior Vice President for Medical Affairs and Dean  
Chief Executive Officer, University of Miami Health System

**Date:** July 25, 2011

**Subject:** Support for the Crohn's and Colitis Center

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PJG

This memo requests support from the Faculty Senate to formally establish the Crohn's and Colitis Center at the University of Miami Leonard M. Miller School of Medicine. The Center's goal is to improve the quality of life for patients with inflammatory bowel disease (IBD). Contributing to the core mission of the Miller School and the University, the Center provides state-of-the-art care, promising research, as well as excellence in medical education.

Maria T. Abreu, M.D., Chief of the Division of Gastroenterology and Martin H. Kalser Chair, Professor of Medicine, and Professor of Microbiology and Immunology, is uniquely suited to direct the Center's staff, a team of professionals including clinical and research faculty (gastroenterologists and colorectal and laparoscopic surgeons), gastroenterology fellows, nurses, a phlebotomist, a dietician, a psychologist, a genetic counselor, a senior patient access representative, and a secretary. Working collaboratively, they are committed to empowering and supporting patients and families of those with IBD.

The Center is funded through philanthropy and clinical revenues. As the activities are an expansion of services currently provided to Crohn's disease and ulcerative colitis patients and their families, it is anticipated that the cost of Center operations will change in parallel with clinical revenues (as clinical revenues increase, required services increase).

I fully endorse formally establishing the Crohn's and Colitis Center. It is a timely addition to the Miller School. The faculty and I are committed to its success in making a difference in the lives of patients with IBD.

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## Memorandum

**To:** Robyn Hardeman  
*Secretary of the Faculty Senate*

**From:** Marc Lippman, M.D. *ML*  
*Kathleen and Stanley Glaser Professor and Chair of Medicine*

**Date:** July 22, 2011

**Subject:** Support for the Crohn's and Colitis Center

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As the Kathleen and Stanley Glaser Professor and Chair of the Department of Medicine at the University of Miami Leonard M. Miller School of Medicine, I am writing to support the proposal to formally establish the Crohn's and Colitis Center. The Center's goal, to improve the quality of life for patients with inflammatory bowel disease (IBD) through state-of-the-art, evidence-based care, strategically complements the Department's goal of delivering leading-edge patient care by top-ranked physicians.


Dr. Maria Abreu, Chief of the Division of Gastroenterology and Martin H. Kalser Chair, Professor of Medicine, and Professor of Microbiology and Immunology, directs the Center. Faculty in the Division conduct research in IBD and the immunology of the gastrointestinal tract and are also experts in irritable bowel syndrome, gastrointestinal cancer, pancreatic diseases, diagnostic and therapeutic gastrointestinal endoscopy, esophageal disorders, and diverticulitis.

In addition to sharing the expertise of the Division of Gastroenterology, the Crohn's and Colitis Center also benefits from other resources within the Department of Medicine and its experience in treating nearly every major organ and physiological support system in the human body. These include but are not limited to the Division of Hepatology and the Division of Endocrinology, Diabetes, and Metabolism, when patients develop complications of the disease requiring their expertise. As the keystone Department of the Miller School, we have recently hired more than 100 new faculty and we enthusiastically support formally establishing the Crohn's and Colitis Center. We are committed to creating a seamless process to help manage complex IBD patients.



## Memorandum

**To:** Robyn Hardeman  
*Secretary of the Faculty Senate*

**From:** Eckhard Podack, M.D., Ph.D.   
*Chairman, Department of Microbiology and Immunology*

**Date:** July 22, 2011

**Subject:** Support for the Crohn's and Colitis Center

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As Chairman of the Department of Microbiology and Immunology at the University of Miami Leonard M. Miller School of Medicine, I am writing to support the proposal to formally establish the Crohn's and Colitis Center. An integral goal of the Center is to expedite promising inflammatory bowel disease (IBD) research from the laboratory to the bedside, which strategically complements the Department's research, including my own in colitis, and our broader mission to solve complex biological and medical questions by integrating investigators with differing expertise and perspectives.

The Director of the Center, Dr. Maria Abreu, Chief of the Division of Gastroenterology and Martin H. Kalser Chair, holds appointments in the Department of Medicine as well as our own Department. Her research focuses on the role of intestinal bacteria in colitis and colon cancer and her laboratory has received numerous grants from the National Institutes of Health and the Crohn's and Colitis Foundation of America.

The faculty of the Department enthusiastically support formally establishing the Crohn's and Colitis Center and look forward to continuing our research collaborations on IBD and the immunology of the gastrointestinal tract, including examining how bacteria are recognized by the gut to cause inflammation and colon cancer, the role of specific T cell populations in causing or ameliorating IBD, and the innate immune system and its role in IBD. These studies will be supported by the establishment of a germ-free animal facility. Moreover, my research has led to the development of several interesting compounds that may someday be used in IBD and the Center will facilitate the mission of the Miller School by allowing us to deliver them to patients with IBD. We are excited to work together to advance the important work of the Center and ultimately improve the quality of life for patients suffering from IBD.

**MEMORANDUM**

**TO:** Faculty Senate

**FROM:** Norman Altman, V.M.D.  
Speaker, Medical School Faculty Council

**DATE:** September 1, 2011

**RE:** To establish the Peggy & Harold Katz Family Drug Discovery Center  
And the Crohn's and Colitis Center

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This memorandum is in support of establishing the new Peggy and Harold Katz Family Drug Discovery Center and the Crohn's and Colitis Center.

On August 9, 2011, the Miller School of Medicine's Faculty Council met and reviewed the proposals to establish the Peggy & Harold Katz Family Drug Discovery Center and the Crohn's and Colitis Center. The proposals were presented by Dr. Jennifer McCafferty-Cepero, Deputy Executive Dean for Research and Research Training. The Medical School Faculty Council has approved both, the Crohn's and Colitis Center and the Peggy & Harold Katz Family Drug Discovery Center.

Should you have any questions or concerns, please contact me at 305-243-1635 or [naltman@med.miami.edu](mailto:naltman@med.miami.edu).

Sincerely,



Norman Altman, V.M.D.  
Speaker, Medical School Faculty Council