



**MEMORANDUM**

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

**From:** Stephen Sapp  
Chair, Faculty Senate *Stephen Sapp*

**Date:** February 28, 2008

**Subject:** Faculty Senate Legislation #2007-37(B) – Establishment of the University of Miami Interdisciplinary Stem Cell Institute (ISCI)

\*\*\*\*\*

The Faculty Senate, at its February 28, 2008 meeting, voted unanimously to approve the Establishment of the University of Miami Interdisciplinary Stem Cell Institute (ISCI). The proposal is enclosed for your reference.

This legislation is now forwarded to you for your action.

SS/rh

enclosure

cc: Thomas LeBlanc, Executive Vice President and Provost  
David J. Birnbach, Vice Provost for University Administration and Faculty Affairs  
Jennifer McCafferty-Cepero, Assistant Dean for Research

*proposal  
not incl.  
on web  
page - for  
JM only*

[Please contact the Senate office to view this proposal]

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**MEMORANDUM**

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

**From:** Stephen Sapp  
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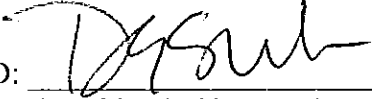
enclosure

**cc:** Thomas LeBlanc, Executive Vice President and Provost  
David J. Birnbach, Vice Provost for University Administration and Faculty Affairs  
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Faculty Senate Legislation #2007-37(B) – Establishment of the University of Miami  
Interdisciplinary Stem Cell Institute (ISCI)

**PRESIDENT'S RESPONSE**

APPROVED:  DATE: 3/2/09  
(President's Signature)

OFFICE OR INDIVIDUAL TO IMPLEMENT: DEAN PASCAL GOLDSCHMIDT

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

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

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



**Proposal for the Establishment of the  
 Interdisciplinary Stem Cell Institute of Miami  
 at the University of Miami Miller School of Medicine**

**1. BACKGROUND**

This proposal seeks to formally establish an Interdisciplinary Stem Cell Institute at the University of Miami Miller School of Medicine that will take its place among the nation's leading stem cell research institutes. The Institute will be called the Interdisciplinary Stem Cell Institute of Miami (ISCI Miami).

Stem cells are undifferentiated cells that have the potential to develop into a variety of different cell types. With their ability to develop into specialized tissue cells, understanding fundamental features of stem cell biology and harnessing this regenerative potential into high impact treatments for devastating diseases are some of the fastest growing areas of basic and clinical science. In fact, one of the most important basic questions in the life sciences today is: What are the properties that allow stem cells not only to differentiate into any cell type in the body, but also to reprogram other cells and repair damaged tissue?

ISCI Miami is a ground breaking scientific enterprise because it is dedicated to finding the answers to these questions and fast-tracking them to patients' bedsides in the form of new treatments for conditions such as Parkinson's disease, diabetes, heart disease, and cancer. Due to the potential of stem cells in the treatment of human disease, significant public attention has been generated regarding the origin of stem cells (embryonic versus adult), nuclear reprogramming, cloning, and organogenesis. The progress in stem cell research together with advances in deciphering of the genetic code and genetic diagnosis requires responsible and ethical conduct in research. Like all research units at the University of Miami, ISCI Miami is committed to conducting responsible and ethical research. In addition, ISCI offers a dynamic venue for the interrogation of the ethics and science policy that surround stem cell research and regenerative medical therapies.

There is an urgent need for an integrated, interdisciplinary institute that offers the expertise, infrastructure, and resources necessary to energize fundamental aspects of stem cell science and advance translational research in regenerative medicine at the Leonard M. Miller School of Medicine.

**2. MISSION**

ISCI Miami seeks to discover and explain the fundamental science of stem cell biology and to pioneer the field of regenerative medicine by applying this knowledge to the development of novel stem cell based therapies for the treatment of incurable diseases.

ISCI Miami is committed to catalyzing basic stem cell research at the Miller School that reveals the characteristics and potential of stem cells and then translating these findings to impact patient care. ISCI Miami-mediated interdisciplinary collaborations aim to increase the number of high-impact publications and investigators receiving extramural funding as well as expand the

visibility of the University of Miami Miller School of Medicine in the national and international research community.

Although ISCI Miami will initially be based at the School of Medicine and focus on the biomedical and bioethical aspects of stem cells and regenerative medicine, it is anticipated that, over time, ISCI Miami will become a locus for the establishment and development of fruitful collaboration across other University Schools and Colleges by bringing together and matching interests and expertise in an intentional and productive manner. At such time as those collaborations are established, ISCI Miami would be taken through the proper University procedure for consideration as a University Institute.

### **3. MARKET ANALYSIS**

The potential establishment of ISCI Miami at the Miller School of Medicine needs to be examined with due consideration of our strengths and weaknesses, the opportunities that are currently open to us, and the challenges that we may face in the future.

#### Strengths

- We are the oldest and most established medical school in South Florida, serving a population of 7 million or more.
- We have a large group of clinicians and researchers who are experts in areas of stem cell biology and regenerative medicine. This situation can pave the way for translational work.
- With the recruitment of Dr. Joshua M. Hare and his colleagues, we are poised to have unmatched expertise in stem cell based therapies.
- With the recruitment of Dr. Ian McNiece and his colleagues, we are poised to have unmatched expertise in cell manufacturing.
- There are a number of ongoing studies and faculty members with unique expertise who would benefit from and who would be assets to an entity such as is proposed. With access to resources and an institute around which to organize, the expertise and research activities in stem cell biology and regenerative medicine already in place would grow and thrive.
- Collaborative agreements with industry partners have been established to facilitate the development of stem cell based therapies.
- The Louis Calder Memorial Library has significant journal subscriptions and book holdings in the areas of stem cell biology and regenerative medicine.

#### Weaknesses

- There is no structure or an organization that fosters intramural collaboration and communication in stem cell biology and regenerative medicine.

The Experimental and Clinical Cell-Based Therapies Program will provide the infrastructure to rapidly translate novel stem cell products from research to clinical therapeutic application. It will encompass all aspects of cell manufacturing, IND preparation, regulatory oversight and will include:

1. Manufacture of cellular products for clinical trials through a cGMP manufacturing facility (cGMP lab).
2. Scale up process development through the Clinical Development Laboratory (CDL). The CDL will develop scale up processes for all cellular manufacturing, develop standard operating procedures (SOPs) for clinical manufacturing and undertake validation studies for IND submission.
3. Support for preclinical validation and animal models through the Preclinical Development Laboratory (PDL). The PDL will support faculty in cellular manufacturing through identification of cGMP reagents for clinical applications, process development and production of cellular products for large animal models and testing.
4. The PDL and CDL will support clinical trials with assay development and performance in particular for defining release criteria and potency testing assays for cellular products.
5. Regulatory Core: All aspects of the clinical manufacture for IND submissions and regulatory oversight will be provided through the Regulatory Core. The Core will include a Quality Manager for all aspects of quality control and quality management and the maintenance of the quality program.

Research Platforms:

The primary research platforms will initially be Blood diseases, Bone diseases, Cancer, Cardiovascular disease, Diabetes, and Nervous system diseases. An additional platform for Ethics and Science Policy will also be supported.

Administrative Support:

ISCI Miami will have dedicated staff for regulatory and compliance issues, operations, and general administrative duties.

ISCI Miami Research Cabinet:

The ISCI Miami Research Cabinet meets quarterly to provide feedback and consultation to the ISCI Miami Director regarding ISCI Miami's scientific progress and technological advances and needs. The Cabinet will be comprised of the ISCI Miami Director, the Director of Experimental and Clinical Cell-Based Therapies Program, and Research Platform Leaders. Other Miller School of Medicine or University leaders will be invited at the discretion of the ISCI Miami Director on an as needed basis.

ISCI Miami Advisory Board:

The ISCI Miami Advisory Board meets annually to provide feedback and consultation to the ISCI Miami Director regarding ISCI Miami's progress and future plans including development and strategic planning. The Board will be comprised of the ISCI Miami Director, the Dean of the Miller School of Medicine and two external scientific luminaries – one world class expert in fundamental aspects of stem cell biology and one international leader in regenerative medicine and/or cell-based therapies. Other Miller School of Medicine or University leaders will be invited at the discretion of the ISCI Miami Director on an as needed basis.

**Membership**

ISCI Miami will have a formal membership application and review process. Membership is open to all faculty at the University of Miami and affiliated institutions according to the criteria listed below. All members must have an appointment in an academic department. Membership categories are independent of academic rank.

New members are recruited to augment established or developing multidisciplinary research activities. At the time of application, members are assigned primary affiliation with one of the ISCI Miami's Research Platforms. Although many members collaborate with colleagues in other Research Platforms, formal alignment is generally assigned to a single Research Platform so that leadership can track collaborations throughout with clarity. Some members are considered affiliated with more than one Research Platform because they make fundamental contributions across Research Platforms.

All new members attend a formal orientation process that includes information on the organizational structure as well as the benefits and responsibilities of membership.

**Types of Membership:**

- Primary members hold faculty appointments at the University of Miami. They may or may not reside in ISCI Miami space. They are required to be affiliated with an ISCI Miami Research Platform. The Executive Committee is drawn from the primary membership.
- Affiliate Members hold faculty appointments at accredited academic institutions outside the University of Miami. They are required to be affiliated with an ISCI Miami Research Platform

**Criteria for ISCI Miami Membership (all are not required for consideration):**

- Demonstrated research activity in stem cell biology or regenerative medicine
- Demonstrated interest in stem cell and/or regenerative medicine research
- Active/Proposed peer-reviewed or non-peer-reviewed funding in research with stem cell and/or regenerative medicine relevance
- Stem cell or regenerative medicine-focused publications
- Agree to fulfill the responsibilities of membership

**Application and Selection Process:**

Interested faculty members should submit:

- Completed Membership Application form (including description of research interest and statement of stem cell or regenerative medicine research focus)
- Current CV and NIH or NSF Biosketch
- Current research funding information

Initial membership appointments will be for three years and will be contingent upon successful completion of an annual review process.

Prospective members are asked to select one of the Research Platforms for alignment, and must consult with the Platform Leader for approval of the application prior to submission. Initially, these include:

- Cardiology
- Diabetes
- Nervous System Diseases
- Bone Diseases
- Cancer
- Blood Diseases
- Ethics and Science Policy

This information is then reviewed by the ISCI Miami Executive Committee, chaired by the ISCI Miami Director, and consisting of the Research Platform Leaders and 7 ISCI Miami members selected by the ISCI Miami Director. Membership is awarded for an initial period of three years. The ISCI Miami Executive Committee will meet yearly to review the entire membership roster, to make sure that it reflects ISCI Miami's mission.

Should an applicant be denied membership, the applicant can appeal in writing directly to the ISCI Miami Director for re-consideration.

Benefits of Membership:

- Eligibility to have access to shared resources at a subsidized rate
- Eligibility to receive developmental funding for innovative ideas
- Administrative support for submission of stem cell or regenerative medicine - related grants and contracts
- Administrative support for management of stem cell or regenerative medicine - related grants and contracts

Responsibilities of Membership:

All ISCI Miami members are expected to contribute to the mission and growth of ISCI Miami. The responsibilities of members include:

- Willingness to work collaboratively with other scientists and clinical researchers on problems related to stem cell biology.
- Active participation in ISCI Miami activities including Research Platforms and other working groups.
- Attendance at scheduled ISCI Miami functions
- Willingness to provide mentoring to junior faculty and other ISCI Miami members.
- All ISCI Miami members will be responsible to provide information updates as required, and must be willing to share this information for the purpose of reporting requirements.

Annual Review:

The ISCI Miami Executive Committee will meet yearly for a thorough review of the entire membership roster. Each member is reviewed on the basis of evidence for:



- Demonstrated independent or collaborative research in stem cell biology or regenerative medicine
- Publications with other ISCI Miami members
- Service as a PI or Co-investigator on grant/grant proposal(s) with other members
- Service as a PI or Co-investigator on clinical protocol with other members
- Participation as a mentor to more junior members
- Participation in ISCI Miami committees, special initiatives and meetings

Members not meeting these criteria are counseled. Membership is withdrawn if progress is not demonstrated in the 12 month period following counseling. Should membership be withdrawn, the member can appeal directly to the ISCI Director for re-consideration.

### **5. Space**

ISCI Miami research activities require well equipped laboratory, analytical and administrative space. Initially research will be conducted in space at the Rosenstiel Medical Sciences Building on the Miller School of Medicine campus. ISCI Miami will have permanent space in the Multidisciplinary Research Building at its completion in 2008.

### **6. Funding Sources and Budget Projections**

ISCI Miami is being initially supported as part of a \$30 million commitment by the Dean of the Miller School of Medicine. These funds are to be expended over a five year period and will be used to create the infrastructure necessary to support ISCI Miami activities and resources as described above. In addition, the initial primary members have brought approximately \$2 million in sponsored research for the current fiscal year as well as a Specialized Center for Cell-Based Therapies (SCCT) Grant. All members are expected to seek external funding for their research, thus there are high expectations for significant growth in sponsored funding. The table below illustrates the five-year financial projections for ISCI Miami.

Year	UM	Sponsored Activity
2007	6,000	2,000
2008	6,000	3,000
2009	6,000	4,000
2010	6,000	5,000
2011	6,000	6,000
Total	30,000	20,000

All amounts are in '000s

## 7. Appendix

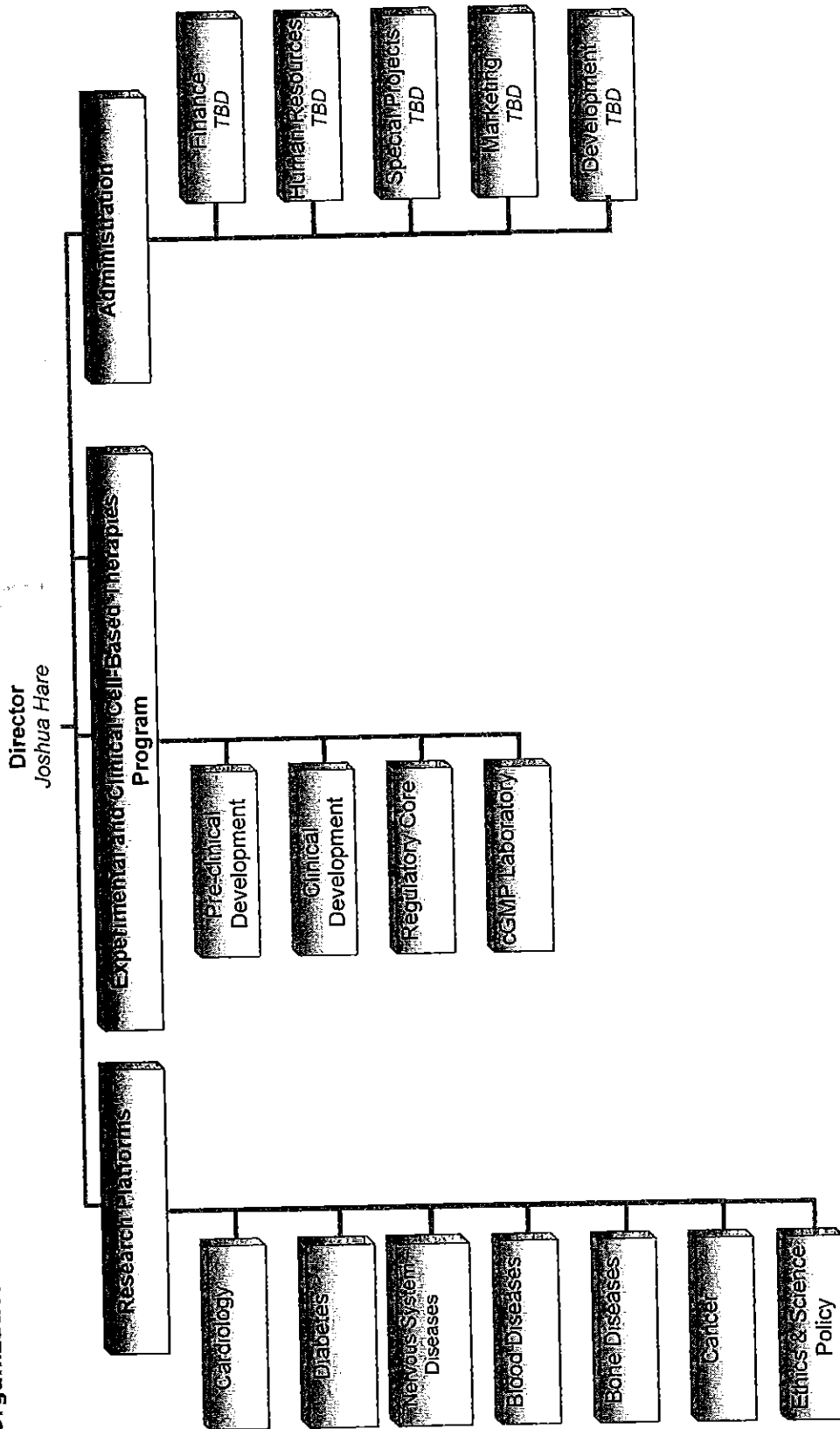
**Table 1. Top ten NIH-funded medical schools in the country (FY 2005)**

1. Johns Hopkins University – Stem Cell Biology Program
2. University of Pennsylvania – Stem Cell Core
3. UC, San Francisco- Institute for Regeneration & Human Embryonic Stem Cell Research Center
4. Washington University – Embryonic Stem Cell Core
5. Duke University – Organogenesis and Stem Cell Biology Program
6. University of Washington – The Institute for Stem Cell and Regenerative Medicine
7. UC, Los Angeles – Eli and Edythe Broad Center of Regenerative Medicine and Stem Cell Research
8. Yale University – Yale Stem Cell Center
9. University of Pittsburgh – Stem Cell Core
10. University of Michigan – Center for Stem Cell Biology & The Michigan Center for Human Embryonic Stem Cell Research

**Table 2. American Association of Universities (AAU) Members with Institutes, Centers. Programs or Cores for Stem Cells and/or Regenerative Medicine.**

- California Institute of Technology
- Case Western Reserve University
- Columbia University
- Cornell University
- Duke University
- Emory University
- Harvard University
- Indiana University
- Johns Hopkins University
- New York University
- Rutgers University
- Stanford University
- University of California, Berkeley
- University of California, Davis
- University of California, Irvine
- University of California, Los Angeles
- University of California, San Diego
- University of Michigan
- University of Minnesota, Twin Cities
- University of Pennsylvania
- University of Pittsburgh
- University of Southern California
- University of Virginia
- University of Washington
- University of Wisconsin – Madison
- Vanderbilt University
- Washington University, St. Louis
- Yale University

Organizational Chart for ISCI



# MILLER

SCHOOL OF MEDICINE

Pascal J. Goldschmidt, M.D., FACC  
*Senior Vice President for Medical Affairs and Dean*  
*Chief Executive Officer, Miami Medicine*

## Memorandum

To: Iris Barrios  
Secretary of the Faculty Senate

From: Pascal G. Goldschmidt, M.D.  
Senior Vice President for Medical Affairs and Dean

Date: January 7, 2008

Subject: Support for the Interdisciplinary Stem Cell Institute

PJG

This memo is to express my strong support for the University of Miami Faculty Senate to approve the creation of the Interdisciplinary Stem Cell Institute (ISCI) at the Miller School of Medicine.

The establishment of the ISCI represents a clear expansion of the School and University efforts in the highly-interdisciplinary arena of stem cell biology and regenerative medicine. The ISCI is a critical piece of the research infrastructure – providing a framework around which to focus our recent recruiting efforts and existing strengths while efficiently providing top-flight shared resources in both expertise and technology.

We are in the middle of a revolution – stem cells offer seemingly limitless potential to shift paradigms across disciplines. Understanding the fundamental features of stem cell biology and harnessing their regenerative potential into high impact treatments for devastating diseases are some of the fastest growing areas of the basic and clinical sciences. The ISCI is innovative because it brings together scientists and clinicians with expertise spanning the basic to the applied with the clear mission of fast-tracking leading-edge therapies for debilitating conditions like heart disease, diabetes and cancer. In addition, ISCI provides a forum for the discussion and investigation of the ethical and moral challenges posed by stem cell research and regenerative medicine. By offering a dynamic and cross-disciplinary platform for these discussions, ISCI will provide a venue for dialogue regarding the ethics and science policy surrounding stem cell research and regenerative medical therapies.



The creation of the ISCI is an important and timely addition to the Miller School of Medicine. The School has earmarked significant financial resources for the development of the stem cell biology and regenerative medicine infrastructure and is fully committed to the success of the ISCI. I fully endorse its creation without hesitation or reservation and look forward to the Senate's approval of this vital institute.



Bioethics Program  
Business Ethics Program  
Pan American Bioethics Initiative

MEMORANDUM

To: Iris Barrios  
Secretary of the Faculty Senate

From: Kenneth W. Goodman, Ph.D. *KG*  
Director, Bioethics Program  
Associate Professor of Medicine

Date: December 17, 2007

Subject: Ethics Programs' Support for the Interdisciplinary Stem Cell Institute

I write to express my enthusiastic support for the creation of the Interdisciplinary Stem Cell Institute (ISCI) at the Miller School of Medicine.

Given (i) the exciting medical and other scientific potential of stem-cell-based therapies, (ii) the importance of those therapies for future translational research, (iii) the role of the ISCI as part of the dramatic transformation of the Miller School of Medicine, and (iv) plans to ensure that ethical, social and legal issues are to be given prominence in the new institute – it is clear that the ISCI will be poised to make major contributions to the School, the University and society.

Leaders of the planned institute, members of the Senate and all students and faculty are well aware that ethical issues loom large in stem cell research. I have long argued that all forms of stem cell research are morally obligatory, and that a robust ethics process is essential to ensuring the harvest of the scientific and clinical fruits of such research.


For these reasons, I offer my unalloyed support and that of the University of Miami Bioethics Program in the establishment of the institute and in its operations. We have an exciting opportunity to ensure the success of an ethically optimized new research platform, and I very much look forward to contributing to it.

Please let me know if you or the Senators have any questions or want more information about the importance of ethics in stem cell research and the utility of our program's role in this exciting new institute.

cc: Pascal G. Goldschmidt, M.D., Senior Vice President for Medical Affairs and Dean,  
UM Miller School of Medicine

**MILLER**  
SCHOOL OF MEDICINE

To: Iris Barrios  
Secretary of the Faculty Senate

From: Marc E. Lippman, M.D.   
Chairman, Department of Medicine

Date: December 12, 2007

Subject: Support for the Interdisciplinary Stem Cell Institute (ISCI)

This memo is to express my enthusiasm for the establishment of the Interdisciplinary Stem Cell Institute (ISCI) at the Miller School of Medicine.

The potential for novel stem cell based therapies for a variety of diseases and disorders is tremendous. The new institute comes at an exciting time of expansion at the Miller School of Medicine and the ISCI is positioned to not only provide leading edge technologies for basic discoveries, but to build bridges transferring new knowledge to the clinic.

Faculty in the Department of Medicine are thrilled at the prospect of collaborating with the new institute and I offer our full cooperation in establishing strong ties with the ISCI.

Cc: Pascal G. Goldschmidt, M.D.





**THE MIAMI PROJECT TO CURE PARALYSIS**  
AN INTERNATIONAL CENTER FOR SPINAL CORD INJURY RESEARCH

W. Dalton Dietrich, Ph.D.  
*Scientific Director*

To: Iris Barrios  
Secretary of the Faculty Senate

Date: December 17, 2007

Subject: Support for the Interdisciplinary Stem Cell Institute (ISCI)

This memo is to request support from the University of Miami Faculty Senate to approve the creation of the Interdisciplinary Stem Cell Institute (ISCI) at the Miller School of Medicine.

The establishment of the ISCI synergizes with our recent recruiting efforts and our existing strengths in stem cell biology. The new institute would position the Miller School of Medicine for rapid expansion and afford the opportunity to create a world-class environment for research in stem cell biology and regenerative medicine. Importantly, the creation of the ISCI would build an interdisciplinary home for stem cell research at the University and allow us to make a significant impact on clinical practices and human health by investigating the potential for stem cell based therapies for a variety of devastating diseases.

The new institute is an important and timely addition to the Miller School of Medicine; the School is fully committed to the success of the ISCI. Faculty within the Miami Project to Cure Paralysis are conducting stem cell research targeting brain and spinal cord injury. Thus, this new Institute will significantly enhance those established programs. I offer the full cooperation of the Miami Project and look forward to establishing strong collaborations with the new Institute. I fully endorse its creation.

Sincerely,

W. Dalton Dietrich, Ph.D.  
Kinetic Concepts Distinguished Chair in Neurosurgery  
Professor of Neurological Surgery, Neurology and Cell Biology and Anatomy  
Scientific Director, The Miami Project to Cure Paralysis

**MILLER**  
SCHOOL OF MEDICINE  
UNIVERSITY OF MIAMI

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December 13, 2007

Iris Barrios  
Secretary of the Faculty Senate

Re: Support for the Interdisciplinary Stem Cell Institute (ISCI)

Dear Colleagues

I write in strong support for the formal establishment of the ISCI within the University Of Miami Miller School Of Medicine. I, and many of my colleagues in the Cancer Center, have taken advantage of the symposia and seminars developed by the ISCI to date. I have been impressed with the inventory of stem cell research developing on campus and the ability of this Institute to coordinate and expand the research in this field. I believe that the activities of the Institute have already had a significant positive impact on the academic environment of our university.

The Cancer Center is collaborating actively with the leadership of the ISCI in a joint recruitment effort to establish a team of investigators with expertise in Cancer Stem Cell Biology. We are also working actively with the Institute to expand our shared research resources. We have been impressed with the collaborative attitude of those involved with the ISCI.

In summary, I think the ISCI has already enriched the academic environment of our university and I strongly support its formal establishment.

Sincerely,

A handwritten signature in cursive script that reads "Jerry Goodwin". The signature is written in dark ink and is positioned above the typed name and title.

W. Jarrard Goodwin, M.D., F.A.C.S.  
Director, UM/Sylvester Comprehensive Cancer Center  
Sylvester Professor of Otolaryngology



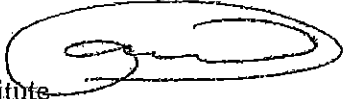


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P.O. BOX 016960 (R-134)  
MIAMI, FL 33101

To: Iris Barrios  
Secretary of the Faculty Senate

From: Camillo Ricordi, M.D.  
Scientific Director, Diabetes Research Institute 

Date: December 13, 2007

Subject: Support for the Interdisciplinary Stem Cell Institute (ISCI)

This memo is to express my enthusiasm and request support from the University of Miami Faculty Senate to approve the creation of the Interdisciplinary Stem Cell Institute (ISCI) at the Miller School of Medicine.

The establishment of the ISCI synergizes with our recent recruiting efforts and our existing strengths in stem cell biology. The new institute would position the Miller School of Medicine for rapid expansion and afford the opportunity to create a world-class environment for research in stem cell biology and regenerative medicine. Importantly, the creation of the ISCI would build an interdisciplinary home for stem cell research at the University and allow us to make a significant impact on clinical practices and human health by investigating the potential for stem cell based therapies for a variety of devastating diseases.

The new institute is an important and timely addition to the Miller School of Medicine; the School is fully committed to the success of the ISCI. I offer the full cooperation of the Diabetes Research Institute and look forward to establishing strong collaborations with the new institute. I fully endorse its creation.

UNIVERSITY  
OF MIAMI  
LEONARD M. MILLER  
SCHOOL OF MEDICINE



# MILLER

SCHOOL OF MEDICINE

Steven E. Lipshultz, M.D.

Professor of Laboratory Training  
Professor of Public Health and Epidemiology  
Professor of Medicine

To: Iris Barros  
Secretary of the Faculty Senate

From: Steven E. Lipshultz, MD *sl*  
Chairman, Department of Pediatrics

Date: December 12, 2007

Subject: Support for the Interdisciplinary Stem Cell Institute (ISCI)

This memo is to request support from the University of Miami Faculty Senate to approve the creation of the Interdisciplinary Stem Cell Institute (ISCI) at the Miller School of Medicine.

The establishment of the ISCI dovetails with our existing strengths in stem cell biology and our recent recruiting efforts. The creation of the ISCI would build an interdisciplinary home for stem cell research at the University, facilitating the development of new stem cell-based therapies for a variety of devastating diseases. The new institute would position the Miller School of Medicine for rapid expansion and afford the opportunity to create a world-class environment for research in stem cell biology and regenerative medicine.

The ISCI is an important and timely addition to the Miller School of Medicine and I offer the full cooperation of the Department in supporting its success. I fully endorse the creation of the ISCI and look forward to establishing strong and fruitful collaborations.



# MILLER

SCHOOL OF MEDICINE

Ralph L. Sacco, MD, MS, FAHA, FAAN  
*Miller Professor of Neurology, Epidemiology & Human Genetics*  
*Chairman, Department of Neurology*  
*Neurologist-In-Chief Jackson Memorial Hospital*

To: Iris Barrios  
Secretary of the Faculty Senate

From: Ralph L. Sacco, MS MD  
Chairman, Department of Neurology

Date: December 12, 2007

Subject: Support for the Interdisciplinary Stem Cell Institute (ISCI)

This memo is to request support from the University of Miami Faculty Senate to approve the creation of the Interdisciplinary Stem Cell Institute (ISCI) at the Miller School of Medicine.

The establishment of the ISCI synergizes with our recent recruiting efforts and our existing strengths in stem cell biology. The new institute would position the Miller School of Medicine for rapid expansion and afford the opportunity to create a world-class environment for research in stem cell biology and regenerative medicine. Importantly, the creation of the ISCI would build an interdisciplinary home for stem cell research at the University and allow us to make a significant impact on clinical practices and human health by investigating the potential for stem cell based therapies for a variety of devastating diseases.

The new institute is an important and timely addition to the Miller School of Medicine; the School is fully committed to the success of the ISCI.

We would look forward to scholarly collaborations between the Institute and the Department of Neurology. We would look forward to helping to recruit a leader in the program in Nervous System Diseases. I offer the full cooperation of the Department and look forward to establishing strong collaborations with the new institute. I fully endorse its creation.



# MILLER

SCHOOL OF MEDICINE

James D. Potter, Ph.D., FAHA  
 Professor and Chairman  
 Department of Molecular and Cellular Pharmacology

To: Iris Barrios  
 Secretary of the Faculty Senate

From: James D. Potter, Ph.D., FAHA  
 Professor and Chairman  
 Department of Molecular and Cellular Pharmacology

Date: December 13, 2007

Subject: Support for the Interdisciplinary Stem Cell Institute (ISCI)



This memo is to request support from the University of Miami Faculty Senate to approve the creation of the Interdisciplinary Stem Cell Institute (ISCI) at the Miller School of Medicine.

The potential for novel stem cell based therapies for a myriad of devastating diseases such as Cancer, Parkinson's disease, Heart disease and Diabetes, is tremendous. The creation of the ISCI would provide the expertise, infrastructure and resources necessary to advance translational research in regenerative medicine and accelerate the pace of new discoveries and treatments. It would also provide numerous opportunities for interdisciplinary collaborations resulting in increased funding, high impact publications and expanded visibility in the national and international research community for the University of Miami.

The ISCI would be an important and timely addition to the Miller School of Medicine, and I offer the full cooperation of the Department of Molecular and Cellular Pharmacology in supporting its success. The faculty and I look forward to establishing strong collaborations with the new institute, and I fully endorse its creation.

JDP:el

cc: Pascal G. Goldschmidt, M.D.



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# MILLER

## SCHOOL OF MEDICINE

Karl L. Magleby, Ph.D.  
Professor and Chairman  
Department of Physiology & Biophysics

### MEMORANDUM

To: Iris Barrios  
Secretary of the Faculty Senate

From: Karl L. Magleby, Ph.D. *Karl L. Magleby*  
Chairman, Department of Physiology and Biophysics

Date: December 14, 2007

Subject: Support for the Interdisciplinary Stem Cell Institute (ISCI)

This memo is to request support from the University of Miami Faculty Senate to approve the creation of the Interdisciplinary Stem Cell Institute (ISCI) at the Miller School of Medicine.

Stem cell research offers the possibility of curing disease by replacing defective tissue with new. The difficulties associated with this simple concept are many and best approached under the umbrella of an Interdisciplinary Stem Cell Institute (ISCI). The establishment of an ISCI at the University of Miami would provide a needed means to bring the different scientific disciplines together for success in developing stem-cell based therapies. The new institute would provide the opportunity to create a world-class environment for research in stem cell biology and regenerative medicine.

The ISCI is an important and timely addition to the Miller School of Medicine and I offer the full cooperation of the Department of Physiology and Biophysics in supporting its success. Such an institute would facilitate the research of many of the faculty in the Department and conversely, many of the faculty have unique skills and knowledge that could facilitate the success of the institute. I fully endorse the creation of the ISCI and look forward to establishing strong and fruitful collaborations.

KLM:rb



Department of Physiology & Biophysics • Edward M. Miller School of Medicine  
Post Office Box 016430 (R-430) • Miami, Florida 33101  
Location: Rosenstiel Medical Sciences Building, Room 5046, 1600 SW 10th Avenue • Miami, Florida 33136  
305-243-6236 • Fax: 305-243-6898 • kmagleby@miami.edu

**MILLER**  
SCHOOL OF MEDICINE

December 18, 2007

To: Faculty Senate

The Department of Microbiology & Immunology enthusiastically supports the establishment of an Interdisciplinary Stem Cell Institute (ISCI) at the Miller School of Medicine at the University of Miami.

The ISCI will greatly facilitate the research efforts of individual faculty members in the Basic Science Departments interested in developmental pathways of embryonal and organ specific stem cells. It will also provide a new platform for collaborative research and the formulation and execution of program project type research including submission of grant applications with multi investigator participation. The Institute also is likely to provide a focus and incentive for charitable donations. Importantly, the visibility of a strong Stem Cell Institute will help to attract talented researchers to the University and further strengthen our research enterprise.

Beyond the Basic Science implications, the ISCI is clearly well suited to provide avenues for clinical and translational research. With the Stem Cell Institute, the University will be well positioned to carry out cutting edge research and provide the next breakthrough in the Medical Sciences.

We therefore strongly and enthusiastically recommend approval of the Interdisciplinary Stem Cell Institute (ISCI) initiative at the Miller School of Medicine by the University of Miami Faculty Senate.

Sincerely,



Eckhard R. Podack, M.D., Ph.D.  
Sylvester Distinguished Professor and Chairman

*c.c. D. McCarthy - epuro  
305 243 3533*



Department of Microbiology and Immunology • Leonard M. Miller School of Medicine  
Post Office Box 016960 (R-138) • Miami, Florida 33101  
Location: 1600 NW 10th Avenue, 3045a RMSB • Miami, Florida 33136  
305-243-6655 • Fax: 305-243-4623 • <http://chroma.med.miami.edu/micro>

**MILLER**  
SCHOOL OF MEDICINE

**MEMORANDUM**

**TO:** Iris Barrios  
Secretary of the Faculty Senate

**FROM:** Robert Warren, Ph.D. *Robert Warren*  
Interim Chair, Chair Biology & Anatomy

**SUBJECT:** Support for the Interdisciplinary Stem Cell Institute

**DATE:** January 22, 2008

This memorandum is to add my enthusiastic support to the proposal from the Miller School of Medicine for the creation of the Interdisciplinary Stem Cell Institute at medical school.

The potential value of stem cell therapy in the treatment of a large variety of illnesses is self-evident to those in the basic sciences and clinical disciplines in the medical school. The time is clearly appropriate to create an interdisciplinary institute that can bring together researchers and clinicians from all departments in the medical school to work together and share their knowledge to create new therapies for old diseases.

The prospect of having a stem cell institute at the medical school is particularly exciting for our department as we anticipate the conclusion of negotiations with our chair select, Doris Taylor, who has already garnered world-wide publicity for her ground-breaking work with cardiac stem cells and heart regeneration. The existence of a stem cell institute would greatly enhance her ability to recruit researchers to the department who can strengthen the school's efforts to develop the potential of stem cell therapies.





## Faculty Senate Office

---

**From:** Faculty Senate Office  
**Sent:** Thursday, March 06, 2008 11:53 AM  
**To:** Birnbach, David J; McCafferty, Jennifer M.; Berg, Shelton G.; Brown, Otis B.; Cabrera, Jose M.; Carpintero, Yvette M.; Fontellio, Dawn J; Garcia, Cecilia; Glemaud, Rose-Kellie; Goldschmidt, Pascal J.; Gonzalez, Martha Lopez; Grogg, Sam; Halleran, Michael Ros; Kahn, Barbara; Lepisto, Catherine; Lynch, Dennis O.; Peragallo, Nilda P; Plater-Zyberk, Elizabeth M.; Prilleltensky, Isaac; Ripoll, Blanca Ileana; Robitaille, Magaly; Rowand, Michele M; Ruiz, Odalis A.; Scandura, Teresa Anne; Stadmire, Dawn Renee; Tien, James M.; Walker, William  
**Cc:** Markowitz, Elizabeth Paz  
**Subject:** Legislation #2007-37(B)-Establishment of the University of Miami Interdisciplinary Stem Cell Institute (ISCI)

The below link is your copy of Legislation #2007-37(B)-Establishment of the University of Miami Interdisciplinary Stem Cell Institute (ISCI) for your records:

<https://www6.miami.edu/faculty-senate/2007-Legislation/2007-37B.pdf>

Thank you,  
Robyn Hardeman

Faculty Senate Office  
325 Ashe Administration Building  
1252 Memorial Drive  
Coral Gables, FL 33146  
305-284-3721  
[www.miami.edu/fs](http://www.miami.edu/fs)

2/27/08  
FS minutes?

**FACULTY SENATE MEETING AGENDA**  
**MEDICAL CAMPUS, Mailman Center, 8<sup>th</sup> Floor**  
**February 27, 2008 – 3:30 p.m.**

<b>A.</b>	<b><u>Introductory Matters</u></b>	<b>Approx. Time</b>
A1.	# <u>Chair's remarks</u>	3:30
A2.	President's remarks	3:35
A3.	Approval of today's agenda	4:00
A4.	# <u>Approval of minutes of January 30, 2008</u>	4:05
A5.	Other announcements	4:10
<b>B.</b>	<b><u>General Matters</u></b>	
B1.	* Interdisciplinary Stem Cell Institute (ISCI) proposal * Interdisciplinary Stem Cell Institute memos of support - Dr. Jennifer McCafferty-Cepero	4:15
B2.	Enhancing the Quality of the Undergraduate Student Body Enhancing the Diversity of our Faculty - Dr. Thomas LeBlanc	4:50
<b>C.</b>	<b><u>Other Business</u></b>	
<b>D.</b>	<b><u>Adjournment</u></b>	

# related material

\* please contact the Senate office for related materials. ([facsen@miami.edu](mailto:facsen@miami.edu) or 305-284-3721)



**Proposal for the Establishment of the  
Interdisciplinary Stem Cell Institute of Miami  
at the University of Miami Miller School of Medicine**

**1. BACKGROUND**

This proposal seeks to formally establish an Interdisciplinary Stem Cell Institute at the University of Miami Miller School of Medicine that will take its place among the nation's leading stem cell research institutes. The Institute will be called the Interdisciplinary Stem Cell Institute of Miami (ISCI Miami).

Stem cells are undifferentiated cells that have the potential to develop into a variety of different cell types. With their ability to develop into specialized tissue cells, understanding fundamental features of stem cell biology and harnessing this regenerative potential into high impact treatments for devastating diseases are some of the fastest growing areas of basic and clinical science. In fact, one of the most important basic questions in the life sciences today is: What are the properties that allow stem cells not only to differentiate into any cell type in the body, but also to reprogram other cells and repair damaged tissue?

ISCI Miami is a ground breaking scientific enterprise because it is dedicated to finding the answers to these questions and fast-tracking them to patients' bedsides in the form of new treatments for conditions such as Parkinson's disease, diabetes, heart disease, and cancer. Due to the potential of stem cells in the treatment of human disease, significant public attention has been generated regarding the origin of stem cells (embryonic versus adult), nuclear reprogramming, cloning, and organogenesis. The progress in stem cell research together with advances in deciphering of the genetic code and genetic diagnosis requires responsible and ethical conduct in research. Like all research units at the University of Miami, ISCI Miami is committed to conducting responsible and ethical research. In addition, ISCI offers a dynamic venue for the interrogation of the ethics and science policy that surround stem cell research and regenerative medical therapies.

There is an urgent need for an integrated, interdisciplinary institute that offers the expertise, infrastructure, and resources necessary to energize fundamental aspects of stem cell science and advance translational research in regenerative medicine at the Leonard M. Miller School of Medicine.

**2. MISSION**

ISCI Miami seeks to discover and explain the fundamental science of stem cell biology and to pioneer the field of regenerative medicine by applying this knowledge to the development of novel stem cell based therapies for the treatment of incurable diseases.

ISCI Miami is committed to catalyzing basic stem cell research at the Miller School that reveals the characteristics and potential of stem cells and then translating these findings to impact patient care. ISCI Miami-mediated interdisciplinary collaborations aim to increase the number of high-impact publications and investigators receiving extramural funding as well as expand the

visibility of the University of Miami Miller School of Medicine in the national and international research community.

Although ISCI Miami will initially be based at the School of Medicine and focus on the biomedical and bioethical aspects of stem cells and regenerative medicine, it is anticipated that, over time, ISCI Miami will become a locus for the establishment and development of fruitful collaboration across other University Schools and Colleges by bringing together and matching interests and expertise in an intentional and productive manner. At such time as those collaborations are established, ISCI Miami would be taken through the proper University procedure for consideration as a University Institute.

### **3. MARKET ANALYSIS**

The potential establishment of ISCI Miami at the Miller School of Medicine needs to be examined with due consideration of our strengths and weaknesses, the opportunities that are currently open to us, and the challenges that we may face in the future.

#### Strengths

- We are the oldest and most established medical school in South Florida, serving a population of 7 million or more.
- We have a large group of clinicians and researchers who are experts in areas of stem cell biology and regenerative medicine. This situation can pave the way for translational work.
- With the recruitment of Dr. Joshua M. Hare and his colleagues, we are poised to have unmatched expertise in stem cell based therapies.
- With the recruitment of Dr. Ian McNiece and his colleagues, we are poised to have unmatched expertise in cell manufacturing.
- There are a number of ongoing studies and faculty members with unique expertise who would benefit from and who would be assets to an entity such as is proposed. With access to resources and an institute around which to organize, the expertise and research activities in stem cell biology and regenerative medicine already in place would grow and thrive.
- Collaborative agreements with industry partners have been established to facilitate the development of stem cell based therapies.
- The Louis Calder Memorial Library has significant journal subscriptions and book holdings in the areas of stem cell biology and regenerative medicine.

#### Weaknesses

- There is no structure or an organization that fosters intramural collaboration and communication in stem cell biology and regenerative medicine.

The Experimental and Clinical Cell-Based Therapies Program will provide the infrastructure to rapidly translate novel stem cell products from research to clinical therapeutic application. It will encompass all aspects of cell manufacturing, IND preparation, regulatory oversight and will include:

1. Manufacture of cellular products for clinical trials through a cGMP manufacturing facility (cGMP lab).
2. Scale up process development through the Clinical Development Laboratory (CDL). The CDL will develop scale up processes for all cellular manufacturing, develop standard operating procedures (SOPs) for clinical manufacturing and undertake validation studies for IND submission.
3. Support for preclinical validation and animal models through the Preclinical Development Laboratory (PDL). The PDL will support faculty in cellular manufacturing through identification of cGMP reagents for clinical applications, process development and production of cellular products for large animal models and testing.
4. The PDL and CDL will support clinical trials with assay development and performance in particular for defining release criteria and potency testing assays for cellular products.
5. Regulatory Core: All aspects of the clinical manufacture for IND submissions and regulatory oversight will be provided through the Regulatory Core. The Core will include a Quality Manager for all aspects of quality control and quality management and the maintenance of the quality program.

Research Platforms:

The primary research platforms will initially be Blood diseases, Bone diseases, Cancer, Cardiovascular disease, Diabetes, and Nervous system diseases. An additional platform for Ethics and Science Policy will also be supported.

Administrative Support:

ISCI Miami will have dedicated staff for regulatory and compliance issues, operations, and general administrative duties.

ISCI Miami Research Cabinet:

The ISCI Miami Research Cabinet meets quarterly to provide feedback and consultation to the ISCI Miami Director regarding ISCI Miami's scientific progress and technological advances and needs. The Cabinet will be comprised of the ISCI Miami Director, the Director of Experimental and Clinical Cell-Based Therapies Program, and Research Platform Leaders. Other Miller School of Medicine or University leaders will be invited at the discretion of the ISCI Miami Director on an as needed basis.

ISCI Miami Advisory Board:

The ISCI Miami Advisory Board meets annually to provide feedback and consultation to the ISCI Miami Director regarding ISCI Miami's progress and future plans including development and strategic planning. The Board will be comprised of the ISCI Miami Director, the Dean of the Miller School of Medicine and two external scientific luminaries – one world class expert in fundamental aspects of stem cell biology and one international leader in regenerative medicine and/or cell-based therapies. Other Miller School of Medicine or University leaders will be invited at the discretion of the ISCI Miami Director on an as needed basis.

### Membership

ISCI Miami will have a formal membership application and review process. Membership is open to all faculty at the University of Miami and affiliated institutions according to the criteria listed below. All members must have an appointment in an academic department. Membership categories are independent of academic rank.

New members are recruited to augment established or developing multidisciplinary research activities. At the time of application, members are assigned primary affiliation with one of the ISCI Miami's Research Platforms. Although many members collaborate with colleagues in other Research Platforms, formal alignment is generally assigned to a single Research Platform so that leadership can track collaborations throughout with clarity. Some members are considered affiliated with more than one Research Platform because they make fundamental contributions across Research Platforms.

All new members attend a formal orientation process that includes information on the organizational structure as well as the benefits and responsibilities of membership.

#### Types of Membership:

- Primary members hold faculty appointments at the University of Miami. They may or may not reside in ISCI Miami space. They are required to be affiliated with an ISCI Miami Research Platform. The Executive Committee is drawn from the primary membership.
- Affiliate Members hold faculty appointments at accredited academic institutions outside the University of Miami. They are required to be affiliated with an ISCI Miami Research Platform

#### Criteria for ISCI Miami Membership (all are not required for consideration):

- Demonstrated research activity in stem cell biology or regenerative medicine
- Demonstrated interest in stem cell and/or regenerative medicine research
- Active/Proposed peer-reviewed or non-peer-reviewed funding in research with stem cell and/or regenerative medicine relevance
- Stem cell or regenerative medicine-focused publications
- Agree to fulfill the responsibilities of membership

#### Application and Selection Process:

Interested faculty members should submit:

- Completed Membership Application form (including description of research interest and statement of stem cell or regenerative medicine research focus)
- Current CV and NIH or NSF Biosketch
- Current research funding information

Initial membership appointments will be for three years and will be contingent upon successful completion of an annual review process.

Prospective members are asked to select one of the Research Platforms for alignment, and must consult with the Platform Leader for approval of the application prior to submission. Initially, these include:

- Cardiology
- Diabetes
- Nervous System Diseases
- Bone Diseases
- Cancer
- Blood Diseases
- Ethics and Science Policy

This information is then reviewed by the ISCI Miami Executive Committee, chaired by the ISCI Miami Director, and consisting of the Research Platform Leaders and 7 ISCI Miami members selected by the ISCI Miami Director. Membership is awarded for an initial period of three years. The ISCI Miami Executive Committee will meet yearly to review the entire membership roster, to make sure that it reflects ISCI Miami's mission.

Should an applicant be denied membership, the applicant can appeal in writing directly to the ISCI Miami Director for re-consideration.

Benefits of Membership:

- Eligibility to have access to shared resources at a subsidized rate
- Eligibility to receive developmental funding for innovative ideas
- Administrative support for submission of stem cell or regenerative medicine - related grants and contracts
- Administrative support for management of stem cell or regenerative medicine - related grants and contracts

Responsibilities of Membership:

All ISCI Miami members are expected to contribute to the mission and growth of ISCI Miami. The responsibilities of members include:

- Willingness to work collaboratively with other scientists and clinical researchers on problems related to stem cell biology.
- Active participation in ISCI Miami activities including Research Platforms and other working groups.
- Attendance at scheduled ISCI Miami functions
- Willingness to provide mentoring to junior faculty and other ISCI Miami members.
- All ISCI Miami members will be responsible to provide information updates as required, and must be willing to share this information for the purpose of reporting requirements.

Annual Review:

The ISCI Miami Executive Committee will meet yearly for a thorough review of the entire membership roster. Each member is reviewed on the basis of evidence for:

- Demonstrated independent or collaborative research in stem cell biology or regenerative medicine
- Publications with other ISCI Miami members
- Service as a PI or Co-investigator on grant/grant proposal(s) with other members
- Service as a PI or Co-investigator on clinical protocol with other members
- Participation as a mentor to more junior members
- Participation in ISCI Miami committees, special initiatives and meetings

Members not meeting these criteria are counseled. Membership is withdrawn if progress is not demonstrated in the 12 month period following counseling. Should membership be withdrawn, the member can appeal directly to the ISCI Director for re-consideration.

**5. Space**

ISCI Miami research activities require well equipped laboratory, analytical and administrative space. Initially research will be conducted in space at the Rosenstiel Medical Sciences Building on the Miller School of Medicine campus. ISCI Miami will have permanent space in the Multidisciplinary Research Building at its completion in 2008.

**6. Funding Sources and Budget Projections**

ISCI Miami is being initially supported as part of a \$30 million commitment by the Dean of the Miller School of Medicine. These funds are to be expended over a five year period and will be used to create the infrastructure necessary to support ISCI Miami activities and resources as described above. In addition, the initial primary members have brought approximately \$2 million in sponsored research for the current fiscal year as well as a Specialized Center for Cell-Based Therapies (SCCT) Grant. All members are expected to seek external funding for their research, thus there are high expectations for significant growth in sponsored funding. The table below illustrates the five-year financial projections for ISCI Miami.

Year	UM	Sponsored Activity
2007	6,000	2,000
2008	6,000	3,000
2009	6,000	4,000
2010	6,000	5,000
2011	6,000	6,000
Total	30,000	20,000

All amounts are in '000s



## 7. Appendix

**Table 1. Top ten NIH-funded medical schools in the country (FY 2005)**

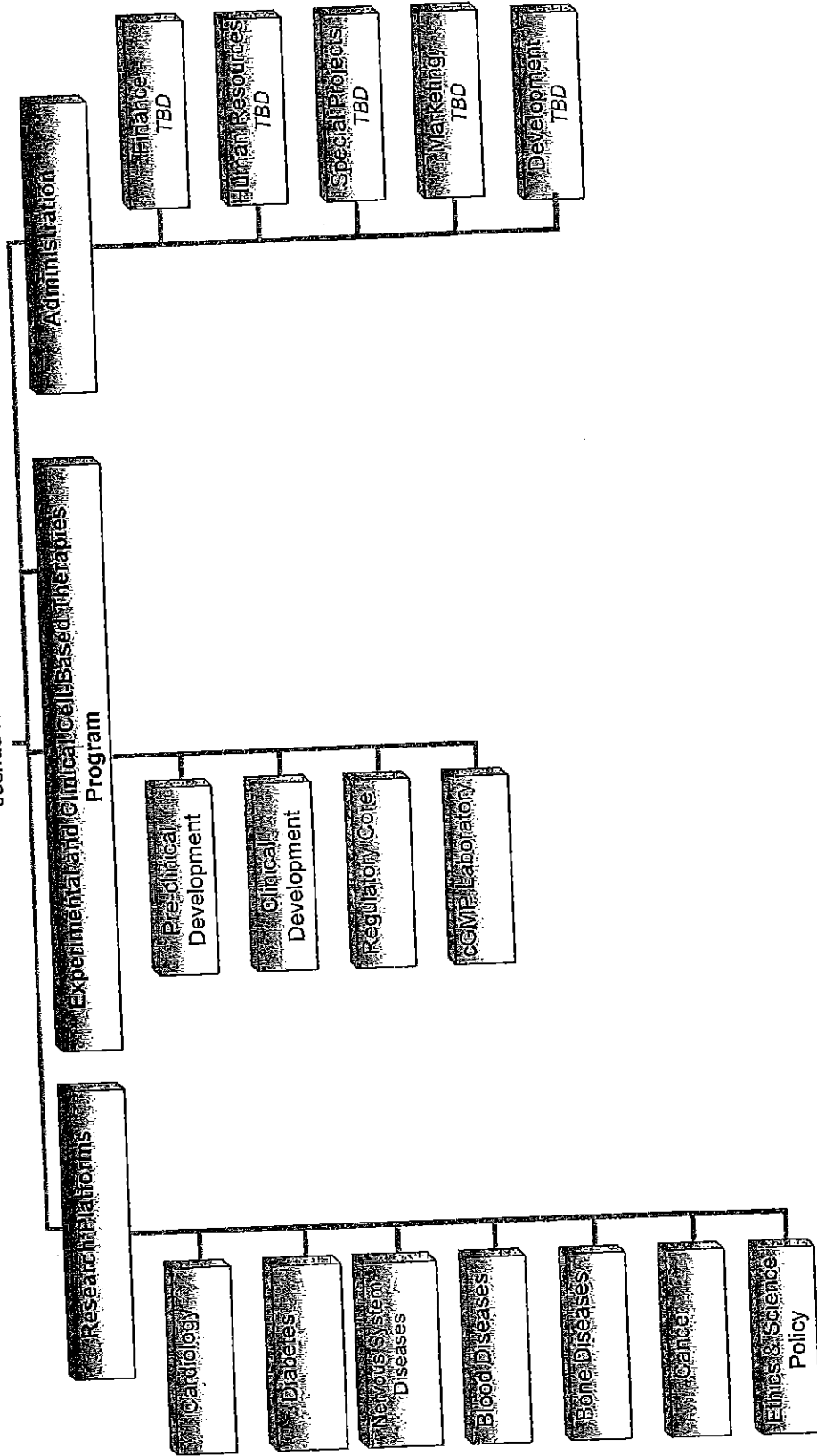
1. Johns Hopkins University -- Stem Cell Biology Program
2. University of Pennsylvania -- Stem Cell Core
3. UC, San Francisco- Institute for Regeneration & Human Embryonic Stem Cell Research Center
4. Washington University -- Embryonic Stem Cell Core
5. Duke University -- Organogenesis and Stem Cell Biology Program
6. University of Washington -- The Institute for Stem Cell and Regenerative Medicine
7. UC, Los Angeles -- Eli and Edythe Broad Center of Regenerative Medicine and Stem Cell Research
8. Yale University -- Yale Stem Cell Center
9. University of Pittsburgh -- Stem Cell Core
10. University of Michigan -- Center for Stem Cell Biology & The Michigan Center for Human Embryonic Stem Cell Research

**Table 2. American Association of Universities (AAU) Members with Institutes, Centers. Programs or Cores for Stem Cells and/or Regenerative Medicine.**

- California Institute of Technology
- Case Western Reserve University
- Columbia University
- Cornell University
- Duke University
- Emory University
- Harvard University
- Indiana University
- Johns Hopkins University
- New York University
- Rutgers University
- Stanford University
- University of California, Berkeley
- University of California, Davis
- University of California, Irvine
- University of California, Los Angeles
- University of California, San Diego
- University of Michigan
- University of Minnesota, Twin Cities
- University of Pennsylvania
- University of Pittsburgh
- University of Southern California
- University of Virginia
- University of Washington
- University of Wisconsin -- Madison
- Vanderbilt University
- Washington University, St. Louis
- Yale University

# Organizational Chart for ISCI

Director  
Joshua Hare



# MILLER

SCHOOL OF MEDICINE

Pascal J. Goldschmidt, M.D., FACC  
Senior Vice President for Medical Affairs and Dean  
Chief Executive Officer, Miami Medicine

## Memorandum

To: Iris Barrios  
Secretary of the Faculty Senate

From: Pascal G. Goldschmidt, M.D. P J G  
Senior Vice President for Medical Affairs and Dean

Date: January 7, 2008

Subject: Support for the Interdisciplinary Stem Cell Institute

This memo is to express my strong support for the University of Miami Faculty Senate to approve the creation of the Interdisciplinary Stem Cell Institute (ISCI) at the Miller School of Medicine.

The establishment of the ISCI represents a clear expansion of the School and University efforts in the highly-interdisciplinary arena of stem cell biology and regenerative medicine. The ISCI is a critical piece of the research infrastructure – providing a framework around which to focus our recent recruiting efforts and existing strengths while efficiently providing top-flight shared resources in both expertise and technology.

We are in the middle of a revolution – stem cells offer seemingly limitless potential to shift paradigms across disciplines. Understanding the fundamental features of stem cell biology and harnessing their regenerative potential into high impact treatments for devastating diseases are some of the fastest growing areas of the basic and clinical sciences. The ISCI is innovative because it brings together scientists and clinicians with expertise spanning the basic to the applied with the clear mission of fast-tracking leading-edge therapies for debilitating conditions like heart disease, diabetes and cancer. In addition, ISCI provides a forum for the discussion and investigation of the ethical and moral challenges posed by stem cell research and regenerative medicine. By offering a dynamic and cross-disciplinary platform for these discussions, ISCI will provide a venue for dialogue regarding the ethics and science policy surrounding stem cell research and regenerative medical therapies.



The creation of the ISCI is an important and timely addition to the Miller School of Medicine. The School has earmarked significant financial resources for the development of the stem cell biology and regenerative medicine infrastructure and is fully committed to the success of the ISCI. I fully endorse its creation without hesitation or reservation and look forward to the Senate's approval of this vital institute.



Bioethics Program  
Business Ethics Program  
Pan American Bioethics Initiative

MEMORANDUM

To: Iris Barrios  
Secretary of the Faculty Senate.

From: Kenneth W. Goodman, Ph.D. *KW Goodman*  
Director, Bioethics Program  
Associate Professor of Medicine

Date: December 17, 2007

Subject: Ethics Programs' Support for the Interdisciplinary Stem Cell Institute

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I write to express my enthusiastic support for the creation of the Interdisciplinary Stem Cell Institute (ISCI) at the Miller School of Medicine.

Given (i) the exciting medical and other scientific potential of stem-cell-based therapies, (ii) the importance of those therapies for future translational research, (iii) the role of the ISCI as part of the dramatic transformation of the Miller School of Medicine, and (iv) plans to ensure that ethical, social and legal issues are to be given prominence in the new institute – it is clear that the ISCI will be poised to make major contributions to the School, the University and society.

Leaders of the planned institute, members of the Senate and all students and faculty are well aware that ethical issues loom large in stem cell research. I have long argued that all forms of stem cell research are morally obligatory, and that a robust ethics process is essential to ensuring the harvest of the scientific and clinical fruits of such research.


For these reasons, I offer my unalloyed support and that of the University of Miami Bioethics Program in the establishment of the institute and in its operations. We have an exciting opportunity to ensure the success of an ethically optimized new research platform, and I very much look forward to contributing to it.

Please let me know if you or the Senators have any questions or want more information about the importance of ethics in stem cell research and the utility of our program's role in this exciting new institute.

cc: Pascal G. Goldschmidt, M.D., Senior Vice President for Medical Affairs and Dean,  
UM Miller School of Medicine

**MILLER**  
SCHOOL OF MEDICINE

To: Iris Barrios  
Secretary of the Faculty Senate

From: Marc E. Lippman, M.D.   
Chairman, Department of Medicine

Date: December 12, 2007

Subject: Support for the Interdisciplinary Stem Cell Institute (ISCI)

This memo is to express my enthusiasm for the establishment of the Interdisciplinary Stem Cell Institute (ISCI) at the Miller School of Medicine.

The potential for novel stem cell based therapies for a variety of diseases and disorders is tremendous. The new institute comes at an exciting time of expansion at the Miller School of Medicine and the ISCI is positioned to not only provide leading edge technologies for basic discoveries, but to build bridges transferring new knowledge to the clinic.

Faculty in the Department of Medicine are thrilled at the prospect of collaborating with the new institute and I offer our full cooperation in establishing strong ties with the ISCI.

Cc: Pascal G. Goldschmidt, M.D.





**THE MIAMI PROJECT TO CURE PARALYSIS**  
AN INTERNATIONAL CENTER FOR SPINAL CORD INJURY RESEARCH

W. Dalton Dietrich, Ph.D.  
*Scientific Director*

To: Iris Barrios  
Secretary of the Faculty Senate

Date: December 17, 2007

Subject: Support for the Interdisciplinary Stem Cell Institute (ISCI)

This memo is to request support from the University of Miami Faculty Senate to approve the creation of the Interdisciplinary Stem Cell Institute (ISCI) at the Miller School of Medicine.

The establishment of the ISCI synergizes with our recent recruiting efforts and our existing strengths in stem cell biology. The new institute would position the Miller School of Medicine for rapid expansion and afford the opportunity to create a world-class environment for research in stem cell biology and regenerative medicine. Importantly, the creation of the ISCI would build an interdisciplinary home for stem cell research at the University and allow us to make a significant impact on clinical practices and human health by investigating the potential for stem cell based therapies for a variety of devastating diseases.

The new institute is an important and timely addition to the Miller School of Medicine; the School is fully committed to the success of the ISCI. Faculty within the Miami Project to Cure Paralysis are conducting stem cell research targeting brain and spinal cord injury. Thus, this new Institute will significantly enhance those established programs. I offer the full cooperation of the Miami Project and look forward to establishing strong collaborations with the new Institute. I fully endorse its creation.

Sincerely,

W. Dalton Dietrich, Ph.D.  
Kinetic Concepts Distinguished Chair in Neurosurgery  
Professor of Neurological Surgery, Neurology and Cell Biology and Anatomy  
Scientific Director, The Miami Project to Cure Paralysis





December 13, 2007

Iris Barrios  
Secretary of the Faculty Senate

Re: Support for the Interdisciplinary Stem Cell Institute (ISCI)

Dear Colleagues

I write in strong support for the formal establishment of the ISCI within the University Of Miami Miller School Of Medicine. I, and many of my colleagues in the Cancer Center, have taken advantage of the symposia and seminars developed by the ISCI to date. I have been impressed with the inventory of stem cell research developing on campus and the ability of this Institute to coordinate and expand the research in this field. I believe that the activities of the Institute have already had a significant positive impact on the academic environment of our university.

The Cancer Center is collaborating actively with the leadership of the ISCI in a joint recruitment effort to establish a team of investigators with expertise in Cancer Stem Cell Biology. We are also working actively with the Institute to expand our shared research resources. We have been impressed with the collaborative attitude of those involved with the ISCI.

In summary, I think the ISCI has already enriched the academic environment of our university and I strongly support its formal establishment.

Sincerely,

A handwritten signature in cursive script that reads "Jerry Goodwin".

W. Jarrard Goodwin, M.D., F.A.C.S.  
Director, UM/Sylvester Comprehensive Cancer Center  
Sylvester Professor of Otolaryngology



LEONARD M. MILLER SCHOOL OF MEDICINE  
Office of the Director • Post Office Box 016960 (D-1) • Miami, Florida 33101  
Location: 1475 N.W. 12th Avenue • Miami, Florida 33136  
305-243-4918 • Fax: 305-243-4901 • jgoodwin@miami.edu • www.sylvester.org  
*Leading the Search for a Cancer Cure*



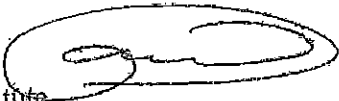


DIABETES  
RESEARCH  
INSTITUTE

1450 NW 10 AVENUE  
MIAMI, FL 33136  
PHONE: 305 / 243-5376  
FAX: 305 / 243-4404

MAILING ADDRESS:  
P.O. BOX 016950 (R-134)  
MIAMI, FL 33101

To: Iris Barrios  
Secretary of the Faculty Senate

From: Camillo Ricordi, M.D.  
Scientific Director, Diabetes Research Institute 

Date: December 13, 2007

Subject: Support for the Interdisciplinary Stem Cell Institute (ISCI)

This memo is to express my enthusiasm and request support from the University of Miami Faculty Senate to approve the creation of the Interdisciplinary Stem Cell Institute (ISCI) at the Miller School of Medicine.

The establishment of the ISCI synergizes with our recent recruiting efforts and our existing strengths in stem cell biology. The new institute would position the Miller School of Medicine for rapid expansion and afford the opportunity to create a world-class environment for research in stem cell biology and regenerative medicine. Importantly, the creation of the ISCI would build an interdisciplinary home for stem cell research at the University and allow us to make a significant impact on clinical practices and human health by investigating the potential for stem cell based therapies for a variety of devastating diseases.

The new institute is an important and timely addition to the Miller School of Medicine; the School is fully committed to the success of the ISCI. I offer the full cooperation of the Diabetes Research Institute and look forward to establishing strong collaborations with the new institute. I fully endorse its creation.

UNIVERSITY  
OF MIAMI  
LEONARD M. MILLER  
SCHOOL OF MEDICINE



# MILLER

SCHOOL OF MEDICINE

Steven E. Lipshultz, M.D.

Professor of Pediatrics  
Professor of Public Health and Epidemiology  
Professor of Medicine

To: Iris Barrios  
Secretary of the Faculty Senate

From: Steven E. Lipshultz, MD *sl*  
Chairman, Department of Pediatrics

Date: December 12, 2007

Subject: Support for the Interdisciplinary Stem Cell Institute (ISCI)

This memo is to request support from the University of Miami Faculty Senate to approve the creation of the Interdisciplinary Stem Cell Institute (ISCI) at the Miller School of Medicine.

The establishment of the ISCI dovetails with our existing strengths in stem cell biology and our recent recruiting efforts. The creation of the ISCI would build an interdisciplinary home for stem cell research at the University, facilitating the development of new stem cell based therapies for a variety of devastating diseases. The new institute would position the Miller School of Medicine for rapid expansion and afford the opportunity to create a world-class environment for research in stem cell biology and regenerative medicine.

The ISCI is an important and timely addition to the Miller School of Medicine and I offer the full cooperation of the Department in supporting its success. I fully endorse the creation of the ISCI and look forward to establishing strong and fruitful collaborations.



# MILLER

SCHOOL OF MEDICINE

Ralph L. Sacco, MD, MS, FAHA, FAAN  
*Miller Professor of Neurology, Epidemiology & Human Genetics*  
*Chairman, Department of Neurology*  
*Neurologist-In-Chief Jackson Memorial Hospital*

To: Iris Barrios  
Secretary of the Faculty Senate

From: Ralph L. Sacco, MS MD  
Chairman, Department of Neurology

Date: December 12, 2007

Subject: Support for the Interdisciplinary Stem Cell Institute (ISCI)

This memo is to request support from the University of Miami Faculty Senate to approve the creation of the Interdisciplinary Stem Cell Institute (ISCI) at the Miller School of Medicine.

The establishment of the ISCI synergizes with our recent recruiting efforts and our existing strengths in stem cell biology. The new institute would position the Miller School of Medicine for rapid expansion and afford the opportunity to create a world-class environment for research in stem cell biology and regenerative medicine. Importantly, the creation of the ISCI would build an interdisciplinary home for stem cell research at the University and allow us to make a significant impact on clinical practices and human health by investigating the potential for stem cell based therapies for a variety of devastating diseases.

The new institute is an important and timely addition to the Miller School of Medicine; the School is fully committed to the success of the ISCI.

We would look forward to scholarly collaborations between the Institute and the Department of Neurology. We would look forward to helping to recruit a leader in the program in Nervous System Diseases. I offer the full cooperation of the Department and look forward to establishing strong collaborations with the new institute; I fully endorse its creation.



# MILLER

SCHOOL OF MEDICINE

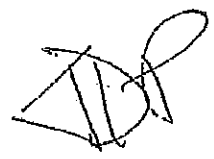
James D. Potter, Ph.D., FAHA  
Professor and Chairman  
Department of Molecular and Cellular Pharmacology

To: Iris Barrios  
Secretary of the Faculty Senate

From: James D. Potter, Ph.D., FAHA  
Professor and Chairman  
Department of Molecular and Cellular Pharmacology

Date: December 13, 2007

Subject: Support for the Interdisciplinary Stem Cell Institute (ISCI)



This memo is to request support from the University of Miami Faculty Senate to approve the creation of the Interdisciplinary Stem Cell Institute (ISCI) at the Miller School of Medicine.

The potential for novel stem cell based therapies for a myriad of devastating diseases such as Cancer, Parkinson's disease, Heart disease and Diabetes, is tremendous. The creation of the ISCI would provide the expertise, infrastructure and resources necessary to advance translational research in regenerative medicine and accelerate the pace of new discoveries and treatments. It would also provide numerous opportunities for interdisciplinary collaborations resulting in increased funding, high impact publications and expanded visibility in the national and international research community for the University of Miami.

The ISCI would be an important and timely addition to the Miller School of Medicine, and I offer the full cooperation of the Department of Molecular and Cellular Pharmacology in supporting its success. The faculty and I look forward to establishing strong collaborations with the new institute, and I fully endorse its creation.

JDP:el

cc: Pascal G. Goldschmidt, M.D.

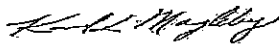


**MILLER**  
SCHOOL OF MEDICINE

Karl L. Magleby, Ph.D.  
Professor and Chairman  
Department of Physiology & Biophysics

MEMORANDUM

To: Iris Barrios  
Secretary of the Faculty Senate

From: Karl L. Magleby, Ph.D.   
Chairman, Department of Physiology and Biophysics

Date: December 14, 2007

Subject: Support for the Interdisciplinary Stem Cell Institute (ISCI)

This memo is to request support from the University of Miami Faculty Senate to approve the creation of the Interdisciplinary Stem Cell Institute (ISCI) at the Miller School of Medicine.

Stem cell research offers the possibility of curing disease by replacing defective tissue with new. The difficulties associated with this simple concept are many and best approached under the umbrella of an Interdisciplinary Stem Cell Institute (ISCI). The establishment of an ISCI at the University of Miami would provide a needed means to bring the different scientific disciplines together for success in developing stem-cell based therapies. The new institute would provide the opportunity to create a world-class environment for research in stem cell biology and regenerative medicine.

The ISCI is an important and timely addition to the Miller School of Medicine and I offer the full cooperation of the Department of Physiology and Biophysics in supporting its success. Such an institute would facilitate the research of many of the faculty in the Department and conversely, many of the faculty have unique skills and knowledge that could facilitate the success of the institute. I fully endorse the creation of the ISCI and look forward to establishing strong and fruitful collaborations.

KLM:rb



**MILLER**  
SCHOOL OF MEDICINE

December 18, 2007

To: Faculty Senate

The Department of Microbiology & Immunology enthusiastically supports the establishment of an Interdisciplinary Stem Cell Institute (ISCI) at the Miller School of Medicine at the University of Miami.

The ISCI will greatly facilitate the research efforts of individual faculty members in the Basic Science Departments interested in developmental pathways of embryonal and organ specific stem cells. It will also provide a new platform for collaborative research and the formulation and execution of program project type research including submission of grant applications with multi investigator participation. The Institute also is likely to provide a focus and incentive for charitable donations. Importantly, the visibility of a strong Stem Cell Institute will help to attract talented researchers to the University and further strengthen our research enterprise.

Beyond the Basic Science implications, the ISCI is clearly well suited to provide avenues for clinical and translational research. With the Stem Cell Institute, the University will be well positioned to carry out cutting edge research and provide the next breakthrough in the Medical Sciences.

We therefore strongly and enthusiastically recommend approval of the Interdisciplinary Stem Cell Institute (ISCI) initiative at the Miller School of Medicine by the University of Miami Faculty Senate.

Sincerely,



Eckhard R. Podack, M.D., Ph.D.  
Sylvester Distinguished Professor and Chairman

*C.C. DeCaffery - Lepore*  
305 243 3533

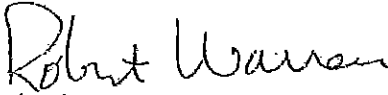


Department of Microbiology and Immunology • Leonard M. Miller School of Medicine  
Post Office Box 016960 (R-138) • Miami, Florida 33101  
Location: 1600 NW 10th Avenue, 3045a RMSB • Miami, Florida 33136  
305-243-6655 • Fax: 305-243-4623 • <http://chroma.med.miami.edu/micro>

**MILLER**  
SCHOOL OF MEDICINE

**MEMORANDUM**

**TO:** Iris Barrios  
Secretary of the Faculty Senate

**FROM:** Robert Warren, Ph.D.   
Interim Chair, Chair Biology & Anatomy

**SUBJECT:** Support for the Interdisciplinary Stem Cell Institute

**DATE:** January 22, 2008

This memorandum is to add my enthusiastic support to the proposal from the Miller School of Medicine for the creation of the Interdisciplinary Stem Cell Institute at medical school.

The potential value of stem cell therapy in the treatment of a large variety of illnesses is self-evident to those in the basic sciences and clinical disciplines in the medical school. The time is clearly appropriate to create an interdisciplinary institute that can bring together researchers and clinicians from all departments in the medical school to work together and share their knowledge to create new therapies for old diseases.

The prospect of having a stem cell institute at the medical school is particularly exciting for our department as we anticipate the conclusion of negotiations with our chair select, Doris Taylor, who has already garnered world-wide publicity for her ground-breaking work with cardiac stem cells and heart regeneration. The existence of a stem cell institute would greatly enhance her ability to recruit researchers to the department who can strengthen the school's efforts to develop the potential of stem cell therapies.



**General Welfare Committee**  
**February 13, 2008**  
**3:30 p.m.**  
**Law Library Conference room, 4<sup>th</sup> floor**

1. Chair's remarks (3:30)
2. Review of Draft Minutes of January 30, 2008 (3:35)
3. Interdisciplinary Stem Cell Institute (ISCI) proposal  
Interdisciplinary Stem Cell Institute memos of support  
Jennifer McCafferty-Cepero, PhD (4:00)
4. Updated Faculty Disclosure Form (to be brought to the Faculty Senate meeting on February 27<sup>th</sup> for an informational) (4:35)
5. Other Matters (4:45)

\*\*\*\*\*

# related material included





**Proposal for the Establishment of the  
Interdisciplinary Stem Cell Institute of Miami  
at the University of Miami Miller School of Medicine**

**1. BACKGROUND**

This proposal seeks to formally establish an Interdisciplinary Stem Cell Institute at the University of Miami Miller School of Medicine that will take its place among the nation's leading stem cell research institutes. The Institute will be called the Interdisciplinary Stem Cell Institute of Miami (ISCI Miami).

Stem cells are undifferentiated cells that have the potential to develop into a variety of different cell types. With their ability to develop into specialized tissue cells, understanding fundamental features of stem cell biology and harnessing this regenerative potential into high impact treatments for devastating diseases are some of the fastest growing areas of basic and clinical science. In fact, one of the most important basic questions in the life sciences today is: What are the properties that allow stem cells not only to differentiate into any cell type in the body, but also to reprogram other cells and repair damaged tissue? The ISCI is a ground breaking scientific enterprise because it is dedicated to finding the answers to these questions and fast-tracking them to patients' bedsides in the form of new treatments for conditions such as Parkinson's disease, diabetes, heart disease, and cancer. Due to the potential of stem cells in the treatment of human disease, significant public attention has been generated regarding the origin of stem cells (embryonic versus adult), nuclear reprogramming, cloning, and organogenesis. The progress in stem cell research together with advances in deciphering of the genetic code and genetic diagnosis requires responsible and ethical conduct in research. Like all research units at the University of Miami, the ISCI is committed to conducting responsible and ethical research. In addition, ISCI offers a dynamic venue for the interrogation of the ethics and science policy that surround stem cell research and regenerative medical therapies.

There is an urgent need for an integrated, interdisciplinary institute that offers the expertise, infrastructure, and resources necessary to energize fundamental aspects of stem cell science and advance translational research in regenerative medicine at the Leonard M. Miller School of Medicine.

**2. MISSION**

The ISCI seeks to discover and explain the fundamental science of stem cell biology and to pioneer the field of regenerative medicine by applying this knowledge to the development of novel stem cell based therapies for the treatment of incurable diseases.

The ISCI is committed to catalyzing basic stem cell research at the Miller School that reveals the characteristics and potential of stem cells and then translate these findings to impact patient care. The ISCI will become a locus for the establishment and development of fruitful collaboration across many disciplines by bringing together and matching interests and expertise in an intentional and productive manner. The presence of the Institute will accelerate the pace of discovery and expand the breadth and width of the impact of these discoveries. These types of

interdisciplinary collaborations will also result in an increase in high-impact publications, a greater number of investigators receiving extramural funding, and expanded visibility in the national and international research community for the University of Miami. Through the ISCI, the University will be able to take pride in being at the crossroads between fundamental research and clinical applications, such that knowledge transfers in both directions, for the ultimate benefit of human health.

### **3. MARKET ANALYSIS**

The potential establishment of the ISCI at the Miller School of Medicine needs to be examined with due consideration of our strengths and weaknesses, the opportunities that are currently open to us, and the challenges that we may face in the future.

#### Strengths

- We are the oldest and most established medical school in South Florida, serving a population of 7 million or more.
- We have a large group of clinicians and researchers who are experts in areas of stem cell biology and regenerative medicine. This situation can pave the way for translational work.
- With the recruitment of Dr. Joshua M. Hare and his colleagues, we are poised to have unmatched expertise in stem cell based therapies.
- With the recruitment of Dr. Ian McNiece and his colleagues, we are poised to have unmatched expertise in cell manufacturing.
- There are a number of ongoing studies and faculty members with unique expertise who would benefit from and who would be assets to an entity such as is proposed. With access to resources and an institute around which to organize, the expertise and research activities in stem cell biology and regenerative medicine already in place would grow and thrive.
- Collaborative agreements with industry partners have been established to facilitate the development of stem cell based therapies.
- The Louis Calder Memorial Library has significant journal subscriptions and book holdings in the areas of stem cell biology and regenerative medicine.

#### Weaknesses

- There is no structure or an organization that fosters intramural collaboration and communication in stem cell biology and regenerative medicine.
- There is no coordination of technological resources related to stem cell biology and regenerative therapy development resulting in them being unavailable or undershared and underutilized.

- There is no coordination of regulatory processes making it difficult to manufacture cellular products or biologics at the scale required for research studies.
- We are one of the few top-level medical schools in the country that does not have an interdisciplinary research unit dedicated to stem cell biology and/or regenerative medicine. In 2005, ten of the top 10 medical schools by NIH funding had such dedicated interdisciplinary research units (Table 1) and approximately 50% of American Association of Universities (AAU) members have such interdisciplinary research units (Table 2).

#### Opportunities

There are a number of world class research programs in stem cell biology and regenerative medicine already functioning at the Miller School of Medicine. With recent high impact recruits, and a new suite of laboratories being built, we are uniquely placed to build upon our assets and overcome our weaknesses. It is the ideal moment to establish an interdisciplinary, integrated, focused organization dedicated to stem cell biology and regenerative medicine. ISCI Miami will provide infrastructure, laboratory resources, and expertise to all research at the University that involves stem cells, and further provides the potential of a focused recruitment program that builds upon and expands existing infrastructure.

#### Challenges

As with all science, timing is of the essence. There are several competing groups within the United States and abroad who are also working on both the fundamental science of stem cells and developing stem cell based-therapies and regenerative medicine techniques. We need to hit the ground running with an institute that will outshine existing efforts, and lead the way in regenerative medicine.

### **4. ORGANIZATION AND MEMBERSHIP**

#### Organization

The proposed ISCI will be directed by Dr. Joshua M. Hare. The ISCI will initially consist of 7 Research Platforms built primarily around groups of related diseases and 1 Program that spans the platforms (Experimental and Cell Based Therapies). The Research Platforms are headed by Platform Leaders and the Program is headed by a Program Director. This organization is explained in more detail below.

#### Proposed ISCI Director:

Dr. Joshua Hare, M.D., Chief, Division of Cardiology, and Louis Lemberg Professor of Medicine, will be the Director of SCI Miami.

#### Experimental and Clinical Cell-Based Therapies Program:

The Program Director is selected and reviewed by the ISCI Director. The proposed Program Director is Dr. Ian McNiece, Ph.D.

The Experimental and Clinical Cell-Based Therapies Program (Cell Therapies Program) will provide the infrastructure to rapidly translate novel stem cell products from research to clinical

therapeutic application. It will encompass all aspects of cell manufacturing, IND preparation, regulatory oversight and will include:

1. Manufacture of cellular products for clinical trials through a cGMP manufacturing facility (cGMP lab).
2. Scale up process development through the Clinical Development Laboratory (CDL). The CDL will develop scale up processes for all cellular manufacturing, develop standard operating procedures (SOPs) for clinical manufacturing and undertake validation studies for IND submission.
3. Support for preclinical validation and animal models through the Preclinical Development Laboratory (PDL). The PDL will support faculty in cellular manufacturing through identification of cGMP reagents for clinical applications, process development and production of cellular products for large animal models and testing.
4. The PDL and CDL will support clinical trials with assay development and performance in particular for defining release criteria and potency testing assays for cellular products.
5. Regulatory Core: All aspects of the clinical manufacture for IND submissions and regulatory oversight will be provided through the Regulatory Core. The Core will include a Quality Manager for all aspects of quality control and quality management and the maintenance of the quality program.

#### Research Platforms:

The primary research platforms will initially be Blood diseases, Bone diseases, Cancer, Cardiovascular disease, Diabetes, and Nervous system diseases. An additional platform for Ethics and Science Policy will also be supported.

#### Administrative Support:

The ISCI will have the standard array of dedicated staff for regulatory and compliance issues, technology transfer, operations, and general administrative duties.

#### ISCI Research Cabinet:

The ISCI Research Cabinet meets quarterly to provide feedback and consultation to the ISCI Director regarding ISCI's scientific progress and technological advances and needs. The Cabinet will be comprised of the ISCI Director, the Director of Experimental and Clinical Cell-Based Therapies Program, and Research Platform Leaders. Other Miller School of Medicine or University leaders will be invited on an as needed basis.

#### ISCI Advisory Board:

The ISCI Advisory Board meets annually to provide feedback and consultation to the ISCI Director regarding ISCI's progress and future plans including development and strategic planning. The Board will be comprised of the ISCI Director, the Dean of the Miller School of Medicine and two external scientific luminaries – one world class expert in fundamental aspects of stem cell biology and one international leader in regenerative medicine and/or cell-based therapies. Other Miller School of Medicine or University leaders will be invited on an as needed basis.

#### Membership

The ISCI will have a formal membership application and review process. Membership is open to all faculty at the University of Miami and affiliated institutions according to the criteria listed

below. All members must have an appointment in an academic department. Membership categories are independent of academic rank.

New members are recruited to augment established or developing multidisciplinary research activities. At the time of application, members are assigned primary affiliation with one of the ISCI's Research Platforms. Although many members collaborate with colleagues in other Research Platforms, formal alignment is generally assigned to a single Research Platform so that leadership can track collaborations throughout the ISCI with clarity. Some members are considered affiliated with more than one Research Platform because they make fundamental contributions across Research Platforms.

All new members attend a formal orientation process that includes information on the structure of the ISCI as well as the benefits and responsibilities of membership.

Types of Membership:

- Primary members hold faculty appointments at the University of Miami. They may or may not reside in ISCI space. They are required to be affiliated with an ISCI Research Platform. The Executive Committee is drawn from the primary membership.
- Affiliate Members hold faculty appointments at accredited academic institutions outside the University of Miami. They are required to be affiliated with an ISCI Research Platform

Criteria for ISCI Membership (all are not required for consideration):

- Demonstrated research activity in stem cell biology or regenerative medicine
- Demonstrated interest in stem cell and/or regenerative medicine research
- Active/Proposed peer-reviewed or non-peer-reviewed funding in research with stem cell and/or regenerative medicine relevance
- Stem cell or regenerative medicine-focused publications
- Agree to fulfill the responsibilities of membership

Application and Selection Process:

Interested faculty members should submit:

- Completed ISCI Membership Application form (including description of research interest and statement of stem cell or regenerative medicine research focus)
- Current CV and NIH or NSF Biosketch
- Current research funding information

Initial membership appointments will be for three years and will be contingent upon successful completion of an annual review process.

Prospective members are asked to select one of the ISCI Research Platforms for alignment, and must consult with the Platform Leader for approval of the application prior to submission.

Initially, these include:

- Cardiology
- Diabetes

- Nervous System Diseases
- Bone Diseases
- Cancer
- Blood Diseases
- Ethics and Science Policy

This information is then reviewed by the ISCI Executive Committee, chaired by the ISCI Director, and consisting of the ISCI Platform Leaders and 7 ISCI members selected by the ISCI Director. Membership is awarded for an initial period of three years. The ISCI Executive Committee will meet yearly to review the entire ISCI membership roster, to make sure that it reflects the mission of the ISCI.

#### Benefits of Membership:

- Eligibility to have access to shared resources at a subsidized rate
- Eligibility to receive developmental funding for innovative ideas
- Administrative support for submission of stem cell or regenerative medicine - related grants and contracts
- Administrative support for management of stem cell or regenerative medicine - related grants and contracts

#### Responsibilities of Membership:

All ISCI members are expected to contribute to the mission and growth of the SCI through support of ISCI activities. The responsibilities of members include:

- Willingness to work collaboratively with other scientists and clinical researchers on problems related to stem cell biology.
- Active participation in ISCI activities including Research Platforms and other working groups.
- Attendance at scheduled functions of the ISCI
- Willingness to provide mentoring to junior faculty and other ISCI members.
- All ISCI members will be responsible to provide information updates as required, and must be willing to share this information for the purpose of reporting requirements.

#### Annual Review:

The ISCI Executive Committee will meet yearly for a thorough review of the entire membership roster. Each member is discussed on the basis of evidence for:

- Demonstrated independent or collaborative research in stem cell biology or regenerative medicine
- Publications with other ISCI members
- Service as a PI or Co-investigator on grant/grant proposal(s) with other members
- Service as a PI or Co-investigator on clinical protocol with other members
- Participation as a mentor to more junior members
- Participation in ISCI committees, special initiatives and meetings

Members not meeting these criteria are counseled. Membership is withdrawn if progress is not demonstrated in the 12 month period following counseling.

**5. Space**

The research activities of the ISCI require well equipped laboratory, analytical and administrative space. Initially research will be conducted in space at the Rosenstiel Medical Sciences Building on the Miller Campus. The ISCI will have permanent space in the Multidisciplinary Research Building at its completion in 2008.

**6. Funding Sources and Budget Projections**

The ISCI is being initially supported as part of a \$30 million commitment by the Dean of the Miller School of Medicine. These funds are to be expended over a five year period and will be used to create the infrastructure necessary to support ISCI activities and resources as described above. In addition, the initial primary members have brought approximately \$2 million in sponsored research for the current fiscal year as well as a Specialized Center for Cell-Based Therapies (SCCT) Grant. All members are expected to seek external funding for their research, thus there are high expectations for significant growth in sponsored funding. The table below illustrates the five-year financial projections for ISCI.

<u>Year</u>	<u>UM</u>	<u>Sponsored Activity</u>
2007	6,000	2,000
2008	6,000	3,000
2009	6,000	4,000
2010	6,000	5,000
2011	6,000	6,000
Total	30,000	20,000

All amounts are in '000s

## 7. Appendix

**Table 1. Top ten NIH-funded medical schools in the country (FY 2005)**

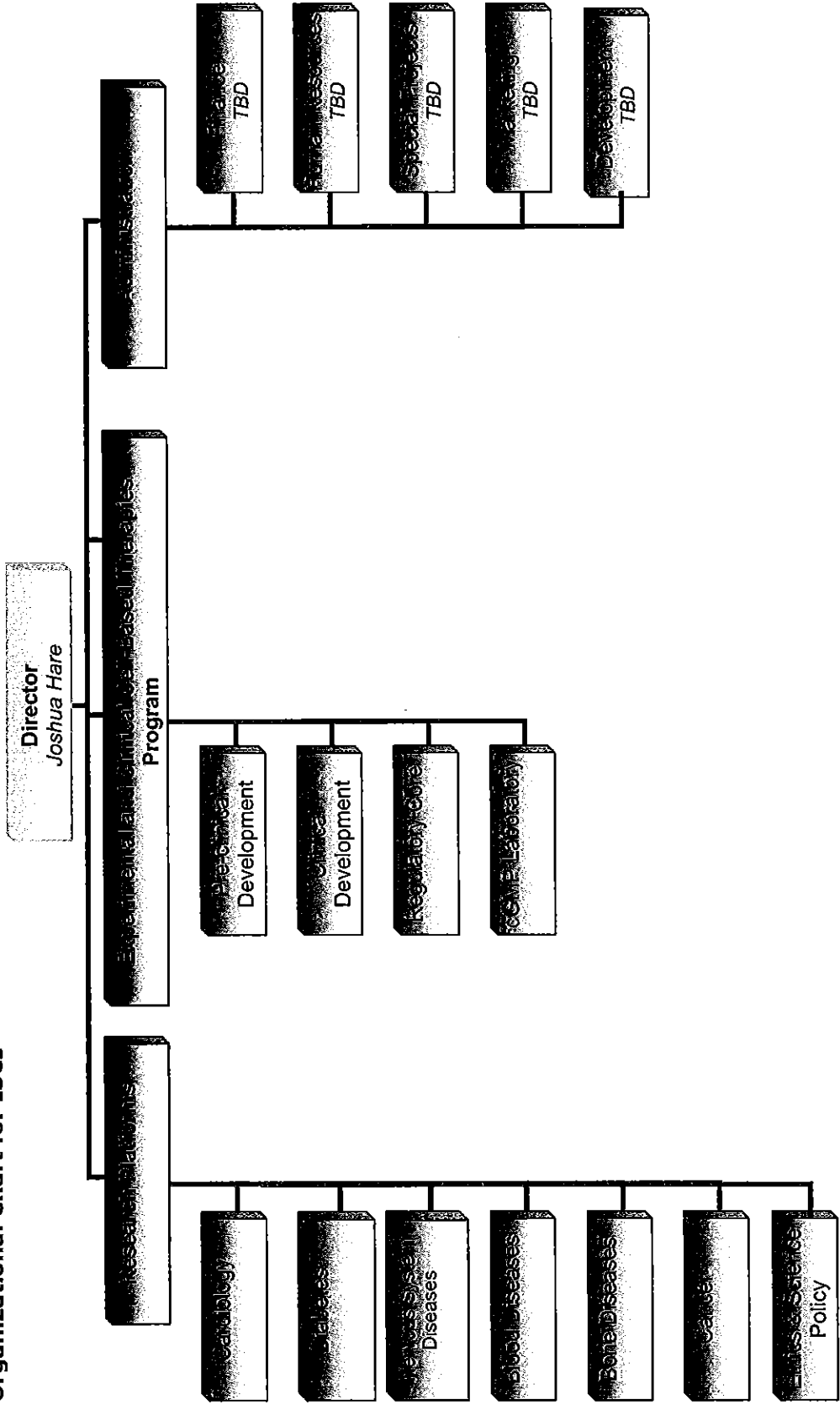
1. Johns Hopkins University – Stem Cell Biology Program
2. University of Pennsylvania – Stem Cell Core
3. UC, San Francisco- Institute for Regeneration & Human Embryonic Stem Cell Research Center
4. Washington University – Embryonic Stem Cell Core
5. Duke University – Organogenesis and Stem Cell Biology Program
6. University of Washington – The Institute for Stem Cell and Regenerative Medicine
7. UC, Los Angeles – Eli and Edythe Broad Center of Regenerative Medicine and Stem Cell Research
8. Yale University – Yale Stem Cell Center
9. University of Pittsburgh – Stem Cell Core
10. University of Michigan – Center for Stem Cell Biology & The Michigan Center for Human Embryonic Stem Cell Research

**Table 2. American Association of Universities (AAU) Members with Institutes, Centers, Programs or Cores for Stem Cells and/or Regenerative Medicine.**

- California Institute of Technology
- Case Western Reserve University
- Columbia University
- Cornell University
- Duke University
- Emory University
- Harvard University
- Indiana University
- Johns Hopkins University
- New York University
- Rutgers University
- Stanford University
- University of California, Berkeley
- University of California, Davis
- University of California, Irvine
- University of California, Los Angeles
- University of California, San Diego
- University of Michigan
- University of Minnesota, Twin Cities
- University of Pennsylvania
- University of Pittsburgh
- University of Southern California
- University of Virginia
- University of Washington
- University of Wisconsin – Madison
- Vanderbilt University
- Washington University, St. Louis
- Yale University



**Organizational Chart for ISCI**



# MILLER

SCHOOL OF MEDICINE

Pascal J. Goldschmidt, M.D., FACC  
*Senior Vice President for Medical Affairs and Dean*  
*Chief Executive Officer, Miami Medicine*

## Memorandum

To: Iris Barrios  
Secretary of the Faculty Senate

From: Pascal G. Goldschmidt, M.D.  
Senior Vice President for Medical Affairs and Dean

Date: January 7, 2008

Subject: Support for the Interdisciplinary Stem Cell Institute

PJG

This memo is to express my strong support for the University of Miami Faculty Senate to approve the creation of the Interdisciplinary Stem Cell Institute (ISCI) at the Miller School of Medicine.

The establishment of the ISCI represents a clear expansion of the School and University efforts in the highly-interdisciplinary arena of stem cell biology and regenerative medicine. The ISCI is a critical piece of the research infrastructure – providing a framework around which to focus our recent recruiting efforts and existing strengths while efficiently providing top-flight shared resources in both expertise and technology.

We are in the middle of a revolution – stem cells offer seemingly limitless potential to shift paradigms across disciplines. Understanding the fundamental features of stem cell biology and harnessing their regenerative potential into high impact treatments for devastating diseases are some of the fastest growing areas of the basic and clinical sciences. The ISCI is innovative because it brings together scientists and clinicians with expertise spanning the basic to the applied with the clear mission of fast-tracking leading-edge therapies for debilitating conditions like heart disease, diabetes and cancer. In addition, ISCI provides a forum for the discussion and investigation of the ethical and moral challenges posed by stem cell research and regenerative medicine. By offering a dynamic and cross-disciplinary platform for these discussions, ISCI will provide a venue for dialogue regarding the ethics and science policy surrounding stem cell research and regenerative medical therapies.



The creation of the ISCI is an important and timely addition to the Miller School of Medicine. The School has earmarked significant financial resources for the development of the stem cell biology and regenerative medicine infrastructure and is fully committed to the success of the ISCI. I fully endorse its creation without hesitation or reservation and look forward to the Senate's approval of this vital institute.

MEMORANDUM

To: Iris Barrios  
Secretary of the Faculty Senate

From: Kenneth W. Goodman, Ph.D. *KW Goodman*  
Director, Bioethics Program  
Associate Professor of Medicine

Date: December 17, 2007

Subject: Ethics Programs' Support for the Interdisciplinary Stem Cell Institute

---

I write to express my enthusiastic support for the creation of the Interdisciplinary Stem Cell Institute (ISCI) at the Miller School of Medicine.

Given (i) the exciting medical and other scientific potential of stem-cell-based therapies, (ii) the importance of those therapies for future translational research, (iii) the role of the ISCI as part of the dramatic transformation of the Miller School of Medicine, and (iv) plans to ensure that ethical, social and legal issues are to be given prominence in the new institute – it is clear that the ISCI will be poised to make major contributions to the School, the University and society.

Leaders of the planned institute, members of the Senate and all students and faculty are well aware that ethical issues loom large in stem cell research. I have long argued that all forms of stem cell research are morally obligatory, and that a robust ethics process is essential to ensuring the harvest of the scientific and clinical fruits of such research.


For these reasons, I offer my unalloyed support and that of the University of Miami Bioethics Program in the establishment of the institute and in its operations. We have an exciting opportunity to ensure the success of an ethically optimized new research platform, and I very much look forward to contributing to it.

Please let me know if you or the Senators have any questions or want more information about the importance of ethics in stem cell research and the utility of our program's role in this exciting new institute.

cc: Pascal G. Goldschmidt, M.D., Senior Vice President for Medical Affairs and Dean,  
UM Miller School of Medicine

**MILLER**  
SCHOOL OF MEDICINE

To: Iris Barrios  
Secretary of the Faculty Senate

From: Marc E. Lippman, M.D.   
Chairman, Department of Medicine

Date: December 12, 2007

Subject: Support for the Interdisciplinary Stem Cell Institute (ISCI)

This memo is to express my enthusiasm for the establishment of the Interdisciplinary Stem Cell Institute (ISCI) at the Miller School of Medicine.

The potential for novel stem cell based therapies for a variety of diseases and disorders is tremendous. The new institute comes at an exciting time of expansion at the Miller School of Medicine and the ISCI is positioned to not only provide leading edge technologies for basic discoveries, but to build bridges transferring new knowledge to the clinic.

Faculty in the Department of Medicine are thrilled at the prospect of collaborating with the new institute and I offer our full cooperation in establishing strong ties with the ISCI.

Cc: Pascal G. Goldschmidt, M.D.





**THE MIAMI PROJECT TO CURE PARALYSIS**  
AN INTERNATIONAL CENTER FOR SPINAL CORD INJURY RESEARCH

W. Dalton Dietrich, Ph.D.  
*Scientific Director*

To: Iris Barrios  
Secretary of the Faculty Senate

Date: December 17, 2007

Subject: Support for the Interdisciplinary Stem Cell Institute (ISCI)

This memo is to request support from the University of Miami Faculty Senate to approve the creation of the Interdisciplinary Stem Cell Institute (ISCI) at the Miller School of Medicine.

The establishment of the ISCI synergizes with our recent recruiting efforts and our existing strengths in stem cell biology. The new institute would position the Miller School of Medicine for rapid expansion and afford the opportunity to create a world-class environment for research in stem cell biology and regenerative medicine. Importantly, the creation of the ISCI would build an interdisciplinary home for stem cell research at the University and allow us to make a significant impact on clinical practices and human health by investigating the potential for stem cell based therapies for a variety of devastating diseases.

The new institute is an important and timely addition to the Miller School of Medicine; the School is fully committed to the success of the ISCI. Faculty within the Miami Project to Cure Paralysis are conducting stem cell research targeting brain and spinal cord injury. Thus, this new Institute will significantly enhance those established programs. I offer the full cooperation of the Miami Project and look forward to establishing strong collaborations with the new Institute. I fully endorse its creation.

Sincerely,

W. Dalton Dietrich, Ph.D.  
Kinetic Concepts Distinguished Chair in Neurosurgery  
Professor of Neurological Surgery, Neurology and Cell Biology and Anatomy  
Scientific Director, The Miami Project to Cure Paralysis

**MILLER**  
SCHOOL OF MEDICINE  
UNIVERSITY OF MIAMI

Lois Pope LIFE Center  
Post Office Box 016960 (R-48) • Miami, Florida 33101  
Location: 1095 NW 14th Terrace • Miami, Florida 33136  
305-243-2297 • Fax: 305-243-6017 • [www.themiamiproject.org](http://www.themiamiproject.org)



December 13, 2007

Iris Barrios  
Secretary of the Faculty Senate

Re: Support for the Interdisciplinary Stem Cell Institute (ISCI)

Dear Colleagues

I write in strong support for the formal establishment of the ISCI within the University Of Miami Miller School Of Medicine. I, and many of my colleagues in the Cancer Center, have taken advantage of the symposia and seminars developed by the ISCI to date. I have been impressed with the inventory of stem cell research developing on campus and the ability of this Institute to coordinate and expand the research in this field. I believe that the activities of the Institute have already had a significant positive impact on the academic environment of our university.

The Cancer Center is collaborating actively with the leadership of the ISCI in a joint recruitment effort to establish a team of investigators with expertise in Cancer Stem Cell Biology. We are also working actively with the Institute to expand our shared research resources. We have been impressed with the collaborative attitude of those involved with the ISCI.

In summary, I think the ISCI has already enriched the academic environment of our university and I strongly support its formal establishment.

Sincerely,

A handwritten signature in cursive script that reads "Jerry Goodwin". The signature is written in dark ink and is positioned above the printed name and title of the signatory.

W. Jarrard Goodwin, M.D., F.A.C.S.  
Director, UM/Sylvester Comprehensive Cancer Center  
Sylvester Professor of Otolaryngology



LEONARD M. MILLER SCHOOL OF MEDICINE  
Office of the Director • Post Office Box 016960 (D-1) • Miami, Florida 33101  
Location: 1475 N.W. 12th Avenue • Miami, Florida 33136  
305-243-4918 • Fax: 305-243-4901 • jgoodwin@miami.edu • www.sylvester.org  
*Leading the Search for a Cancer Cure*

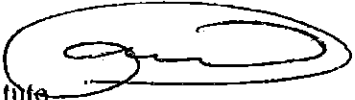


DIABETES  
RESEARCH  
INSTITUTE

1450 NW 10 AVENUE  
MIAMI, FL 33136  
PHONE: 305 / 243-5376  
FAX: 305 / 243-4404

MAILING ADDRESS:  
P.O. BOX 016960 (R-134)  
MIAMI, FL 33101

To: Iris Barrios  
Secretary of the Faculty Senate


From: Camillo Ricordi, M.D.  
Scientific Director, Diabetes Research Institute 

Date: December 13, 2007

Subject: Support for the Interdisciplinary Stem Cell Institute (ISCI)

This memo is to express my enthusiasm and request support from the University of Miami Faculty Senate to approve the creation of the Interdisciplinary Stem Cell Institute (ISCI) at the Miller School of Medicine.

The establishment of the ISCI synergizes with our recent recruiting efforts and our existing strengths in stem cell biology. The new institute would position the Miller School of Medicine for rapid expansion and afford the opportunity to create a world-class environment for research in stem cell biology and regenerative medicine. Importantly, the creation of the ISCI would build an interdisciplinary home for stem cell research at the University and allow us to make a significant impact on clinical practices and human health by investigating the potential for stem cell based therapies for a variety of devastating diseases.





# MILLER

SCHOOL OF MEDICINE

Steven E. Lipshultz, M.D.

Professor and Chairman of Pediatrics  
Professor of Public Health and Epidemiology  
Professor of Medicine

To: JFS Barros  
Secretary of the Faculty Senate

From: Steven E. Lipshultz, MD *SL*  
Chairman, Department of Pediatrics

Date: December 12, 2007

Subject: Support for the Interdisciplinary Stem Cell Institute (ISCI)

This memo is to request support from the University of Miami Faculty Senate to approve the creation of the Interdisciplinary Stem Cell Institute (ISCI) at the Miller School of Medicine.

The establishment of the ISCI dovetails with our existing strengths in stem cell biology and our recent recruiting efforts. The creation of the ISCI would build an interdisciplinary home for stem cell research at the University, facilitating the development of new stem cell based therapies for a variety of devastating diseases. The new institute would position the Miller School of Medicine for rapid expansion and afford the opportunity to create a world-class environment for research in stem cell biology and regenerative medicine.

The ISCI is an important and timely addition to the Miller School of Medicine and I offer the full cooperation of the Department in supporting its success. I fully endorse the creation of the ISCI and look forward to establishing strong and fruitful collaborations.



ERROR: ioerror  
OFFENDING COMMAND: image

STACK:

-dictionary-  
-mark-  
-savelevel-

## Tracking Sheet

**Subject:** Interdisciplinary Stem Cell Institute

### History of Action Taken

DATE	ACTION TAKEN
09/18/06	<p>At our weekly staff meeting I advised SS that I read an article teaching a new Interdisciplinary Stem Cell Institute and believed hat is should have come to the Senate for approval. He agreed and asked that I send Dean Goldschmidt an email to let him know that this required Senate approval.</p> <p>I sent Dean Goldschmidt an email stating that this requires Senate approval and I supplied him with a link to the guidelines.</p>
09/19/06	Maggie emailed me and said that she would bring this to the Deans attention.
09/27/06	Received email from Maggie stating that the Dean received my previous email and thanked me for the reminder.
09/29/06	<p>I replied to Maggie asking her to let Dean know that there is a provisional approval option available. Maggie replied that she printed it out and turned it over to Dick.</p> <p>Follow up tickler set for 10/23/06- Just prior to SS's meeting with the Dean on 10/24/06.</p>
	Will not be ready for November mtgs.
	Follow up tickler set for 11/23/06.

# Tracking Sheet

KL

Subject: Interdisciplinary Stem Cell Institute

## History of action taken

DATE	ACTION TAKEN
9/13/06	<p>At our weekly staff mtg, I advised SS that I read an article regarding a new Interdisciplinary Stem Cell Institute &amp; believed that it should have come to the senate for approval. He agreed &amp; we both agreed that I send Dean Coldschmidt an e-mail to let him know that this requires senate approval.</p>
	<p>I sent Dean Coldschmidt an e-mail stating that this requires senate approval &amp; I supplied him w/ a link to the guidelines.</p>
9/19/06	<p>Maggie e-mailed me &amp; said that she would bring this to the Dean's attention.</p>
9/27/06	<p>Received e-mail from Maggie stating that the Dean received my previous e-mail &amp; thanked me for the reminder.</p>
9/29/06	<p>I replied to Maggie asking her to let the Dean know that there is a provisional approval option available.</p>
	<p>Follow up tickler set for 10/23/06 - Just prior to SS's mtg with the Dean on 10/24/06</p>
	<p>Maggie replied that she printed it out &amp; turned it over to DKK.</p>

## Faculty Senate Office

---

**From:** Robitaille, Magaly [MRobitai@med.miami.edu] on behalf of Goldschmidt, Pascal (Dean - School of Medicine) [PGoldschmidt@med.miami.edu]  
**Sent:** Wednesday, September 27, 2006 6:21 PM  
**To:** Faculty Senate Office  
**Subject:** RE: Interdisciplinary Stem Cell Institute

Dear Kim,

The Dean is in receipt of your email and thanks you for the reminder. We are working on it, and are aware of the process.

Many thanks again for your kind reminder.

Maggie

Magaly A. Robitaille  
Assistant Chief of Staff  
Office of the Senior Vice President for Medical Affairs and Dean University of Miami  
Leonard M. Miller School of Medicine Post Office Box 016099 (R-699) Miami, Florida 33101  
305.243.6545 Office  
305.243.4888 Facsimile  
mrobitai@med.miami.edu

-----Original Message-----

**From:** Faculty Senate Office [mailto:facsen@miami.edu]  
**Sent:** Monday, September 18, 2006 1:01 PM  
**To:** Goldschmidt, Pascal J.  
**Cc:** Robitaille, Magaly  
**Subject:** Interdisciplinary Stem Cell Institute

Dean Goldschmidt:

I recently read an article regarding the new Interdisciplinary Stem Cell Institute. Please note that the creation of institutes such as this require Faculty Senate approval. Copied below is a link containing the requirements for submission of proposals. In reading the article it appears that this will involve faculty from either different schools and/or departments. If this is correct, item 1(a) in the linked procedures will be the appropriate section to use for reference. If not, please follow the guidelines in the appropriate section.

Centers-Institutes Guidelines

[http://www6.miami.edu/UMH/CDA/UMH\\_Main/0,1770,2460-1;27036-3,00.html?pf=](http://www6.miami.edu/UMH/CDA/UMH_Main/0,1770,2460-1;27036-3,00.html?pf=)

1

The proposal will need to come first before the Senate's General Welfare Committee, and if approved there, the full Senate. Visit [www.miami.edu/fs](http://www.miami.edu/fs) for a list of meeting dates. Proposals need to be submitted two weeks prior to the GWC meeting that this item will be discussed.

If you are not the person that I should be directing this e-mail to, please point me in the right direction.

Contact me at your convenience if you have any questions.

Thank you.

-Kim

Kimberly Litman  
Faculty Senate Office

325 Ashe Admin. Bldg.

Loc 4634

(305)284-3721 (office)

(305)284-5515 (fax)

<http://www.miami.edu/FacultySenate>

**Checklist for proposals for University center or institute (guideline I(a))**

A **University Center or Institute** (Faculty Manual Bylaw B6.5) is an independent academic unit of the University with its primary mission being multidisciplinary or interdisciplinary research in an area specified in its charter. It involves faculty from different schools or different departments of a single school. A University Center or Institute, or any other such academic unit, however named or titled, shall not award tenure, confer degrees, or offer primary faculty appointments (**See I (a)**).

Item	Received [✓]	Comments
A charter that describes the mission, funding sources, organization, and administration, including reporting relationships of the director and any other appropriate aspects of governance.		
A detailed budget		
Description of the procedures for ongoing evaluation, for faculty affiliation, for amending the charter, and for the appointment and review of the director.		
Center/Institute named with "University of Miami" preceding title.		
Memo from the department chair(s) signifying approval of the faculty of the appropriate department(s).		
Memo from the dean(s) signifying approval of the faculty of the appropriate school(s)/college(s).		
Memo from the dean(s) and/or Provost indicating approval of the proposed budget.		
Memo indicating approval of the Academic Deans Policy Council (ADPC).		
Proposal reviewed/approved by GWC		
Proposal reviewed/approved by the FS		
If approved by GWC/FS, proposal sent to President as Class B legislation.		
Periodic review schedule-if applicable: Make a reminder tickler and tracking sheet if Senate or the Provost require a periodic review (FM section C18.2.3)		

Follow up  
Hickler Set  
for 10/3/06

## Faculty Senate Office

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**From:** Faculty Senate Office  
**Sent:** Monday, September 18, 2006 1:01 PM  
**To:** Goldschmidt, Pascal J.  
**Cc:** Robitaille, Magaly  
**Subject:** Interdisciplinary Stem Cell Institute

Dean Goldschmidt:

I recently read an article regarding the new Interdisciplinary Stem Cell Institute. Please note that the creation of institutes such as this require Faculty Senate approval. Copied below is a link containing the requirements for submission of proposals. In reading the article it appears that this will involve faculty from either different schools and/or departments. If this is correct, item 1(a) in the linked procedures will be the appropriate section to use for reference. If not, please follow the guidelines in the appropriate section.

### Centers-Institutes Guidelines

[http://www6.miami.edu/UMH/CDA/UMH\\_Main/0,1770,2460-1;27036-3,00.html?pf=1](http://www6.miami.edu/UMH/CDA/UMH_Main/0,1770,2460-1;27036-3,00.html?pf=1)

The proposal will need to come first before the Senate's General Welfare Committee, and if approved there, the full Senate. Visit [www.miami.edu/fs](http://www.miami.edu/fs) for a list of meeting dates. Proposals need to be submitted two weeks prior to the GWC meeting that this item will be discussed.

If you are not the person that I should be directing this e-mail to, please point me in the right direction.

Contact me at your convenience if you have any questions.

Thank you.

-Kim

Kimberly Litman  
Faculty Senate Office  
325 Ashe Admin. Bldg.  
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(305)284-3721 (office)  
(305)284-5515 (fax)  
<http://www.miami.edu/FacultySenate>



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### Renowned Johns Hopkins Cardiologist to Head Stem Cell Institute and Division of Cardiology at UM Miller School of Medicine

9/5/2006

Joshua M. Hare, M.D., a Johns Hopkins University cardiologist who is pioneering the use of stem cell therapy to repair damaged hearts, has been named chief of the Division of Cardiology and director of the new Interdisciplinary Stem Cell Institute at the University of Miami Miller School of Medicine.

"Josh Hare is an outstanding cardiologist who directs the heart failure programs at Johns Hopkins, a premier heart center in the U.S. Hare, the thought leader in our field, rejects the idea that we are doing enough for our patients with injured hearts," said Pascal J. Goldschmidt, M.D., senior vice president for medical affairs and dean of the Miller School of Medicine. "He has come to the realization that once a heart attack has caused irreversible damage, standard therapies involving surgery, stents and medications no longer suffice. The need is for novel interventions that aim at reconstituting normal cardiac tissue where the heart has been destroyed."

The use of cell therapy to repair the damaged heart provides patients afflicted with the nation's most common disorder "an opportunity that is unmatched, barely explored, and incredibly promising," Goldschmidt said.

Hare, who also heads cardiac transplantation at Hopkins, says he has a "very strong commitment to learning about regenerative medicine and applying it to people with a variety of chronic diseases."

"With very recent scientific discoveries, we've uncovered a major new paradigm in biology," Hare said. "Our organs and our bodies contain stem cells and with them have an incredible capacity to heal themselves far beyond what we had previously imagined. We are harnessing the body's ability to heal itself."

In the case of congestive heart failure, the need is acute and widespread. The demand for heart transplants far exceeds the available organs, leaving millions of people who could benefit from heart repair. At UM Hare will conduct research and direct patient care in cardiology. "That works well because research starts in the lab but advances to patient care as soon as possible," Hare said.

Post-doctoral fellows, technicians and graduate students from Hare's lab at Johns Hopkins will also make the move to Miami. "The University of Miami School of Medicine is a wonderful environment in which to do translational research in general and regenerative medicine specifically," Hare said. "The president and the dean have a very forward-thinking approach to academic medicine, one in which I think academics will flourish."

Hare, Professor of Medicine and Biomedical Engineering, graduated from the University of Pennsylvania and has a medical degree from Johns Hopkins. He did his residency at Hopkins and fellowships at Hopkins, Harvard University and The Brigham and Women's Hospital in Boston.

Dean Goldschmidt hails Hare as the ultimate success story. "The fact that we were able to recruit a physician and scientist of the caliber and stature of Josh Hare is a clear indication that the Miller School of Medicine is ready for a new era," Goldschmidt said. "While we already have great champions on our faculty who contribute extensively to our strength as a school, recruiting an individual like Josh Hare with all the skills and technical tools that he brings represents an unprecedented opportunity that will impact our faculty, our staff, our trainees and, most importantly, our patients."

*Need Senall approval?*

*J*



UM Home > Faculty Senate Home page > **Centers-Institutes Guidelines**

## Centers-Institutes Guidelines

### REQUIREMENTS FOR THE SUBMISSION OF PROPOSALS FOR THE ESTABLISHMENT OR NAME CHANGE OF UNIVERSITY CENTERS OR INSTITUTES AND OTHER NAMED OR TITLED ACADEMIC UNITS.

(See Faculty Manual sections B6 and C18 for more information)

A **University Center or Institute** (Faculty Manual Bylaw B6.5) is an independent academic unit of the University with its primary mission being multidisciplinary or interdisciplinary research in an area specified in its charter. It involves faculty from different schools or different departments of a single school. A University Center or Institute, or any other such academic unit, however named or titled, shall not award tenure, confer degrees, or offer primary faculty appointments (**See I (a)**).

**Other Named or Titled Academic Units** (Faculty Manual Bylaw B6.6) coordinate and promote research, instruction, conferences, seminars, workshops, etc., within a specified area. No such unit may award tenure, confer degrees, or offer primary faculty appointments independent of a department (**See I (b)**).

**Note:** A provisional name consistent with these policies may be used prior to the name and unit being approved. This provision applies to both **University Centers and Institutes** and **Other Named or Titled Academic Units** the sponsors are pursuing specific funding opportunities, such as sponsored awards or gifts. For development to proceed with use of a provisional name, approval must be obtained from the faculty of the units developing the proposal, the deans of the schools involved, and the Executive Vice-President and Provost. The Faculty Senate is to be informed at the earliest opportunity that such planning is underway and the date by which a formal proposal may be expected for review. Any such provisional name may not be used for more than one year without the approval of the Faculty Senate.

#### **I(a). For submission of proposals for the establishment of a University Center or Institute, proponents should provide to the Faculty Senate a proposal that includes:**

- A charter that describes the mission, funding sources, organization, and administration, including reporting relationships of the director and any other appropriate aspects of governance, and a detailed budget (do not include names, just titles). The proposal shall also describe the procedures for ongoing evaluation, for faculty affiliation, for amending the charter, and for the appointment and review of the director.
- The entities shall be named with "University of Miami" preceding such titles and are the only academic units in addition to schools and departments that ordinarily may use the unqualified prefix "University of Miami."
- A memo from the department chair(s) signifying approval of the Faculty of the appropriate department(s).
- A memo from the dean(s) signifying approval of the Faculty of the appropriate school (s)/college(s).
- A memo from the dean(s) and/or Provost indicating approval of proposed budget.
- A memo indicating approval of the Academic Deans Policy Council (ADPC)

#### **I(b). For submission of proposals for the establishment of Other Named or Titled Academic Units, proponents should provide to the Faculty Senate a proposal that includes:**

- A brief description of the unit, including its operating rules.
- The entity must use the name of the department or school as an immediate prefix to the name of the unit except as provided for below. They are administrative and academic components of a department or school and may be referred to by a

designation such as consortium, clinic, program, laboratory, project, center, institute, or other appropriate name. At the time of the establishment of any such unit under Bylaw 6.6, the unqualified prefix "University of Miami" may be approved if the unit is a cooperative venture with an entity outside of the University and its mission is justified as being of university-wide significance or if there are other special circumstances.

- A memo from the department chair(s) signifying approval of the Faculty of the appropriate department(s).
- A memo from the dean(s) signifying approval of the Faculty of the appropriate school (s)/college(s).

## II. For name changes of existing University Centers/Institutes and Other Named or Titled Academic Units, proponents should provide to the Faculty Senate:

- A memo explaining the reason for the change and indicating that the new title is justified and does not result in undue overlap with titles of other existing programs.
- A memo from the department chair(s) signifying approval by the faculty of the appropriate department(s).
- A memo from the dean(s) signifying approval of the faculty of the appropriate school (s)/college(s).
- A memo indicating approval of the Academic Deans Policy Council (ADPC) (for **University Center or Institute proposals only**)

## III. Senate approval process

- Submission of the proposal to the General Welfare Committee. The proposal should be received at least two weeks in advance of the relevant General Welfare Committee meeting in electronic and paper form. Visit [www.miami.edu/FacultySenate](http://www.miami.edu/FacultySenate) or contact the Senate office at (305)284-3721 for a list of meeting dates. The proponent should present only a summary of the proposal to the General Welfare Committee assuming that the Committee has already reviewed the document.
- Upon the recommendation of the General Welfare Committee, the proposal will be placed on the Senate agenda. A proponent should be present at the Faculty Senate meeting to answer questions and to present a summary of the proposal if requested. Visit [www.miami.edu/FacultySenate](http://www.miami.edu/FacultySenate) or contact the Senate office at (305)284-3721 for a list of meeting dates.
- Approval of the proposal by the Faculty Senate as Class B legislation will be forwarded to the President by the Faculty Senate Chair.

## IV. Required approvals beyond the Senate

- Approval of the President.

Periodic five year reviews may be conducted on all programs as deemed appropriate by the Faculty Senate or the Executive Vice President and Provost (per **Faculty Manual** section C18.2.3).