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## MEMORANDUM

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

**From:** Tomas A. Salerno  
Chair, Faculty Senate

A handwritten signature in black ink, appearing to read 'Tomas A. Salerno'.

**Date:** April 2, 2015

**Subject:** Faculty Senate Legislation #2014-29(B) – Establish a Miller School of Medicine Institute for Bioethics and Health Policy at the University of Miami

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The Faculty Senate, at its March 25, 2015 meeting, voted unanimously to approve the establishment of a Miller School of Medicine Institute for Bioethics and Health Policy<sup>1</sup> at the University of Miami. As noted in the proposal, the mission of the Institute is to “build on a reputation as a leading institute in the practice and advancement of bioethics.” The Bioethics Program has been in existence since 1991, and has proven to be very successful by establishing a “crucial presence in the life of the medical school and its community.”

UM will be joining many other prestigious medical schools that have established bioethics centers or institutes to enhance and serve the pedagogic, research, service and intellectual interests of the institutions.

This legislation is now forwarded to you for your action.

TAS/rh

Enclosure

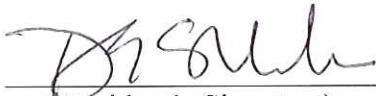
cc: Thomas LeBlanc, Executive Vice President and Provost  
Pascal J. Goldschmidt, Sr. Vice President and Dean, Chief Executive Officer, Miller School of Medicine  
Kenneth Goodman, Professor and Director, Bioethics Program, Miller School of Medicine

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

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

**CAPSULE:** Faculty Senate Legislation #2014-29(B) – Establish a Miller School of Medicine  
Institute for Bioethics and Health Policy at the University of Miami

APPROVED:  DATE: 4/6/15  
(President's Signature)

OFFICE OR INDIVIDUAL TO IMPLEMENT: Dean Goldschmidt

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

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

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

University of Miami Leonard M. Miller School of Medicine

# Institute for Bioethics & Health Policy



UNIVERSITY OF MIAMI  
MILLER SCHOOL  
of MEDICINE

Kenneth W. Goodman, PhD  
Director, Bioethics Program  
University of Miami School of Medicine

March 6, 2015

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## **The Institute for Bioethics & Health Policy University of Miami Miller School of Medicine**

This proposal seeks to establish the Institute for Bioethics & Health Policy at the University of Miami Leonard M. Miller School of Medicine.

### **INTRODUCTION**

Bioethics emerged as a formal discipline in the 1960s and 1970s, and quickly became a fixture in North American medical schools in the 1980s. Driven in part by noteworthy contemporary public cases and controversies, the discipline was nevertheless heir to ancient values. It became clear that competence in ethics should be a core component of the education of physicians, biomedical scientists and allied health professionals. The insight was sound: fledged on end-of-life care, privacy and confidentiality, consent for research and treatment, and justice in access to healthcare, bioethics was ready to provide education, research and service for a society that sought guidance in genetics, assisted reproduction, health information technology and, indeed, all the technologies that came to transform 20<sup>th</sup>-Century biomedical practice and research.

Today, the Liaison Committee for Medical Education, the Joint Commission and the Accreditation Council for Graduate Medical Education all have bioethics requirements. Great medical schools established bioethics centers and institutes, and these entities have served the pedagogic, research and intellectual lives of their institutions.

UM's peer institutions all embrace a Bioethics center or institute. It is time for the University of Miami Miller School of Medicine to establish and nourish a bioethics institute commensurate with the school's status and excellence.

### **BACKGROUND AND HISTORY**

In 1991, the University of Miami Medical School Council established what it is today known as "The University of Miami Bioethics Program" in an effort to create here what had begun to thrive elsewhere: a fully-fledged, school-wide ethics presence. In many respects, the University of Miami Bioethics Program has already been functioning as an institute – establishing a crucial presence in the life of the medical school and its community.

For nearly a quarter century, the UM Bioethics Program has provided education to medical and science students, hospital clinicians and the community; has pioneered and supported research in new technologies; and has served the institution's scientists, administration and community. This proposal is not aspirational; it is not a promissory note. Our Bioethics Program has become an essential emblem of our excellence, achieved international recognition and helped transform and enrich the institution that embraced it.

Since 1991, the Bioethics Program has broadened UM's undergraduate, graduate, and postgraduate curricula; fostered internationally recognized research; and earned some \$6 million in external funding, including federal and foundation grants, government contracts, philanthropic largesse, and community education grants. To the best of our knowledge, this sum exceeds the external funding of all other Florida medical school bioethics programs – combined. Our internal budget is stable, in part thanks to the program's pedagogic, research, administrative and compliance-related contributions.

This proposal seeks institutional recognition and support to continue to build on what we started more than two decades ago and to reify the administrative status of a thriving program. In support of the shared mission to establish a top-ranked research university and medical school, the University of Miami Miller School of Medicine has an opportunity to help propel the current program into the next level of visibility and growth, and accord it a proper place as co-equal partner and collaborator with the nation's other bioethics institutes and centers.<sup>1</sup>

Support for the establishment of the Institute for Bioethics & Health Policy will demonstrate the commitment of the Miller School of Medicine to the rigorous application and practice of health care ethics, positioning it at the center of its pedagogic, research and professional missions.

<sup>1</sup> For instance:

- Baylor College of Medicine Center for Medical Ethics and Health Policy
- Columbia University Center for Bioethics
- Duke University Trent Center for Bioethics, Humanities, and History of Medicine
- Emory Center for Ethics
- Georgetown University Medical Center, Edmund D. Pellegrino Center for Clinical Bioethics; and Georgetown University Kennedy Institute of Ethics
- Harvard University Center for Bioethics (recently transformed from the Division of Medical Ethics)
- Indiana University Center for Bioethics
- Johns Hopkins Berman Institute of Bioethics (jointly with medical, nursing and public health schools)
- Loyola University Neiswanger Institute for Bioethics
- New York University Center for Bioethics, Life, Health and Environment
- Medical College of Wisconsin Center Bioethics and Medical Humanities,
- Oregon Health Sciences University Center for Ethics in Health Care
- Princeton University Center for Human Values
- Stanford University Center for Biomedical Ethics
- The University of Louisville Institute For Bioethics, Health Policy and Law
- University of Buffalo Center for Clinical Ethics and Humanities in Health Care
- University of Chicago McLean Center for Clinical Medical Ethics
- University of Houston Health Law and Policy Institute
- University of Minnesota Center for Bioethics
- University of Pennsylvania Perelman School of Medicine Department of Medical Ethics & Health Policy
- University of Pittsburgh Center for Bioethics & Health Law
- University of Virginia Center for Biomedical Ethics & Humanities
- Wake Forest University Center for Bioethics, Health, and Society
- Washington University in St. Louis Center for Clinical Research Ethics

## MISSION OF THE INSTITUTE

The goal of the Miller School's Institute for Bioethics & Health Policy is to build on a reputation as a leading institute in the practice and advancement of bioethics by continuing to:

- Prepare future generations of physicians and scientists in ethics; and promote education and training for students, investigators, scientists, policymakers, healthcare professionals and the general public
- Conduct and publish innovative and interdisciplinary research, and cement global leadership in several areas of excellence
- Provide guidance and support in the shaping of institutional and public policy
- Serve the larger community that depends on and supports the Miller School
- Serve in alignment with the institution's Strategic Plan.

## GROWTH OPPORTUNITIES

Under the new administrative status, the Bioethics Institute will continue to thrive in realizing its potential as a leading program. It will do this by capitalizing on several growth opportunities:

- Leveraging Trustee Adrienne Arsht's previous generous gifts to the University-wide Ethics Programs (and making clear that a Bioethics Institute is a worthy recipient of philanthropic support)
- Creating and expanding on-demand educational programs (e.g. certificate programs, Master's degrees, dual programs, etc.), attracting an ever-wider range of learners from students to established health care professionals
- Enhancing competitiveness to obtain the funding necessary to energize research on evolving and interdisciplinary fields
- Facilitating the recruitment of interdisciplinary full-time faculty and post-doctoral fellows, a cohort that will continue to contribute to the legacy established by the institute's founders
- Fostering greater opportunities for collaboration with other well-established national and international partners

## PROGRAMS AND SERVICES

The Bioethics Program and, hence, the Bioethics Institute rest on four pillars: education, practice, research and service.

### Education

#### *Clinical Bioethics*

Physicians and biomedical researchers are more than ever confronted with complex ethical issues. Education in ethics and professionalism is essential to the preparation of future physicians and scientists. From the program's inception, bioethics faculty have contributed to this pedagogic mission.

*PELM and special initiatives:* Bioethics faculty help prepare and deliver content to all UMMSM students as part of the Professionalism, Ethics and Legal Medicine component of the Doctoring curriculum. This includes material on valid consent, end-of-life care, privacy and confidentiality and social medicine and access to care. We regularly host ethics rounds in the Obstetrics and Gynecology clerkship, contribute to sessions on patient safety, international medicine externships, reproductive medicine and a variety of ad hoc special sessions on other topics.

*MD-MPH Program:* The Miller School's path-setting MD-MPH degree program includes a bioethics core that features pedagogic sessions on ethics in public health, public health informatics and the foundations of bioethics.

*Ethics and Humanities Pathway:* Bioethics Program leaders founded and direct the UMMSM's four-year medical student pathway. Participants complete projects in the medical humanities or biomedical ethics and make these domains a key component of their Miller School experience. The goal of the Pathway "is to provide selected medical students with a coherent, substantial, educational experience in ethics and the humanities as they relate to the medical profession. The vision is an integrated curriculum that enhances the study of clinical medicine by providing educational experiences in a variety of ethics- and humanities-related interests, including art, economics, philosophy, film and theater, history, law, literature and public policy. "

*Medical Ethics Journal Club:* Bioethics faculty helped fledge the new, medical student-created and led journal club.

*Mentorship and Special Projects:* Miller School students are creative and motivated, and many seek out additional opportunities in bioethics. The Program's faculty have a long track record in mentoring and guiding students on special projects and events.<sup>2</sup> We also have provided as-needed counseling for students with disciplinary issues.

*Institutional:* The Bioethics Program is responsible for all ethics education at UM, including:

- Some 30 Grand Rounds presentations on the medical school campus
- Innovative Department of Pediatrics ethics sessions
- Hundreds of panels, workshops and conferences
- The Annual "Florida Bioethics: Debates, Decisions, Solutions" conference in conjunction with the Florida Bioethics Network (see below). In April 2015, we will host the conference, the oldest and largest community bioethics conference in the country, for the 23<sup>rd</sup> time. . The Bioethics Program is the Miller School Division of Continuing Medical Education's longest-running client.

<sup>2</sup>These mentorships have been striking in the extent to which they have resulted in peer-reviewed contributions to the literature. In the past two years:

Landy DC, Goodman KW, Brosco JP. Clinical ethics and patient satisfaction: The practical significance of distinguishing ethics and morals. *The American Journal of Bioethics* 2012;12(5):20-22. doi: 10.1080/15265161.2012.671888. PMID: 22548518

Amber KT, Dhiman G, Goodman KW. Conflict of interest in online point-of-care clinical support websites. *Journal of Medical Ethics*. 2014 Feb 3. doi: 10.1136/medethics-2013-101625. [Epub ahead of print]. PMID: 24493079

Dhiman GJ, Amber KT, Goodman KW. Comparative Outcome Studies of Clinical Decision Support Software: Limitations to the Practice of Evidence-Based System Acquisition. Forthcoming, *Journal of the American Medical Informatics Association*.



- A nationally-recognized training program in privacy and HIPAA, created and maintained from 2003-2012 and since absorbed by the CITI Program.
- "Ethics and Epidemiology," the world's first course on the topic.
- On the Gables campus, the world's first courses in "Ethics and International Health" (International Studies) and "Ethics and Health Informatics" (Engineering).
- In conjunction with the American College of Epidemiology, we have prepared a collection of syllabi on ethics in public health and epidemiology.

### *Research Ethics*

The Bioethics Program is, and has been for the past 21 years, responsible for UM-wide education in research ethics, including the NIH-required curriculum in the responsible conduct of research (RCR). We have contributed to the education of every Miller School bioscience student for more than two decades. (This component will continue to receive financial support from the Office of the Provost after the establishment of the Institute; see "Sources of Funding," below.)

Bioethics faculty offer on-demand inservices and consulting to all research departments and faculty; see Research Ethics Consulting Service, below.

Moreover, we maintain a longstanding collaboration with the UM Institutional Review Board, co-organizing IRB Grand Rounds and contributing periodically to various IRB educational programs.

Bioethics faculty have contributed to the core of UM's Collaborative Institutional Training Initiative (CITI) Program, developing curricula in privacy, confidentiality and HIPAA; genetics; publication and authorship; and conflicts of interest. Indeed, the Bioethics Program and CITI co-evolved and have jointly supported a number of faculty members and special projects.

### **Bioethics Practice**

The Bioethics Program is responsible for Joint Commission-mandated ethics services for all University of Miami and Jackson Health System hospitals:

- The University of Miami Hospital and the UMMG<sup>3</sup>
- The UM Hospital and Clinics and Sylvester Comprehensive Cancer Center
- Jackson Health System, including Jackson Main, North and South

This comprises the ethics committees for University of Miami Hospital, University of Miami Hospital and Clinics and Jackson's Adult and Pediatric Ethics Committees. The committees are therefore responsible for ethics services at six hospitals, one nursing home and all off-site clinics as detailed by the American Society for Bioethics and the Humanities and the UM Bioethics Program-based Florida Bioethics Network including:<sup>4</sup>

- A 24/7/365 consult service, including consultations required by state law. Many cases deal with end-of-life issues and disputes.
- Hospital policy creation and review. Recent efforts have addressed withdrawing/

<sup>3</sup> This committee is available to The Ann Bates Leach Eye Hospital and Bascom Palmer Eye Institute.

<sup>4</sup> de Velasco RE, Fiore RN, Goodman KW, Moseley R, Spike J, Weldon KM, eds. *Guidelines for Ethics Committees: A Resource for Hospitals, Nursing Homes and Hospices*. Miami: The Florida Bioethics Network, 2011.

- withholding treatment, organ procurement and transplantation, and Ebola preparedness.
- Education on ethical issues for hospital faculty and staff.

Part of this effort has contributed to a complete revision of institutional policies on death and dying, including a nearly complete project to draft and adopt a progressive suite of end-of-life policies, forms and orders for all UM and JMH hospitals. Our work includes guidance on hospital policies ranging from organ transplantation to do-not-resuscitate orders.

We believe our bioethics practice is the largest in the state and one of the largest in the country.

## Research

The Bioethics Program established the University of Miami Miller School of Medicine as the world's leader in research on ethics and health information technology, including policy issues. This pioneering initiative fostered scholarship on diagnostic and prognostic scoring systems, bioinformatics and public health informatics. Recent developments:

- Editorship of a special section on Ethics and Health Information Technology for the *Cambridge Quarterly of Healthcare Ethics*.
- Collaboration with Indiana University to establish a National Center of Excellence for Ethics and Health Information Technology.
- Collaboration with Middlesex University in London on a transatlantic ethics-and-informatics education initiative.

This area of excellence has established, fostered or fertilized recognition in a variety of forms:

- The Bioethics Program Director has been named a Fellow of the American College of Medical Informatics, the only bioethics scholar ever to be elected.
- The *Cambridge Quarterly* editorship, mentioned just above.
- Invited collaborations with the World Health Organization and the European Group on Ethics in Science and New Technologies.

Most generally and especially, the UM Bioethics Program established a new area of research, to wit, scholarship on the ethical issues arising in the use of health information technology or biomedical informatics. Books, articles, conferences and workshops have secured the Miller School's reputation as the first and leading venue for sustaining an important and innovative area of inquiry.

Equally important, our international initiatives and research have established the institution's status as a leader in global bioethics, with extensive partnerships and collaborations in Latin America, Europe and, in conjunction with the CITI Program, Asia. A WHO Collaborating Center, we maintain ongoing projects with the Pan American Health Organization in Washington and WHO headquarters in Geneva. The University of Miami Miller School of Medicine is the only in the country that provides ethics expertise to the European Union's Horizon 2020 Programme, Europe's NIH-like funding entity. A UM ethics faculty member was appointed to serve on the International Research Panel of the Presidential Commission for the Study of Bioethical Issues.

The Bioethics Program also pioneered work on ethics in newborn screening, epidemiology and public health and made noteworthy contributions to the literature in ethics and evidence-based medicine, end-of-life care and feminist bioethics. The program was one of the first sites in the world to develop a suite of consent tools to permit tissue banking for genetic research. Versions of these

tools have been adapted or used by a variety of academic research centers, pharmaceutical firms and the federal government.

We maintain several initiatives related to the research ethics, including:

- **Dialogues in Research Ethics speakers series** provides an opportunity for UM faculty, staff, students, visitors and members of the community to exchange ideas about ethical issues in the relaxed atmosphere of a lunch-time conversation.
- **Responsible Conduct of Research** is a longstanding collaboration with the UM Office of Research to provide, as above, instruction in the the Responsible Conduct of Research. RCR classes are held throughout the year, on all UM campuses, to ensure compliance with NIH and NSF requirements.
- **Research Ethics Consultation Service** is a free resource for students, staff, faculty and administrators confronting ethical issues or questions during the development, conduct, analysis or reporting of research. The RECS service has been a resource to the Miller School for more than 20 years. It is a component of the institution's Clinical and Translational Science Institute (CTSI) grant.

In addition, we have coordinated under the Arsht Ethics Initiatives seven years of grant awards for applied ethics, distributing \$1 million in support for some 50 internal projects in applied ethics.

### *Grants and Funded Projects*

While the CTSI is perhaps the most visible source of external funding, the University of Miami Bioethics Program received an extensive variety of grants and related support. Over 23 years, these grants have supported work on issues ranging from reducing the under-representation of minorities in the biosciences and developing curricula for guardians to ethical issues in personal health records and research ethics in Latin America

The Bioethics Program has earned support for special projects and educational initiatives from the NIH, the Florida Department of Health, the Florida Developmental Disabilities Council, the American College of Epidemiology, the U.S. Department of Education (in conjunction with Miami-Dade Public Schools) and numerous hospitals and other health care organizations, in these cases for support of the annual bioethics conference.

## **Service**

In this section we review Bioethics Program service contributions to the institution; the local community; to state, national and international organizations; and to the academic peer review process.

### *Institutional Service*

Bioethics faculty relish the opportunities of service and contribute to a broad array of Miller School and other UM units. Several ethics faculty serve and have served in key roles on all institutional ethics committees (UM, JMH and the VA), institutional review boards (UM-JMH and VA) and

institutional animal care and use committees (UM and VA<sup>5</sup>). In this way we contribute to core components of clinical practice and research.

We serve on UM's Conflict of Interest Committee and the Executive Compliance Committees, both of which have a major role in Miller School operations and processes.

Over the years we have contributed to institutional committees on privacy and HIPAA, the reopening of Cancer Center trials, and the medical curriculum; we contributed to the LCME re-accreditation process.

We have chaired and served on the Division of Continuing Medical Education's Advisory Board and participated in the unit's reaccreditation.

Also, currently: UMMSM Academy of Medical Educators, IRB Planning Committee, Interdisciplinary Stem Cell Institute Director's Advisory Committee and UM Graduate Faculty (and have served on a number of dissertation committees).

Previously: UMMG Clinical Operations Committee, Embryonic Stem Cell Research Oversight Committee, CITI Executive Advisory Board, Responsible Conduct of Research Educational Initiative Committee, Advisory Group for Education in Human Subjects Protections, Fetal Board Registry, University of Miami Department of Obstetrics and Gynecology, Medical Informatics Programs Steering Committee, etc.

### *South Florida*

Community service is a special privilege, and Bioethics Program faculty are regularly asked to contribute to local entities. The state's leading program confers a number of duties and opportunities, including the Health Council of South Florida Ethics Committee, Miami-Dade County Commission on Ethics and Public Trust, Guardianship Program of Miami-Dade County, Palm Beach County Commission on Ethics, etc. With UMMSM leadership approval, we helped fledge Florida International University's School of Medicine, providing two years of ethics education to FIU students.

### *State of Florida*

Bioethics Program faculty have participated in special projects, or served on committees for the Florida Department of Health, including work on pandemic preparedness and response policies; the Department of Elder Affairs, contributing to educational programs and developing a curriculum in ethics and guardianship; and the Department of Corrections, serving on a Division of Health Care Ethics Committee (disbanded after the committee recommended that physicians not participate in lethal injections).

The DOH has been a consistent supporter of the UM-FBN annual bioethics conference.

Bioethics faculty participated as experts and provided official testimony for a state Panel for the Study of End-of-Life Care charged with revising Florida's law on advance directives; the Bioethics Program director helped draft parts of what is current state law on end-of-life care.

<sup>5</sup> VA contributions have flagged over the past decade, but the VA is noted here to provide historical documentation.

### *United States*

It was a measure of the UM Bioethics Program's status that the Presidential Commission for the Study of Bioethical Issues chose the University of Miami Hospital and Miller School to host a 2013 meeting, on medical counter-measures for children, with a focus on anthrax preparedness. In six years, the other cities hosting the commission are Washington, D.C., Philadelphia, Atlanta, New York, Boston, Chicago, San Francisco and Salt Lake City. In recognition of our international initiatives, a Bioethics Program faculty member was appointed to serve on the Commission's International Research Panel.

UM faculty have worked with the U.S. Centers for Disease Control and Prevention for two decades, helping the CDC develop what in retrospect was the world's first online research ethics curriculum and, more recently, serving on the Ethics Subcommittee of the Advisory Committee to the Director and a Public Health Ethics Collaboration Steering Group. We served on the CDC's Coordinating Office for Terrorism Preparedness and Emergency Response study section.

At the Institute for Medicine, we served on a committee assessing "Strategies to Protect the Health of Deployed U.S. Forces," and reviewed the report of a Committee on Battlefield Radiation Exposure Criteria.

The Bioethics Program's Director has had a longstanding relationship with AMIA (the American Medical Informatics Association), co-founding and serving as the first chair of its Ethics Working Group, two terms as chair of Ethics Committee, as a member of the International Affairs Committee and on the Conflict of Interest Committee. He chaired a Task Force on Vendor Contracts, leading to a key publication in health informatics and public policy.

Also, for the American College of Epidemiology, we provided a consultant to the Ethics Committee and, later, chaired the committee; American Medical Association Council on Ethical and Judicial Affairs, we reviewed a report on "Ethical Guidelines for the Use of Electronic Communication between Patients and Physicians"; and American Society for Bioethics and the Humanities, we served on the first Web Editorial Board.

### *International*

What is perhaps the greatest external validation of the Bioethics Program's efforts came with designation as a World Health Organization Collaborating Centre in Ethics and Global Health Policy. UM's center is one of six in the world, the others being in Canberra, New York, Toronto, Singapore and Zurich. UM faculty chaired the network of collaborating centers and participated in a variety of projects, consultations and reviews. The designation was premised on prior extensive international work and collaborations with WHO programs, including, in our case especially, the Pan American Health Organization.

Since 2012, UM has provided ethics expertise to the European Union, first to the Seventh Framework Programme and currently to the Horizon 2020 Programme; these successive entities function like the NIH by awarding grants in biomedical and behavioral research. As above, the Miller School of Medicine is the only school in the United States that provides ethics expertise to the EU.

We have worked extensively in Latin America for some 20 years and have arguably contributed more to ethics education in the region than any other U.S. program. In part with funding from the NIH Fogarty International Center, we established relationships with individuals and programs in Argentina, Brazil, Chile, Colombia, Costa Rica, Cuba, Guatemala, Honduras, Jamaica and Peru. We maintain a number of formal Memoranda of Understanding with regional universities, and under one of these we have worked for nearly a decade to help fledge an ethics center at the University of the West Indies in Jamaica, Barbados and Trinidad and Tobago. Additionally, we supported the development of nonpolitical ethics education and scholarship in Cuba.

Most recently, we have partnered with Middlesex University in London to try to establish a transatlantic program to study ethical issues in health informatics.

## **SPECIALIZATIONS / CENTERS OF EXCELLENCE**

In addition to the existing research, education, and community service programs currently underway, the new Institute plans to focus efforts and resources on strengthening and expanding two areas of expertise: Global Bioethics and Health Informatics. Support for new faculty in these areas of excellence may be the greatest contribution to the Bioethics Programs' evolution into a fully-fledged institute.

### **Global Bioethics**

Globalization magnifies ethical challenges. These challenges are based on social and epidemiological disparities and the increasing costs of providing healthcare, as well as the ways clinical trials are conducted, their methodological design, and how rules, standards, and cultural practices are translated into international sites, especially as regards research integrity.

Epidemics that were once confined to countries isolated from the developed world now pose threats to industrialized nations, putting at stake their healthcare systems and also creating new ethical dilemmas about justice, surveillance, privacy, stigma, and actions that could affect free travel, individual liberties and privacy.

The Bioethics Program has a quarter-century track record of international activities, including extensive links to global academic centers. As above, UM's leadership in international bioethics provides a platform for truly transformational change and progress. We look forward to an ensemble of research and education opportunities:

- National and international meetings with scholars, NGOs, industry, scientific associations, academia, funding agencies, journalists and other stakeholders for supporting the development of whitepapers, policy guidelines and best-practice statements.
- Continued curriculum development in various languages.
- International scholar and student exchanges.
- Continued robust grant and publication efforts.
- Possible relocation to UM of the leading international bioethics journal, *Acta Bioethica*.

We plan to continue our emphases on challenges created by international data sharing and transnational health data analyses; issues related to priority setting and resource allocation for biomedical research; biosecurity and dual use research; and research integrity.

## Global Health Information Technology

As made clear throughout this document, the UM Bioethics Program has been fortunate to have achieved global leadership in ethics and health informatics. As an institute, we envision a dramatic, dynamic – and visible – transformation.

We are planning, as noted above, the creation of a National Center of Excellence for Ethics and Health Information Technology in conjunction with Indiana University, where the Regenstrief Institute has achieved world leadership in global health research. As mentioned, a collaboration with Middlesex University in London on a transatlantic ethics-and-informatics education initiative will be strengthened by adding international partners.

Our editorship of an international journal section on ethics and health information technology provides enviable underpinning for the documentation of the Miller School's expanding excellence and leadership.

As with the focus on global bioethics, we plan:

- National and international meetings to generate whitepapers, policy guidelines and best-practice statements.
- Curriculum development in various languages.
- International scholar and student exchanges.
- Continued robust grant and publication efforts.

The intersection of our two centers of excellence, "global health informatics ethics", is a precious if not priceless opportunity for UMMSM leadership in education, research and service. When the Bioethics Program was created, we followed a number of intellectual muses and began work in (i) international bioethics and (ii) health information technology. A quarter-century later, UM enjoys its status as a global institution, and ethics-and-informatics is among the hottest topics in the academy and in government and industry.

The creation of Institute for Bioethics & Health Policy at the University of Miami Leonard M. Miller School of Medicine will cement the institution's status as a thoughtful and progressive leader in some of the most important and challenging areas of education, practice and research.

## **Institute Governance and Organization**

The Institute will provide bioethics expertise through a wide range of efforts in education, research, patient care, and community service.

The Institute will be led by a **Director** who will be responsible for articulating and representing the vision of the Institute as well as providing overall leadership and management of the Institute's programs and resources. The Director will report to the Dean of the medical school. The Dean will review the activities of the director annually.

International, informatics and other **Program Directors** will be selected by the Institute's director, in conjunction with the Executive Committee. Each program director will work with the Institute director to oversee, develop and administer such program within the Institute's mission and vision. Program directors will report to and be reviewed by the Institute director. Program directors will hold faculty appointments in an appropriate academic department and will participate in and help guide the intellectual life of the Institute.

The Institute will be served by an **Executive Committee** that will provide advice and assistance on the Institute's management, operations and overall governance including program and project prioritization, resource allocation and strategic planning. The Executive Committee reviews and approves applications for Institute appointments and reviews the Institute's progress every three years. This Committee comprises:

- The Institute Director
- Co-Directors: we currently recognize directors of Pediatrics, post-graduate education, etc. These will be continued.
- Three at-large Institute members identified by the Executive Committee: these members will be University of Miami faculty who are demonstrated leaders in their field and who have established research programs with a strong track record of service, pedagogy and/or research.
- The members will be determined by a majority vote of the Executive Committee and will serve for three-year terms: terms of service are renewable at the discretion of the director.

The Executive Committee should reflect the interdisciplinary nature of the Institute and include representation from several medical school departments. At the discretion of the director, other members of the University research community may be invited to attend Executive Committee meetings.

The Executive Committee will be chaired by the Institute director, who will convene the Committee at least quarterly.

## **Institute Appointments**

Faculty members from all UM campuses and schools/colleges are invited to request and maintain appointments in the Institute through a formal application and review process. All institute members must have a faculty appointment in an academic department, though exceptions may be approved by the director. Membership categories are independent of academic rank. Any interested faculty from the University of Miami or affiliated institutions are eligible for appointment to the Institute according to the criteria listed below. Faculty appointments within the institute are for a three-year term and are renewable.



Criteria for Institute appointment might include one or more of the following:

- Demonstrated interest in bioethics and/or health policy
- Demonstrated research activity in bioethics and/or health policy
- Active or proposed funding in bioethics and/or health policy
- A history of publications in bioethics and/or health policy

Should an applicant be denied membership, the applicant can appeal in writing directly to the Institute director for re-consideration.

### **Space/Facilities**

The Bioethics Program currently occupies and pays rent for space in Dominion Towers. The Bioethics Programs have occupied 10 offices over 23 years. A long-term goal is the acquisition of office, teaching and meeting space commensurate with that of other U.S. bioethics Centers and Institutes. We seek to stimulate interactions among faculty and students, but this is not now possible with our current space.

### **Sources of Funding**

The Bioethics Program has been financially stable for two decades. Since CITI's inception, the Bioethics Program has helped build the CITI Program, providing leadership support, on-line content and international resources that have contributed to CITI's success. CITI funds (approximately \$1 Million) have been put aside to support faculty and post-doctoral appointments and special projects. An Oversight Committee (see organizational structure below) will be appointed by the Dean to monitor the investments of these resources, work with the Director to set the Institute's milestones, and track adherence to the business plan.

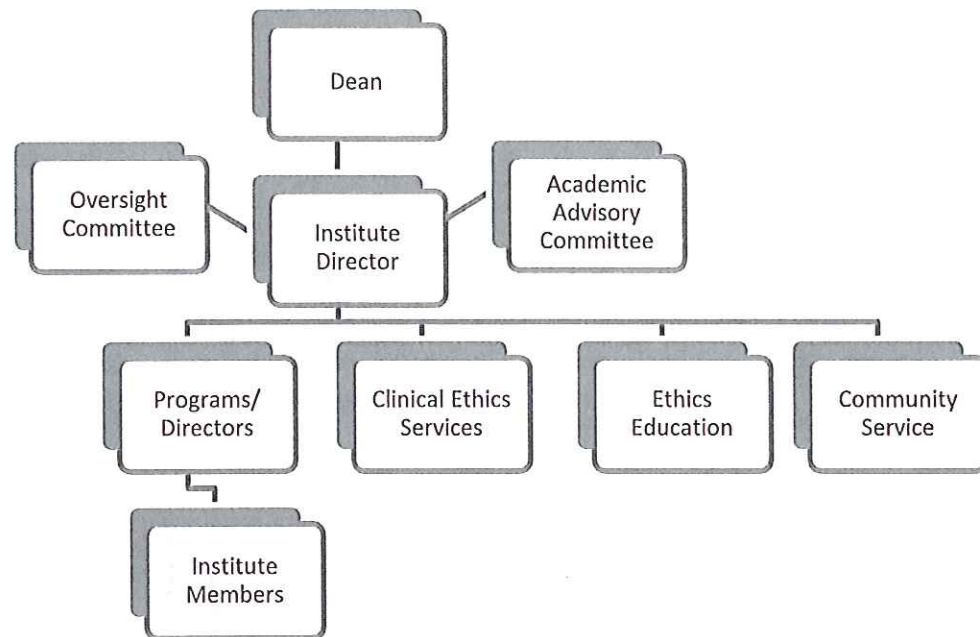
The Institute will also be supported with existing recurrent funds from other, pre-existing sources:

- UM Administration –Medical School/ Dean's Office. The Bioethics Program's core annual budget is approximately \$575,000. It is understood that that sum will be maintained.
- UM and JMH hospital support, currently \$300,000 annually, part of the existing AOA agreement
- Philanthropic support. We plan to use remaining funds from the Arsht Ethics Initiatives to support the Institute's centers of excellence. We estimate this to be approximately \$200,000 annually for the next five years.

All bioethics centers and institutes seek naming gifts. We believe a thriving and visible Bioethics Institute at the Miller School will be attractive to donors, and seek leadership support to help realize a naming gift. All members of the Institute will be expected to seek external funding.

## Organizational Structure

The Institute's director, supervised by the Dean and monitored by the Oversight Committee, supervises the subsidiary programs or centers of excellence and the Institute's various clinical, pedagogic, research and service missions. The Institute's director is also matrixed to the Academic Advisory Committee, which will provide feedback and guidance on academic matters. The chart displays the institute's organizational structure.



## Conclusion

The Institute for Bioethics & Health Policy at the University of Miami Leonard M. Miller School of Medicine has been nearly a quarter-century in the making. Designation as an institute reifies, expands and recognizes the Miller School's bioethics initiative as a leading worldwide entity. Establishment of the Institute is a signal that medical school leadership is committed both to supporting traditional bioethics research and teaching and to making a greater contribution – to a body committed to and with a track record of excellence that parallels that of the school itself.

This Institute's foundations – creative education, innovative research, high-quality clinical service and progressive community contributions – have been recognized regionally, nationally and internationally. We are grateful for the opportunity to continue to build on this platform and to continue to serve the institution in meeting the challenges of 21<sup>st</sup> Century biomedicine.

## **Budget**

The Institute for Bioethics & Health Policy at the University of Miami Leonard M. Miller School of Medicine will have the following revenue stream to support its operations:

### **Budget information redacted**

The planned expansion will be supported by the Provost Investment. All other line items are part of the recurring budget for the existing Ethics Program.

<u>Letter of Support</u>	<u>Title</u>	<u>Approval / Support Letter</u>
Carl Schulman, M.D., M.S.P.H., Ph.D.	Chair, Medical Faculty Council	Approval Letter
Thomas J. LeBlanc, Ph.D.	Executive Vice President & Provost	Support Letter
Pascal J. Goldschmidt, M.D.	Sr. Vice President for Medical Affairs and Dean, UM Miller School of Medicine	Support Letter
Laurence B. Gardner, M.D.	Chief Executive Officer, University of Miami Health System Executive Dean for Education and Policy Miller Professor, and Chair Emeritus, Department of Medicine	Support Letter
Omaida C. Velazquez, M.D., FACS	Executive Dean for Research, Research Education & Innovative Medicine Professor of Surgery	Support Letter
Patricia D. White	Chief, Division of Vascular and Endovascular Surgery David Kimmelman Endowed Chair in Vascular Surgery	Support Letter
Eugene Anderson	Dean and Professor of Law University of Miami School of Law	Support Letter
Leonidas Bachas	Dean, University of Miami School of Business Administration	Support Letter
Otávio Bueno, Ph.D.	Dean, University of Miami College of Arts & Sciences	Support Letter
David W. Kling, Ph.D.	Professor and Chair Department of Philosophy, College of Arts & Sciences	Support Letter
Margaret Pericak-Vance, Ph.D.	Professor and Chair Department of Religious Studies, College of Arts & Sciences	Support Letter
and Stephan Zuchner, M.D., Ph.D.	Director, John P. Hussman Institute for Human Genomics Dr. John T. Macdonald Foundation Professor of Human Genetics	Support Letter
	Interim Chair, Dr. John T. Macdonald Department for Human Genetics Professor for Human Genetics and Neurology	Support Letter

February 11, 2015

Tomas Salerno, M.D.  
Chair, Faculty Senate  
University of Miami  
Ashe Building, Suite #325  
252 Memorial Drive  
Coral Gables, FL 33146

*Re: Council Approved a Proposal for an Establishment for a Bioethics & Health Policy Institute.*

Dear Dr. Tomas Salerno,

This is to inform the Faculty Senate that the Medical School Faculty Council met on February 10<sup>th</sup>, 2015 to review the ***Proposal for an Establishment of a Bioethics & Health Policy Institute.***

The proposal seeks institutional recognition and support to continue to build on what was started more than two decades ago and to reify the administrative status of a thriving program.

The council members voted to *approve* the proposal.

Respectfully submitted,



Carl Schulman, M.D., M.S.P.H., Ph.D.  
Speaker, Medical Faculty Council

UNIVERSITY  
OF MIAMI



Thomas J. LeBlanc, Ph.D.  
Executive Vice President & Provost

P.O. Box 248033  
Coral Gables, Florida 33124-4628

Ph: 305-284-3356  
Fax: 305-284-6758

March 2, 2015

Kenneth W. Goodman, Ph.D., FACMI  
Professor of Medicine  
Director, Bioethics Program  
Leonard M. Miller School of Medicine  
University of Miami  
P.O. Box 016960 (M825)  
1400 NW 10th Avenue, Suite 916A  
Miami, Florida 33136

Dear Ken,

I am pleased to offer my support and provide \$1 million to fund the expansion of Bioethics Program into an Institute for Bioethics and Health Policy at the University of Miami Leonard M. Miller School of Medicine.

The decision to establish a comprehensive bioethics institute is part of the successful evolution of a program which has, under your leadership for more than two decades, advanced ethics research, pedagogy and service institutionally, nationally and abroad.

I am confident that you and your team will continue to be successful in maintaining a pre-eminent role for the University of Miami. I also look forward to expanded service at the Miller School and, indeed, to the rest of the University through interdisciplinary and inter-campus collaborations.

Sincerely,

Thomas J. LeBlanc, Ph.D.  
Executive Vice President & Provost



UNIVERSITY OF MIAMI  
MILLER SCHOOL  
of MEDICINE

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

February 11, 2015

Kenneth W. Goodman, Ph.D., FACMI  
Professor and Director, Bioethics Program  
University of Miami Leonard M. Miller School of Medicine  
1400 NW 10th Avenue, Suite 916A (M825)  
Miami, Florida 33136

Dear Ken,

It gives me great pleasure to write this letter of support for the creation of the Institute for Bioethics and Policy at the University of Miami Leonard M. Miller School of Medicine.

The establishment of this institute is the next step in the evolution of the Miller School's long standing activities in ethics education, research, and service. I am excited by this opportunity, given that the program has a long track record of important accomplishments such as the designation of the program as a 6th World Health Organization Collaborating Center in Ethics and Global Health.

I am fully committed to the success of the Bioethics Institute and endorse its formal establishment.

With best regards,

A handwritten signature in black ink that reads 'Pascal'.

Congratulations!

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

/dr



UNIVERSITY OF MIAMI  
MILLER SCHOOL  
of MEDICINE

Laurence B. Gardner, M.D.  
*Miller Professor of Medicine*  
*Executive Dean for Education and Policy*

February 11, 2015

Kenneth W. Goodman, Ph.D., FACMI  
Professor and Director, Bioethics Program  
University of Miami Leonard M. Miller School of Medicine  
1400 NW 10th Avenue, Suite 916A (M825)  
Miami, Florida 33136

Dear Ken,

This letter is to express my enthusiastic support for your efforts to transform the University of Miami Bioethics Program into the University of Miami Leonard M. Miller School of Medicine Institute for Bioethics and Health Policy.

Bioethics education is essential to the preparation of future physicians and scientists. Over the years, the numerous education projects developed by the bioethics faculty have become a vital component of the medical students' learning experience. This endeavor will become ever more critical as the healthcare environment continues to grow more complex with difficult ethical challenges and scrutiny.

I fully endorse the creation of an integrated and interdisciplinary center in bioethics and look forward to expanding our longstanding collaboration with you and your faculty for the benefit of our medical students.

Sincerely,

Laurence B. Gardner, M.D.  
Executive Dean for Education and Policy  
Miller Professor, and Chair Emeritus, Department of Medicine





UNIVERSITY OF MIAMI  
MILLER SCHOOL  
of MEDICINE

February 11, 2015

Kenneth W. Goodman, Ph.D., FACMI  
Professor and Director, Bioethics Program  
University of Miami Leonard M. Miller School of Medicine  
1400 NW 10th Avenue, Suite 916A (M825)  
Miami, Florida 33136

Dear Ken,

As Executive Dean for Research, I am excited about the creation of the Institute for Bioethics and Health Policy at the Miller School of Medicine.

The Bioethics Program has over the years not only fostered international research initiatives in Latin America and Europe but has been responsible for establishing the medical school's reputation as the first and leading contributor in the area of biomedical informatics research.

I fully endorse the creation of the Bioethics Institute as I am sure that researchers all over the medical school and University will benefit from the new and exciting interdisciplinary research collaborations proposed by the Institute.

Sincerely,

Omaid C. Velazquez, M.D., FACS  
Executive Dean for Research, Research Education and Innovative Medicine  
Professor of Surgery  
Chief, Division of Vascular and Endovascular Surgery  
David Kimmelman Endowed Chair in Vascular Surgery

UNIVERSITY OF MIAMI  
SCHOOL of LAW



Office of the Dean

P.O. Box 248087  
Coral Gables, Florida 33124

Ph: 305-284-2394  
Fax: 305-284-3210  
pwhite@law.miami.edu

Patricia D. White  
Dean and Professor of Law

February 1, 2006

Robyn Hardeman  
Secretary of the Faculty Senate  
1252 Memorial Drive  
325 Ashe Administration Building  
Coral Gables, FL 33146

Dear Robyn:

It is my pleasure to write a letter in support of the creation of a bioethics institute in the Miller School. Such an entity would not conflict with any School of Law mission, program or activity. Indeed, the new institute would be synergistic and I look forward to continued collaboration.

I fully support the efforts of the Bioethics Program. Any program that will heighten the learning process in research, education, and professional services will only increase the benefits to our students, campus, and the community at large.

Sincerely,

A handwritten signature in black ink, appearing to read 'P. White'.

Patricia D. White  
Dean and Professor of Law

UNIVERSITY OF MIAMI  
SCHOOL of BUSINESS  
ADMINISTRATION



Office of the Dean  
P.O. Box 248027  
Coral Gables, FL 33124

Phone: 305-284-4643  
Fax: 305-284-6526

MEMORANDUM

TO: Robyn Hardeman  
Secretary, Faculty Senate

FROM: Eugene Anderson, Dean

A handwritten signature in black ink, appearing to read 'E. Anderson', followed by an exclamation point.

SUBJECT: Creation of an Institute for Bioethics and Health Policy in the Miller School of Medicine

DATE: February 6, 2015

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The School of Business Administration fully supports the creation of the Institute for Bioethics and Health Policy at the Miller School of Medicine. We see no conflict with our own Business Ethics Program or Center for Health Management and Policy at all. Indeed, we envision and welcome opportunities to continue the long-standing collaboration among the faculty involved in all endeavors.

I enthusiastically support the creation of this institute and I look forward to continuing to work with the Faculty Senate regarding this and other initiatives.

EWA:

UNIVERSITY OF MIAMI  
COLLEGE of  
ARTS & SCIENCES



Office of the Dean

1252 Memorial Drive  
Ashe Building, Suite 227  
Coral Gables, Florida 33146

Ph: 305-284-4117  
[www.as.miami.edu](http://www.as.miami.edu)

February 13, 2015

Kenneth W. Goodman, Ph.D., FACMI  
Professor and Director, Bioethics Program  
WHO Collaborating Center for Ethics and Global Health Policy  
University of Miami Miller School of Medicine  
POB 016960 (M-825)  
Miami FL 33101 USA

Dear Ken,

I would like to express my support for the proposed creation of an Institute for Bioethics and Health Policy. I see no conflict with the name designation in the College of Arts and Sciences. I wish you success in obtaining approval. I look forward to continuing our collaborations.

Best regards,

Leonidas Bachas  
Dean

UNIVERSITY  
OF MIAMI



Department of Philosophy  
P.O. Box 248054  
Coral Gables, Florida 33124-4670

Phone: 305-284-4757  
Fax: 305-284-5594

February 14, 2015

Kenneth W. Goodman, Ph.D., FACMI  
Professor of Medicine  
Director, Bioethics Program  
Leonard M. Miller School of Medicine  
University of Miami  
P.O. Box 016960 (M825)  
Miami, Florida 33136

Dear Ken,

I am delighted to hear of the advancing initiative to create an Institute for Bioethics and Health Policy at the University of Miami Miller School of Medicine.

This is truly wonderful news. It is not only recognition of your years of effort: it is an affirmation of an equal number of years of very close collaboration between the Bioethics Program and the Department of Philosophy—collaboration which has provided countless valuable opportunities for our students.

Your faculty affiliation with our Department has been an exemplar of inter-campus effort. Your willingness to mentor our students, work with our faculty and help supervise the special summer ethics internship program—which you created!—are indicators of a rare symbiosis.

I am therefore writing to express my enthusiastic support of the creation of the new Institute, and very much look forward to years of continued collaboration.

Please let me know how I can help to assure the success of the new Institute.

Sincerely,

Otávio Bueno, Ph.D.  
Professor and Chair  
Department of Philosophy

Cc: Dean Leonidas Bachas, College of Arts & Sciences

UNIVERSITY  
OF MIAMI

COLLEGE of ARTS & SCIENCES



Department of Religious Studies Ph: 305-284-4733  
P.O. Box 248264 Fax: 305-284-2772  
Coral Gables, Florida 33124-4651 umrelstud@miami.edu

February 13, 2015

Kenneth W. Goodman, Ph.D.  
Professor and Director, Bioethics Program  
Leonard M. Miller School of Medicine  
University of Miami  
P.O. Box 016960 (M825)  
Miami, Florida 33136

Dear Ken,

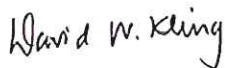
This letter is to express my enthusiastic support for the establishment of an Institute for Bioethics and Health Policy at UM's Miller School of Medicine.

My predecessors have made clear the extent of the Bioethics Program's collaborations with the Department of Religious Studies over the years. They laid an important foundation, and I look forward to its evolution under the new Institute. The cooperative endeavor between the Department of Religious Studies and the Institute will greatly enhance our department's track on religion and health care as well as the College's recently established Medical Humanities Minor.

Please let me know what I can do to further these exciting interdisciplinary efforts.

My keen support for the creation of the new Institute comes with a willingness to work with you on these efforts.

Very best regards,



David W. Kling, Ph.D.  
Professor and Chair  
Department of Religious Studies

Cc: Leonidas Bachas, Dean, UM College of Arts & Sciences

February 27, 2015

Kenneth W. Goodman, Ph.D., FACMI  
Professor of Medicine and Director, Bioethics Program  
Leonard M. Miller School of Medicine  
University of Miami  
P.O. Box 016960 (M825)  
Miami, FL 33136

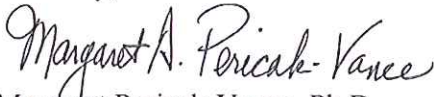
Dear Ken,

Thank you for the opportunity to express our full and enthusiastic support for the creation of the Institute for Bioethics and Health Policy at our medical school.

Such an entity will foster precisely the kinds of collaboration we have contemplated. Ethics plays a huge role in genome science, and the John P. Hussman Institute for Human Genomics and the Dr. John T MacDonald Department for Human Genetics are eager to help foster such collaboration. These are exciting times in the evolution of genomic research, and it pleases us both to be able to insure that we include attention to the ethical issues our work raises.

All good wishes for the success of the new Institute.

Sincerely,



Margaret Pericak-Vance, Ph.D.  
Director, John P. Hussman Institute for Human Genomics  
Dr. John T. Macdonald Foundation Professor of Human Genetics



Stephan Zuchner, M.D., Ph.D.  
Chair (Interim), Dr. John T MacDonald Department for Human Genetics  
Professor for Human Genetics and Neurology