



MEMORANDUM

To: Donna E. Shalala, President

From: Richard L. Williamson
Chair, Faculty Senate

A handwritten signature in blue ink, appearing to read 'Richard L. Williamson', is written over the 'From:' field.

Date: October 27, 2011

Subject: Faculty Senate Legislation #2011-19(B) – Establish a Master of Science in Clinical and Translational Investigation

At its October 26, 2011 meeting, the Faculty Senate unanimously approved the establishment of a Master of Science in Clinical and Translational Investigation. The proposal explains that the 30-hour curriculum will “provide training to students who have or are pursuing clinical degrees (MD, PhD) and those pursuing non-clinical degrees (PhD, DSci) who are interested in expanding into the field of clinical and translational research.” Courses will include biostatistics, bioinformatics, ethics, community-based research and health disparities, genetics and genomics, and an overview seminar in clinical and translational research current topics. This program comes in response to the evolution of the new discipline of translational science and the focus on developing a “workforce capable of translating research findings in a way that directly address and reduce health disparities” over the last 20 years.

The supporting materials are enclosed for your reference.

This legislation is now forwarded to you for your action.

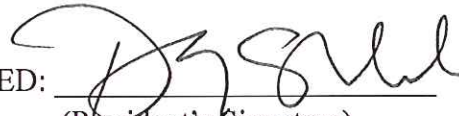
RW/rh

Enclosure

cc: Thomas LeBlanc, Executive Vice President and Provost
Pascal Goldschmidt, Senior Vice President and Dean, Miller School of Medicine
John Bixby, Sr. Associate Dean for Graduate and Postdoctoral Studies, Miller School of Medicine
Daniel Armstrong, Presenter and Professor, Miller School of Medicine
Joshua Hare, Presenter and Professor, Miller School of Medicine
Teresa Scandura, Dean, The Graduate School
Office of Planning, Institutional Research and Assessment
Office of the Registrar

CAPSULE: Faculty Senate Legislation #2011-19(B) – Establish a Master of Science in Clinical and Translational Investigation

PRESIDENT’S RESPONSE

APPROVED:  DATE: 11/1/11
(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): _____

Proposal: Master's Degree in Clinical and Translational Investigation

1. Rationale

a. Title of Degree. Master of Science in Clinical and Translational Investigation

Executive Summary

This Master's of Science in Clinical and Translational Investigation (MScTI) at the University of Miami is being established to create a structured educational program that offers trainees of diverse cultural and educational backgrounds formal graduate training in the principles and practice of translational science and clinical research. Our highly integrated, cross-disciplinary program has been designed to further the new discipline of translational science by providing a foundation for the development of future practitioners and leaders of translational science who are prepared to deal with the perceived bottlenecks that inhibit translational research: institutional culture and practice, scientific complexity of translational research design and methodology, and regulatory and ethical processes. The overall goal of this curriculum development award is to engage promising new and Early Stage Investigators in the discipline of translational science, so that they make the pursuit of academic translational science their own professional goal. The program will provide training to students who have or are pursuing clinical degrees (MD, PhD) and those pursuing non-clinical degrees (PhD, DSci) who are interested in expanding into the field of clinical and translational research. A 30-hour curriculum will include courses in biostatistics, bioinformatics, ethics, community based research and health disparities, genetics and genomics, and an overview seminar in clinical and translational research current topics. Each student will complete a research proposal (6 credit hours) that focuses on a translational research topic.

b. Purpose and Goals.

In the 1990s, Congress supported a doubling of the National Institutes of Health (NIH) budget for health research, but with this financial expansion came an expectation that the funded research would have a defined link to improvement in the health of the American people. This expectation led to a reorganization of priorities at the NIH. While basic and clinical research remain the primary methods for obtaining new knowledge, the leadership of the NIH and broader scientific community recognized that a new strategy and methodology was needed to promote the linkages between basic laboratory investigations, clinical investigations, applications of clinical trials outcomes in community settings, and decisions about public health policy. One outcome of this recognition was the creation of the NIH Roadmap, with funding priorities that emphasized multi-disciplinary and trans-disciplinary approaches to translating discoveries in one research paradigm to another, ultimately leading to improved health outcomes.

As a result of this funding priority, a new discipline of translational science gradually evolved. This discipline provides a structure that expedites the translation of important discoveries that improve healthcare into practical applications. This evolution forced changes in how we view basic and clinical science, since in this new paradigm, neither basic nor clinical research is considered an end unto itself, but instead part of a sequence of research activities along a continuum, each informed by the activities of the others. Such discoveries typically begin at "the bench" with basic research in which scientists study disease at a molecular or cellular level, then progress to the clinical level, or the patient's "bedside" and into the community. Basic scientists provide clinicians with new tools for use in patients and for assessment of their impact, and clinical researchers make novel observations about the nature and progression of disease that often stimulate basic investigations. Unfortunately, the discoveries of many studies fail to be translated to usable knowledge and therapies to change medicine and improve health in the clinic and community. Barriers in this process have been identified at three junctures, designated T1, T2 and T3.

For purposes of this proposal, we use the following definitions:

- T1 is the threshold of translation of basic, laboratory research to human and clinical application, largely through clinical trials. T1 research brings novel understandings of fundamental biology to “first-in-human” and then to clinical research studies;
- T2 is the threshold of translation of controlled human/clinical studies to clinical settings in the community; and
- T3 is threshold of translation of clinical observations in communities to health services, health policy, and health care guidelines and activities that need to be adapted in order to change clinical care and population health.

These barriers present themselves in various areas of medical science. The pharmaceutical industry, for example, supported discoveries in genomics, biologics, nanotechnologies, and stem cell treatments, but the translation of these basis findings to the development of new drugs with clinical applications (a T1 issue) are ‘disturbingly limited’ (Roehr, 2010). Exciting progress has been achieved in the basic science of gene therapy, yet patients with genetic disease are not yet routinely treated with new gene therapies, largely due to health policy decisions (a T3 issue). The same can be said for advances in the field of neuroscience that have lead to numerous clinical trials that have shown improvement of psychiatric disorders, yet physicians still address these diseases with treatments based on research from 30 years ago (a T2 issue). “The uncomfortable truth is that scientists and clinicians have been unable to convert basic biology advances into therapies or resolve why these conversion attempts so often don't succeed” (Nature, 2010).

The issue is exacerbated with growing barriers such as (a) increasing complexity and sophistication of scientific research design, (b) compliance with regulatory and ethical processes, and (c) workforce and culture in academic institutions. Each of these barriers has, in one way or another, hindered the flow of information between the lab and the health of the community at a time when the need for translation is most eminent. With an aging population, rising health care costs, and an increase in technology, there is a need for creating translational research training. The world’s academic institutions have the intellectual and scientific resources to enable them to develop action plans based on science and assume a greater degree of responsibility for global health (Adli et al., 2010).

The NIH recognized this desperate need for a revitalization of the way clinicians and researchers practice science and have allocated many resources towards schools and programs that wish to “synergize multi-disciplinary and inter-disciplinary clinical and translational research and researchers to catalyze the application of new knowledge and techniques to clinical practice at the front lines of patient care” (NIH Re-Engineering the Clinical Enterprise, para 7). Over 30 academic medical centers developed Masters in Clinical and Translational Research or Investigation, including institutions such as Duke University, University of California San Francisco, and University of Florida.

Like these other institutions, the University of Miami has the opportunity to contribute to the development of a workforce of clinicians and scientists who are prepared to work in a world where translational approaches to research are the norm rather than the exception. We also have an opportunity and obligation to serve, train, and address healthcare concerns of the many underrepresented populations who inhabit South Florida, particularly in the University’s surrounding communities, thus contributing to the development of a workforce capable of translating research findings in a way that directly address and reduce health disparities. According to the Agency for Healthcare Research and Quality (AHRQ), 17 percent of Hispanic, and 16 percent of black Americans report they are in only fair or poor health, compared with 10 percent of white Americans. These ethnic groups make up nearly 70% of the South Florida population. The Institute of Medicine has recommended that one strategy to improve health outcomes and reduce health disparities related to access and social/ethnic status for individuals of diverse ethnic and cultural backgrounds is to improve the diversity climate of the physician workforce (Smedley, et. al., 2004). Minority patients report higher levels of satisfaction and participation when cared for by minority physicians (Cooper-Patrick, et al, 1999). Likewise, ethnic minority physicians are more likely to practice in underserved neighborhoods and care for patients of similar race/ethnicity and low-income patients (Moy, 1995), increasing access to care. Ethnic diversity in medical schools is associated with enhanced educational experience to all students (Corbie-Smith, et. al., 1999). Importantly, minority faculty serve as role models and mentors to trainees. Therefore, a companion goal of the

MS in Clinical and Translational Investigation is to recruit and train doctors and scientists who will be prepared to appropriately address and reduce health disparities that face our South Florida residents.

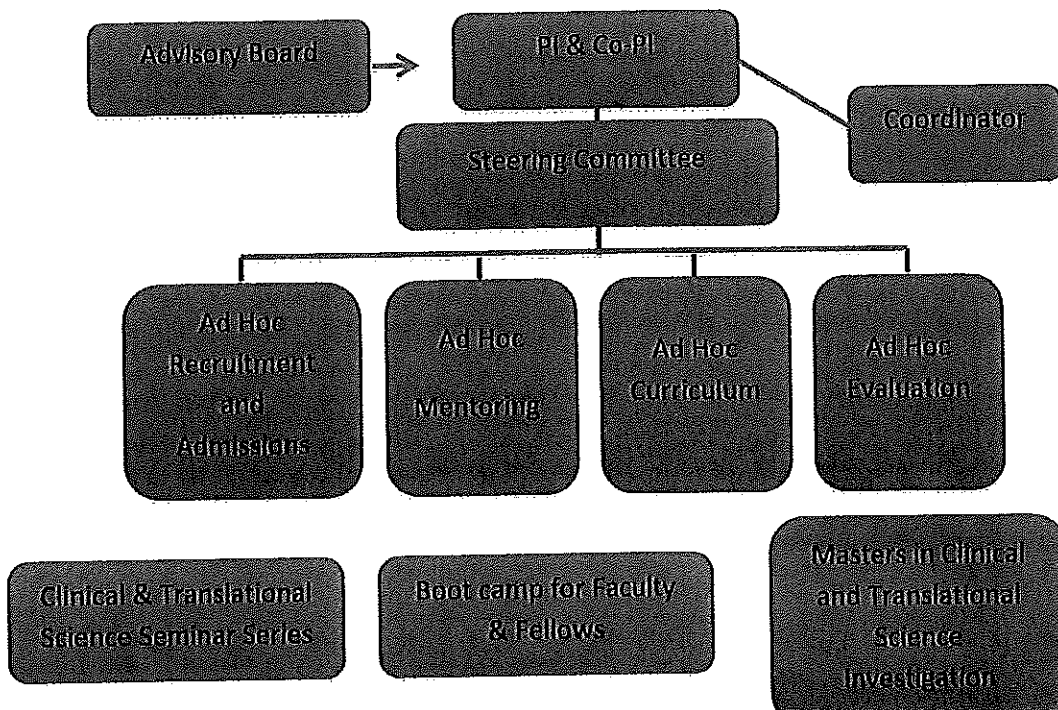
This Master's of Science in Clinical and Translational Investigation (MSCTI) at the University of Miami is being established to create a structured educational program that offers trainees of diverse cultural and educational backgrounds formal graduate training in the principles and practice of translational science and clinical research. Our highly integrated, cross-disciplinary program has been designed to further the new discipline of translational science by providing a foundation for the development of future practitioners and leaders of translational science who are prepared to deal with the perceived bottlenecks that inhibit translational research: institutional culture and practice, scientific complexity of translational research design and methodology, and regulatory and ethical processes. The overall goal of this curriculum development award is to engage promising new and Early Stage Investigators in the discipline of translational science, so that they make the pursuit of academic translational science their own professional goal.

This program will initially serve three groups of individuals:

- 1) Individuals who have completed terminal healthcare degrees (e.g., MD, PhD, DO, RN) who are interested in pursuing additional formal didactic training to become independent investigators in clinical and/or translational science;
- 2) Individuals who have completed terminal scientific degrees (e.g., Ph.D., DSci) who are interested in pursuing additional formal didactic training to improve knowledge and skills related to translation of basic to clinical applications; and
- 3) Individuals who are currently enrolled in a terminal degree program (e.g., MD, PhD) who are interested in adding a year to their program to obtain a MCTSI concurrent with their terminal degree.

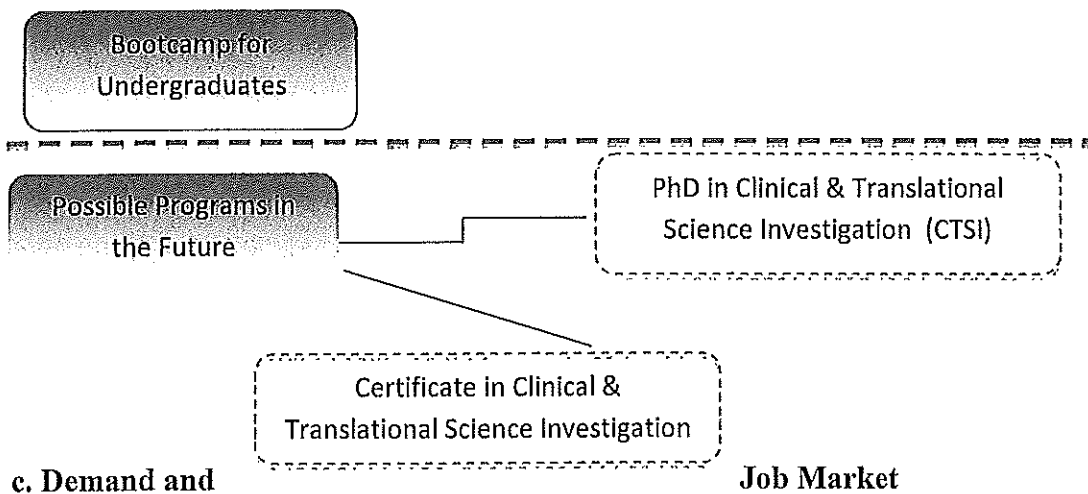
This MCTSI proposal is the central component of a K30 Training Grant ("UM Graduate Training Program in Translational and Clinical Investigation" -1-K30-RR030288-01) that was funded in 2010. The K30 is overseen by a PI (Daniel Armstrong, PhD, Professor of Pediatrics and Director of the Mailman Center for Child Development) and Co-PI (Joshua Hare, MD, Professor of Medicine and Director of the Institute for Stem Cell Institute- ISCI). An Advisory Board, comprised of senior faculty from across the University of Miami, meets annually to review progress and plans for the K30. A Steering Committee, comprised of interdisciplinary core faculty from the teaching program, assists Drs. Armstrong and Hare with program development and implementation. Ad hoc working groups are formed from the membership of the Steering Committee to address program needs in the areas of curriculum development, recruitment and admissions, mentoring, and evaluation. (See Figure 1)

Figure 1: Organizational Structure of the K30



The K30 includes several training components. The MSCTI is the core feature of the grant, but we also implement week-long, 40 hour intensive training programs on clinical and translational science each year for faculty and fellows (Bootcamp). We also have plans to implement a Bootcamp for undergraduates at some point in the 3-year grant cycle. We have designed a seminar series that will begin in the Fall of 2011 to promote clinical and translational science for the larger University community. This is a weekly, hour-long seminar held on Wednesday afternoons that features both invited speakers from UM and from other institutions. We also anticipate that after the MSCTI is implemented, we will develop a certificate program in Clinical and Translational Science Investigation for individuals with Bachelor or Master degrees who work as research coordinators (e.g., RNs, ARNPs, Clinical Research Associates). This program will also be integrated into a planned Ph.D. in Clinical and Translational Science that is part of the University of Miami's Clinical and Translational Science Institute (CTSI) pending funding from the NIH (June, 2011). (Figure 2)

Figure 2: K30 Program Components



c. Demand and

Job Market

With the recent global trend calling for academic institutions to stand at the forefront of translational programs, and the government's allocation of funds towards translational research, the demand for physician-scientists who are able to conduct translation research at every level is increasing. Because this is a new and emerging field that represents a transformation in concept and practice, the workforce is small but growing, and it appears that there will be many opportunities for scientists trained in this area.

The translation of research and education into health gains and the transformation of research and scientific innovation into policy changes have international implications. The 2010 World Health Summit concluded that academia, health-care and social systems must collaborate and have a mutual understanding to improve the health of individuals world-wide. Scientists from all fields should be engaged in the influence of policy, assuring that "policy makers should not be left to interpret research" (Adli, 2010). This international call for a strong globalization process in medical education that differentiates and supports diverse medical career models supports the need for young scientists who have the appropriate training to fill future positions in government and in the newly developed training programs that focus on translation of science to practice and policy. Institutions have started to recognize that "if you give [basic scientists] the vocabulary of medicine and a sense of how physicians think about problems that they encounter with patients, they'll find it easier to do research that is both scientifically rigorous and relevant to disease processes and patient care" (Carpenter, 2007).

At the national level, the Patient Protection and Affordable Care Act (PPACA; HR 3590) of 2010 has brought into sharp focus the need and opportunity for an expanded continuum of biomedical research. The PPACA places a deliberate emphasis on patient- and population-outcome-oriented science and the development of preventative health care strategies. Current "silo" approaches to research produce barriers that hinder positive patient outcomes; translational research is a major strategy to overcoming these barriers, and training of young scientists is essential to provide the workforce necessary for such fundamental change. This kind of transition is

not unprecedented. In the 1960s, President Kennedy and his sister, Eunice Kennedy Shriver, initiated a national effort to address the health and education needs of individuals with several intellectual and other disabilities. These efforts led to the establishment of the National Institute of Child Health and Human Development (NICHD), passage of laws mandating special education, and efforts to move individuals with disabilities out of institutions and into communities. Evident from the beginning was the lack of a workforce to implement this monumental national change. From that awareness, Mrs. Shriver and Dr. Robert Cook of Johns Hopkins University designed a federal program to build facilities devoted to training interdisciplinary scientists and practitioners to address the workforce needs of the new federal initiatives related to disability. The University of Miami's Mailman Center for Child Development was one of the original eleven University Affiliated Centers built and funded for this purpose. Today, the Clinical and Translational Science Award (CTSA) represents a similar federal initiative to implement research and training to address the translational research needs of the next decades. Like the early disability initiatives, the clinical and translational science initiative is also incentivized; universities and their research faculty who are poised to respond to the translational opportunities have greater access to grant funding as scientists and clinicians making breakthroughs in translational research are giving priority in a number of funding mechanisms.

According to an article in *Science Careers*, demand for The Mayo Clinic's master's program and a 1-year certificate program in clinical and translational science, both aimed mostly at M.D.'s, "has mushroomed...and enrolls more students than all other master's programs at Mayo together" (Carpenter, 2007). The article quotes Sherine Gabriel, director of education resources at the Mayo Clinic who says, "There is such a hunger to do this. My biggest challenge is dealing with the queue outside my door."

http://sciencecareers.sciencemag.org/career_magazine/previous_issues/articles/2007_08_17/caredit.a0700117

The University of Miami does many things well, but the recruitment of clinical trainees from graduate clinical programs (MD & clinical PhD) and our residencies and fellowships into productive academic career is a weakness that has been recognized in numerous federal reviews of our programs. The number of training grants (e.g., T32s) is smaller than would be expected of a top-50 NIH funded research university, and one of the criticisms of continuation applications for existing training grants has been the lack of impact in science after completion of the training program. In contrast, we produce top clinicians who have had considerable clinical expertise and are able to handle the most complex clinical cases, and often contribute clinical observations that are the stimulus for other investigators research ideas. Unfortunately, these outstanding clinical graduates typically transition to clinical practice and do not pursue careers as clinician-scientists. While we need outstanding clinicians, the need for clinicians who are able to work with basic, community, and policy scientists and experts to implement team approaches to translational challenges is at least as critical.

Over the last year the Education and Career Development Committee of the Miami Institute for Translational Medicine in Diverse Communities has met weekly with multiple faculty members and trainees from essentially all areas of our medical campus to explore ways to increase the relevance of academic medicine as a career choice for our trainees. The general consensus is that (1) we truly need effective mechanisms to develop academic careers and (2) by the time trainees are exposed to clinical research it is too late in their career-planning trajectory. Participants in these meetings expressed concern that clinical students and trainees at the University of Miami are missing early exposure to research, particularly to translational science, followed by in depth programs of translational and clinical research training.

To address these concerns, since 2007 UM has offered "Foundations of Translational Science Bootcamp," a full-time, one-week endeavor in which senior members of the faculty from disciplines across Schools and Departments present overviews of key topics along with their own research. This Bootcamp exposes young scientists to translational research at an impressionable time in order to have an impact on career choice. Not only have we found the time, work and money from this program highly gratifying, but results have shown that 54% of Bootcamp attendees wish to pursue additional research training or degree programs that are not readily available.

Within Florida, there is only one existing program in Translational Science, located at the University of Florida (UF), which was awarded a CTSA in 2008. A required part of the CTSA is a training program in clinical and translational science. UF has developed a training program that is similar to our proposed

curriculum. UF's core courses focus primarily on topics in Epidemiology, Biostatistics, Ethics, and Literature Review. Given that the UF program emphasizes training for those already employed or in residency at the University, the UF program would not pose a direct competition to this MSCTI proposal, and might even be complementary to our effort. The existence of the UF program does, however, provide a Florida benchmark for the success of the UM MSCTI.

In addition to UF, the 59 other institutions awarded CTSA's employ a similar training program, as it is a requirement of the Education and Training Component of the award. ("CTSAWeb," n.d.) Of the top twenty-one-ranked medical schools in the country, all have NIH funding for this grant. For the remainder of the top fifty-ranked, almost every school, with the exception of a few institutions, has either a CTSA or a K30 award ("US News Education," 2011 and "CTSAWeb," n.d.). This degree is prevalent amongst the most prestigious medical institutions in the United States, a group to which the University of Miami belongs, ranked 45 ("US News Education," 2011). Therefore, this degree would be a smart addition in order to remain comparable with other institutions of our caliber,

d. The relationship of the proposed program to other cognate fields

According to *Science Careers*, "translating research--taking an innovative scientific idea from the lab, through clinical testing, then into clinics and the community--takes a village of talented scientists from a variety of fields" (Webb, 2009). This observation is supported by a new vocabulary in research that emphasizes interdisciplinary and transdisciplinary collaboration and team science, and funding opportunities that are restricted to investigators providing evidence of this kind of research approach. Since the idea of translational research stems from a holistic, extensive and well-rounded knowledge base, we plan to implement this MSCTI degree using an interdepartmental, cross-disciplinary approach. This starts with the leadership of our program by Daniel Armstrong, PhD (psychology and pediatrics; Director of the Mailman Center for Child Development and the UM Sickle Cell Center) and Joshua Hare, MD (clinical cardiology and basic stem cell research; Director of the Interdisciplinary Stem Cell Institute), two senior faculty members whose research careers have consistently involved an interdisciplinary and translational focus. Our core and elective curriculum elements are drawn from existing courses in various departments such as Epidemiology, Computer Science, Political Science, Genetics and Genomics, Psychology, and many others. The program's committees consist of equal if not more multiple disciplines including representatives from Pediatrics, Medicine, Biomedical Engineering, Neuroscience, and the School of Nursing and Health Studies. More detailed information on specific courses from each department will be outlined in section 3.e.

e. Discuss the relationship of the proposed program to undergraduate and professional programs.

i) Relationship to undergraduate programs Exposure to translational research at an early stage is crucial in the impact of career choice for young scientists. The Bootcamp, in modified form, is an ideal mechanism to engage undergraduates by providing early exposure to the field of clinical and translational research. As part of the K30 training grant, we are exploring implementation of a Bootcamp for undergraduates during the third year of the grant period (see Figure 2). In anticipation of this, we have begun tailoring our existing Bootcamp to meet the needs of undergraduates in a science track. The undergraduate Bootcamp experience will include a similar broad exposure to that provided in our existing Bootcamp for fellows and junior faculty. Its purpose will be to generate interest in a translational science career and offer opportunities for networking. Naturally, most undergraduate students have a less defined view of their futures as compared to graduate students, so our involvement at this stage will provide better insight into the scientific opportunities available after completing their undergraduate degree.

ii) Interdepartmental Collaboration and Relationships to Other Professional Programs

As stated above, the composition of our curriculum and our Steering Committee structure draws from a large cadre of departments from all three of UM's campuses. In developing this program, we have held numerous meetings with faculty from diverse departments at UM. We have assembled a steering committee for the K30 and the MSCTI that consists of faculty from these various departments. The Steering Committee has two primary functions: (1) to facilitate the integration of existing UM courses into the MSCTI curriculum in a

manner that is seamless and non-disruptive to department efforts, and (2) to jointly and iteratively develop modifications of existing courses and eventually new courses that integrate clinical and translational concepts both into the core of each course and across all of the courses. Not only are we proposing a new degree program, but we are implementing a plan that will, over time, develop a knowledgeable, integrated faculty in clinical and translational science at the University of Miami. This approach is crucial to the success of the MSCTI to ensure that our program will be interdisciplinary and will offer a "value-added" benefit to the existing disciplinary training and degree programs. In addition to this core Steering Committee, we have assembled Advisory Board of senior faculty and research leaders to guide the implementation of the program (Cheung, Bixby, Sacco, McCain) (see Figure 1 above).

At the initiation of this new MSCTI, the majority of the core coursework will included existing graduate courses at UM. The impact on these existing courses will be minimal, since we anticipate that the initial participation (two to three years) will be limited to between five and eight students. At the beginning, there will be significant overlap with existing Masters and PhD programs that use these same courses, with the exception of the introductory overview course and the 6-hour research requirement. The greatest similarity will be with the Masters of Public Health or Masters/PhD in Epidemiology. As this new field and MSCTI evolve, we plan for this overlap to diminish as courses with specific clinical and translational science focus and content to form the core of the MSCTI. The timeline for evolution of these significantly modified/new courses is three to four years following program initiation. The modified/new courses will be developed by the Steering Committee working in close collaboration with faculty and administration of the departments and schools where these courses will be housed. We envision no restrictions that would limit students in other degree programs from taking these courses as electives, given permission of their core program.

Strategies used throughout the program are planned with a goal of building and mentoring cross-disciplinary groups of experts in translational investigation and clinical research. Our Steering Committee (see Figure 2) will include faculty with research and teaching expertise in bioethics, genetics, epidemiology, bioinformatics, health disparities, community-based participatory research, behavioral research, laboratory science, and clinical trials.

Courses in our curriculum include the departments of Epidemiology, Biostatistics, Genetics and Genomics, Computer Science, Ethics, Education, Business, and Biostatistics. The degree caters to anyone in the health science field. We envision that graduates from this program will gain a perspective of disease, medicine and research influenced by integration of multiple various disciplines leading to innovative translational research that will improve the outcomes for individuals and communities.

2. Physical Resources

a. Library analysis

i. Resources, services, and subject specialists currently available. Students will have access to the UM libraries on the Coral Gables (Richter) and Medical (Calder) campuses. These libraries have physical collections of books, library resources, extensive journal collections, and other resources. The libraries are somewhat independent since medical school libraries are part of a different library system. Richter is the central library for UM. Most importantly, both libraries have on-line subscriptions to a wide range of journals as well as extensive access to on-line reference systems (e.g., Pub Med). Since the field of clinical and translational research is rapidly emerging, much if not most of the reference materials needed by students will be current or recently peer-reviewed journal articles.

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b. Teaching and Computing Infrastructure

The infrastructure for teaching for the courses that will be included as part of the MSCTI is already established, since existing courses will form the foundation for the program during its beginning years. Classrooms are available across the medical campus in the Clinical Research Building (CRB), Rosensteel Medical Sciences Building, Bachelor Children's Research Institute, and Mailman Center for Child Development. The computing infrastructure is also in place with access to the medical information system using both T1 lines and wireless access from most buildings on the campus. Videoconferencing facilities are available in the Bachelor Children's Research Institute and the Mailman Center, and the information technology infrastructure includes access to web-based training through Blackboard stream-video archiving of lectures. Funding has been included in the K30 Grant to support the archiving of lectures from the Bootcamp and monthly seminars. There are two auditoriums available for the program. The university-wide weekly seminar will be held in the auditorium of the Mailman Center for Child Development and the Bootcamp will be held at the auditorium of the RSMAS.

c. Other physical equipment necessary for the graduate program.

The MSCTI will be housed in the Department of Pediatrics, where the K30 grant is housed. The Department of Pediatrics includes the Mailman Center for Child Development and the Bachelor Children's Research Institute. The coordinator for the MSCTI will be housed in either the Mailman Center for Child Development, or optimally, because of proximity to the planned location of the CTSI and majority of student classes, near the office of Research and Graduate Education in the Clinical Research Building. The reason for this location is to assure that the coordinator has regular opportunities for interaction with staff of the CTSI, the yet- to- be developed PhD in clinical and translational research, and to be located in the facility where the majority of courses in the program are being taught.

The plan for the MSCTI includes completion of six hours of co-mentored research plan development, leading to the completion of a K-award, R21 or R01-type application. Students will also have hands-on training in existing research laboratory settings. These experiences will be associated with the labs of research mentors located on the Coral Gables, Medical, or RSMAS campuses. Research labs, for purposes of this program, may include basic science (wet-bench or animal), clinical settings, or community settings.

3. Curriculum

a. Major divisions.

All students in the MSCTI will complete eight courses in a core set of content areas. These include:

- Overview of Clinical and Translational Research (Required of MSCTI students)
- Biostatistics

- Ethics
- Community Based Research & Health Disparities
- Genetics & Genomics
- Bioinformatics
- Epidemiology

The specific course taken in each content area will vary based on prior coursework and experience. We anticipate that none of our MSCTI students will have significant mastery of content information in all of the selected areas, but some may have significant prior exposure in a few. For this reason, some students may elect to take courses that are more advanced than those taken by their peers in some content areas, and basic content courses in areas for which they have less exposure. Students will then have the opportunity to take an additional elective course in any of these fields, or with the approval of the Steering Committee, courses in other relevant areas.

Upon completion of coursework, students in the MSCTI will have the opportunity to emphasize a research focus in any of the three types of translational research, T1 (bench to clinical), T2 (clinical trial to community), or T3 (clinical/community to public policy or health services research. Each student will have two mentors for their research project, one from each of their area of emphasis. Thus, students interested in T1 research will have co-mentors, one from the basic sciences, and one from the clinical sciences. This same model will apply to T2 and T3 translational research.

Mentors for these projects will be recruited from our Steering Committee and core faculty, as well as other senior faculty who supervise post-doctoral fellows and junior faculty who are supported by K-awards and other new investigator mechanisms. An incomplete listing of likely mentors during the first two to three years includes:

Basic Research

Joshua Hare, MD(see 3.d.iv)

Dalton Dietrich, PhDDr. Dalton Dietrich is Scientific Director at The Miami Project to Cure Paralysis at the University of Miami Miller School of Medicine. For the last 25 years, his laboratory has been working on investigating various pathophysiological mechanisms associated with neuronal vulnerability, including cytotoxicity, free radicals, apoptosis and inflammatory cascades.

Clinical Research

Daniel Armstrong, PhD (see 3.d.iv)

Gwendolyn Scott, MDGwendolyn B. Scott, MD is the Director of the Division of Pediatric Infectious Disease and Immunology and Professor of Pediatrics. She is a clinical investigator who has been funded since 1987 as a Principal Investigator for several NIH grants including the International Maternal, Pediatric and Adolescent AIDS Clinical Trials Grant (IMPAACT), several grants to study the natural history of HIV infection in children as well as a laboratory based grant to study the immune and viral correlates of HIV progression.

Neil Schneiderman, PhDDr. Neil Schneiderman is Professor and Director of the Health Division of the Department of Psychology and director of the Behavioral Medicine Research Center whose interests spans behavioral medicine translational research in cardiovascular disease, HIV and cancer, and CNS control of circulation and conditioning.

Alan Delamater, PhD. Dr. Delamater is Professor of Pediatrics and Psychology with a 20 year history of NIH funding for research on behavioral aspects of diabetes in children. His work also involves community translation of clinical research findings, particularly in Hispanic communities.

Community Research

Erin Kobetz, PhD(see 3.d.iv)

Olveen Carasquillo, MDDr. Carrasquillo is Associate Professor of Medicine and Chief of the Division of General Internal Medicine at the University of Miami's Miller School of Medicine. He has served as

Principal investigator on over a dozen government and foundation sponsored research and training grants in the areas of minority health, health disparities, community based participatory research and access to care.

Sarah Messiah, PhD. Dr. Messiah is a Research Associate Professor in Pediatrics whose research focuses on the epidemiology of obesity and childhood obesity in community settings as possible predictors of adult disease.

Policy Research

Kenneth Goodman, PhD(see 3.d.iv)

Jeffrey Brosco, MD, PhD. Dr. Brosco is Professor of Pediatrics and History with a research emphasis on history of public policy and current impact on child health policy.

Faculty Competence in CTI and Development Plan.

Since students will be entering the program from the various disciplines of medicine, there will be a number of variations in training and career path emphasis. This means advisors and mentors must have a sufficient knowledge base to properly assess and advise the research and career direction of our students. In addition, our diverse student body will bring to the classroom varying knowledge-bases, training and education. Both professors and students must be conscious of the fact that students may either lack depth or excel in certain subjects due to differing educational backgrounds.

The MSCTI and the university emphasis on clinical and translational science are at an early stage of development. Because of this, a plan has been developed to iteratively create a faculty with the knowledge and competence to promote and expand a program in CTI. During the year prior to the first class of the MSCTI, the core faculty will meet monthly to discuss how courses can be developed and modified over time to include, in an integrated and synergistic fashion, the clinical and translational perspective found in existing courses. The model for this faculty development symposium will involve having each faculty member present the content of the course they are teaching at one of the faculty development seminars. They will then engage the rest of the teaching faculty in a discussion about how this course integrates with courses in the other content areas, and how it can be modified to emphasize the CTI content. We anticipate that this faculty development seminar will accomplish two things. First, it will enable the faculty to develop, over time, courses that include unique content related to CTI, and to do so in a way that the content is integrated across courses. Second, it will provide a structure for development of faculty expertise in an emerging field. While the University of Miami has significant faculty resources and expertise in the component parts of the spectrum of clinical and translational research, the integration of these components requires additional effort, as nearly every other major institution that has undertaken a similar initiative has discovered. Developing this expertise will benefit not only the student since MSCTI, but also the larger effort of the university to create an environment conducive to active and meaningful clinical and translational science.

b. Evaluation of current undergraduate and graduate curricular structure.

At present, there is no undergraduate track in Translational Science. However, undergraduate courses in most of the subjects that feed into our curriculum exist. Furthermore, the requirements for admission for an undergraduate are simply those pursuing a health science career with outstanding credentials. At this starting point for this program, current curriculae that are in place will suffice. However, as the MSCTI program progresses, and we can identify gaps, we may develop guidelines for undergraduate students to aid in their selection of classes or participation in open seminars (e.g., the Clinical and Translational Research weekly seminar or grant writing seminars) that would better prepare them for the Master's Clinical and Translational course structure. For now, however, there are no proposed changes to existing undergraduate offerings.

In terms of graduate programs, there are no structural changes to existing offerings yet. We have a full evaluation structure set up in order to thoroughly assess our program. Input, context, process, and outcome components of the program, research curriculum and courses, faculty (including directors of the program), teaching strategy, students, and research will be assessed by student, faculty, administrative, and executive

governance "participants" at regularly scheduled intervals, mid-term, and completion of each component in bi-directional directions as well as across peer level. Through these means, we can decipher if students feel unprepared for the classes and take further action. However, due to the nature of the courses, it is highly unlikely any changes will be needed for existing programs for the first 2 years of the MSCTI.

c. Current/anticipated work with other parts of UM or external agencies.

As part of the emerging Miami Clinical and Translational Science Institute (CTSI) plan for a Clinical and Translational Science Award, a novel structure of "living discovery laboratories" is being developed that will accommodate multidisciplinary team-based translational and clinical research and research training. The network of "laboratories" is comprised of a Clinical Research Center that is closely integrated with existing, successful and externally funded practice- and community-based programs where externally-funded research is already being conducted successfully by UM investigators. Research and training activities throughout the network focus on under-represented groups, particularly those of Hispanic or African background. Constituents include the Center for Haitian Studies, Bascom Palmer Clinics, Jefferson Reaves, UM DCFAR Clinics, Health Choice Network, El Centro, Miami Dade County School District as well as Jackson Memorial Hospital (JMH)'s clinics (the latter is community-based because, JMH is the primary charity facility for our surrounding and indigent communities: Overtown, Liberty City, and Little Haiti). Through our current efforts, these previously disparate (even isolated) units are being integrated into an interconnected network of "*living discovery laboratories*" aimed at supporting translational and clinical research at the patient care and community levels. If the CTSI is funded and these relationships are fully implemented, this will be an invaluable resource for our trainees. Even if the CTSI is not funded, the collaborative training, service, and research relationships with the many community partners that have already been established will be available to students in the MSCTI, since a number of our Steering Committee faculty have their own personal research based in these community settings (e.g., Kobetz, Delamater, Armstrong, Wilkinson).

In addition, the University of Miami has many alliances with health care organizations around the South Florida area. Depending on their area of research, students can utilize these strong connections when composing their thesis or other projects required through classes. From 2001-2006, Dr. Armstrong led a community pediatrics training initiative funded by the Dyson Foundation and the American Academy of Pediatrics. This program developed a unique student-faculty-community based organization partnership with small-grant funding to support innovative approaches to improving child health in our community. Over the five years, 29 projects were funded; nearly 50% of these received large, extramural support and are continuing today. This model can be applied to collaborations between our students and established community partners. Again, as the MSCTI program is an interdepartmental collaboration, the students will naturally have to work with various departments and areas of UM. It is inherent in the structure.

d. Detailed description of program.

• Program requirements written in a manner consistent with a graduate bulletin masthead.

The Masters in Clinical and Translational Investigation program is a one to three –year (time dependent on goals and responsibilities of accepted students), 30 credit program that includes completion of structured content courses, participation in small group interactive seminars, and completion of a K-award, R21, or R01-type interdisciplinary clinical/translational research proposal that will serve as a thesis or a formal master thesis, to be evaluated by a thesis committee consisting of one member of the Steering Committee, two faculty members, each representing one component of the translational focus (T1, T2, T3) of the student, and another investigator not affiliated with the K30 program.

The core curriculum is as follows:

Completion of the CITI-certification for research with human participants

Introduction to Clinical and Translational Research (This introductory core course will be taught by the PI and Co-PI, and will include special topics in translational science, ethics in translational science, communication of science, introduction to bioinformatics, research with underserved/under-represented populations, regulatory considerations, and a grant writing seminar)

Clinical Trials (EPH 604)

BIOINFORMATICS (one of the following)

- **Introduction to Health Informatics (CIS 450)**
- **Bioinformatics Tools (BIL552 / CSC552)**
- **Applied Data Management and Analysis (EPH 503)**
- **Database Design & Management (EEN 567)**

Bioinformatics Lab The aim of this course is to provide graduate students with the skills needed to conduct basic bioinformatics data retrieval and analysis as relevant to research in genomics and molecular biology. Currently, this course is a required component of the PIBS curriculum. We are currently working with Dr. Nicholas Tsinoremas, a core faculty member of the program, to make necessary additions to the existing course to transform it into a formal, one-credit class.

BIostatISTICS (one of the following)

- **Medical Biostatistics (EPH 501)**
- **Statistical Methods in Epidemiology (EPH 603)**

EPIDEMIOLOGY

Principles of Epidemiology (EPH 521)

ETHICS

Research Ethics (RST720) (This is a new course for Fall 2011 taught by Drs. Reid Cushman and Thomas Champney. This course will be part of the curriculum for a new degree in Bioethics, which plans to launch in Fall 2012.

GENETICS

Genetics (HGG630) (A revamping of HGG620 and HGG630 combined into this new course)

CULTURAL DIVERSITY AND COMMUNITY ENGAGEMENT

One of the following:

- **Community Based Participatory Research**
- **Community and Social Change (EPS 648)**

ii) Assessment methods (i.e., qualitative and quantitative) intended to measure student attainment of learning outcomes.

Examinations and grades for each individual course will be given as required by the graduate school. Determination of grades will be the responsibility of the faculty members designated as the course instructor. Student progress will be reviewed by the Evaluation Sub-Committee at mid-year point and by the Steering Committee at the end of each year. These formal reviews will result in a letter from the Steering Committee to the student providing feedback related to any areas of deficiency, requirements for remediation, or commendation for excellence. Successful completion of the MSCTI will require a GPA of 3.0 or greater with

no grades below C in any courses (these can be retaken and improved grades substituted) and successful completion of the thesis project.

The program will be evaluated by obtaining data on multiple components of the program from students, faculty, administrative, and the advisory board. Data will include satisfaction ratings from both students and faculty, performance of students in the core curriculum, assessment of the degree to which courses meet both course and program objectives, and whether the program structure produces graduates with knowledge and competency in clinical and translational science. The Steering Committee will use these data to adapt established faculty, course, and student evaluation forms according to specifications for each in relative objectives, and the success of the Steering Committee in accomplishing this objective will be reviewed annually by the Advisory Board.

During our program, students will be working with human research volunteers in order to complete certain requirements for the degree. In order to evaluate students performance and to ascertain how well students adhere to quality standards in study protocols implemented in human research volunteers, we will review existing study participant satisfaction survey results obtained when participants end study participation.

Research processes will also be assessed. The ability of the students to progress in an expedient manner through administrative and oversight approvals for their research will be tracked.

iii) Course descriptions, including a syllabus, if possible, for each new course.

One new course will be developed for the MSCTI, with existing courses used in the early years of the program. The Bioinformatics Lab that is part of the PIBS program will be converted to a for-credit (1 hour) course for MSCTI students, but will remain a required, though non-credit course for participant in the PIBS program. The faculty development process will be used to incrementally modify the content of existing courses, with a planned evolution of new courses specific to clinical and translational research over the first five years of the program. New courses with a specific focus on clinical and translational research are anticipated in the areas of ethics, health disparities, and community based participatory research.

Overview of Clinical and Translational Science. This will be a new course in which key topics in translational science will be addressed. These include the basic science foundations for translation, the T1 bench-to-bedside translation process, clinical research issues including feasibility and study design, and the T2 bedside to health care translation process. This course will provide a global overview of the scope of translational science and will have lecturers from the domains of basic science, clinical research, and health care. We will also cover the areas of challenges, limitations and opportunities presented in the translational research process. After this course, students will be able to:

- Formulate a well-defined clinical or translational research question to be studied in human or animal models
- Propose study designs for addressing a clinical or translational research question
- Identify resources from multiple areas of research that can be used as tools in the development of translational proposals (e.g., genetics/genomics, technology, bioinformatics)
- Assess the strengths and weaknesses of possible study designs for a given clinical or translational research question
- Identify a target population for a clinical or translational research project
- Identify measures to be applied to a clinical or translational research project
- Determine resources needed to implement a clinical or translational research plan
- Compare the feasibility, efficiency, and ability to derive unbiased inferences from different clinical and translational research study designs
- Assess threats to internal validity in any planned or completed clinical or translational study, including selection bias, misclassification, and confounding.

- Integrate elements of translational research into given study designs that could provide the bases for future research, such as the collection of biological specimens nested studies and the development of community-based interventions
- Assess data sources and data quality to answer specific clinical or translational research questions.

Anticipated Future Course Development

Ethics in Translational Science. UM has developed a comprehensive ethics program that involves schools and departments across the university. With a gift from Adrienne Arsht, the named Arsht Ethics program provides formal and informal ethics education through monthly research ethics seminars, a nationally attended bioethics conference, a university ethics symposium, a grant mechanism to support ethics research, and the development of research tools that are used around the world. The Collaborative Institutional Training Initiative (CITI) program, was created and founded in March 2000 as collaboration between UM and the Fred Hutchinson Cancer Research Center to develop a web based training program in human research subjects protections. As of May 2010, the CITI Program is used by over 1130 participating institutions and facilities from around the world. 1,300,000 people have registered and completed a CITI course since September 2000 and now more than 35,000 new learners complete a CITI Program course every month ("CITI," 2010). The Ethics program is in the process of creating a formal masters in ethics, with new courses being developed. For the MSCTI, a planned new course is being developed that will be available to students. Topics to be covered include: (1) Research Misconduct; (2) data acquisition and management; (3) Responsible authorship; (4) Responsible peer review; (5) Mentoring; (6) Conflicts of interest; (7) Collaborative research; (8) Conducting research with human subjects, and (9) Conducting research with laboratory animals. After taking this course, students should be able to:

- Implement quality assurance systems with control procedures for data intake, management, and monitoring for different study designs.
- Summarize the history of research abuses and the rationale for creating codes, regulations, and systems for protecting participants in clinical research that requires community input.
- Critique a clinical or translational research proposal for risks to human subjects
- Determine the need for a risk-benefit ratio that is in balance with the outcomes in clinical and translational research.
- Describe the elements of voluntary informed consent, including increasing knowledge about research, avoiding undue influence or coercion, and assuring the decision-making capacity of participants.
- Assure the need for privacy protection throughout all phases of a study.
- Assure the need for fairness in recruiting participants and in distributing the benefits and burdens of clinical research
- Apply the main rules, guidelines, codes, and professional standards for the conduct of clinical and translational research.
- Adhere to the procedures to report unprofessional behavior by colleagues who engage in misconduct in research.
- Implement procedures for the identification, prevention, and management of financial, intellectual, and employment conflicts of interests.
- Apply the rules and professional standards that govern the data collection, sharing, and protection throughout all phases of clinical and translational research.
- Apply elements of voluntary informed consent, of fostering understanding of information about clinical research, and for avoiding undue influence or coercion, and taking into consideration the decision-making capacity of participants.
- Explain the need for privacy protection and best practices for protecting privacy throughout all phases of a study.

- Explain the need for fairness in recruiting participants and in distributing the benefits and burdens of clinical research.
- Explain the function of the IRB.

iv) Proposed schedule of required courses.

Because we are using existing classes, the students are subject to take the courses when available. In order to accommodate the variety of backgrounds and schedules of our students, we have allowed for flexibility in the program. There is no required or necessary course sequence; the requirements just need to be filled within three years.

Core faculty and members of our Steering Committee include: Drs. Joshua Hare, Daniel Armstrong, Nicholas Tsinoremas, Kenneth Goodman, Erin Kobetz, Bill Scott, Susan Blanton, Marie Guerda Nicolas, Mei-Ling Shyu, Dimitris Papamichail, and Sara Rushinek.

F. Daniel Armstrong, Ph.D. (Program Director) is Professor and Associate Chair of Pediatrics and Director of both the Mailman Center for Child Development and the University of Miami Sickle Cell Center. He is a pediatric psychologist with a secondary appointment in the Department of Psychology. Dr. Armstrong is a leader of interdisciplinary training and research programs at UM, and has led multi-center, multidisciplinary clinical trials groups (Pediatric Oncology Group, Children's Oncology Group, Cooperative Study of Sickle Cell Disease; BABY HUG Trial; Multicenter Study of Hydroxyurea; Mixed chimerism in treatment of sickle cell disease; and the Clinical Trials Consortium in Sickle Cell Disease). Dr. Armstrong has supported the development of basic science research, led a HRSA-funded establishment of a small-bore animal magnet imaging program as a core medical center resource, currently leads a program and spearheads an integrated approach to health disparities research for the Sylvester Cancer Center, and is the only non-physician PI of a NHLBI Comprehensive Sickle Cell Center/Basic and Translational Research Program in Sickle Cell Disease (U54) in the United States. He was the PI for a HRSA/MCHB funded Leadership Education in Neurodevelopmental Disabilities (LEND) program for more than 10 years. LEND is an interdisciplinary training program (11 disciplines) that also includes a strong focus in the areas of advocacy and public policy research. At the federal level, Dr. Armstrong has served on multiple NIH task forces, and was chair of the NHLBI Sickle Cell Disease Advisory Committee, and has been a consultant to the Director of the NIH, the Institute of Medicine, and the White House. He is currently a member of the Florida Biomedical Research Advisory Council that oversees \$42M of annual funding for tobacco- and cancer-related research in Florida. Thus, Armstrong's background is one of a behavioral scientist, and he has led basic, clinical, and translational research related to brain development, cancer, hematology, pulmonary function, neuroimaging, immunology, and stem cell transplantation, and have also designed and led a large training program throughout his career.

Joshua Hare, M.D., F.A.C.C., F.A.H.A. (Co-Program Director) is the Louis Lemberg Professor and Director of the Interdisciplinary Stem Cell Institute (ISCI) at the University of Miami Miller School of Medicine. Dr. Hare is an expert in cardiovascular medicine and specializes in heart failure, myocardial infarction, inflammatory diseases of the heart, and heart transplantation. Dr. Hare is one of the world's pioneers in stem cell therapy for heart attack and heart failure, and currently sees patients from throughout the world for evaluation for this new experimental therapy. At the Miller School of Medicine, Dr. Hare is the founding director of the Interdisciplinary Stem Cell Institute, an Institute devoted to the new field of regenerative medicine. The Institute houses more than 30 independent research groups devoted to basic scientific and translational work in the field of stem cell therapy and regenerative medicine. Dr. Hare conducted a first-in-man study of allogeneic bone-marrow derived mesenchymal stem cells (MSCs) to treat patients with heart damage due to myocardial infarction, and has pioneered the use of a new catheter to deliver stem cells to the heart. Dr. Hare's work is supported by the National Institutes of Health. Under Dr. Hare's leadership, ISCI has active programs in regenerative medicine devoted to applying this new field to treat patients with cancer, heart

disease, neonatal complications, skin diseases, bone diseases. In addition, ISCI has a program devoted to the ethics of stem cell therapy.

Nicholas Tsinoremas, Ph.D., is the Founding Director at the Center for Computational Science and has extensive leadership experience with projects that combine informatics and computational approaches for gene expression analysis. He holds faculty appointments in the Departments of Medicine, Health Informatics, and Computer Science at the University of Miami. Dr. Tsinoremas has in-depth knowledge of the drug discovery and development, high performance computing, health informatics and information technology, chem-informatics and clinical genomics. His expertise is in combined informatics and computational approaches with gene expression profiling and genetics to discover, prioritize, and define drug target genes.

Kenneth W. Goodman, Ph.D., is founder and director of the University of Miami Bioethics Program and its Pan American Bioethics Initiative and co-director of the University's Ethics Programs, including its Business Ethics Program. The Ethics Programs have been designated a World Health Organization Collaborating Center in Ethics and Global Health Policy, one of six in the world and the only one in the United States. Dr. Goodman is a Professor of Medicine at the University of Miami with appointments in the Department of Philosophy, Department of Epidemiology and Public Health, Department of Electrical and Computer Engineering, School of Nursing and Health Studies and Department of Anesthesiology. He chairs the Ethics Committee of the American Medical Informatics Association, for which he co-founded the Ethical, Legal and Social Issues Working Group. He is a Fellow of the American College of Medical Informatics, the only philosopher or ethicist to be elected. His research has emphasized issues in health information technology, including bioinformatics or the use of computers in genetics, and in epidemiology and public health. He has published a book about ethics and evidence-based medicine for Cambridge University Press, co-authored a book of case studies in ethics and health computing for Springer-Verlag and co-authored another volume of case studies, in ethics in public health, for the American Public Health Association. He has also co-authored a book on artificial intelligence, edited a book on ethics and medical computing, co-edited a volume on artificial intelligence, and published and presented hundreds of papers in bioethics, including end-of-life care, the philosophy of science, and computing. He has edited a book on the Terri Schiavo case for Oxford University Press.

Erin Kobetz, Ph.D., is an Assistant Professor in the Department of Epidemiology and Public Health at the University of Miami (UM) Miller School of Medicine. She is also a member of the Cancer Epidemiology and Prevention program at the UM Sylvester Comprehensive Cancer Center, the Director of the Center's Disparities and Community Outreach Core Resource, and the Scholar in Residence at the Jay Weiss Center for Social Medicine and Health Equity. Dr. Kobetz joined UM in September 2004 after completing her PhD at the University of North Carolina at Chapel Hill. Prior to her doctoral degree, Dr. Kobetz earned a master's in public health from the Rollins School of Public Health at Emory University (1999). In 2004, Dr. Kobetz established Patnè en Aksyon (Partners in Action), the campus-community partnership between UM Sylvester Comprehensive Cancer Center and key community-based organizations in Little Haiti, the predominately Haitian area in Miami, Florida. The primary goal of Patnè en Aksyon is to reduce the excess disability and death from breast and cervical cancer among Haitian women. To accomplish this goal, university and community partners work together to conduct research, which can inform behavioral and social change. This partnership employs the methods of Community-Based Participatory Research (CBPR) to address the excess burden of cancer experienced by Haitian women residing in the United States and abroad. Under Dr. Kobetz's leadership, Patnè en Aksyon has since secured over one million dollars in extramural research funding. Dr. Kobetz has been personally recognized for her contributions to cancer disparities research by numerous agencies and organizations.

Bill Scott, Ph.D., primarily focuses his research on the identification of gene and environment interactions that increase risk for diseases such as Parkinson's disease, age-related macular degeneration and tuberculosis. For example, Dr. Scott recently led efforts that identified gene-environment interactions between variations in the

inducible nitric oxide synthase gene and cigarette smoking in both Parkinson disease and age-related macular degeneration. In addition, Dr. Scott is well known for his work with the Amish communities of Indiana and Ohio, as he seeks to identify genetic and environmental factors that lead to successful aging (preservation of cognition, physical function, and social engagement in the oldest old) among this unique population. A recently completed study suggested that areas of chromosomes 6, 7, and 14 are likely locations for genes promoting successful aging in Amish living past age 80. In addition to maintaining an active research program, Dr. Scott serves as the Director of the Interdepartmental PhD program in Human Genetics and Genomics, and Vice-Chair for Education and Training in the Dr. John T. Macdonald Department of Human Genetics.

Susan Blanton, Ph.D., received her Ph.D. in Human Genetics from Virginia Commonwealth University in 1985. Over the past 21 years, Dr. Blanton's primary research has focused on the mapping of Mendelian and complex diseases. Deafness, retinal diseases, skeletal dysplasias, cleft lip/palate, and club foot are among the diseases which she currently studies. She has also been involved in developing and implementing genetic education materials for Federal and appellate level judges and science writers in an ELSI sponsored project. Her current research involves determining the level of genetic knowledge and attitudes towards genetic testing among the deaf. She is Associate Director of Communications and Compliance at the John P. Hussman Institute for Human Genomics, and Associate Professor in the Dr. John T. Macdonald Foundation Department of Human Genetics and the Project coordinator for the Genomedical Connection.

Marie Guerda Nicolas, Ph.D., serves as the Chairperson of the Educational and Psychological Studies Department and Associate Professor, School of Education, University of Miami. As a multicultural (Haitian American) and multilingual (Spanish, French, and Haitian Creole) psychologist, her research is reflective of her background and interests. Dr. Nicolas's current research focus is the integration of race and culture and well-being for ethnically diverse and immigrant communities. Some of the projects on which she is currently working include: spirituality across the life span among ethnic minorities, and culturally effective mental health interventions for ethnic minority adolescents, with a specific focus on immigrant children, adolescents, and families. In addition, Nicolas conducts research on social support networks of Caribbean populations with a specific focus on Haitians. She has published several articles and book chapters and delivered numerous invited presentations at national and international conferences in the areas of women's issues and depression, as well as her other areas of expertise. She is a frequent media consultant on issues of Haitian mental health.

Mei-Ling Shyu, Ph.D., has been an Associate Professor at the Department of Electrical and Computer Engineering (ECE), University of Miami (UM) since June 2005. Prior to that, she was an Assistant Professor in ECE at UM dating from January 2000. She received her Ph.D. degree from the School of Electrical and Computer Engineering, Purdue University, West Lafayette, Indiana, U.S.A. in 1999, and her three master degrees from Computer Science, Electrical Engineering, and Restaurant, Hotel, Institutional, and Tourism Management from Purdue University in 1992, 1995, and 1997, respectively. Her research interests include multimedia data mining, management & retrieval, and security. She has authored and co-authored more than 190 technical papers published in various prestigious journals, book chapters, and refereed conference proceedings. Dr. Shyu was elected a Fellow of the Society for Information Reuse and Integration (SIRI) in 2010 for her contributions to Multimedia Data Mining, Information Retrieval, and Knowledge Management. She also received the "Best Student Paper Award" with her student from the Third IEEE International Conference on Semantic Computing (ICSC2009) in September 2009. Dr. Shyu has been an Associate Editor for several journals including the IEEE SMC Transactions, Part C: Applications and Reviews, an editorial board member of many other journals, and a program chair of more than 15 IEEE and ACM international conferences, symposiums, and workshops.

Sara Rushinek, Ph.D., is a Professor of Computer Information Systems at the University of Miami. She earned her Ph.D. at The University of Texas at Austin. Sara Rushinek's research, teaching and consulting interests include health information technology and informatics, computer and network security, computer

forensics and litigation support, business intelligence and data mining for decision-making; e-learning and digital multi-media video webcast streaming, e-commerce security, and Mobile(m) Medical Trials. Dr. Rushinek is a frequent speaker at academic, business, health, and technology conferences. Her current research is with medical practices and vendors to investigate ways to increase "ROI and Search Engine Domination by Repurposing Surveillance Systems for Telehealth".

v) Anticipated program mission and learning outcomes

The program intends to create at UM a solid foundation for a Master's Program that offers trainees of diverse backgrounds and at various levels of entry formal graduate training in the principles and practice of translational science and clinical research, with particular attention to the three bottlenecks of translation: T1, T2, and T3 (defined in section 1). The program's graduates will learn how to properly address clinical and translational research questions, compose a thorough literature critique, devise and evaluate a study design, be well-versed in sources of error in study measurements, have a solid understanding of ethics and responsible conduct of research, develop a sensitivity to cultural diversity in research, be aware of emerging technologies applicable to clinical and translational research, and be able to approach learning in a cross-disciplinary manner.

e. Teaching Style

Due to the nature of courses, students will learn via lecture, discussion series, online learning and seminar style teaching. Biostatistics courses will be supplemented by a computing lab to further learning, and students will spend some time observing and/or working in functioning research labs of their mentors. We also will offer some online learning courses. Tutoring and additional help from professors will be offered.

f. Describe the expected distribution of graduate students among advisors.

Our plan for selection and distribution of advisors per student is as follows: The Admissions Subcommittee will suggest an advisor for each trainee. The advisory may be the faculty sponsor for the student's research (e.g., formal K-award mentor) or a member of the Steering Committee or MSCTI teaching faculty. The recommended advisor will meet with the student individually; ultimately, however, the student will select an advisor, to be approved by the Steering Committee. This faculty advisor will guide the professional development of the trainee in the program, including her/his choice of electives and trajectory through our program. The advisor will assist the student in identifying research co-mentors for the thesis research project, and may serve as a member of the thesis committee if appropriate.

The Master's Thesis that the students must compose will be evaluated by a thesis committee consisting of one member of the Steering Committee, two faculty members, each representing one component of the translational focus (T1, T2, T3) of the student, and another investigator not affiliated with the K30 program. The thesis committee will be chosen by the student with guidance from his/her faculty advisor, and approved by the MSCTI Steering Committee.

g. Describe any colloquia series, special seminars, or conferences that will be held.

As listed and described in detail in Section 3.d.iii, our new courses will be in the format of seminar series. In addition, we offer a weekly university seminar during the academic year on "hot topics" in clinical and translational research that faculty and students (including, but not limited to, the MSCTI students) from across the University will be encouraged to attend, schedules permitting. Speakers are recruited from the University faculty, along with invited national and international visiting faculty.

Should such an opportunity arise during a course where a seminar on or off campus will benefit the student body, students will receive appropriate notification.

4. Faculty:

a. Include the complete C.V. of each faculty member who will participate in the program. The graduate teaching experience and grants received of the person concerned should be included in each C.V.

b. Estimate the need for additional faculty, including in each instance

- **Specialization desired.**
- **Degree of experience desired.**
- **Salary anticipated.**

Individuals eligible to become faculty in the MSCTI include those with recognized teaching skills in one of the core content areas required by the MSCTI, as well as an interest in participating as part of the Steering Committee. We have held extensive group and individual meetings with potential faculty, and are obtaining written statements of commitment to be part of the Steering Committee faculty. We do not anticipate, at this time in the planning process, that new, incremental faculty recruitments will be necessary.

During the second planning year (2011-12) the Steering Committee will finalize the curriculum for the MSCTI and, as a group, review each of the courses to ensure that a core understanding and knowledge of the content and dynamics of clinical and translational research is included consistent with the goals of the program. This curriculum development and review will take place in monthly MSCTI teaching faculty meetings during the current K30 planning phase, and then six times a year once the Masters is fully implemented. Using this model, we will assure that all teaching faculty are aware of the role that ethics, diversity, biostatistics, bioinformatics, regulatory activities, and genomics play in all kinds of clinical and translational research. This will also create a mechanism for the development of interdisciplinary cohesive teaching approaches, opportunities for co-teaching, and creation of small group activities for students that operationalize classroom concepts of interdisciplinary clinical and translational research.

The teaching faculty will comprise a MSCTI Steering Committee (see Figure 2) that will advise the PI and Co-PI on program implementation and evaluation, as well as oversee implementation of the Masters of Science in Clinical and Translational Research. This Committee will also include selected scientists not involved directly in teaching but who will serve in a senior mentor capacity for candidates involved in the Masters program. These senior mentors include those faculty members listed in Section 3a: Joshua Hare, MD; Dalton Dietrich, PhD; Daniel Armstrong, PhD; Gwendolyn Scott, MD; Neil Schneiderman, PhD; Alan Delamater, PhD; Erin Kobetz, PhD; Olveen Carasquillo, MD; Sarah Messiah, PhD; Kenneth Goodman, PhD; Jeffrey Brosco, MD, PhD.

c. Describe the interaction of the proposed program with other graduate programs, e.g., thesis and dissertation committees.

As noted in Section 1.d. working with other graduate programs is inherent in the design of the degree program with course offerings in so many various disciplines. Students will have the opportunity to work with many of the committees set up in our structure.

For graduation, the Steering Committee will review each graduating trainee and recommend, on the completion of all requirements, the award of the MSCTI to the Graduate School.

The proposed Masters has been designed to be closely coordinated with our existing training programs in order to serve as a broad-based centralized program of patient-oriented translational and clinical research training. Importantly, this proposed curriculum will also serve to interact with and strengthen new training programs at UM, such as Cancer Biology and Human Genetics.

5. Students

a. Number and Pool

We anticipate that our initial class size will be five (5), with a target of 10 students by the third year. Future class size may be increased, based on outcome assessments. As previous Bootcamp attendees expressed such a strong interest in our program, we estimate our first class will come from a pool of students who have already received exposure to the materials. In addition to those, eligible participants will include clinical or basic scientists who have earned doctoral degrees (MD, DO, PhD, PsyD, DDS), medical students, nursing students,

and doctoral students interested in combining the MS in Clinical/Translational Research with their primary doctoral degree studies. Students who have completed a Bachelor's degree who have outstanding academic credentials and an interest in obtaining a MS prior to a career in clinical translational research or a graduate program will also be eligible.

b. Describe requirements for admission to and expected retention of students in the proposed program.

Applicants will be U.S. citizens, non-citizen nationals, or U.S. permanent residents. They should hold or be in the process of concurrently obtaining professional degrees in Medicine, Dentistry, Nursing, Clinical Psychology, Pharmacology, or other clinical disciplines. Evaluation of applicants will be made by the Ad Hoc Recruitment and Admissions Subcommittee (a subset of the Steering Committee appointed by the K30 PI and Co-PI) and will include assessment of college and graduate school transcripts, clinical training, a personal statement, three letters of reference, and an interview. Admissions decisions will be made by our Ad Hoc Recruitment and Admissions Subcommittee, and approved by our Steering Committee, using additional criteria: (1) scientific background and (2) commitment to a career in patient-oriented translational investigation.

A minimum cumulative GPA of 3.0 will be required at the end of the first semester, and 3.0 for each semester thereafter. Students falling below these cumulative GPA will be put on probation for one semester, and if not above this standard after one semester on probation, will be discontinued from the program.

Since nearly half of our Bootcamp participants have requested such formal training, we are more than certain retention will be high. However, circumstances such as moving to take a new job, changes in job assignments and family reasons, including pregnancy, preclude some students from completing the program. That is inherent in any graduate level program.

A major barrier to retention in this program is the high tuition cost of UM graduate programs (\$1,480 per credit for 30 hours; total \$44,400), qualified and motivated applicants may be able to complete this masters degree at no personal cost if the tuition is included as part of a K-award or other federal grant that includes tuition for trainees as an allowable cost. Tuition remission is available to other full-time University of Miami employees and faculty. Several approaches will be deployed to address tuition costs. Because this training program will be highly beneficial to ongoing research programs at UM, faculty will be encouraged to apply for tuition supplements to funded grants from NIH. Department chairs who have active translational programs will also be encouraged to support tuition for post-graduate trainees within their departments. The MSCTI will also be made available to individuals submitting K-Award applications to partially meet the research training plan components of these applications. Full to partial tuition payments are permissible as part of the K-Award budget. Boilerplate language will be available on the web for use by K-Award applicants. Department chairs and institute/center directors will also be informed about this option for their junior faculty. These efforts are designed to increase retention rates so that applicants may complete the full run of the Masters.

For the Masters degree, students must complete CITI-certification for entry and successfully finish 30 core credits that include a 6-credit mentored research project. In general, 2 years will be required for completion, but some students may be able to complete the program in as little as one year, while others may require up to three years. The actual time committed to completion is anticipated to vary as a function of the funding source. Students who are bearing the total cost for the program personally will be able to complete the program more quickly than those who have competing responsibilities associated with their funding sources for the program (e.g., K-award, research fellows). This variation is an expected component of this kind of program for the targeted students.

c. Describe the anticipated need for and specific use of teaching assistants and research assistants in the program. Include the number and estimated stipends for each assistant (indicate stipend level and whether 9-month or 12-month).

We do not anticipate the need for additional teaching and/or research assistants beyond those already in place for the various existing courses.

6. Administration:

Budget information is deleted from the web version of this legislation.

- c. Describe the arrangements for administration and for academic direction of the program as it pertains to:**
- i) The day-to-day administration of the program.*
- The Advisory Board (see Figure 1) will advise the graduate program directors, Drs. Daniel Armstrong and Joshua Hare, on program implementation and evaluation, and will meet biannually to review progress. The Program Directors will advise the Coordinator, who will be responsible for providing day-to-day support and administration to students and program, including orientation of students, enrollment, and recruitment, admission, and initial academic advising of admitted students.

ii) The academic policy-making mechanisms used to implement the program, including criteria for membership in the faculty of the program.

Various committees and subcommittees who carry out and implement program changes exist for the graduate program. They are as follows:

Advisory Board (See Figure 1): Our program will appointed and will administratively support an Advisory Board. That board will consist of senior faculty and leaders of Schools and Departments at the University of Miami who are engaged in or support basic, clinical, community, or health policy research. The Advisory Board will consist of senior scientists from the University, including Drs. Herman Cheung, Gail McCain, John Bixby, Kenneth Goodman, and Jeanette Mladenovic. This Board will advise the Steering Committee on the overall direction and progress of the training program. Members of the Advisory Board will meet with the PIs and the Steering Committee once a year for structured meetings. We will also consult them as needed throughout the year on issues of clinical and translational research training strategies.

Steering Committee (See Figure 1): The Steering Committee will be co-chaired by Drs. Armstrong and Hare. This committee will meet once per month during the planning stages (year 1) and quarterly thereafter. The Steering Committee will be composed of the core faculty for the MSCTI. Ad Hoc subcommittees will be appointed to conducted time-limited functions for the MSCTI, including Recruitment and Admissions, Mentoring, Curriculum, and Evaluation.

Budget information is deleted from the web version of this legislation.

Budget information is deleted from the web version of this legislation.

Budget information is deleted from the web version of this legislation.

Comparisons to 5 Other Master's in Biostatistics Programs

For comparison purposes the 5 schools are:

Mayo Clinic

Tufts University

Columbia University

University of Iowa

University of Pennsylvania

All schools have membership in the CTSA Consortium. They are prestigious Universities employing this degree and provide excellent benchmarks and sources for ideas to enhance our program.

a. Contrast with Mayo Clinic

The Mayo Clinic's program, like ours, is a 2 year course requiring a number of completed credits and a Master's Thesis for Graduation and the option of obtaining a certificate in the field of Translational Science. Mayo Clinic's core courses reflect the same areas as ours--Epidemiology, Biostatistics, Ethics—however, our curriculum contains a more diverse class set. For example, Communications of Science, Research with underserved populations, Computer Science databases, This gives us an advantage as it will allow UM to cater to and attract interest from a wider variety of students. However, like us, Mayo's elective courses pull from various unique topics and differing disciplines. Because Mayo Clinic is solely a medical facility, however, their program does not offer the Psychology, Sociology, or Communications aspects that we can.

Further information is available at: <http://ctsa.mayo.edu/education/masters-curriculum-registration.html>

b. Contrast with Tufts University

Tufts University divides its program into three possible tracks, or concentrations for its students: Evidence-based Clinical Effectiveness Research, which includes the areas known as Comparative Effectiveness Research (CER), Evidence Based Medicine (EBM), and related areas that advance the translation of information about the effectiveness of treatments and healthcare strategies into practice. Clinical Investigation is intended for clinician-investigators desiring methodologic grounding for the full range of patient-oriented clinical research including randomized controlled trials, and Phase I, II, and III trials. Lastly, Health Services and Outcomes Research is intended for students emphasizing application of a variety of methods to the investigation of population health improvement and the organization, delivery, financing, and outcomes of health care services. In addition to selecting a Concentration, Tufts's students may select another typically clinical discipline for a Focus in that discipline. For example, a student could select a Concentration in Evidence-based Clinical Effectiveness Research and a Focus in Nutrition or a Concentration in Clinical Pharmacology. Tufts requires 37.5 credits, allocated differently than ours and also offers the option of PhD program which builds upon the

Masters. Tufts has a class in Meta-Analysis, something which UM does not. Tufts also utilizes a mentoring program.

Further information is available at: <http://www.tuftsctsi.org/Education-and-Career-Development/~media/A42C14ECDDCB40C9A52151510A9D1719.ashx>

c. Contrast with Columbia University

Columbia University's program differs the most from our program. It is housed under the Mailman School of Public Health and labeled as a Masters in Biostatistics/Patient Oriented Research. Its curriculum consists of 30 credits in total, including 18 credits of required coursework, 3 credits towards a Master's essay, and 6 to 9 credits of elective coursework. The specific coursework, electives and core, are more closely focused on Epidemiology, Statistics, and Community Health. Unlike Miami's program Core courses do not require any community health work, those are listed in the optional electives courses.

Further information is available at: <http://www.cumc.columbia.edu/dept/mailman/biostat/por/index.html>

d. Contrast with University of Iowa

The University of Iowa's Masters Degree in Translational Biomedicine is a 54 credit, 3 year program that prepares skilled clinicians to pursue new knowledge about health and disease through patient-based research. It also includes a summer semester, different from any of the other listed schools. Like University of Miami, Iowa's curriculum offers a course in Career Development. Its curriculum is very similar to ours. Students also must write a proposal for a K23 Mentored Patient-Oriented Research Career Development Award from the National Institutes of Health. For M.S. students, the K23 proposal replaces the thesis.

Further information is available at: <http://www.icts.uiowa.edu/content/ms-translational-biomedicine-research>

e. Contrast with University of Pennsylvania

The University of Pennsylvania's Master's in Translational Research shares the same goals as our program: to produce a cadre of highly trained and sophisticated investigators adept in the skills necessary for the translational investigator; to prepare students for an academic career and to position them for future careers as successful academic researchers who will become leaders in their field of research interest. UPenn also shares the same philosophy and structure for a mentorship program. Unlike the other programs, UPenn offers an online, easily accessible handbook which delineates coursework and a thorough explanation of all of the program facets and the reasoning behind them as well as a detailed time line for students. UPenn also requires that students participate in non-credit, more socially oriented parts of the program such as the Journal Club.

Further information is available at: http://www.itmat.upenn.edu/cts/mti/docs/student_handbook4.8.09.pdf

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Collaborative Institutional Training Initiative (CITI) <https://www.citiprogram.org/Default.asp?>

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What Health Care Reform Means For Cancer Research. <http://www.aacr.org/home/public--media/science-policy--government-affairs/aacr-cancer-policy-monitor/aacr-cancer-policy-monitor---april-2010/what-health-care-reform-means-for-cancer-research.aspx>

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Budget information is deleted from the web version of this legislation.

UNIVERSITY OF MIAMI
GRADUATE SCHOOL



Terri A. Scandura, Ph.D.
Dean of the Graduate School

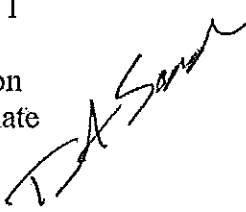
Graduate School
P.O. Box 248125
Coral Gables, FL 33124-3220

Phone: 305-284-4154
Fax: 305-284-5441
graduateschool@miami.edu

MEMORANDUM

DATE: September 20, 2011

TO: Richard Williamson
Chair, Faculty Senate

FROM: Terri A. Scandura 
Dean, The Graduate School

SUBJECT: New Degree Program -- Master of Science in Clinical and Translational Investigation

At the September 15, 2011, meeting of the Graduate Council, the new degree program Master of Science in Clinical and Translational Investigation was unanimously approved by those present after the second reading.

cc: Dr. John Bixby
Dr. Daniel Armstrong
Dr. Joshua Hare
Office of Planning, Institutional Research and Assessment



UNIVERSITY OF MIAMI
MILLER SCHOOL
of MEDICINE

MEMORANDUM

TO: Faculty Senate

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

DATE: August 17, 2011

RE: To establish a Master's Degree in Clinical and Translational Investigation

This memorandum is in support of establishing a new degree program, Master's Degree in Clinical and Translational Investigation.

On August 9, 2011, the Miller School of Medicine's Faculty Council met and reviewed the proposal to establish a new degree program, Master's Degree in Clinical and Translational Investigation. The proposal was presented by Dr. Joshua M. Hare, the Director of the Interdisciplinary Stem Cell Institute. The Medical School Faculty Council unanimously approved and endorsed the proposal.

Should you have any questions or concerns, please contact me at 305-243-1635 or naltman@med.miami.edu.

Sincerely,

A handwritten signature in black ink, appearing to read 'Norman Altman', written over a printed name and title.

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



UNIVERSITY OF MIAMI
MILLER SCHOOL
of MEDICINE

Joshua M. Hare, M.D., F.A.C.C., F.A.H.A.
Louis Lemberg Professor of Medicine
Director, Interdisciplinary Stem Cell Institute

August 2, 2011

F. Daniel Armstrong, PhD
Professor and Associate Chair, Department of Pediatrics
Director, Mailman Center for Child Development
Associate Chief of Staff, Holtz Children's Hospital
Mailman Center for Child Development
PO Box 016820 (D-820)
Miami, FL 33101

Dear Dr. Armstrong,

As your co-Director for the Masters in Clinical and Translational Investigation, I want to express my excitement at the final launch of our degree. In the past year, we have worked to create an innovative and meaningful curriculum for our future class of students, and I look forward to it coming to fruition.

You have been an excellent partner in this project, and I appreciate all of the ideas and work you contributed to this program.

As the Director of the Interdisciplinary Stem Cell Institute, and active participant in the Clinical and Translational Science Award (CTSA) application, I am aware of the great need for this degree at the University of Miami. Through this process, we have learned of the global indications of translational research, its effect on the quality of research and the quality of patient care, and its effect on the allocation of NIH funds. Now is a crucial time for UM to make its mark on this burgeoning field.

I am confident that the talented group of faculty we have gathered will successfully carry out our intentions through their classes. The few meetings we have held have been more than productive, and the next year should bring about even more benefits to the program.

Thank you for helping me with this endeavor.

Sincerely,

A handwritten signature in black ink, appearing to read 'Joshua Hare', written over a horizontal line.

Joshua M. Hare, M.D., F.A.C.C., F.A.H.A.

Interdisciplinary Stem Cell Institute • Leonard M. Miller School of Medicine
Post Office Box 016960 (R-125) • Miami, Florida 33101
Biomedical Research Building • 1501 NW 10th Avenue, Suite 824 • Miami, Florida 33136
Tel: 305-243-5579 • Fax: 305-243-5584

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

October 12, 2011

F. Daniel Armstrong, PhD
Professor and Associate Chair, Department of Pediatrics
Director, Mailman Center for Child Development
Associate Chief of Staff, Holtz Children's Hospital
Mailman Center for Child Development
PO Box 016820 (D-820)
Miami, FL 33101

Joshua M. Hare, M.D., F.A.C.C., F.A.H.A.
Louis Lemberg Professor of Medicine
Director, Interdisciplinary Stem Cell Institute
University of Miami Miller School of Medicine
Biomedical Research Building / Room 824
P.O. Box 016960 (R-125)
Miami, FL 33101

Dear Drs. Armstrong and Hare,

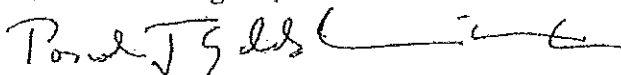
On behalf of the University of Miami M. Leonard Miller School of Medicine (UMMSM), I wish to express my strong and unequivocal support for the development of a Master's of Science in Clinical and Translational Investigation (MSCTI). As you know, I was a strong advocate for the Clinical and Translational Science Award application, and understand the extreme importance of bringing translational education to our community.

It is also well known that many medical schools, namely our academic competitors and role models, have already developed this program. It is clear that this Master's will soon become a crucial component to expanding what is already a modern-day, highly interdisciplinary scientific enterprise. We must keep our young scientists at the forefront of scientific research.

The addition to the program to the University of Miami will put our school in the cadre of medical schools already pursuing the goals of the NIH Roadmap initiative. I fully approve your proposed curriculum, structure, and budget for the MSCTI. In the event of a lapse in funding for the renewal of the K30 grant, the School of Medicine will provide the funds to continue this support until all enrolled students have completed the degree program or until renewal. These resources will be derived from all available institutional sources of support and are contingent on availability of funds.

Best of luck to you both in this endeavor, and thank you for taking on this significant task.

With warmest regards,



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

UNIVERSITY OF MIAMI
MILLER SCHOOL
of MEDICINE



24. August 2011

Dr. Richard Williamson
Chair, Faculty Senate
325 Ashe Building
Coral Gables, Florida 33146

Dear Richard,

I am pleased to present to the Faculty Senate a proposal to create a new MS degree in Clinical and Translational Investigation. In my role as Sr. Associate Dean for Graduate & Postdoctoral Studies, I strongly support this proposal.

As you know, one of the ultimate goals of biomedical research is to translate the fundamental knowledge obtained in the laboratory into clinical practice, initially in the hospital setting and ultimately in the community at large. Achieving this goal requires the contributions of a number of dedicated researchers combining discipline-specific knowledge with the ability and expertise to perform clinical/translational research in a rigorous and ethical manner. The goal of the proposed MS program is to develop a cadre of researchers who fill this niche. Drs. Hare and Armstrong, as clinical researchers with strong scientific (and training) expertise, are the ideal team to develop such a program at UM, and their proposal is well thought out and appropriately scaled.

The proposed MS program has obtained the explicit support of the Medical School Council, the Dean, the Executive Dean for Research, and myself. Please let me know if the Senate requires any additional information. Drs. Armstrong, Hare and I look forward to meeting with the Senate to discuss any suggestions or concerns that might arise.

Yours Sincerely,

John L. Bixby, Ph.D.
Professor and Sr. Associate Dean

UNIVERSITY OF MIAMI
MILLER SCHOOL
of MEDICINE



José Szapocznik, Ph.D.
August 8, 2011

Joshua M. Hare, M.D., F.A.C.C., F.A.H.A.
Louis Lemberg Professor of Medicine
Director, Interdisciplinary Stem Cell Institute
University of Miami Miller School of Medicine
Biomedical Research Building / Room 824
P.O. Box 016960 (R-125)
Miami, FL 33101

F. Daniel Armstrong, PhD
Professor and Associate Chair, Department of Pediatrics
Director, Mailman Center for Child Development
Associate Chief of Staff, Holtz Children's Hospital
Mailman Center for Child Development
PO Box 016820 (D-820)
Miami, FL 33101

Dear Drs. Hare and Armstrong,

As the Executive Director for Research and Research Training, and as the Chair of the department of Epidemiology and Public Health, I commend you on your efforts to develop a Masters in Clinical and Translational Investigation (MCTI).

As you know, I am heavily invested in the need for translational research at the University of Miami. I am the PI of the Clinical and Translational Science Award (CTSA) application, and am a strong advocate of bringing it to the Miller School through any and every avenue possible. Thank you for taking the initiative to do so.

The UMMSM's mission is to provide excellence in medical education and to provide quality care to those in need of it. It is only natural that we adopt the practices of translational research, which bridges the gap between clinical care and basic science, in order to successfully carry out this goal.

I am pleased that the MCTI will include four courses taught by the Graduate Programs in the Department of Epidemiology and Public Health (DEPH). These courses include:

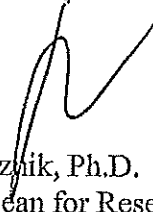
Executive Dean for Research and Research Training
Chair, Department of Epidemiology and Public Health
1120 NW 14th Street, Suite 650D | Miami, FL 33136
Ph: 305-243-8331 | Fax: 305-243-8157
jszapocz@med.miami.edu

Medical Biostatistics (EPH501) or Statistical Methods in Epidemiology (EPH 603)
Fundamentals of Epidemiology (EPH 521)
Community-Based Participatory Research (EPH 647)
Clinical Trials (EPH 604)

As discussed, it is our expectation that our program will be reimbursed for tuition costs associated with the teaching of these courses. DEPH graduate program leadership will work with both of you to finalize the tuition arrangements. I am honored you have selected my department's classes as part of your curriculum, and I know they are thrilled to participate.

All of the luck with this to you both.

Sincerely,



José Szapocznik, Ph.D.
Executive Dean for Research & Research Training
Chair, Department of Epidemiology and Public Health



UNIVERSITY OF MIAMI
MILLER SCHOOL
of MEDICINE

Marc E. Lippman, M.D.
Kathleen & Stanley Glaser Professor
Chairman, Department of Medicine

F. Daniel Armstrong, PhD
Professor and Associate Chair, Department of Pediatrics
Director, Mailman Center for Child Development
Associate Chief of Staff, Holtz Children's Hospital
Mailman Center for Child Development
PO Box 016820 (D-820)
Miami, FL 33101

Joshua M. Hare, M.D., F.A.C.C., F.A.H.A.
Louis Lemberg Professor of Medicine
Director, Interdisciplinary Stem Cell Institute
University of Miami Miller School of Medicine
Biomedical Research Building / Room 824
P.O. Box 016960 (R-125)
Miami, FL 33101

Dear Drs. Hare and Armstrong,

As the Chair of Medicine at the University of Miami, I congratulate you on your efforts to develop the new Masters in Clinical and Translational Investigation (MCTI) at the Miller School of Medicine. I am confident that this initiative will create wonderful opportunities for the University.

As you both are aware, translational research is a growing area in the field of science. It is important for the University to take on this significant degree. Many clinicians who come through my department would benefit greatly from the curriculum you have devised. I look forward to seeing the MCTI progress in the coming years.

Personally, most of my breast cancer research reflects the special relationship between clinical and basic science. Therefore, I am well-versed in the importance of this degree program and fully support its existence at UM. Thank you for taking the reins on this project.

Best of luck to you both!

Sincerely,

A handwritten signature in black ink, appearing to read 'Marc E. Lippman'.

Marc E. Lippman, MD, MACP
Kathleen and Stanley Glaser Professor
Chairman, Department of Medicine;
Deputy Director, Sylvester Comprehensive Cancer Center



UNIVERSITY OF MIAMI
MILLER SCHOOL
of MEDICINE

August 28, 2011

F. Daniel Armstrong, PhD
Professor and Associate Chair, Department of Pediatrics
Director, Mailman Center for Child Development
Associate Chief of Staff, Holtz Children's Hospital
Mailman Center for Child Development
PO Box 016820 (D-820)
Miami, FL 33101

Joshua M. Hare, M.D., F.A.C.C., F.A.H.A.
Louis Lemberg Professor of Medicine
Director, Interdisciplinary Stem Cell Institute
University of Miami Miller School of Medicine
Biomedical Research Building / Room 824
P.O. Box 016960 (R-125)
Miami, FL 33101

Dear Drs. Armstrong and Hare,

As the Chair of the Department of Surgery at the University of Miami, I would like to express my excitement for your new project, the Masters in Clinical and Translational Investigation (MCTI). You are two of the strongest leaders at UM, and I have every confidence that you will guide this program successfully.

Translational research is an ever-expanding field, and is where the NIH is allocating a large portion of its funds. In order to continue to make meaningful contributions to science, it is eminent that UM begins to train its investigators and clinicians to think in this manner. I appreciate your efforts to bring this program to the University.

In the Department of Surgery, our investigators and clinicians would strongly benefit from a program such as this. The University already does such incredible science, and this degree will expedite our essential goal of turning these discoveries into meaningful outcomes for the community.

All my best,

Alan Livingstone, MD
Lucille & DeWitt Daughtry Professor and Chairman
DeWitt Daughtry Family Department of Surgery

UNIVERSITY OF MIAMI
SCHOOL of NURSING
& HEALTH STUDIES



Nilda (Nena) P. Peragallo, DrPH, RN, FAAN
Dean and Professor

F. Daniel Armstrong, PhD
Professor and Associate Chair, Depart of Pediatrics
Director, Mailman Center for Child Development
Associate Chief of Staff, Holtz Children's Hospital
Mailman Center for Child Development
PO Box 016820 (D-820)
Miami, FL 33101

Joshua M. Hare, M.D., F.A.C.C., F.A.H.A.
Louis Lemberg Professor of Medicine
Director, Interdisciplinary Stem Cell Institute
University of Miami Miller School of Medicine
Biomedical Research Building / Room 824
P.O. Box 016960 (R-125)
Miami, FL 33101

Dear Drs. Armstrong and Hare:

On behalf of the University of Miami School of Nursing and Health Studies (SONHS), I would like to congratulate you for developing a not only significant, but much needed degree of Clinical and Translational Investigation. Through my involvement with the Clinical and Translational Science Award (CTSA) application, I am more than well-versed in the urgency of this program at the University. Many thanks for taking charge on this initiative.

I am sure I speak for the many other departments that offer clinical and research services when I express the need to fill the interface between basic and clinical sciences in order to address the health concerns of our patients and the South Florida community. I understand that in the future, you plan to develop a mechanism to support the training of research nurses and clinical coordinators. With this initiative in tow, I fully support your efforts.

I look forward to seeing this degree come to fruition. Developing a master's program is a difficult feat, and I offer you any support you will need along the way.

Sincerely,

A handwritten signature in black ink, appearing to read 'N Peragallo', with a long horizontal line extending from the end of the signature.

Nilda (Nena) P. Peragallo, DrPH, RN, FAAN
Dean and Professor

UNIVERSITY OF MIAMI
SCHOOL of
EDUCATION



Office of the Dean
Isaac Prilleltensky, Ph.D.
Dean and Professor
Erwin and Barbara Mautner
Chair in Community Well-Being

P.O. Box 248065
Coral Gables, FL 33124-2040
Phone: 305-284-3711
Fax: 305-284-3003
www.education.miami.edu

July 21, 2011

F. Daniel Armstrong, PhD
Professor and Associate Chair, Department of Pediatrics
Director, Mailman Center for Child Development
Associate Chief of Staff, Holtz Children's Hospital
Mailman Center for Child Development
PO Box 016820 (D-820)
Miami, FL 33101

Joshua M. Hare, M.D., F.A.C.C., F.A.H.A.
Louis Lemberg Professor of Medicine
Director, Interdisciplinary Stem Cell Institute
University of Miami Miller School of Medicine
Biomedical Research Building / Room 824
P.O. Box 016960 (R-125)
Miami, FL 33101

Dear Drs. Armstrong and Hare,

On behalf of the School of Education, let me offer you every encouragement to you in your efforts to develop a Master's degree in Clinical and Translational Science.

The School of Education has recently started a master's program in Community and Social Change. I am honored that you will be using one of our classes, taught by Dr. Marie Guerda Nicolas, in your curriculum. At the School of Education, we strive to improve the health and wellness of the surrounding community. Your program, which will help bridge the interface between clinical science and basic research, is essential in meeting this goal.

It is quite an undertaking to start a new program, which is why I wish you the best of luck. Thank you for enhancing the educational experience of students at the University of Miami.

Yours sincerely,

Isaac Prilleltensky, PhD
Professor and Dean
Erwin and Barbara Mautner Chair in Community Well-being



UNIVERSITY OF MIAMI

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

July 22, 2011

F. Daniel Armstrong, PhD
Professor and Associate Chair, Department of Pediatrics
Director, Mailman Center for Child Development
Associate Chief of Staff, Holtz Children's Hospital
Mailman Center for Child Development
PO Box 016820 (D-820)
Miami, FL 33101

Joshua M. Hare, M.D., F.A.C.C., F.A.H.A.
Louis Lemberg Professor of Medicine
Director, Interdisciplinary Stem Cell Institute
University of Miami Miller School of Medicine
Biomedical Research Building / Room 824
P.O. Box 016960 (R-125)
Miami, FL 33101

Dear Drs. Hare and Armstrong,

I am delighted to offer my full support to you in your goal to develop a new master's program in Clinical and Translational Science. This degree is a more than necessary addition to the educational opportunities provided by the University, and I look forward to seeing it come to fruition.

As Scientific Director of the Diabetes Research Institute (DRI), I am excited to see the University making progress towards meeting the goal of speeding medical discoveries to patients' bedsides and into widespread practice. In looking to find a cure for diabetes, we partner with many institutions and believe in the philosophy that by spreading knowledge and working together, we will be more successful in changing patients' lives. This interdisciplinary degree expands this philosophy to many disease areas and is an initiative to which I am proud to endorse.

I wish you all the success and look forward to the many opportunities for collaboration that your program promises.

Sincerely,

A handwritten signature in black ink, appearing to read "Camillo Ricordi".

Camillo Ricordi, M.D.
Stacy Joy Goodman Professor of Surgery
Distinguished Professor of Medicine
Professor of Biomedical Engineering, Microbiology & Immunology
Director, Diabetes Research Institute and Cell Transplant Center
University of Miami

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UNIVERSITY OF MIAMI
MILLER SCHOOL
of MEDICINE

Ralph L. Sacco, MD, MS, FAHA, FAAN
*Chalman, Department of Neurology
Oleberg Family Chair in Neurological Disorders
Miller Professor of Neurology, Epidemiology, & Human Genetics
Leonard M. Miller School of Medicine
University of Miami
Chief of Neurology Service, Jackson Memorial Hospital*

F. Daniel Armstrong, PhD
Professor and Associate Chair, Department of Pediatrics
Director, Mailman Center for Child Development
Associate Chief of Staff, Holtz Children's Hospital
Mailman Center for Child Development
PO Box 016820 (D-820)
Miami, FL 33101

Joshua M. Hare, M.D., F.A.C.C., F.A.H.A.
Louis Lemberg Professor of Medicine
Director, Interdisciplinary Stem Cell Institute
University of Miami Miller School of Medicine
Biomedical Research Building / Room 824
P.O. Box 016960 (R-125)
Miami, FL 33101


Dear Drs. Armstrong and Hare,

On behalf of the Department of Neurology, I would like to congratulate you for undertaking the challenge of developing a not only significant, but much needed degree of Clinical and Translational Science. We desperately need to train more health care professionals in the methods and approaches to conduct high-quality clinical and translational research. I was involved in similar K30 and T32 programs at Columbia University before coming to the University of Miami and know how beneficial they can be for trainees. Through my involvement with the UM Clinical and Translational Science Award (CTSA) application, I am more than well-versed in the urgency of this program at the University. I thank you for taking charge on this initiative.

I am sure I speak for the many other departments that offer clinical and research services when I express the need to fill the interface between basic and clinical sciences in order to address the health concerns of our patients and the South Florida community. This program serves as a perfect tool in which to do so. We have unique opportunities in Miami to extend this type of training to under-represented investigators and advance research among under-served populations at the greatest health risk.

I look forward to seeing this degree come to fruition. Developing a master's program is a difficult feat, and I offer you any support you will need along the way. We have faculty in our department in our new Clinical and Translational Research Division who look forward to helping mentor trainees.

Sincerely,



Ralph L. Sacco, MD
Chairman, Department of Neurology

August 2, 2011

F. Daniel Armstrong, PhD
Professor and Associate Chair, Department of Pediatrics
Director, Mailman Center for Child Development
Associate Chief of Staff, Holtz Children's Hospital
Mailman Center for Child Development
PO Box 016820 (D-820), Miami, FL 33101

Joshua M. Hare, M.D., F.A.C.C., F.A.H.A.
Louis Lemberg Professor of Medicine
Director, Interdisciplinary Stem Cell Institute
University of Miami Miller School of Medicine
Biomedical Research Building / Room 824
P.O. Box 016960 (R-125), Miami, FL 33101

Dear Drs. Armstrong and Hare,

On behalf of the Department of Human Genetics and the John P. Hussman Institute for Human Genomics, I congratulate you on your efforts to develop a Masters Program in Clinical and Translational Science Investigation (MCTSI) at the University of Miami Miller School of Medicine (UMMSM). This is a significant undertaking, and I have every confidence in your endeavors.

I am thrilled to know that my faculty, namely my Vice Chair, Dr. Bill Scott, and Dr. Susan Blanton, will be teaching classes in your program. Drs. Scott and Blanton are both excellent teachers and leaders in the field of human genetics, and I am sure their contributions will be significant. This collaboration should provide meaningful benefits for both my program and yours. I look forward to seeing its outcomes as the program grows.

Our young investigators must start learning the language of translational research. Thank you for making it available to the University of Miami.

Best wishes on this project.

Sincerely,



Jeffery M. Vance M.D., Ph.D.
Professor and Chair, Dr. John T. Macdonald Foundation
Department of Human Genetics
Professor of Neurology
Director, Center for Genomic Medicine, Hussman Institute for Human Genomics
Miller School of Medicine, University of Miami



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

W. Dalton Dietrich, Ph.D.
Scientific Director

F. Daniel Armstrong, PhD
Professor and Associate Chair, Department of Pediatrics
Director, Mailman Center for Child Development
Associate Chief of Staff, Holtz Children's Hospital
Mailman Center for Child Development
PO Box 016820 (D-820)
Miami, FL 33101

July 22, 2011

Joshua M. Hare, M.D., F.A.C.C., F.A.H.A.
Louis Lemberg Professor of Medicine
Director, Interdisciplinary Stem Cell Institute
University of Miami Miller School of Medicine
Biomedical Research Building / Room 824
P.O. Box 016960 (R-125)
Miami, FL 33101

Dear Drs. Armstrong and Hare,

On behalf of the Miami Project to Cure Paralysis, I would like to offer every encouragement in your efforts to develop a Master's of Science in Clinical and Translational Research.

As you know, there are few individuals who are able to bridge the gap between scientific discoveries in the lab and scientific discoveries in the clinic. A Master's in Clinical and Translational Science will help lessen this disparity, and in turn bring us closer to the cures, treatments, and outcomes that we seek.

As an ever-improving institution, the University of Miami holds an obligation to train its residents, faculty members and students in translational science. Colleges around the country, namely some of the University of Miami's biggest competitors, now offer this program. It is a quickly expanding trend around the country in which UMMSM should take part.

The Miami Project devotes its time and resources to finding a cure for paralysis due to brain and spinal cord injury. We know the significant changes this degree can bring about, and therefore are in complete support of this new program.

I look forward to participating any way that I can. Best of luck to you both.

Sincerely, 

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

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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

UNIVERSITY
OF MIAMI
ETHICS PROGRAMS



P.O. Box 016960 (M-825)
Miami, Florida 33101

Ph: 305-243-5723
Fax: 305-243-6416
ethics@miami.edu
www.miami.edu/ethics

August 2, 2011

F. Daniel Armstrong, Ph.D.
Professor and Associate Chair, Department of Pediatrics
Director, Mailman Center for Child Development
Associate Chief of Staff, Holtz Children's Hospital
PO Box 016820 (D-820)
Miami, FL 33101

Joshua M. Hare, M.D., F.A.C.C., F.A.H.A.
Louis Lemberg Professor of Medicine
Director, Interdisciplinary Stem Cell Institute
University of Miami Miller School of Medicine
P.O. Box 016960 (R-125)
Miami, FL 33101

Dear Drs. Armstrong and Hare,

Thank you for this unalloyed opportunity to write on behalf of the University of Miami Bioethics Program and extend my full support for, and enthusiastic congratulations regarding, development of a Masters degree in Clinical and Translational Investigation.

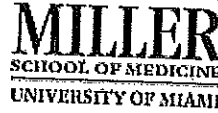
As a component leader in the Miami Clinical and Translational Science Award (CTSA) application, I am quite familiar with the need for translational education at our institution. I commend you on taking the initiative to bring such an important program to the School of Medicine – and for making bioethics a component.

It will therefore be a great privilege to contribute to the development and roll-out of this program, and to participate as a faculty member when the program is established. The ethical challenges posed by translational research are interesting and important and, in my view, essential parts of any such curriculum. It will be an honor to join the outstanding team you have assembled.

The rapid growth of translational science makes your project an essential part of the transformation of the research enterprise. Thank you for including me, and for letting me know how else I can contribute to the success of this exciting endeavor.

Sincerely,

Kenneth W. Goodman, Ph.D., F.A.C.M.I
Professor of Medicine, and jointly of Philosophy
Director, Bioethics Program



Barth A. Green, M.D., F.A.C.S.
Professor and Chairman of Neurological Surgery
Professor of Orthopedics
Professor of Rehabilitation Medicine
Specializing in Spinal Injury & Diseases

August 1, 2011

F. Daniel Armstrong, PhD
Professor and Associate Chair, Department of Pediatrics
Director, Mailman Center for Child Development
Associate Chief of Staff, Holtz Children's Hospital
Mailman Center for Child Development
P O Box 016820 (D-820)
Miami, FL 33101

Joshua M. Hare, MD, FACC, FAHA
Louis Lemberg Professor of Medicine
Director, Interdisciplinary Stem Cell Institute
University of Miami Miller School of Medicine
Biomedical Research Building / Room 824
P O Box 016960 (R-125)
Miami, FL 33101

Dear Danny and Josh,

It is with great pleasure, in my role as Chair of the Department of Neurological Surgery and The Miami Project to Cure Paralysis at the University of Miami Miller School of Medicine, that I offer total support and encouragement for the development of a Masters program in Clinical and Translational Investigation (MCTI). I cannot think of two better or more skilled healthcare and research professionals to implement this exciting and timely opportunity to students as well as faculty of our medical center. Bringing basic science information from the bench into the clinics and hopefully impacting the lives of our patients is the dream and ambition of every physician and scientist and this program does it all. Providing its trainees with the skill set necessary to change the lives of our fellow human beings in a positive manner and most importantly with evidence based information and data.

If any of the faculty, personnel, or resources of my department or The Miami Project would be beneficial in enhancing your efforts, it would be our pleasure to provide them in a timely fashion. Best wishes to both of you on this project, and I congratulate you for raising the bar at our institution and providing this wonderful opportunity.

Sincerely,

A handwritten signature in cursive script that reads 'Barth A. Green'.

Barth A. Green, M.D., F.A.C.S.
Professor and Chairman

BAG/ls