

Fall 2015

THE PROJECT

A Publication of The Miami Project To Cure Paralysis & The Buoniconti Fund To Cure Paralysis

30

"When we make progress quickly, it feeds our emotions. Then, when there's a period of waiting or we hit a plateau, we find out how committed we really are and whether we're going to see things through to the finish or quit."

Joyce Meyer



UNIVERSITY OF MIAMI
MILLER SCHOOL
of MEDICINE





It is hard to believe that it's been 30 years since my paralyzing spinal cord injury. What an amazing journey in medical discovery and in my own personal life. It is as if The Miami Project and I grew up together. I was just a 19 year old kid when I sustained my injury and The Miami Project was just a fledgling concept from a frustrated neurosurgeon who felt that science could offer more than building a better wheelchair.

Since my injury, I've had the privilege of witnessing a revolution in neuroscience and am proud that The Miami Project is helping lead the way. I often feel that I see life in two separate dimensions, as both quadriplegic and scientist. As a quadriplegic, I am chomping at the bit and desperately trying to break-free out of the chains of paralysis. As someone closely involved with the scientists, I understand the intricacies and the complexities of curing paralysis, and compared to other diseases and disorders, The Miami Project has made the most scientific progress in a relatively short amount of time.

While we are confident that we are on the right track, our success has only fueled our fire of optimism and perseverance to deliver on that promise and get everyone out of their wheelchairs, once and for all!

I continue to balance my internal struggle of what could be described as being "impatiently patient". While I feel myself being pulled in two different directions, I believe that the combination has perfectly equipped me to handle and overcome my paralysis. I have been given a rare opportunity to help lead a scientific team into an unknown future with the dedication and commitment to change the world.

It has been and continues to be my greatest privilege to be able to work with two of my biggest heroes: my Dad and Dr. Barth A. Green. Together, we share a tremendous gratitude towards all of our amazing donors who continuously astonish us by their passionate and never-ending benevolence.

Thirty years ago, Dr. Barth A. Green saved my life and my Dad made a promise that he would do everything in his power to help me. Today that promise symbolizes the millions of people around the world that are paralyzed and who deserve a second chance. The Miami Project, and all of us who work there have changed medical history and we now realize that the finish line to a cure is just on the horizon. While we are confident that we are on the right track, our success has only fueled our fire of optimism and perseverance to deliver on that promise and get everyone out of their wheelchairs, once and for all!

Thank you for your support!

A handwritten signature in dark ink, reading "Marc Buoniconti". The signature is fluid and cursive, with the first name "Marc" being more prominent.

Marc A. Buoniconti, President
The Buoniconti Fund and
The Miami Project



Thirty years have passed since The Miami Project to Cure Paralysis was founded following my son Marc becoming a quadriplegic while making a tackle in a college football game and suffering a paralyzing injury. Since 1985, The Miami Project has become the world's most comprehensive research center dedicated to finding more effective treatments and, ultimately, a cure for paralysis from spinal cord injury (SCI). The groundbreaking work of our international team continues to amaze me and I am devoted to doing all that I can to support their research. Spinal cord injury resulting in paralysis is a global medical priority and the millions of paralyzed individuals around the world look to The Miami Project to find a cure to reverse paralysis.

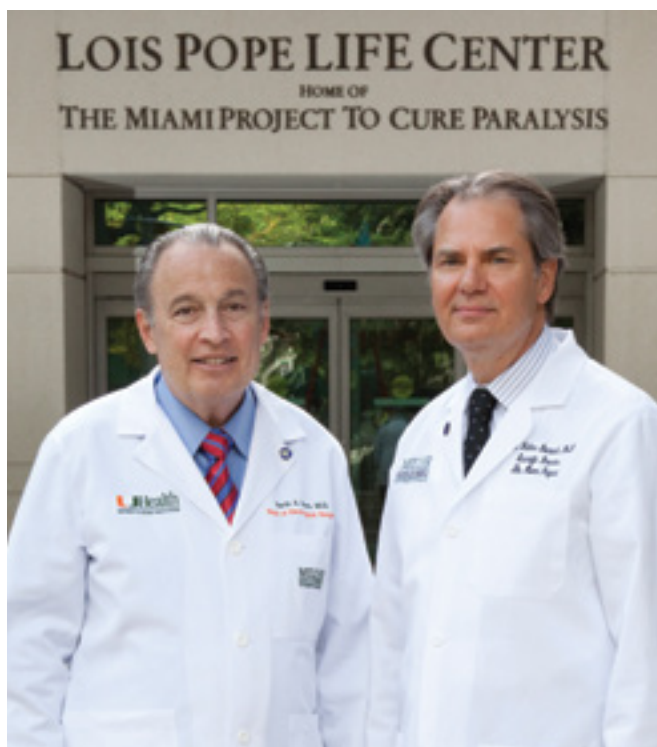


I have some **incredibly good news** to share! The Miami Project has obtained **five** (5) FDA (Food and Drug Administration) approved clinical trials targeting spinal cord injury! As always, our scientific researchers are faithful to the principles of good clinical practices involving human subjects. Our Phase 1 safety trial to evaluate human Schwann cell transplantation involving individuals as both donors and recipients in **acute** (recent) injury is ongoing. The first six participants were enrolled and they are moving on successfully without any safety issues. We also received FDA approval to proceed with a Phase 1 clinical trial in 2015 to test this therapy in individuals with **chronic** SCI (those paralyzed for a year or more). Our first patient will receive their transplantation on September 22nd and the second transplantation will take place in November. What a momentous and medical history changing breakthrough development this is! Another approved trial using Schwann cells targets peripheral nerve injury to promote regeneration and The Miami Project's first patient in this study is actually walking again. Deep brain stimulation (DBS) is also being evaluated for the first time to target neuropathic pain in individuals with SCI and our first subject was successfully treated. Our brain-machine interface program is focused on the end goal of enabling individuals to move their upper extremities, thereby enhancing independence. The FDA has also approved testing the effect of adult mesenchymal stem cells.

These trials are very expensive (\$250,000 per patient) and The Miami Project and The Buoniconti Fund are committed to raising the funds needed so that not one of our research participants will have to pay. For thirty years the Great Sports Legends Dinner has raised incredible financial resources and awareness for The Miami Project's groundbreaking spinal cord injury research. I want to sincerely **thank you** all -- The Buoniconti Fund's dedicated Board of Directors, the Great Sports Legends, Honorees, Dinner attendees, our new University of Miami President Dr. Julio Frenk, and all those who have advanced the efforts to find a cure for paralysis. I think about the paralyzed individuals and their families all the time and I find it hard to accept them living with such hardship. I **promise** I will always continue to work hard for the millions of paralyzed people who hope to walk again.

Nicholas A. Buoniconti, Co-Founder
The Buoniconti Fund and
The Miami Project





Barth Green, M.D.,F.A.C.S.
W. Dalton Dietrich, Ph.D.

Dear Friends and Colleagues,

This year has been the most exciting in our 30 year history regarding new discoveries and treatments for spinal cord injury (SCI). We have made significant progress in changing the way we treat people with paralysis and improving functional outcomes. In our first FDA approved Schwann cell clinical trial, subject recruitment is complete and we have successfully transplanted Schwann cells with no serious risk factors. Encouraging results are also being seen in some subjects, including minor improvements in sensory function. Based on the success of this Initial trial, we have initiated a second chronic SCI study where an extensive rehabilitation protocol will be combined for the first time with Schwann cell transplantation. We have already recruited the first 2 subjects for this groundbreaking trial and will be transplanting them later this year.

In addition to SCI, direct trauma to upper and lower extremities causes peripheral nerve injury and severe paralysis. A new trial combining a nerve bridging strategy with Schwann cell administration is generating remarkable results with return of sensory and motor function after 1 year. Together, these experimental trials are establishing new treatment strategies that could benefit thousands of persons living with acute and chronic paralysis.

In addition to Schwann cell transplantation, The Miami Project is also actively recruiting subjects for multicenter stem cell programs and other pharmacological treatments within the United States. We were the first center in the United States to transplant FDA approved stem cells into a person living with cervical SCI. Other clinical studies include neurostimulation techniques where direct brain stimulation is used to promote return of arm and hand function or walking by stimulating specific brain circuits.





Yes, these are very exciting times, and we greatly appreciate the critical support from our friends and colleagues that are helping to move these investigations forward.

Another exciting study uses deep brain stimulation to target non-treatable neuropathic pain. We are learning much from these clinical studies and greatly appreciate the commitment of our volunteers who are helping us move this research forward. In the future, brain machine interface work, in collaboration with industry, will allow state-of-the-art neuroengineering approaches to be combined with cell therapies and other experimental treatments to maximize benefits.

Our neuroprotection hypothermia studies continue to be successful in limiting the detrimental effects of SCI and brain trauma in severely injured patients. Multicenter trials throughout the United States and other countries are being conducted. Extramural funding is also helping to support our laboratory studies where new discoveries are demonstrating novel treatment strategies that in the future may also be translated to our clinical programs targeting paralysis.

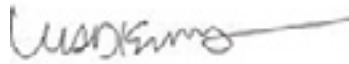
In addition to all of these research activities, our Educational Outreach and Training Programs continue to grow.

We have over 2,300 Individuals Interested in all of our clinical studies that are being contacted and recruited for over 25 active clinical studies. Neuroscience graduate students, post-doctoral fellows and visiting scientists from around the world are being trained in our laboratories to become successful investigators in paralysis research.

Yes, these are very exciting times, and we greatly appreciate the critical support from our friends and colleagues that are helping to move these investigations forward.



Barth A. Green, M.D., F.A.C.S
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In Our Words

- 2 Message from the President, Marc Buoniconti
- 3 Letter from the Founder, Nick Buoniconti
- 5 Message from the Chairman,
Dr. Barth A. Green, and Scientific Director,
Dr. W. Dalton Dietrich

Research Journal Features

- 8 STEPS to a CURE
- 12 Cell Therapies Under Investigation for SCI
- 15 Training the Next Generation of Scientists
- 16 Dr. Monica Perez - “Home” is Truly
Where the Greatest Opportunity Lies
- 18 Clinical Trial Coordinators
- 20 A Time of Transitions

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Chapters

Francine Schoen, Director, Foundation Relations

Jon-Roi Vega, Director, Sponsored Programs

Events to Benefit The Miami Project

- 22 29th Annual Great Sports Legends Dinner
- 26 Christine E. Lynn Rehabilitation Center
- 30 Darrell Gwynn "Comes Home"
- 34 The Buoniconti Fund National Chapters
- 36 Jack Nicklaus 13th Annual Buoniconti Fund Celebrity Golf Invitational
- 37 Poker4Life
- 38 19th Annual Ricky Palermo Spinal Injury Golf Tournament
- 43 Buoniconti Fund Board of Directors

In Memoriam

- 40 Frank Gifford
- 41 John Gray
- 42 Benjamin P. Brown



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STEPS TO A CURE

Miami Project Progress Over 30 Years

W. Dalton Dietrich, PhD,
Scientific Director

The Miami Project to Cure Paralysis is a unique research center for many reasons, including the use of a multi-disciplinary approach to attack the problem of paralysis after spinal cord injury (SCI). This strategy grew out of the realization that SCI was an extremely complex injury that would necessitate the involvement of many different kinds of scientist with different skill sets to help clarify multiple cell death mechanisms and the development of novel therapeutic interventions that could protect and promote reparative mechanisms. Thus, it became clear that a simple or single discovery was most likely not going to produce the cures that our scientific programs were targeting. Indeed, the concept of a single “silver bullet” leading to successful regenerative and reparative processes that would produce clinically meaningful improvements in function and quality of life for people living with paralysis was not likely correct. Based on an emerging scientific literature, our scientists and clinicians emphasized that most likely, multiple steps or approaches each bringing us closer to the cure would be the means by which our goals could be met. Even in the early years of The Miami Project, investigators were attempting to translate new approaches into the clinical area or conducting clinical studies that would serve as a foundation for future clinical trials.

To capitalize on our chances of making real progress on the complicated problem of SCI paralysis, appropriate steps or therapeutic targets needed to be identified to enhance the translation of our discoveries into people. Because of this over arching research goal and our attempt to clarify why a center such as The Miami Project was unique and important to the field, the concept of Five STEPS to a Cure was originally advanced. Today after 30 years of research, our Miami Project scientific community has made major advances in the areas of discovery science, translational programs, and clinical studies. Indeed, our successful translation of several of our discoveries into people living with SCI is already making a real difference in those people’s lives. In the following paragraphs, success stories can be highlighted with many more to come in the future.

Participant Selection and Pre-training:

Today, over 5 million people are living with some form of paralysis due to injury to the nervous system. The importance of selecting a particular SCI subject

population for a specific treatment strategy was highlighted early as an important step in targeting paralysis. This strategy emphasized the need to determine which subpopulation of people living with SCI might benefit the most from personalized regenerative therapies including cellular transplantation trials. Even at that time, it was clear that the SCI subject population was heterogeneous and the use of specific interventions targeting selective therapeutic targets might be critical when considering treatment strategies. Also, the need for various training and rehabilitation strategies specifically for those with chronic injuries was emphasized to ensure significant cardiovascular or skeletal integrities supporting increased function. Today, our educational and clinical trial programs have accumulated a listing of over 3,500 persons living with paralysis due to SCI whom are interested in clinical trials. This secured registry contains information about injury characteristics that is useful for selecting specific subgroups of SCI for different studies. The ability to identify specific SCI groups to participate in clinical studies allows The Miami Project to conduct hypothesis driven research that provides a platform for future multicenter clinical trials with colleagues throughout the world. Indeed, over the years we have learned from unsuccessful FDA approved trials that patient selection is a key factor in determining whether a new therapy is beneficial. We acknowledge and thank all of our volunteers for participating in our research studies.

With these goals in mind, The Miami Project initiated a conditioning rehabilitation program on the first floor of the Lois Pope LIFE Center which prepares subjects for potential cell therapies including Schwann cell transplantation. The important topic of aging with paralysis has also been recently emphasized and stresses the need for good dietary and exercise programs to inhibit or reduce established co-morbidities associated



with SCI including cardiovascular disease, obesity, and diabetes. On any given day of the week, individuals are working out in our 1st floor facility using specialized equipment under the supervision of our expert staff and scientists. Conditioning strategies have already been reported to improve several indicators of cardiovascular function, strength, endurance, and metabolic function. Neurorehabilitation strategies to promote locomotor and arm and hand function have been implemented using cutting edge approaches as well as state-of-the-art robotic systems. Thus, individuals can undergo a variety of multimodal tasks to enhance function that will help prepare them for the intensive rehabilitation strategies that will be required to promote muscle function and healthy aging or enhance processes including circuit plasticity with cellular transplantation approaches.

In this regard, a special program called “The Miami Boot Camp” has been initiated that is assessing multimodal training paradigms for future candidates for cellular transplantation treatments. Over several weeks, individuals that meet specific inclusion criteria are put through a concentrated program to monitor and improve specific outcomes such as motor function, sensory dysfunction, and endurance. It is also envisioned that similar training and neurorehabilitation approaches will be used after transplantation procedures to enhance regenerative processes and ultimately increase treatment potential. The combining of multimodal rehabilitation approaches including a pre- and post-surgery training strategy is now a reality as we continue to move our FDA approved Schwann cell therapy programs forward to chronically injured individuals.

Surgical interventions and Neuroprotection:

Each year approximately 11,000 new cases of traumatic SCI occur in the United States with 250,000 - 500,000 cases worldwide. Through the

development of better critical care procedures in the initial minutes and hours after an injury, more patients are surviving these severe injuries and living long productive lives. Another STEP that was emphasized early in our program development was surgical interventions and neuroprotection. These topics are relevant as we consider therapeutic strategies to target both the acute and more chronic injury states. For example, refined surgical measures including

Miami Project researchers have spent the last several years developing and testing transplantation strategies that we are now utilizing in individuals with acute or chronic spinal cord injury.

early decompression procedures are improving outcomes by reducing cord swelling and improving blood flow to the damaged cord. In subjects where cellular transplantation into the injured spinal cord is proposed, a reproducible and safe approach needs to be established and tested to administer millions of cells to protect and enhance circuit reorganization and repair. Miami Project researchers have spent the last several years developing and testing transplantation strategies that we are now utilizing in individuals with acute or chronic spinal cord injury.

Using both small and large animal models of spinal cord injury, evidence for the successful surgical application of cells into the injured spinal cord has been developed. During this testing period, our scientists worked with biotech companies and surgical colleagues to help promote the successful translation of these cell transplantation procedures to people. We know from previous clinical trials conducted by others in the field that injecting cells into the spinal cords of people can have adverse effects. Thus, this was an important step that had to be mastered prior to initiating our clinical studies. An FDA approved

approach for administering cells safely into the injured spinal cord has been successfully used in our clinical trial.

The use of therapeutic hypothermia and targeted temperature management as a means to protect the spinal cord was first discovered by Miami Project researchers using clinically relevant models of SCI. Based on very encouraging results, the successful translation of these preclinical findings to patients with acute severe SCI has

been accomplished with encouraging results. Indeed, multicenter trials led by The Miami Project are planned and should provide the safety and efficacy data necessary to conclude whether hypothermic therapy in thousands of neurotrauma patients is beneficial. These seminal studies may help change the way we treat people with various types of neurological injuries including traumatic brain injury and stroke. It is very gratifying to know that our research and clinical programs have already helped change medical practice in a way that has helped patients with severe injuries.

In addition to hypothermia research, the discovery and testing of a number of neuroprotective molecules and drugs have also resulted in exciting findings. Secondary injury mechanisms that promote neuronal or oligodendrocyte cell death and neuroinflammation are being investigated as relevant targets for new drug discovery. Compounds that have been used in other disease conditions or recently discovered novel agents are being tested in clinically relevant models and showing promise for future translation into the clinic. The potential use of pharmacological treatments in combination with temperature management and



therapeutic hypothermia strategies represents a fruitful area for continued investigations.

Cellular Transplantation and bridging strategies:

Various cell types and bridging strategies have been evaluated by The Miami Project as well as by other centers throughout the world targeting spinal cord and peripheral nerve injury. Both adult and embryonic stem cells have been shown to enhance recovery in some preclinical models of SCI and continue to be a research

hostile environment of the injured spinal cord. Based on years of research and published studies, an Investigational New Drug Application (IND) was approved by the FDA for the use of autologous Schwann cell transplantation to target injured individuals with subacute severe SCI. Subject recruitment for this Phase 1 safety trial has been completed with the long term monitoring of these individuals to be continued over the next few years. Because of the overall goal of The Miami Project to develop new therapies for people today

in a chronic SCI patient has also been approved and tested. These studies are moving forward with several individuals already recruited into this study. Together, these cellular transplantation studies in people with spinal cord and peripheral nerve injury therefore represent one of the most active clinical programs in the world.

Barriers and Molecular Regulators for Regeneration:

The Miami Project continues to grow by recruiting the next generation of outstanding scientists dedicated to paralysis research. New technologies and approaches are allowing our programs to branch out into different areas of human medicine that may help provide answers to this complex problem. For example, in addition to the importance of studying extrinsic mechanisms underlying the control of successful regeneration, new research is targeting endogenous or intrinsic mechanisms that may limit reparative processes in the mature nervous system. Novel molecules and molecular targets are being identified that appear to be critical regulators of axonal growth that have never been investigated. In addition, new information is being obtained on the molecular control mechanisms for promoting neurogenesis and neovascularization in the injured brain and spinal cord.

focus. Various bridging strategies including the use of biological grafts show promise in terms of helping axons grow across injury-induced gaps in the spinal cord. Thus, major strides have been made regarding novel regenerative strategies including cellular therapies that may offer real hope for successful regeneration.

The Miami Project made an informed decision to concentrate on the human Schwann cell as a means to promote repair in the acute and chronically injured spinal cord. Based on studies from both small and large animals, Schwann cell transplantation was reported to be safe and effective in improving functional outcome in these clinically relevant animal models. The ability to use an individual's own Schwann cells and inject them autologously is believed to be a major advantage as we test these new therapies in people. In addition, to enhance cell survival after transplantation and obtain FDA approval for clinical studies, good manufacturing procedures and cell processing strategies have been established over the last several years to ensure that cells that are injected are healthy and will function in the

living with spinal cord injury, a new clinical protocol was proposed and approved by the FDA where Schwann cell transplantation will be initiated in chronically injured subjects. In these studies, additional rehabilitation programs such as the Boot Camp are being combined for the first time with cell transplantation. Currently, subjects have been recruited into this chronic trial and are undergoing their pre-training protocol prior to Schwann cell transplantation. It's a truly special feeling for our Miami Project researchers to see their research discoveries translated to the SCI community. This important FDA approved trial represents an important step in our goal to develop new therapies to improve function and quality of life for the SCI community.

Based on the exciting possibility of using stem cells to improve function after SCI, Miami Project researchers have also obtained FDA approval for these clinical trials. In collaboration with StemCells, Inc, scientists are working on a multicenter trial to test the safety and effectiveness of transplanted neural stem cells in acute SCI patients. Additionally, the use of mesenchymal stem cell transplantation

The fourth STEP concentrated on overcoming barriers for regeneration and repair. As our scientific knowledge has progressed, it is clear that various molecules originating from inflammatory cells or the breakdown of myelin may inhibit axonal growth and lead to unsuccessful regeneration. Thus, Miami Project scientists have focused on identifying molecules that may help to overcome or target these inhibitory factors in both cell culture as well as animal models. For example, it has been recently discovered that the fibrotic scar that



forms after SCI may be an important target for successful regeneration. Our scientists have also pioneered the use of large-scale screening strategies to identify genes and signaling networks underlying nerve cell regeneration and restoration of function. Recently, multiple signaling molecules important for cell survival and regeneration have been identified and are being tested in preclinical models. Ultimately, the use of cell therapies combined with clinically relevant strategies to alter these molecular regulators of regeneration, synaptic function, and repair may be an important therapeutic strategy to consider in future FDA applications.


NeuroRehabilitation and Bioengineering approaches to improve motor and sensory function:

The Miami Project has a long history of utilizing novel rehabilitation strategies to enhance motor and sensory function in people living with SCI. Robotic walking machines such as the Locomat, Exoskeleton, and other rehabilitation strategies have been successfully used to help promote functional improvements important to SCI subjects. Combining locomotor training protocols, electrical stimulation, and vibration approaches are providing encouraging clinical findings that can be applied to the general SCI population. Transcranial brain or deep brain stimulation protocols are helping to clarify specific circuits responsible for motor control and modulating circuit function to promote motor recovery in SCI subjects. Another exciting direction included in this STEP is the use of brain-computer interface technology that allows functional connections between the brain and spinal cord to be introduced by novel engineering technologies. In the future, Miami Project scientists will be utilizing these neurorehabilitation approaches and neuroengineering systems that

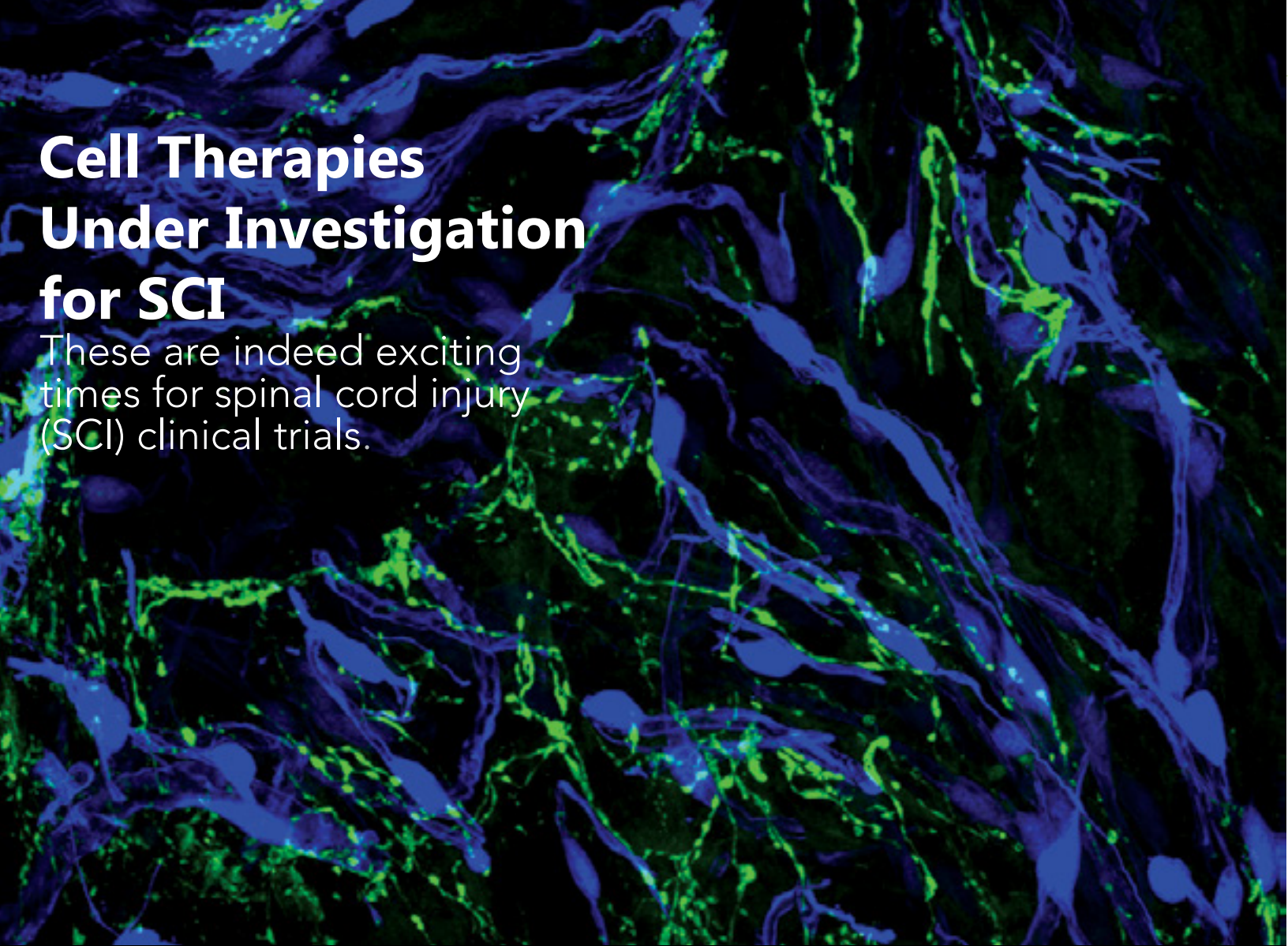
will allow paralyzed individuals to voluntarily move their hands or legs. These neurorehabilitation strategies combined with the biological approaches, including Schwann and Stem cell transplantation that have already been described, represent a path to promoting significant clinical recovery in persons living with SCI and overall improvement of their quality of life. With the successful implantation of cells or growth-promoting drugs or molecules, enhanced axonal regeneration coupled with these innovative rehabilitation tools could help modify and enhance axonal growth to appropriate targets that could lead to enhanced function.

Many people with SCI are living with the terrible situation of pain resulting from spinal damage. Miami Project researchers were some of the first to uncover the high frequency of neuropathic pain in the subject population and began to investigate mechanisms underlying this important consequence of SCI. Today we know that more than 50% of people living with SCI have some form of neuropathic pain that in many cases is not successfully treated. In response to this need, researchers have uncovered cellular and molecular mechanism that may participate in this pathogenesis and tested novel treatment strategies including cell and drug treatments. Our faculty are involved in clinical trials to clarify pain phenotypes and to test new pain reducing agents that provide significant relief in many subjects. Established surgical approaches including deep brain stimulation are also showing promise in treating sensory deficits after injury. Regarding another quality of life issue, discovery research is helping to clarify the mechanisms underlying fertility problems in men with SCI. Based on recent findings, clinical studies are being conducted to improve impairments to male fertility after SCI that could provide hope for hundreds of couples trying to have children.

Concluding Remarks:

The Miami Project is an internationally established research center that has remained focused on its discovery, translational, and clinical research programs targeting paralysis following SCI. Since 1985, The Miami Project's scientific community has published hundreds of peer reviewed papers and chapters have been written and findings presented at national and international meetings. Our list of discoveries and advancements continue to grow and impact multiple neuroscience fields including traumatic brain injury, stroke and neurodegenerative diseases including Alzheimer's disease and Multiple Sclerosis. The successful translation of many of our programs into the clinic emphasizes the significant progress that our scientific family has made over these 30 years. We continue to work on novel strategies that target the complex field of SCI research to determine how best to advance our scientific programs. Importantly, our center is positioned and scientifically equipped to make major steps forward in terms of our neuroprotective, cellular transplantation, regenerative, and rehabilitation strategies that will make a real difference in people's lives today. We sincerely acknowledge our scientific colleagues and critical supporters for their everlasting support for our research mission. Over the last three decades, our research programs have undergone significant change and redirection without ever losing sight of our ultimate goal. ***That is the uniqueness of The Miami Project – having the multi-disciplinary depth to address all of the complex pathology associated with SCI, yet never losing focus of the end goal of helping people living with SCI.*** In the years to come, we will continue to conduct the best science we can and pursue scientific questions that will help find the cures for people living with paralysis. 





Cell Therapies Under Investigation for SCI

These are indeed exciting times for spinal cord injury (SCI) clinical trials.

Above: Polysialic acid expressing Schwann cells (blue) supporting brainstem axon growth (green) in the chronically injured spinal cord"

There are trials ongoing around the world targeting different repair strategies. In this article we want to take the opportunity to explain some of the high profile clinical trials ongoing in the United States utilizing cells as a therapeutic intervention.

Miami Project Schwann Cells

As many of our readers know, The Miami Project's 1st Phase I clinical trial testing Schwann cells began in November 2012 and we are happy to announce that the final participant was transplanted in August 2015. Schwann cells come from your own body and they are a type of cell found throughout the entire peripheral nervous system (PNS). The PNS includes all nerves going out to muscles as well as sensory nerves coming from the muscles back to the spinal cord. Schwann cells are a type of "support" cell in the PNS and some important points about Schwann cells are that they 1) insulate (myelinate) individual nerve fibers (axons), which is necessary for sending appropriate electrical signals throughout the nervous system, 2) are not stem cells, they are adult cells and can only be Schwann cells, and 3) can be obtained from each person's own body thereby eliminating the need for immunosuppression medicine.

This trial is specifically targeting people with new SCI, less than 30 days after injury, having sustained a trauma-induced lesion between thoracic levels T3-T11 and whom were neurologically complete. This is a dose escalation treatment trial, meaning that



We believe that this combination of cell therapy with intense rehabilitation prior to and following cell transplantation will enhance our chances of seeing improved recovery in the chronic setting.

we will test 3 different doses: 5 million, 10 million, and 15 million Schwann cells. There were a total of 39 people screened for eligibility, 9 were enrolled, and 6 participants were transplanted. The first two participants received the 5 million cell dose, the second two received the 10 million cell dose, and the final two received the 15 million cell dose. Thus far, there have been no treatment-related adverse effects in any of the transplanted subjects, which is excellent news. Remember, safety is the determinate of success for this Phase I trial. We are not releasing any other information about the participants or results because the trial is still ongoing and we cannot compromise the data. After the final participant is 12 months post-transplant we will prepare the results for publication in a peer-reviewed scientific journal.

Our 2nd Phase I clinical trial began in February 2015 for chronic SCI and will also be primarily focused on safety, but in addition it will involve a preliminary evaluation of the efficacy of combining Schwann cells with exercise and rehabilitation. For humans with chronic SCI, we hypothesize that axons might show improved function if myelin repair is induced with the implantation of autologous Schwann cells. In addition, spinal cord cavitation may be reduced and neural sprouting and plasticity may be enhanced via neurotrophic effects. In this trial, participants will receive three months of fitness conditioning and locomotor rehabilitation *prior to transplantation* in order to validate the stability of their neurological baseline as well as to enhance their fitness level thereby reducing any deconditioning effects. They will also receive fitness conditioning and rehabilitation for six months *post-transplantation* to maintain health and promote neuronal activity and potential neuroplasticity. We believe that this combination of cell therapy with intense rehabilitation prior to and following cell transplantation will enhance our chances of seeing improved recovery in the chronic setting <https://clinicaltrials.gov/ct2/show/NCT02354625>.

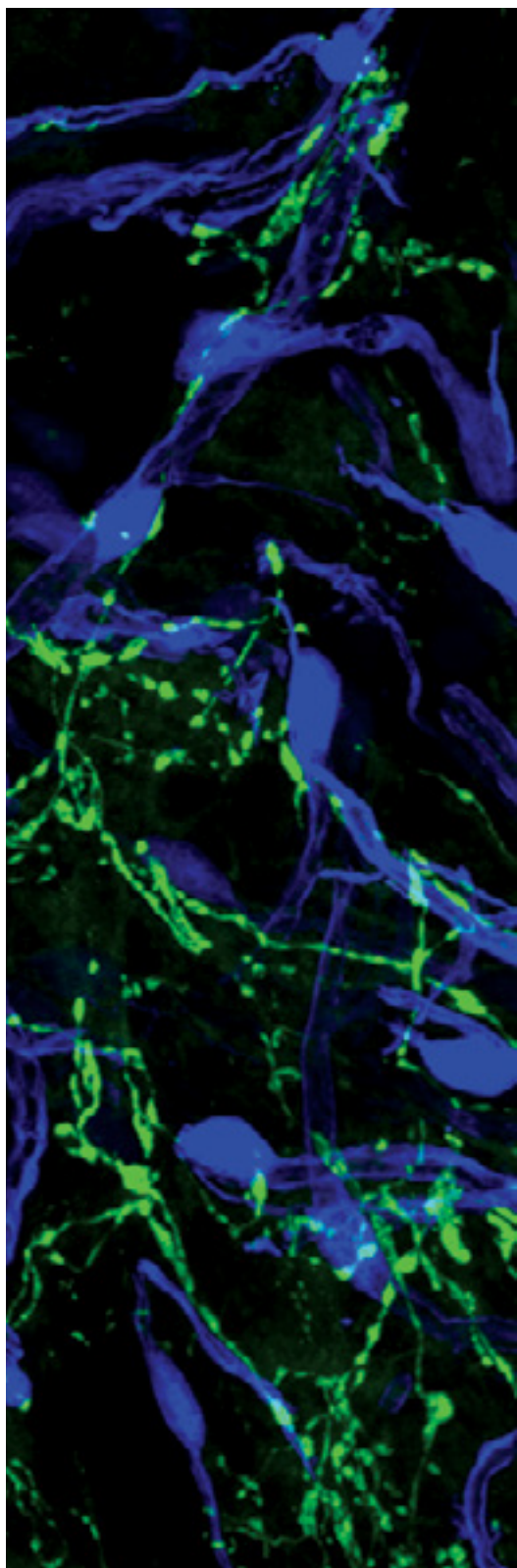
StemCells Inc

Drs. Allan Levi and Kim Anderson, along with several other University of Miami faculty members, are also participating in a clinical trial testing a different cell therapy – neural stem cells. That trial, referred to as the Pathway Study, is sponsored by a company called StemCells, Inc.

The Pathway Study is testing the safety and potential benefit of a very specific stem cell type known as a neural stem cell; these are not Schwann cells. The neural stem cells being used in the Pathway Study were derived from fetal brain tissue and have the ability to self-renew and become the main types of mature cells found both in the brain and spinal cord. These cells do not come from your own body, therefore anyone who receives them into their body has to be on immunosuppression medicine. Studies of SCI in animals have shown that these human neural stem cells can survive and lead to recovery of function through remyelination and possibly neuronal cell replacement.

Prior to the Pathway Study, the company conducted a Phase I/II safety & preliminary efficacy clinical trial in humans with thoracic SCI. Twelve participants were transplanted within 3 to 12 months of injury. The results they have disclosed at scientific meetings indicate that neural stem cell transplantation appears to be safe; several participants have regained some sensation.

The Pathway Study is a larger Phase II efficacy clinical trial designed to determine if neural stem cells can help people with cervical SCI recover spinal cord function and gain strength and sensation. They will enroll up to 52 participants. Individuals may be able to join the study if they are 18 to 60 years old, have a cervical SCI that is classified as ASIA Impairment Scale grade A, B, or C, are less than two years post-injury, and are generally in good health. Individuals that are eligible for the study will participate for approximately 12 months. There are several



sites around the country that are enrolling <https://clinicaltrials.gov/ct2/show/NCT02163876>.

Asterias Biotherapeutics

Many of you have probably heard of the Geron clinical trial that was prematurely halted a few years ago for financial reasons. In 2013, a new company called Asterias Biotherapeutics took over the rights for everything related to the prior trial. The first trial was a Phase I safety trial using a human embryonic stem cell line pre-differentiated into oligodendrocyte progenitor cells. The oligodendrocyte progenitor cells are targeting reduction of the size of the injury cavity as well as remyelination of demyelinated axons to restore conduction. These cells also cannot be obtained from your own body, hence require immunosuppression medicine as well when administered to anyone. In that trial, 5 individuals with complete thoracic injury received the cells within 14 days after their injury. The results they have disclosed at scientific meetings indicate that the cell transplantation appears to be safe and that four of the five participants appear to have a smaller cavity when evaluated by MRI.

In 2015, they began a Phase I/IIa dose escalation trial, the SCI-Star study. This trial is enrolling individuals with cervical injury between levels C5-C7 whom are neurologically complete. The cells have to be injected between 14 to 30 days post-injury; up to 13 participants will receive the cells. There are at least 3 centers enrolling <https://clinicaltrials.gov/ct2/show/NCT02302157>.

Neuralstem

The final cell therapy of high profile is being conducted by a company called Neuralstem. This is a Phase I safety trial using human fetal spinal cord neural precursor cells. These stem cells are targeting growth factor replacement and possibly neuronal cell replacement. Again, because these cells do not come from one's own body, they require immunosuppression medicine. The company previously completed a Phase I safety trial using the same cells in individuals with Lou Gehrig's disease. They transplanted 18 participants in mid- to late stages of the disease and demonstrated safety. The company then obtained approval for the SCI Phase I trial. A total of 4 participants with complete thoracic injury, between one and two years post-injury, will be transplanted. The study procedures are all performed in California <https://clinicaltrials.gov/ct2/show/NCT01772810>.

To find out more information about the trials being conducted at The Miami Project, contact The Miami Project Education Department at 305-243-7108 or MPinfo@med.miami.edu. More information about all of our clinical trials and studies is available at <http://www.themiamiproject.org/trials>.



Training the next generation of scientists

is an important component of The Miami Project's mission. We are very proud to share that recently three of our graduate students received highly competitive fellowship awards from the National Institute of Neurological Disorders & Stroke.



Back row: Dr. Daniel Liebl, Enmanuel Perez Martinez
Front row: Poincyane Assis-Nascimento, Nicole Wilson, Dr. Coleen Atkins

Nicole Wilson, Neuroscience Ph.D. Candidate in the laboratory of Dr. Coleen Atkins

Project – *The Role of*

Phosphodiesterase 4B in Inflammation after Trauma

In the literature, the anti-inflammatory effects of non-specific (pan)-phosphodiesterase 4 (PDE4) inhibitors are well established in central nervous system (CNS) injury models. However, knock out studies have indicated that the PDE4 subfamily, PDE4B, is predominantly responsible for the anti-inflammatory effects of pan-PDE4 inhibition. The recent development of a PDE4B specific inhibitor has made it possible for Nicole to investigate the role of this enzyme in the context of traumatic brain injury (TBI). Thus, her project is focused on establishing the therapeutic potential of PDE4B inhibition for reducing inflammation and improving outcome after TBI.


Poincyane Assis-Nascimento, Neuroscience Ph.D. Candidate in the laboratory of Dr. Daniel Liebl

Project – *Eph Receptors Regulate Vascular Growth Following Traumatic Brain Injury*

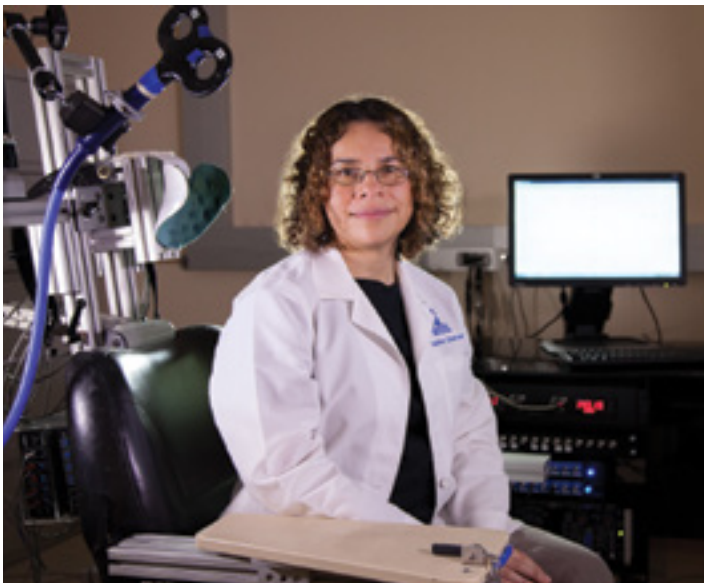
One of the earliest and most profound deficits associated with TBI comes from damage to blood vessels that ultimately underlie much of the progressive pathology. Unfortunately, little is known of the cellular signs and responses that regulate blood vessel integrity and/or regeneration in the injured brain. The objective of Poincyane's studies is to examine a novel family of membrane-bound proteins, called Eph receptors, on blood vessel regeneration and blood-brain barrier (BBB) integrity following TBI. Examining mice that are missing Eph receptors shows that these proteins play clear roles in regulating BBB integrity, which can significantly impact the inflammatory response where peripheral immune cells enter the brain after injury. In addition, she is working to understand the relative contributions of local signals in the brain versus peripheral signals from circulating stem/progenitor cells on blood vessel regeneration. Like many other systems in the body, both growth promoting and inhibiting signals contribute to regulate regeneration, and her studies are designed to address both of these important regulatory events.

Enmanuel Perez Martinez, Neuroscience Ph.D. Candidate in the laboratory of Dr. Daniel Liebl

Project – *Modulating Post-injury Gliotransmitter Levels leads to improved Synaptic Function*

Enmanuel is interested in examining the contribution of glial cells in the stabilization and formation of synapses (electrical or chemical connections between nerve cells). Maintaining and regenerating neuronal connections within the brain and spinal cord are essential for all bodily functions, including sensation, movement, and thinking. The largest component of functional losses in the CNS is synaptic damage, thus understanding the molecular mechanisms that regulate synaptic stability and reformation are very important. His research will examine whether glial cells play important roles in synaptic functions after traumatic injury, and identify specific factors that regulate communication between neuronal processes and glial cells. These studies will not only advance our understanding of synaptic formation, but will help establish a therapeutic strategy to protect and regenerate the injured CNS. 





Dr. Monica Perez

Monica Perez, P.T., Ph.D. “Home” is Truly Where the Greatest Opportunity Lies

“The Miami Project is such a special place, and we really wanted to be a part of the best center, the leading research center in the fields, so that is why we moved.”

When Dr. Monica Perez, Associate Professor of Neurological Surgery and The Miami Project, and her husband Martin Oudega, Ph.D., Research Associate Professor of Neurological Surgery and The Miami Project, left Miami in 2003, little did they know that a dozen years later their careers would come a full circle. They never thought that their paths would return them to Miami where their careers and life together started, so the old saying that you can’t go home again doesn’t hold true for their story.

To better understand where you are going, it sometimes make sense to look back to where you started. Early in her career Dr. Perez started working as a physical therapist and it quickly became apparent to her that she wanted to play a role in understanding how humans control movement, and inspiration struck. She found that many of the therapy protocols needed a stronger rationale, or scientific basis so she decided to go for her Ph.D. and try to be one of the individuals who contributes to the understanding of movement control and to use that knowledge to improve therapies.

Dr. Perez wanted to be one of those individuals who tried to develop the best therapies or protocols that might have a positive translation to individuals living with spinal cord injury (SCI). In order to have a voice in that discussion, she felt the Ph.D. program at the University of Miami and a job at The Miami Project would be a great place start. She had a special interest in SCI research from the beginning of her career, so she applied to UM specifically because of The Miami Project.

As someone who dreamed as a younger woman of being a writer, she finally found a way to combine her need to have a voice in the field with her love of writing. Her passion for writing is still there, but now it is used to write scientific manuscripts and grant proposals. She gets to not only gather the results of her studies, but gets to communicate those results so that people can read and understand the complexities, as well as the beauty, of science. At the end of the day, if you do great experiments, but fail to communicate the findings properly to people, they will ultimately never know the results.

During her initial stint in Miami, she credits the growth of her love of the field to her early mentors like current researchers Drs. Christine Thomas and Mark Nash and former colleagues Drs. Edelle Field-Fote and Blair Calancie. Her career path was solidified by her two post-doctoral fellowship at the Department of Physiology, University of Copenhagen, Denmark and Human Cortical Physiology Section, National Institute of Neurological Disorders and Stroke, National Institutes of Health. She was fortunate to work at two of the best places in the world studying motor control in humans with two very distinct individuals (Professors Jens Bo Nielsen and Leonardo Cohen). The roots of her curiosity started in The Miami Project, and the line of her research career continued to be defined during those all-important training steps.

“In many ways returning to Miami is very special for us. It’s more than getting a job at a prestigious institution, it is getting a job at a prestigious institution that played a



role in my initial steps as a scientist. I think this is a fantastic place to do SCI research,” said Dr. Perez. “The Miami Project is a unique comprehensive research center, and we really wanted to be a part of this leading center in the field, so that is why we moved.”

Now that her laboratory is established in Miami, the work moving forward is underway. Her space consists of five laboratories for human electrophysiology, and the locomotor lab, and experiments are running. In a few short months, Dr. Perez and her staff, which currently consists of seven post doctorate fellows, a nurse helping recruit research participants and one student, have already screened more than a hundred potential research participants and started to address several research questions related to movement control after SCI.

The goal of Dr. Perez and her group is to use electrophysiology to characterize existing physiological deficits in individuals with SCI. This physiological information is later on used to develop strategies aiming to recover function so every strategy used is based on actual physiology. It is her philosophy that human non-invasive electrophysiology can be successfully used to guide interventions after SCI. Her group targets residual neuronal pathways which might represent a critical avenue for enhancing recovery of function and voluntary motor output after an injury to the spinal cord.

She’s bringing her expertise in motor control to The Miami Project and feels that understanding how the brain and spinal cord control movement plays a vital role in the design of successful therapeutic strategies. Motor control is one important aspect, and she sees her line of research as complimentary to



Members of Dr. Perez’ lab performing an experiment using brain stimulation

others in The Miami Project, such as regeneration, neuroprotection, exercise physiology, and pre-clinical studies. Her lab brings to the table a neural mechanistic approach to the control of movement. It’s important that all disciplines work together to design better therapies.

Some future protocols in Dr. Perez’s lab will aim to combine the physiological information that is gathered and translate that into motor training strategies in the acute and chronic phase of SCI. It’s important after SCI to better understand how neuronal connections are affected and if they are able to generate movement or not. What changes in transmission are taking place and where are the deficits? If we can understand these neural mechanisms, Dr. Perez feels that we can ultimately design better strategies for training and rehabilitation. Several of the lines of experiments that she has worked on in the last years in SCI now are becoming part of her translational approach to training that will help

gain a better understanding not only of paralysis, but also of recovering movement after paralysis. One in particular is a protocol based on the principles of spike timing dependent plasticity. This work was published in *Current Biology* in 2012 showing that spike timing-dependent plasticity like changes can be elicited at residual corticospinal synapses after human spinal cord injury. Importantly those physiological changes resulted in improvements in voluntary motor output.

“There are many places in the world where people with SCI are being trained to enhance their motor output, which is very positive, and we also do that here at The Miami Project. However, as a group our approaches aim to understand key elements in our different disciplines and our lab specifically contributes to understand aspects of human motor control,” Dr. Perez concluded. “I think you cannot just train people, you have to understand what you are training to be more successful.” 🧠

Clinical Trial Coordinators

The Heart of Our Trials



Clinical trials coordinators:
Letitia Fisher, Marine Dididze,
Kathleen Nagle, Carlos Bidot
and Vianca Caridad (not
pictured)

The Principal Investigator holds the ultimate responsibility for the trial, but the clinical trial coordinator makes the wheel turn.

Clinical trials are a massive amount of work. Obtaining approval from the FDA (Food and Drug Administration) and IRB (Institutional Review Board) to begin a trial is one thing, but conducting all of the daily operations of a trial is an entirely different topic. The Principal Investigator (PI) holds the ultimate responsibility for the trial, but the clinical trial coordinator (CTC) makes the wheel turn.

Clinical trial coordinators are involved in recruiting, screening, and enrolling participants; helping to obtain participant informed consent; scheduling tests and procedures with the multitude of departments and co-investigators involved with a particular trial; ensuring that participants show up to the various tests and procedures; collection of clinical research data and completing case report forms; ensuring the accuracy of documentation; watching and querying participants

for adverse events and informing the PI; dispensing study medications if applicable; managing the use of investigational devices if applicable; maintaining databases, maintaining regulatory documentation; working with external monitors and auditors.

All of these responsibilities can sometimes be too much for a single person, so many of our trials have two clinical trial coordinators. They work tirelessly for the success of the clinical trial, from coming to work at the crack of dawn for surgery, to staying late at night to receive cells being shipped, to working on the weekends or even over holidays if need be; they help research participants with all kinds of questions and problems; and they even have to hunt down investigators sometimes! We truly appreciate our clinical trial coordinators and everything they do because without their dedication and hard work we would not be able to do all of the trials we are doing. 🙏



SPINE CLINICAL TRIALS	PI and CTC
The Safety of Autologous Human Schwann Cells in Subjects with Subacute Spinal Cord Injury	Dr. Allan Levi; Marine Dididze, Kathleen Nagle
Long-term Safety Monitoring of Recipients of Autologous Human Schwann Cells	Dr. Allan Levi; Marine Dididze, Kathleen Nagle
Expanded Access for Single Patient Treatment of Autologous Human Schwann Cells (ahSC) for Peripheral Nerve Repair	Dr. Allan Levi; Marine Dididze,
The Safety of ahSC in Chronic SCI with Rehabilitation	Dr. Allan Levi; Marine Dididze, Kathleen Nagle
ahSC Augmentation of Peripheral Nerve Repair	Dr. Allan Levi; Marine Dididze, Kathleen Nagle
A Single-Blind, Randomized, Parallel Arm, Phase II Proof-of-Concept Study of the Safety and Efficacy of HuCNS-SC Transplantation in Cervical Spinal Cord Injury	Dr. Allan Levi; Marine Dididze, Kathleen Nagle
North American Clinical Trials Network Spinal Cord Injury Registry	Dr. James Guest; Marine Dididze,
A Post Approval Investigation of the BRYAN Cervical Disc Device at a single Level for Symptomatic Cervical Disc Disease	Dr. Allan Levi; Marine Dididze,
Efficacy of Intravenously Instituted Hypothermia Treatment in Improving Functional Outcomes in Patients Following Acute Spinal Cord Injury	Dr. Allan Levi; Marine Dididze,
Treatment of Pain and Autonomic Dysreflexia in Spinal Cord Injury with Deep Brain Stimulation (DBS)	Dr. Jonathan Jagid; Letitia Fisher, Alberto Vitores
Early Feasibility Study of a Medtronic Activa PC+S System for Persons Living with Spinal Cord Injury	Dr. Jonathan Jagid; Letitia Fisher
RISCS - A Multi-Center, Randomized, Placebo-Controlled, Double-Blinded, Trial of Efficacy and Safety of Riluzole in Acute Spinal Cord Injury	Dr. James Guest; Vianca Caridad; Marine Dididze
Evolution of Traumatic Spinal Cord Injury (SCI) Severity and Outcome using Paired Cerebrospinal Fluid and Serum for Markers for Secondary SCI Ischemia and Neuronal Injury	Dr. Michael Wang; Marine Dididze; Vianca Caridad
Analysis of the Incidence of Post-Operative Wound Infections after Spine Surgery: A Prospective Study	Dr. Allan Levi; Marine Dididze
Safety and Efficacy of SA4Ag Vaccine in Adults Having Elective Posterior Instrumented Lumbar Spinal Fusion Procedure (STRIVE)	Dr. Michael Wang; Vianca Caridad
Single Patient expanded access IND to deliver bone marrow mesenchymal stem cells (BMSCs) to the spinal cord of a young woman with a subacute complete C3 cervical spinal cord injury (SCI)	Dr. James Guest; Vianca Caridad

BRAIN CLINICAL TRIALS	PI and CTC
TRACK TBI - Transforming Research and Clinical Knowledge in Traumatic Brain Injury	Dr. Ross Bullock and Dr. Gillain Hotz; Carlos Bidot; Vianca Caridad
TBI Registry: A Prospective Examination of Mild to Severe TBI Patients Cared for by UM Neurotrauma Service to Evaluate Patient Status, Progress and Standard of Care	Dr. Ross Bullock; Carlos Bidot; Vianca Caridad
H.O.P.E.S. - Hypothermia for Patients requiring Evacuation of Subdural Hematoma: A Multicenter, Randomized Clinical Trial	Dr. Jonathan Jagid; Carlos Bidot; Vianca Caridad
Evaluation of Traumatic Brain Injury Severity and Outcome Using Paired Cerebrospinal Fluid and Serum Markers for Secondary Brain Ischemia and Neuronal Injury	Dr. Ross Bullock; Carlos Bidot; Vianca Caridad
Culture of Neuronal Progenitor Cells from Patients with Acute Brain Damage	Dr. Ross Bullock; Carlos Bidot
Near real time Detection of Cytokines and Biomarkers in Severe Human Traumatic Brain Injury	Dr. Ross Bullock; Carlos Bidot; Vianca Caridad





It is a time of transitions in the Department of Neurological Surgery. After 20 years as the Chairman, Dr. Barth Green will be stepping down and Dr. Allan Levi will be stepping up.



A Time of Transitions

Dr. Green was recruited to Miami in 1975 as a junior faculty member in the University of Miami Miller School of Medicine Department of Neurological Surgery. He established long-term clinical and research collaborations with the Departments of Orthopaedics and Rehabilitation, Neurology, and Radiology. He worked tirelessly providing clinical care to those who suffered spinal cord damage. In 1978 he helped establish and co-direct the first South Florida Regional Spinal Cord Injury (SCI) Model System of Care. He and his colleagues were working to continually improve early, comprehensive care to achieve the best outcome for individuals with SCI. By 1985 he had become a full Professor and founded The Miami Project to Cure Paralysis, and in 1995 was appointed as Chairman of the Department of Neurological Surgery.

Dr. Allan Levi also has a long history with The Miami Project, which now spans over 2 decades. He earned his PhD with Dr. Richard P. Bunge in 1994 studying human Schwann cell biology. In 1997, Dr. Levi came back to Miami permanently and began the equivalent of two careers. He began his clinical career in neurosurgery specializing in spine and peripheral nerve disorders. At the same time he was advancing in his clinical career, he was equally successful in his basic science research career. He led a basic science laboratory for 15 years studying human Schwann cell biology and SCI in a variety of animal models. By 2007, he was a fully tenured Professor in Neurosurgery and began evaluating the safety and efficacy of therapeutic hypothermia as a neuroprotective treatment for severe SCI. In 2012, Dr. Levi was appointed the Robert M. Buck Distinguished Chair in Neurological Surgery and has been focusing all of his research efforts on clinical trials.

Dr. Green will not be retiring by any means. He will continue to be very active clinically and will take on an important senior leadership role at the University of Miami Miller School of Medicine. He will concentrate on specific activities he is excited about including international outreach and health longevity programs that

are important to the University and Medical Center. The new rehabilitation hospital and fundraising for The Miami Project remain a high priority for Dr. Green.

The Department has several very strong faculty members that will take on new clinical leadership roles.

Allan D. Levi MD, PhD

Chairman of Neurosurgery

Chief of Neurosurgery JMH

Jacques Morcos, MD

Co-Chair of Neurosurgery

Chief of Cranial Service JMH

Michael Wang, MD

Chief of Neurosurgery UMH

Director of Neurosurgical Spine Fellowship

Program UM

Director of the MIS Institute UM

Ross Bullock, MD, PhD


Clinical Director of Neurotrauma and Translational Research Programs JMH

Steve Vanni, DO

Chief of Neurospinal Services JMH

Glen Manzano, MD

Co-Director of the Acute SCI Unit JMH

An ever important component of the Department is The Miami Project and the strong research faculty. The Project is the world's most comprehensive SCI research center and has been the model by which many other research centers have been built. We have made a multitude of advances on all fronts including injury prevention, neuroprotection, cell replacement, regeneration, scar manipulation, rehabilitation, exercise conditioning, muscle spasticity, pain, and male fertility. Dr. Levi is the ideal person to lead the department into the exciting era of translating our knowledge into clinical trials. There are currently over 20 clinical trials being conducted by different faculty members targeting spinal cord injury and traumatic brain injury. These are indeed exciting times and we look forward to the future with Dr. Levi leading the Department. 





The 29th Annual Great Sports Legends Dinner A Huge Success For The Buoniconti Fund To Cure Paralysis

Hakeem Olajuwon, Warren Sapp, Pedro Martinez, Bill Cowher, Tom Brokaw, Grant Hill and more joined forces to "Stand up for those who can't"



Celebrities, sports legends, corporate leaders and more joined NFL Hall of Famer **Nick Buoniconti**, his son **Marc**, and Event Chair **Mark Dalton** as they hosted a sold out crowd in celebration of the 29th Annual Great Sports Legends Dinner presented by Carnival Corporation & PLC and the Carnival Foundation. Held at New York's famed Waldorf Astoria, the dinner paid tribute to philanthropic heroes and sports icons that inspire and motivate those affected by spinal cord injuries, and raised important funds for research and the Human Clinical Trials Initiative. **Tom Brokaw** of NBC News served as Master of Ceremonies of the dinner to support the efforts of **The Buoniconti Fund to Cure Paralysis**, and to honor this year's Great Sports Legends: **Hakeem Olajuwon, Warren Sapp, Pedro Martinez, Joe Sakic, Bill Cowher, Mary Lou Retton** and **Lauryn Williams**. Music legend **Smokey Robinson** treated guests to a very special performance.





2014 Legends and Honorees

Seven-time NBA All-Star **Grant Hill** and retired NFL Pro-Bowl running back **Calvin Hill** each received the 2014 Buoniconti Fund Award. Professional Golfer **Erik Compton**, a two-time heart transplant patient who finished runner-up at the 2014 U.S. Open Championships, was the 2014 Inspiration Award recipient. **Bill Simon**, former President and CEO of Walmart U.S., received The Buoniconti Fund's Outstanding Business Leader Award.

The annual event benefits The Buoniconti Fund to Cure Paralysis and raises funds to support the cutting-edge spinal cord injury research done by researchers at the University of Miami Miller School of Medicine's Miami Project to Cure Paralysis. Since its inception in 1985, the Great Sports Legends Dinner has honored more than 300 sports legends and honorees and has raised more than \$100 million for The Miami Project's spinal cord injury research programs.

Additional notables in attendance included: Grammy winning Producer and Musician **Emilio Estefan**, eighteen-time Grammy Award-winning singer **Aretha Franklin**, actor **Christian Slater** (*Robin Hood: Prince of Thieves*, *Interview with the Vampire*), five-time Olympic gold medal-winning gymnast **Nadia Comăneci**, 10-time Olympic swimming medalist **Gary Hall, Jr.**, *Friday Night Lights*' **Brad Leland**, NFL Hall of Famer **Harry Carson**, NHL Hall of Famer **Brian Leetch**, former NY Giants linebacker **Brian Kelly**, actor **Colin Egglesfield** (*Something Borrowed*, *The Client List*) and many, many more.

Sponsors for the evening were: Carnival Corporation & PLC and the Carnival Foundation, Tiffany & Co., HBO Sports, Barton G. and Diageo. 🍹



Tom Brokaw



Aretha Franklin and
Smokey Robinson



Bill Cowher and
Lauryn Williams



Nick and Marc Buoniconti



Alex Rodriguez and
Pedro Martinez



Chuck Jackson, Mark Dalton
and Phylicia Rashād



Nick and Lynn Buoniconti with Marc Buoniconti and
Willie and Christina Geist



Andre Dawson, Grant Hill, Emilio Estefan, Hakeem Olajuwon and Dr. Barth Green





Mark Dalton



Calvin and Grant Hill



Erik Compton with Terry and Marc Buoniconti



Diana Morrison, Grant Hill, Christine Lynn, Hakeem Olajuwon and Victoria Ranger Nunez



Christian Slater and Tom Brokaw



Paul DiMare with Donna Shalala and Swanee Dimare




Linda Coll with Mike Eruzione and Nadia Comaneci

Groundbreaking Ceremony Of The Christine E. Lynn Rehabilitation Center



Marc Buoniconti and Christine E. Lynn

Dignitaries
Gather For The
Groundbreaking
Ceremony Of The
Christine E. Lynn
Rehabilitation Center
For The Miami
Project To Cure
Paralysis At Uhealth/
Jackson Memorial

Nick and Marc Buoniconti, University of Miami President Donna E. Shalala, Jackson Health System President and CEO Carlos A. Migoya, and other dignitaries gathered on the morning of April 29 to celebrate the groundbreaking of the Christine E. Lynn Rehabilitation Center for The Miami Project to Cure Paralysis at UHealth/Jackson Memorial. Mrs. Lynn's \$25 million donation helped spearhead the fundraising effort for the center. Miami-Dade voters in 2013 overwhelmingly supported a general obligation bond to upgrade Jackson's infrastructure and build new facilities, which provided additional funds for the rehabilitation center. Once completed, the Christine E. Lynn Rehabilitation Center will offer state-of-the-art rehabilitation that will unite the spinal cord and brain injury clinical, basic science and translational research excellence of the University of Miami's Miami Project and Jackson Memorial. Alan and Michael Stillman of Quality Meats Restaurant Miami Beach hosted a celebration in honor of Christine Lynn, Nick and Marc Buoniconti and The Buoniconti Fund. 





Dr. Barth Green, Marc Buoniconti, Christine E. Lynn and Nick Buoniconti



Dr. Steve Falcone, Dr. Pascal Goldschmidt, Donna Shalala, Dr. Dalton Dietrich and Stuart Miller



UHealth, Jackson and Miami Dade County Dignitaries Breaking Ground



Dr. Pascal Goldschmidt, Donna Shalala, Christine E. Lynn, Stuart Miller and Keith Tribble



Marc Buoniconti and Cynthia Vijitakula



Nat Moore, Nick Buoniconti, Dick Anderson



Suzie and Dr. Eugene Sayfie



John Gallo, Christine E. Lynn and Kandy Kramer



Teresa Rodriguez and Dr. Allan Levi



Tim Gannon, Nick Buoniconti with Kristin and Matthew Whitman Lazenby



Nancy and Jon Batchelor



Dr. Barth and Kathy Green, Nick Buoniconti and Carlos Migoya



Brownyn Miller, Marc Buoniconti, Swanee DiMare and Alan Stillman





Lisa Sayfie, Stephanie Sayfie Aagaard, Christine E. Lynn, Suzie Sayfie and Amy Sayfie Zichella



Nick and Lynn Buoniconti with Alan Stillman



Marc Buoniconti and Christine E. Lynn



Donald and Judy Lefton



Nat Moore, Sally Heyman, Christine E. Lynn and Paul DiMare



Gina Buoniconti Bruce, John Gray, Terry Buoniconti, Chris Pederson and Frances Sevilla Sacasa



Michelle and Jason Rubell



Morten Aagaard and Stephanie Sayfie Aagaard



Colleen and Chris Anderson with Denise DiMare



Hall of Fame Drag Racer

Darrell Gwynn

'COMES HOME'

Nearing the 25th anniversary of both his last National Hot Rod Association (NHRA) win and the accident that left him paralyzed, Hall of Fame Drag Racer Darrell Gwynn announced today that he will begin a new chapter in his journey to support those living with paralysis. Gwynn will officially become the Director of The Darrell Gwynn Quality of Life Chapter of The Buoniconti Fund to Cure Paralysis. The Buoniconti Fund is the fundraising arm of The Miami Project to Cure Paralysis, the world's most comprehensive spinal cord injury research center, located at the University of Miami Miller School of Medicine.

"I am happy to 'come home' to The Buoniconti Fund and join Nick and Marc Buoniconti as they work to better the lives of those suffering from paralysis. As a racer, I believed in the cause and have supported them in their efforts for more than 25 years. After my accident we continued to help and now I am thrilled to be side by side with the Buonicontis," said Gwynn.

"As a racer, I believed in the cause and have supported them in their efforts for more than 25 years. After my accident we continued to help and now I am thrilled to be side by side with the Buonicontis,"

As a world champion racer in the 80's, Gwynn was at the top of his game and chose to donate a portion of his winnings to The Miami Project and continued after his accident. He felt so strongly about Marc Buoniconti's struggle to find a cure for paralysis, and the plight of those suffering from paralyzing spinal cord injuries, that he personally placed the iconic Miami Project wheelchair logo in a prime location on his race car to show his support.



Hall of Fame Drag Racer unites with Marc Buoniconti to help find a cure for paralysis and help those living with paralysis have an improved quality of life

Sixteen years ago, Darrell and his wife Lisa were direct beneficiaries of some of The Miami Project's miraculous research advances when they gave birth to their daughter Katie through The Miami Project's research program that helps paralyzed men achieve fatherhood. This 13 year relationship has blossomed through the Darrell Gwynn Foundation's Patient Assistance Fund, including yearly donations in support of many of the scientific efforts at The Miami Project.

Since its inception in 2002, the Darrell Gwynn Foundation has provided support for people with paralysis and worked to prevent spinal cord injuries through their Wheelchair Donation Program and Education & Prevention Program. He will continue to achieve these goals through his work with The Darrell Gwynn Quality of Life Chapter of The Buoniconti Fund, under the umbrella of The Miami Project's fundraising arm.

For those not familiar with his background, Darrell grew up watching and helping his father, Jerry, a former NHRA world champion, who drove Alcohol Funny Cars. While Darrell obviously got his love of the sport from his dad, he didn't even attempt to drive Funny Cars. He went directly to dragsters. At 7 years old, Darrell was piloting a scaled down dragster designed and hand built by his father. By 17, he had earned his first professional competition license. When Darrell began his racing career in 1980 in



Marc Buoniconti with Richard Petty and Darrell Gwynn

"Darrell has been a true champion in all aspects of his life," said Marc Buoniconti, President of The Buoniconti Fund and The Miami Project. "His foundation has touched thousands of lives and we are thrilled to have him truly come home to the Buoniconti Fund family. We will continue to do great things as we strive toward our mutual goals of helping better the lives of those living with paralysis and ultimately finding a cure."



Darrell with his father Jerry Gwynn

the Alcohol Dragster category of the National Hot Rod Association, he attacked the sport with fierce determination. Not only did he have 10 wins as an Alcohol Dragster, he also was the Top Alcohol Dragster World Champion in 1983. At the age of 23, he moved up to the Top Fuel category. By 1990, Darrell had worked his way through the ranks to become one of America's hottest NHRA Top Fuel drag racers, but 1990 would be the year that everything changed, it would bring him his 18th and final win as a driver.

Fate took Gwynn to England in April 1990. In an exhibition race at Santa Pod Raceway, his dragster suddenly broke and veered left into the retaining wall at halftrack at approximately 240mph, causing major life-threatening injuries to the 28-year-old driver. A terrific battle of faith and determination allowed him to survive the ordeal, he was left paralyzed and he lost his left arm.

Since that time, Gwynn changed roles from star driver to team owner. He employed Frank Hawley, Mike Brotherton, Mike Dunn, Andrew Cowin and Cory McClenathan to handle the driving duties. Jerry Gwynn, the biggest influence on Darrell's career decisions, was a vital part of the team as manager. Despite all the changes, he was still the driving force that kept the team focused and directed toward a championship.

Gwynn's signature style of barrier busting continued both in front of and beyond the reach of the public eye. In 2001, at the biggest event in NHRA's 50th anniversary year, the U.S. Nationals at Indianapolis, Gwynn demonstrated his willingness and ability to live life to the fullest. At the site of his most prestigious racing win, Gwynn shocked and wowed a capacity crowd by driving a custom-built, hand-controlled dragster down the Indianapolis Raceway Park quarter-mile track in a special exhibition run.

Although the Darrell Gwynn Racing NHRA Race Team had a tremendous amount of sentimental value to Darrell, at the end of 2003 with travel becoming increasingly more difficult Darrell chose to sell the team. Darrell decided helping others through his charitable efforts, and spending more quality time with his wife and daughter would be a greater reward than any race won.

April 2015 marked the 25th anniversary of Darrell's racing accident. 🇺🇸



Darrell posing alongside his dragster



Darrell with his New York Yankees race team



Lisa Darrell and Katie Gwynn



DESTINATION FASHION



Enrique Iglesias



SEAL



Tommy Lee Jones, Dawn Jones and
Delfina Blaquier and Nacho Figueras



Dwayne "The Rock" Johnson



Helio Castroneves

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www.thebuonicontifund.com



Don Shula and
Nick Buoniconti



Julio Iglesias with Gloria and
Emilio Estefan



Kyle Chandler and
Jerry Rice



Marc Buoniconti and
Jack Nicklaus



Joe Manganiello and
Tom Brokaw

*Past Destination Fashion events featured above.



National Volunteer Chapters

The Woody Foundation held its **4th Annual Golf Classic** on April 30 at the International Links Miami golf course. Nearly 100 golfers, sponsors and volunteers came out to support this great day of golf, community and spinal cord injury research awareness. The Woody Foundation donated \$40,000 to the Miami Chapter of The Buoniconti Fund, which has been the beneficiary and partner for this tournament since 2012 with nearly \$150,000 donated from The Woody Foundation to support the ongoing research at The Miami Project to Cure Paralysis.



James “Woody” Beckham, Bill Beckham and Marc Buoniconti

The Woody Foundation, Inc. is a 501(c)(3) not for profit organization formed in 2011 to raise funds for the recovery of spinal cord injured persons. James “Woody” Beckham suffered his spinal cord injury making a rugby tackle in January 2011.



The Jones Family at 11th Annual Raise a Glass for a Cure

On November 8, 2014, the Philadelphia Chapter hosted more than 300 guests at Vie in Philadelphia for the **11th Annual Raise a Glass for a Cure** event. The event, led by Volunteer Regional Co-Directors Dan and Caren Jones along with a dedicated committee, featured tasting stations, live entertainment, celebrity guests, and live and silent auctions. This signature gala raised more than \$160,000 to support our spinal cord injury research at The Miami Project and Magee Rehabilitation Hospital. The Philadelphia Chapter has been the leading fundraiser of the Buoniconti Fund Volunteer Chapters, raising more than \$1 million in support of The Miami Project to Cure Paralysis.

On January 17, the Miami Chapter hosted the **6th Annual Coral Gables Block Party** presented by Hillstone Coral Gables. The event, which raised \$15,000, brought more than 400 guests and community partners out for an amazing



NBC 6 Anchor Adam Kuperstein, Christian Slater, Marc Buoniconti, NBC 6 Roxanne Vargas



night under the stars with sumptuous food by Hillstone, craft beer and spirits, local and national celebrities, live music, dancing and auction.



Summit 2015 attendees with Marc Buoniconti at The Miami Project to Cure Paralysis

The Buoniconti Fund hosted its eighth **SUMMIT 2015** on August 6-9. More than 60 volunteers, representing twelve Chapters from around the country, and a dozen guests from Spinal Network peer support groups, came to Miami to exchange ideas, promote volunteerism and increase awareness of spinal cord injury research. The weekend conference featured a Research Update and tours of The Miami Project to Cure Paralysis, educational workshops, and social and appreciation events. Attendees heard the latest news of the FDA approved Human Clinical Trials, scientific achievements and progress from our Scientific Director Dr. Dalton Dietrich and an esteemed panel of Miami Project researchers.



Summit 2015 Scientific Update with Dr. Dietrich and Dr. Pearse at The Miami Project to Cure Paralysis

SUMMIT 2015 was graciously supported by Hollister Incorporated, Permobil and Nuance Communications, as well as hospitality partners including Loews Miami Beach, Smith & Wollensky Miami Beach, Shorty's Bar-B-Q, Coca-Cola, E & J Gallo Winery, Zuni Transportation, and Dolphin Limousine.



Chapters Challenge is in its fifth year as a successful campaign that encourages our volunteers and supporters participating in local, national and international races to utilize our web-based program to raise funds and awareness on behalf of The Buoniconti Fund and The Miami Project to Cure Paralysis. Race participants can establish their own page, fundraising goals, contact friends and family, track their success, and make donations directly to The Buoniconti Fund. Our goal is to have our supporters walk, run, swim, bike or wheel their way across the finish line!

<http://chapterschallenge.thebuonicontifund.com>

Let us know if your community could benefit from a Volunteer Chapter which develops fundraising events and awareness campaigns to help us reach our goal of finding a cure for paralysis. There's no better time to create SCI awareness in your community! Email bfchapters@med.miami.edu or call (305) 243-3863 to get started. Visit www.thebuonicontifund.com/chapters for the latest events and community outreach and join the Buoniconti Fund Chapters on Facebook.

CHAPTERS UPCOMING EVENTS

October 17-18 ~ Southeast Michigan Chapter ~ Detroit Marathon 'Run for a Reason' ~ Detroit, MI

October 31 ~ Charleston Chapter ~ 9th annual Tailgate Party ~ Charleston, SC

November 6 ~ Philadelphia Chapter ~ 12th annual Raise a Glass for a Cure ~ Philadelphia, PA

November 7 ~ Tampa Chapter ~ 8th annual Golf Classic ~ Tampa, FL

November 21 ~ Darrell Gwynn Quality of Life Chapter ~ Hot Rods & Reels Charity Fishing Tournament ~ Miami, FL

December 3 ~ Chicago Chapter ~ 17th annual Indulgence Night ~ Chicago, IL

Golf Legend Jack Nicklaus Hosts 13th Annual Buoniconti Fund Celebrity Golf Invitational

Presented By The Tudor Group

The Bear's Club event has raised millions to help fund Miami Project research programs

Jack Nicklaus, the greatest golfer who ever lived, along with NFL Hall of Famer Nick Buoniconti and his son Marc hosted the 13th Annual Buoniconti Fund Celebrity Golf Invitational Presented by Tudor Group at Nicklaus' home club and course, The Bear's Club in Jupiter, Florida. For the past 13 years, the tournament and dinner has allowed some of the world's top business leaders and celebrities to join forces to find a cure for spinal cord injuries. Since its inception, The Bear's Club event has raised millions to help fund research programs at The Miami Project to Cure Paralysis at the University of Miami Miller School of Medicine.

Golfers and celebrities including Bon Jovi drummer Tico Torres, NFL Hall of Famer Harry Carson, former Marlin great Jeff Conine, NFL #1 draft pick in 1995 Ki-Jana Carter, Super Bowl MVP Mark Rypien, World Series Champion Pitcher Scott Erickson, Actor from *All My Children* and *Dancing with the Stars* Aiden Turner, Eight-time NBA Champion with the Boston Celtics John Havlicek, Three-time NBA Champion with the San Antonio Spurs Bruce Bowen, Actor DB Sweeney from *Eight Men Out* and *Lonesome Dove*, and many more enjoyed the Celebrity Dinner affair and an exciting day of golf on the prestigious golf course.

Special thanks to Mark Dalton, Tudor Group, PGA National Resort and Spa, Tiffany & Co., Aventura Worldwide Transportation Services, The Collection, and more. 🇺🇸

Join us in the Spring of 2016 for the 14th annual event.



Tico Torres



Jack Nicklaus with Mark Dalton

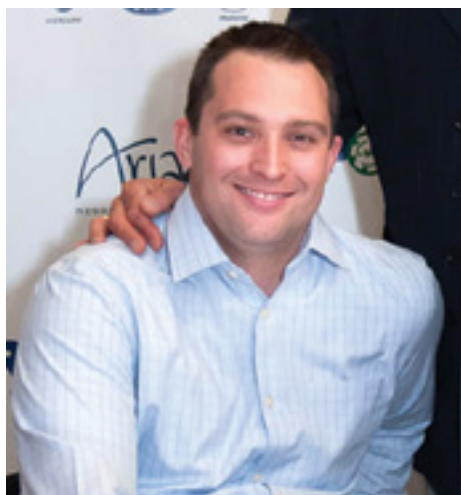


Jack Nicklaus, Barbara Nicklaus with Christine E. Lynn, Marc Buoniconti and Nick Buoniconti





Ethan Ruby and Jeremy Schwartz, through their successful series of events Poker4Life (P4L), held the 10th Annual Poker4Life tournament again at The Tunnel in NYC. Nearly 300 players bought in to the event with another 200 spectators for this milestone event. This year Marc Buoniconti was a special guest and went deep in the tournament and joined in the festivities with Ethan and Jeremy as they gave out awards to sponsors, friends and event supporters.



Ethan Ruby

“It was an honor to share 10 years of Poker4Life with the man who has inspired so many. Marc has dedicated his life to curing SCI and we are committed to helping him have

the resources to continue doing so. Poker4Life was created to help people that help others...and we all have a great time in the process,” said Ethan.

P4L has been solidly established as one of the best attended and run charity poker events in the NYC area. True to recent P4L tradition, this year’s winners again enjoyed prizes that included seats in the 2015 World Series of Poker (WSOP) Main Event that took place this past summer in Las Vegas, Nevada, NYC sports team packages, jewelry, and seats to the 2015 Great Sports Legends Dinner, to name a few.

This year’s field again featured a good mix of both professional and casual players from around the country, all doing their best to be the one who dons the coveted 2015 P4L bracelet at the end of the evening. The event winners each receiving a seat at the 2015 WSOP Main Event and they were Dan Roitman at 1st place with 2nd place going to Scott Seamon. Seamon had an impressive showing and went deep in the WSOP Main Event, ending up “in the money” and calling it an experience of a lifetime. The 3rd place winner was Roger Chang, and all three players agreed to wear the P4L patch in Las Vegas.



Dana Humphries, Ellen Leikend, Joan Pelzer, Jeremy Schwartz

“I’ve witnessed amazing things over the past 10 years hosting this event. I’m humbled by the continued support of everyone who comes out to our events in search for the SCI Cure. Poker4Life will continue to spread the ‘Positive Power of Poker’ and to support Marc and The Buoniconti Fund family throughout the next decade and beyond,” said Jeremy Schwartz

The mission of Poker4Life is a forum for poker players to come together and support causes they believe in while playing a game they enjoy. Poker4Life has attracted thousands of poker players and philanthropists with its exclusive charity poker tournaments. Over the last 10 years more than \$1,400,000 has been raised through their NYC poker events with The Buoniconti Fund being their charity of choice. A very special thank you to our friends at Jewelry on 5th who have supported this event for many years and ZYR Vodka who has supported the event from day one, both always go above and beyond in their support of P4L. 🍀



19th Annual Ricky Palermo Spinal Injury Golf Tournament

In 1986, Ricky Palermo was one of The Miami Project's first research participants to take part in a research study to test if someone with paralysis could ride a FES bike. Since that first trial, Ricky has developed an FES bike program at the YMCA in Batavia, New York and continues to participate in numerous clinical trials at The Miami Project.

On August 1st, Ricky and his family hosted the 19th Annual Spinal Injury Golf Tournament. The tournament was the most successful to day with more than 450 people attending the tournament and dinner. The event has raised more than \$1.1 million for The Miami Project's research programs. Important funds that continue to help people and their families who have suffered the devastation of paralysis and others in need.

Ricky has become a leading advocate for those paralyzed in Western New York and around the country. He was recently awarded the New York State Senate Liberty Award. The award is the highest civilian honor that a New Yorker can receive. Similar to the national Congressional Gold Medal, the award is given to individuals who have merited special commendation for exceptional, heroic, or humanitarian acts and achievements on behalf of their fellow New Yorkers.

Ricky and his family have raised money for the treatment and care of those paralyzed at United Memorial Medical Center and Rochester's Strong Memorial Hospital. The Palermos have put on lacrosse, soccer, basketball, tennis clinics and comedy shows to raise funds and awareness for the cause. The Miami Project and entire spinal cord injured community are grateful to call Ricky and his family a friend and ally.

Top: Ricky surrounded by family and volunteers
Middle: Annie Palermo and Gene Cummings with Ricky and Jim Palermo
Bottom: Ricky Palermo





Ernie Els



Kelly Slater



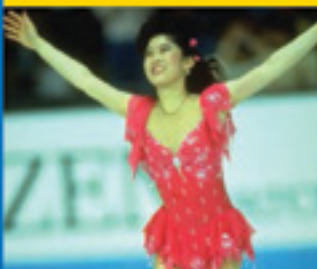
John Elway



Shaquille O'Neal



Muhammad Ali



Kristi Yamaguchi



Tommy Lee Jones



Cal Ripken Jr.



Tony Hawk



Wayne Gretzky



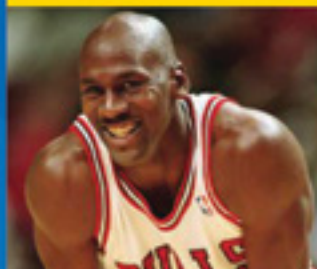
Shawn Johnson



Dara Torres



Gloria Estefan



Michael Jordan



Andre Agassi



Willie Mays

SAVE THE DATE



**Thirty-First Annual
GREAT SPORTS LEGENDS DINNER**

The Buoniconti Fund to Cure Paralysis
The Fundraising Arm of The Miami Project to Cure Paralysis

Monday, September 12, 2016

5:30 PM

Waldorf Astoria, New York City

RESERVE YOUR TABLE AND TICKETS TODAY!

For table and ticket purchase information, please contact
Stephanie Sayfie Aagaard at 305-243-4656 or
email to saagaard@miami.edu
www.thebuonicontifund.com/gslid

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*Past legends and honorees featured.





Frank Gifford

1930 - 2015

Frank Gifford dutifully served as Master of Ceremonies for the Great Sports Legends Dinner from 1987-2001. In addition to his feats on and off the field, which led to a NFL Hall of Fame career, Frank was a true friend to The Miami Project and The Buoniconti Fund. Frank is missed by his loving wife Kathy Lee, children and extended personal and NFL families.





John Gray

1951 - 2015

John Gray was a longtime member of the Buoniconti Fund Board of Directors. His warm and friendly personality made everyone he met feel as though they were friends for years. His steadfast support of The Miami Project and The Buoniconti Fund was second to none. John is truly missed by his lovely wife Karen, daughters Andrea, Carrie, and his extended family.

Benjamin P. Brown

1964 - 2015

Ben Brown was Nick Buoniconti Jr.'s best friend from high school. He without hesitation began his support of The Miami Project and The Buoniconti Fund from the beginning. As an attendee of every Great Sports Legends Dinner, he has tirelessly donated his time and money to help his friend in his time of need. Ben is, and will be missed by his family, Jonna his wife and his 3 daughters, Coco, Peyton and Preslie, as well as all his many friends.



Thank you to our Buoniconti Fund Board of Directors

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Nick Buoniconti, Paul DiMare with Christine E. Lynn



Matthew Whitman Lazenby



Thomas LeBlanc, Victoria Ranger Nuñez and Dalton Dietrich



Mark Dalton



Diana Morrison



Sergio Gonzalez, Christine E. Lynn and Adam Carlin



Jack Schneider, Richard Gray and Tim Gannon



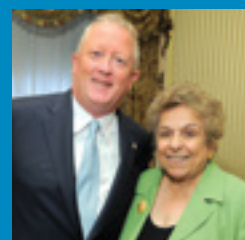
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Kandy Kramer



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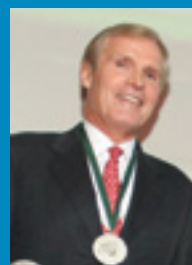
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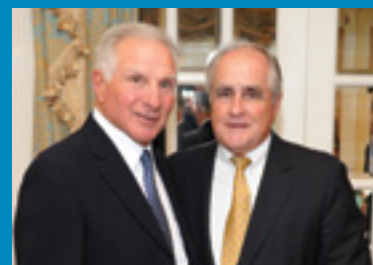
Bill Simon



Nick Buoniconti and Jay Jordan



Ray Chambers



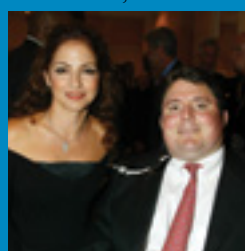
Nick Buoniconti and James Callahan, Sr.



Marc Buoniconti and Pascal Goldschmidt, M.D.



Nick Buoniconti and Alex Chudnoff



Gloria Estefan and Marc Buoniconti



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"We salute the dedication and persistence of our scientific staff, the determination of our Spinal Cord Injured community and the generosity of our donors as we continue our mission to find a cure."

