

We welcome you to the Cellular Hope Institute family and we would like to thank you for allowing us to provide our services and the opportunity to help you in your journey toward health.



We would like to give you an overview of what to expect when using our Services and walk you through what your Stem Cell procedure at Cellular Hope Institute is going to entail.

Our objective is to enhance your body's ability to regenerate itself by using the latest regenerative medicine technology to reverse disease and repair tissue while avoiding invasive surgical techniques and harmful medications.

In traditional medicine, patient injuries are treated with invasive surgeries that introduce foreign materials into the human body; diseases are treated with pharmaceuticals. These "manage" symptoms, but create a wide variety of side effects that patients are expected to accept as part of living with their ailment.

Fixing the problems we see in the traditional medicine model is a daunting task and not the fight we have chosen to fight. Instead we choose to provide a humanitarian alternative that uses the latest regenerative medicine techniques to treat, not individual symptoms, but the whole patient toward a reversal of their disease(s) and eradicating the source(s) of their pain and symptoms.



### **HOW WE CAN HELP YOU**

The concept of regenerative medicine is harnessing your body's own healing potential to reverse some of the effects of different degenerative diseases and possibly injuries.

The idea behind Cellular Hope Institute is that we can utilize something called cellular therapy to reverse some of these effects that are caused by disease. Every single one of us has stem cells in our body, and the main purpose of these cells is to maintain and repair the surface of the tissue in which they reside.

Our treatment plan is based upon three advantages that regenerative cells, also known as Mesenchymal stem cells, exhibit. They release anti-inflammatory proteins over an extended amount of time, they have an immunomodulatory effect, which means that they can be used to help control and regulate the immune system, and they also have a paracrine effect, which means that they secrete things like exosomes to change the behavior of cells, and communicate with these cells to bring them to areas of damaged tissue. These three aspects Mesenchymal stem cells carry play a big part in treating patients and garnering results, especially in autoimmune disorders and chronic degenerative diseases.





# WHY UNDERTAKE A TREATMENT OUTSIDE OF THE UNITED STATES?

Highly-manipulated cellular therapies are those that use a laboratory to culture and grow cells through the cell's population. Through this process, samples of cells are grown to contain larger quantities of Mesenchymal Stem Cells, which leads to better patient results. In the case of complex conditions, including chronic degenerative conditions or neurodegenerative conditions, the best results are obtained through an infusion of a larger amount of cells directly to the diseased area. That is the reason why many patients are opting to find the best results in the best facilities available, which are overseas, since current regulations prevent practices in the States from treating their patients in this manner.

## **CAN STEM CELL THERAPY CURE MY MEDICAL CONDITION?**

When we treat a medical condition, we are just treating the condition, not curing it. Neither fresh cells nor cultured cells can cure every disease, but they can do great things as far as reducing the severity of symptoms and stopping the advancement of the condition. Normally, in a lot of chronic degenerative conditions or neurological conditions, several treatments will be needed because the effect of cellular therapies has a time limit. Our unique approach includes a multi-dose treatment plan, in which we apply the cells once, with follow-ups at three, six, and twelve month mark. If symptoms begin to occur, another round of treatment is needed.





## WHEN WILL I SEE RESULTS?

After the first dose, results can already begin to make themselves apparent, but this depends largely on the type of disease/condition the patient is afflicted with, as well as its severity and current phase of progression. Once the stem cell treatment begins, the body needs a minimum of four weeks to recognize the initial regenerative effects, which become more apparent at the six-month mark. Regenerative medicine is considered a multi-dose treatment, and reinforcements are usually required every six to twelve months. However, depending on a patient's condition, they could be needed up to twenty-four months after the initial procedure. This is why cryogenically banking and storing stem cells is extremely important.

# WHAT ARE THE DIFFERENT CELLULAR THERAPIES AVAILABLE FOR YOU?

Our comprehensive stem cell treatment protocols employ well-targeted combinations of Exosomes, allogeneic human Mesenchymal cells, and autologous bone marrow and Adipose derived stem cells to treat different diseases and conditions. Our treatment plans are mostly focused on a systemic or whole-body approach to ensure these patients receive the highest quality and quantity of cellular products during their time in our hospital

Of the different kinds of cellular products available for use, there are two main sources that can be used to target the conditions that have been previously discussed.





Autologous procedures are those in which the patient is their own donor for the cellular therapy treatment. In these kinds of procedures, a doctor takes a sample (usually of bone marrow or adipose tissue) and harvests the cells from it, before administering it locally to the diseased or damaged area.

Allogeneic procedures are those in which the patient receives cells that have been sourced from a donor that is not the patient. These samples are neonatal tissue and are composed of umbilical cord blood. They are extensively screened to ensure the quality and health of the cells.

The type of treatment used depends on a variety of factors, including medical history and age, but at the Cellular Hope Institute, we endeavor to give each patient a personalized, case-by-case treatment plan to ensure that the only possible outcome is a positive one.

# WHICH ARE THE DIFFERENT ADMINISTRATION METHODS THAT WE USE AT CELLULAR HOPE INSTITUTE?

After you've been selected as a candidate, you will meet with our highly-trained team of medical professionals to devise a treatment plan tailored specifically to have the best results possible given your current condition. Below we will outline the different methods of administering cellular therapies that we use in our medical facilities:

#### intrathecal-intraarterial

This form of implantation is ideal for neurological conditions because the stem cells are injected past the blood-brain barrier and directly into the spinal fluid, which enables them to reach the spinal cord and brain.

During the procedure, an experienced anesthesiologist inject stem cells into the spinal canal through the lower vertebrae under local anesthesia. They are all performed in a positive airflow room under sterile conditions, and the procedure usually takes about thirty minutes.

#### Intravenous IV

The safest and simplest method for delivering the stem cells throughout the body. Anesthesia is not required. We may use Lidocaine topical spray to needle prick area beforehand. IV administration usually takes about 20 – 30 minutes.

#### Intramuscular IM

The stem cells are injected directly into the muscle. Intramuscular implantation is very safe and does not require anesthesia.



### UNDERSTANDING YOUR TREATMENT IN CANCUN

Your journey will begin as you depart from your hometown for beautiful Cancún, México. In Cancún they will be greeted at the International Airport by our patient coordinator, then transferred to your accommodations. Once settled in, the patient coordinator will provide them a welcome package that will contain:

· City vouchers.

· A list of frequently asked questions.

· Contact info during your stay.



### FIRST CONSULTATION

The day before your procedure takes place, you will have a one-on-one with your specialized team, at which point your attending physician will go over your procedure and expectations. At this time, you may ask your doctor any additional questions you may have. This day will include:

- · Analysis of current condition of the patient.
- · New lab tests run.
- · Specialist doctor evaluation according to the medical condition to be treated.
- · Anesthesia evaluation.
- · Establishment of final protocols to follow according to previous indicators.

#### TREATMENT DAY

You will be picked up two hours before the procedure is scheduled to begin, please ensure that you do not eat eight hours before the procedure. Once you arrive at the hospital you will be asked to sign all the necessary patient consent forms and you will be prepped for your procedure. The procedure will take 3-4 hours, once the cells are harvested and prepared they will be administered to the patient in accordance with their. After the procedure is complete you will either be returned to your hotel or, depending on the procedure, your hospital suite for overnight observation.

# POST-OPERATIVE CARE

The day after the patient's procedure, you will go to your follow up appointment, where your garment and bandages will be removed, your incisions will be cleaned and inspected, and you will get your first ultrasound scan.





### **BOOSTER WITH HIGHLY MANIPULATED STEM CELLS:**

(Sixth day stay). The physician or patient coordinator will notify you for the procedure with the stem cells that have been expanded in the laboratory. The patient receives a final booster through systematic approach via an intravenous line with the cultured cells.

After this, the physician team will make a final evaluation and, most likely, discharge the patient.

## **DEPARTURE DAY**

A driver will pick you and the patient up at your accommodation, and you will be dropped off at the airport at least two hours prior to your flight's departure. Your patient coordinator will let you know when the next virtual consultation will take place.

### SERVICES INCLUDED IN YOUR TREATMENT

- · Medical general assessment.
- · Critical care evaluation.
- · Specialist doctor evaluation.
- · Anesthesiology evaluation.
- · Perioperative care.
- Pharmacy and Supplies.
- · Operating room.
- · Anesthesia Services.
- · Diagnostic/therapeutic imaging.

- · Autologous stem cell acquisition.
- · Pathology services.
- · Hemodynamics suite.
- · Patient coordination fee.
- · Catheterization procedure.
- · Mannitol injection.
- · Med Surg Supplies sterile.
- · Spinal tap procedure.
- · Recovery.

- · Laboratory fee.
- · Culture/Expansion autologous BM derived stem cells.
- · Med Surg room.
- · IV infusion.
- $\cdot$  Follow up and recommendations.
- Pick up / Drop off from airport to accommodation and vice versa.
- $\cdot$  Pick up/Drop Off the day of the procedure to and from hospital.



# WHAT TYPES OF CONDITIONS ARE WE SPECIALIZED IN PROVIDING CELLULAR THERAPIES?

#### **AUTISM**

Autism is a spectrum of disorders characterized by marked abnormalities in communication and social interactions. Two common consistent findings associated in children with this disorder are diminished oxygenation in specific areas of the brain and a chronic immunologically mediated inflammatory condition in the gut.

The rationale behind treating autism with Mesenchymal stem cells is that autism, and its degree of severity, has been significantly correlated inflammatory and neuro-inflammatory cytokines including macrophage-derived chemokine (MDC) and thymus and activation-regulated chemokine (TARC). Intravenous administration of umbilical cord MSCs has been shown in multiple clinical trials to decrease inflammation. Decreasing inflammation in the autistic patient may alleviate symptoms of autism.

Through administration of mesenchymal stem cells, we have observed improvement in patients treated at our facilities.





#### **MULTIPLE SCLEROSIS**

Multiple Sclerosis (MS) is caused by an immune mediated attack targeting components of the myelin sheath. The myelin sheath is known to act as an "insulator" for neurons so that they can communicate properly with each other.

At present there are no FDA-approved treatments that specifically target the abnormal immune responses in MS. Current approaches, such as interferon, copaxone, or immuno-suppressants all act in a nonspecific manner blocking immune responses against the myelin sheath. While these approaches are useful for reducing the severity of disease, they do not repair the damage to nervous system tissue that has already occurred and therefore they cannot cure multiple sclerosis. Mesenchymal stem cells (MSCs), have immune regulatory properties which may stop the immune system from attacking the myelin sheath.

#### **AUTOIMMUNE DISEASES**

Autoimmune diseases are conditions in which the patient's immune system generates cellular and antibody responses to substances and tissues normally present in the body. This might be restricted to one organ or involve a particular tissue in different places. As a result of this immune response, damage to different organs occurs. Examples of autoimmune diseases that have responded to stem cell therapy either in animals or humans include rheumatoid arthritis, multiple sclerosis, and lupus.

Currently, autoimmune conditions are treated with immunosuppressive agents such as steroids, methothrexate, cyclosporine, gold, and more recently infliximab (Remicade). Despite inducing temporary improvement, these approaches possess the possibility of long-term adverse effects, as well as need for life-long treatment.

Stem cell therapy has been demonstrated to induce profound healing activity in animals with various forms of autoimmune disorders. Besides healing damaged tissues, stem cells have the unique ability to modulate the immune system so as to shut off pathological responses while preserving its ability to fight off disease. Stem cells and specifically, mesenchymal stem cells hone to inflamed tissue and start producing anti-inflammatory agents. These mediators act locally and do not suppress the immune response of the patient's whole body. Additionally, mesenchymal stem cells induce the production of T regulatory cells, a type of immune cell whose function is to protect the body against immunological self-attack.







#### SPINAL CORD INJURY

Spinal cord injury (SCI) occurs when the spinal cord becomes damaged, most commonly, when motor vehicle accidents, falls, acts of violence, or sporting accidents fracture vertebrae and crush or transect the spinal cord.

Damage to the spinal cord usually results in impairments or loss of muscle movement, muscle control, sensation and body system control. Presently, post-accident care for spinal cord injury patients focuses on extensive physical therapy, occupational therapy, and other rehabilitation therapies; teaching the injured person how to cope with their disability.

A number of published papers and case studies support the feasibility of treating spinal cord injury with allogeneic human umbilical cord tissue-derived stem cells and autologous bone marrow-derived stem cells. Through administration of umbilical cord tissue-derived mesenchymal stem cells, we have observed improvements in spinal cord injury patients treated at our facilities.

#### **NEURODEGENERATIVE DISEASES**

(NDs), such as Alzheimer's disease, Huntington's disease, and Parkinson's disease are characterized clinically by their subtle onset but chronic progression and involve the degeneration of defined neuronal phenotypes in the central nervous system (CNS).

In recent years, numerous studies have shown that stem cell transplantation elicits neurogenesis and angiogenesis by releasing neuroprotective factors brain- derived neurotrophic factor (BDNF) and nerve growth factor (NGF). Results have provided proof of principle that cell replacement can work in humans with Parkinson's disease, however there are still many obstacles to the use of stem cells as a cure for neurodegenerative disease, especially because we still don't fully understand the true mechanisms of these diseases and clinical data is still scarce.

Despite substantial research and the development of a number of neuroprotective drugs to treat NDs and to improve patient survival, no effective therapy for these diseases is currently available.

Concentrated human stem cell product comprised of donated cord blood, that has been processed to remove excess plasma, red blood cells, vascular material and tissue solids leaving stem cells and other cellular components, which are then concentrated and banked through a validated process. Therapeutic approaches involving the transplantation of stem cells focuses primarily on the replacement of lost neurons and the restoration of neural tissue structure. UCB cell-induced neuroprotection involves anti-inflammatory and immunomodulatory effects, and that neurotrophic factors act through paracrine and/or autocrine interactions between transplanted UCB-derived cells and the neural microenvironment.





#### CHRONIC OBSTRUCTIVE PULMONARY DISEASE

COPD is caused by a combination of small airway disease (obstructive bronchiolitis) and parenchymal destruction (emphysema). The pathophysiology of COPD is mediated primarily by a pathogenic triad: inflammation, oxidative stress, and protease-antiprotease imbalance. The inflammatory process in the lungs of COPD patients involves concentration of macrophages, neutrophils, CD8+ cytotoxic lymphocytes in the small airways and the subsequent release of humoral factors cytokines, chemokines, and elastolytic enzymes.

To provide the patient with a treatment that regenerate lung structure and induce lung functional recovery through reduction of inflammation, and induction of immunomodulation.

### **SAFETY AND EFFICACY**

All of our procedures follow the strict cGTP guidelines that regulate the methods, facilities, and controls used for the manufacture of HCT/Ps (defined as: articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient)—these guidelines are there to ensure patient safety and that all procedures prevent the introduction, transmission, or spread of communicable diseases by HCT/Ps (§1271.150(a)).



# ADVANTAGES OF CELLULAR HOPE INSTITUTE TREATMENT

- · Extremely Low Risk of Rejection.
- · Alternative Treatment for Degenerative Diseases, Which Do Not Have Effective Traditional Therapies.
- They Offer Treatments with High Possibility of Recovery and Improvement of Hope and Quality of Life.
- · Can Reverse or Slow the Progression of Disease.
- MSCs of Adipose and Bone Marrow Tissues are Obtained Through Ambulatory, Low-Risk Procedures Under Local Anesthesia.
- · Wharton Jelly MSCs of Umbilical Cord are Available at All Times in the Incubators of the Cellular Hope Institute Cell Bank, No Extraction Surgery.
- · Can Be Used for Rejuvenation and Anti-Aging Treatments.



