



Informed Consent for Stem Cell Therapy

You have a pain problem that has not been relieved by routine treatments. A procedure, specifically an injection or operation, is now indicated for further evaluation or treatment of your pain. There is **NO** guarantee that a procedure will cure your pain, and in rare cases, it could become WORSE, even when the procedure is performed in a technically perfect manner. The degree and duration of pain relief varies from person to person, so after your procedure, we will reevaluate your progress, then determine if further treatment is necessary. Your physician will explain the details of the procedure listed below. Tell the physicians if you are taking any blood thinners such as **PLAVIX, Aspirin, Coumadin, Lovenox and HEPARIN** as these can cause excessive bleeding and a procedure should **NOT** be performed. Alternatives to the procedure include medications, physical therapy, acupuncture, surgery, etc. Benefits include increased likelihood of correct diagnosis and /or of decrease or elimination of pain. The patient is an appropriate candidate for consideration of **bone marrow aspiration from the iliac crest and injection of aspiration concentrate**. An extensive discussion was conducted of the natural history of the disease and the variety of surgical and non-surgical treatment options available to the patient. A risk/benefit analysis was discussed with the patients reviewing the advantages and disadvantages of intervention at this time. A full explanation was given of the nature and the purpose of the procedures and anesthesia, its benefits, possible alternative methods of treatment, the risks involved, the possibility of complications, the foreseeable consequences of the procedures and the possible results of non-treatment. **No guarantee or assurance was made**, as to the results that may be obtained from the procedure/treatment. Specifically, the risks were identified including but are not limited to the following:

- **Increased pain and allergic reaction** from local anesthetics, iodine, contrast (X-Ray dye), materials containing latex, IV anesthetics and/or other medications
- **From bone marrow aspiration of iliac crest:** Perforation of ileum and iliac bone, delayed healing of wound and bone, pain at the injection site, pulmonary embolism, uncontrolled bleeding, blood vessel injury
- **Infection** on skin, tissue, bones, joints, discs, nerves, ligaments, possibly blood stream (Sepsis), brain and spinal cord (Meningitis) may require hospitalization
- **Bleeding** into epidural space (Epidural Hematoma) and into spinal canal (Spinal Hematoma) may require surgical interventions such as an evacuation of blood from epidural space, spinal canal and decompression surgery, blood vessel injury
- **Nerve damage**, tissue injury, tissue damage, temporary and permanent numbness and/or weakness, paralysis, spinal cord injury, urinary and/or fecal incontinence
- **Headache** (“Spinal headache”) may require blood patch (Injecting your own blood into epidural space) and hospitalization
- **Joint injection:** In addition to the above complications, injection and fluid collection in the joint(s) may require antibiotic treatment, fluid aspiration and surgical interventions.
- **Allergic reaction from steroid;** facial flushing, elevation in blood glucose, headache, increased appetite, weight gain, swelling, menstrual irregularities, hoarseness, numbness, infection, abnormal heartbeats, increased blood pressure, stroke, heart attack, insomnia, ect.
- **Death**

I understand clearly that Regenerative Medicine including PRP (Platelet Rich Plasma) and Stem Cell injection therapy is NOT FDA approved.

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Patient's Name Patient's Signature Date

