Informed Consent for PRP (Platelet-Rich Plasma) 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.

Platelet-rich plasma is a fraction of your blood which contains a high concentration of platelets. These are known to contain large quantities of growth factors which attract stem cells and stimulate the healing of damaged tissues. Clinical work over the last several years has established the safety and usefulness of platelet-rich plasma (PRP) for tissue repair and healing in joints resulting in reduced pain and improved function for many who have had this procedure. Platelet Rich Plasma is an established treatment technique used to tighten and strengthen weak and damaged ligaments and tendons which are believed to cause pain and instability. It is also used to decrease pain and improved function. The technique requires the injection of Platelet Rich Plasma derived from your own blood. The sight of the injection is where the ligament or tendon attaches to the bone, at the joint capsule or inside the joint. 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
- **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, etc.
- **Death**

Patient's initial: _____ Date: _____

Patient will be injected with PRP to the following area(s):

□ Right □ Left □ Shoulder □ Elbow □ Wrist □ Hand □ Hip □ Knee □ Foot

□ Bilateral (Both) □ Ankle □ Cervical Spine □ Thoracic Spine □ Lumbar Spine

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The incidence of serious complications listed above requiring treatment is low, but it may still occur. Your physician believes the benefits of the procedure outweigh its risks or it would not have been offered to you, and it is your decision and right to accept or decline to have the procedure done. **I have read or had read to me** the above information. I **UNDERSTAND** there are risks involved with this procedure, to include rare complications, which may not have been specifically mentioned above. The risks have been explained to my satisfaction and I accept them and consent to any procedure which is performed by **Dr. Young Lee, Dr. U. Purewal, Dr. M. Purewal, Dr. Ezeadichie, Dr. Rinnier, Dr. Manabat, Dr. Puri, Dr. Reyes, Dr. Pryzbylkowski and/or their associates in Relievus, LLC**. I herein authorize physicians, nurse practitioners and their associates in Relievus, LLC to perform this procedure. I also understand that one of the greatest risks involved with pain management procedures involves various medications taken, allergies and my general medical condition. I will inform the doctor of any blood thinning medication taken or any changes in other medications, allergies or medical condition prior to any procedure.

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

_____ X _____ _____

Patient's Name | Patient's Signature | Date

Physician Declaration: I and/or my associate have explained the procedure and the pertinent contents of this document to the patient and have answered all the patient's questions. To the best of my knowledge, the patient has been adequately informed and the patient has consented to the above described procedure.

_____ X _____ _____

Physician's Name | Physician's Signature | Date

_____ X _____ _____

Witness's Name | Witness's Signature | Date