REGENERATIVE
SPINE & JOINT CENTER

CONSENT TO MEDICAL PROCEDURE FOR PLATELET RICH PLASMA

I (or my authorized representative, i.e., parent guardian),_____, consent to the elective medical procedures outlined below to be performed by_____and his/her staff, associates, or assistants to whom the physician(s)/nurse practitioner performing the procedure may assign designated responsibilities. In the event one or more of the physicians/nurse practitioners providers is unable to perform or complete the procedure, a qualified substitute provider will perform or complete the procedure. The proposed elective medical procedure is **Autologous Platelet Rich Plasma** for the treatment of damaged or injured tendons, ligaments, cartilage, joints, or muscles. The procedure has been explained to me in terms that I understand.

The explanation included:

- The nature and extent of the procedure to be performed.
- The most frequently occurring risks of the procedure involved, and those risks which are unlikely to occur but which may involve serious consequences, include but are not necessarily limited to the following. Pneumothorax, headache during back injections, allergic reaction to the solution, injury to the nerve and/or muscle, spinal cord injury during back injections, death from complications of the treatment, temporary or permanent nerve paralysis.
- General risks which may include pain, scarring, bleeding, itching, nausea, vomiting, and dizziness, fainting, temporary blood sugar increase, and infection.
- The benefits of the procedure.
- The estimated period of incapacity or convalescence, if any.
- The risks and benefits of any reasonable alternatives to this procedure including having no treatment at all.

I was given the opportunity to ask any questions I have regarding the procedure and I have had those questions answered to my satisfaction. I understand that I may consult or could have consulted with another physician about this procedure. I understand that I have the right to refuse any medical/surgical treatment recommended at any time prior to its performance.

I authorize my physician to perform such additional procedures which in his/her judgment are incidentally necessary or appropriate to carry out my treatment. If any unforeseen condition arises during this procedure which requires transportation to a hospital, additional procedures, operation or medication including anesthesia and blood transfusions, I further request and authorize my physician to do whatever he/she deems advisable on my behalf.

I understand that many things involved with this procedure may be considered off-label uses of medicine and medical products. All medications and medical products, and specifically products derived from plasma products, used have been approved for medical use by the FDA. However, some of these devices and medical products were FDA approved for only specific types of treatment. Use of these devices and medications for other types of treatment is legal, but considered "off label." Medications and medical products that we use in an off label fashion include, but are not limited to, using the plasma product for orthopedic type conditions. While these medicines and medical products have not been approved by the FDA for these particular uses, they are used in naturopathy for this purposes and are considered accepted practices

I am aware that the practice of medicine and surgery is not an exact science, and I acknowledge that no guarantees have been made to me concerning the results of this procedure.

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I acknowledge that the products being used are regulated by Section 361 of the Public Health Act as being, among other things, "minimally manipulated." This section allows a manufacturer to self-determine whether a product may be released to market without pre-approval from the FDA. I have been informed that FDA has not made a determination that the products are regulated under this Section and may, in fact, find that the products are subject to regulations under additional or different sections of the Public Health Act or other federal laws which would impose greater testing and regulation as a medical device, drug or a biological product. I hereby waive any rights or causes of actions that may accrue to me in the event that the FDA changes the classification of the products as being regulated under Section 361 of the Public Health Act thereby requiring additional testing, pre-approval and licensing.

I acknowledge that I have read (or had read to me) and fully understand the above information. Furthermore, I certify that all my questions and concerns regarding the procedure, its attendant risks, benefits and alterna-tives have been explained to my satisfaction. I hereby authorize my physician to perform the above discussed procedure.

Patient Initials. _____/Date_____ (Full signature required below)

Sedative Analgesia [Moderate Sedation; Conscious Sedation] INCLUDE IF APPLICABLE
I understand the administration of sedative analgesia may be recommended. The benefit of the sedation is greater comfort throughout the procedure. It has been explained to me that all forms of sedation involve some risks. I understand that no guarantees or promises can be made concerning the results of my procedure or the sedation technique administered. Complications with sedative analgesia can occur and include: inadequate sedation, drug reaction, the possibility of infection, bleeding or injury to blood vessels at the intravenous site. More severe complications could include depression of respiration and heart problems that could lead to serious consequences, including even loss of life. Alternatives to sedation include no sedation at all, and have been explained to me.

I acknowledge that I have read (or had read to me) and understand the above information on sedative analgesia. Furthermore, I certify that all my questions and concerns regarding the administration of conscious sedation, its attendant risks, benefits and alternatives have been explained to my satisfaction. I agree not to drive a car, operate machinery or make any legal decision within 24 hours as the effect of sedation may remain in my system for this period of time. I hereby authorize my physician and/or individuals qualified to do so, to administer this analgesic.

I hereby sign this consent on the ___ day of _____, 20_____

_____ _____
Patient's Signature/Power of Attorney/Guardian Date of Birth

I verify that I have explained the information contained in this document to the patient or person giving consent. It is my opinion that the person granting consent has fully understood all subjects discussed.

_____
Physician/Nurse Practitioner