MOUNTAIN VIEW REHABILITATION MEDICAL ASSOCIATES AUTHORIZATION FOR PROCEDURE REGENEXX[™] SUPER CONCENTRATED PRP AND/OR PLATELET LYSATE

TO THE PATIENT: You have the right, as a patient, to be informed about your condition and the recommended surgical, medical or diagnostic procedure to be used, so that you may make the decision whether or not to undergo the procedure after knowing the risks and hazards involved. This disclosure is not meant to scare or alarm you; it is simply an effort to make you better informed so you may give or withhold your consent for this procedure.

I voluntarily request Joel D. Richnak M.D. as my physician, and such associated technical assistants and other health care providers as he/she may deem necessary, to treat my condition, which has been explained to my satisfaction in layman's terms.

Diagnosis: This procedure is usually performed for any of the conditions listed:

- Tendon injury/Tendonitis-Tendons are the connectors between the muscle and bone. A tear in the tendon may cause pain, limited range of motion or disability. Tendons may also become swollen or have smaller tears (micro tears) which may cause similar symptoms.
- **Muscle Tear**-Muscles help move your joints. A tear in the muscle can cause pain in that muscle.
- **Ligament Tear**-Ligaments help to hold joints together. Stretched, torn, or damaged ligaments can lead to instability.
- **Arthritis**-A joint can lose its normal cartilage and other supporting structures and become arthritic. This can cause pain, swelling, and stiffness.

Explanation of Procedure: I understand that the following procedure is planned for me, and I voluntarily consent and authorize these procedures(s) (lay terms): Insertion of a needle into my vein to take blood, processing of that blood to concentrate platelets, and a re-injection of those concentrated platelets into the area in need of healing. Platelets contain healing growth factors and it's expected that over a course of 1-2 weeks, the injected platelets will release growth factors that may help my healing process.

I understand that my physician may discover other different conditions which may require additional or different procedures than those planned. I authorize my physician, and said such associates, technical assistants and other health care providers to perform such other procedures which are advisable in their professional judgment.

<u>No Guarantee and Research Disclosure</u>: I understand that no warranty or guarantee has been made to me as to the result of this procedure or anticipated care. I understand that my results may be used in a published research study without my name being identified or without additional prior consent. In addition, I understand that I will be tracked by a treatment registry run by the medical clinic where I am receiving care. This will include someone contacting me via e-mail or phone, my filling out questionnaires, answering questions, etc... at certain times and that this is planned to continue indefinitely or until I elect out of the registry in writing.

Possible Side Effects of Procedure: Just as there may be risks and hazards in continuing my present condition without treatment, there are also risks and hazards related to the performance of the surgical, medical and/or diagnostic procedures planned for me. I realize that general risks of all procedures of this type (injections into joints) are temporary increased swelling and pain, infection, hemorrhage, or bruising. This additional pain and discomfort could last a little as a few days to as much as a few weeks or longer. I also realize the following hazards may occur depending on this particular procedure: 1) Increased local pain 2) Cellulitis at a blood draw site 3) Allergic drug reaction 4) Numbness 5) Injury to the bone, muscle or nerve 6) Drop in blood pressure 7. Loss of consciousness 8. Abnormal heartbeat 9) Bone infection 10. Further damage to a tendon, ligament, muscle, or joint. The above risks and complications are not the only possible side effects.

Possible Side Effects of Anesthesia (if any): I understand that I can elect to have anesthesia and that it involves additional risks and hazards. Anesthesia means that I will be given a vein injection of medication or a numbing injection or both. I realize the anesthesia may have to be changed, possibly without explanation to me, depending on my pain tolerance, body weight, and sensitivity to medications. I understand that certain complications may result from the use of any anesthetic, and that these range from minor discomfort to injury to vocal cords, teeth or eyes. If IV anesthesia is needed, one rare complication could be loss of ability to breathe on my own for which I would need medical assistance to breathe until the medications wear off. In all instances, general anesthesia carries the very rare risk of death. I understand that other risks and hazards resulting from spinal or epidural anesthetics include headache and chronic pain. If IV anesthesia is not used, which is most common for spinal procedure, then a local anesthetic will be used to numb tissues. Possible side effects could include nerve or blood vessel injury from the numbing injection, allergic reaction to the anesthetic, bruising, swelling, or deformity.

Investigational Procedure Acknowledgement: This medical procedure is still considered experimental. This means it is not yet standard of care in the medical community. While your doctor may believe it can help you, there are no large research studies that show it is effective. This means that it may do <u>nothing</u> to relieve your pain, cure your condition, or otherwise repair your tissues.

<u>Treatment Alternatives</u>: These may include: surgical repair of a ligament, tendon, or muscle; total or partial joint replacement with an artificial joint, arthroscopic or open surgery to "clean up" the joint in an attempt to repair or remove damaged tissue, medications, physical therapy, or alternative medicine remedies.

<u>**Risks of Not Receiving Treatment</u></u>: Your problem may get better with time on its own. This is less likely when the issue is more severe. It may also worsen on its own.</u>**

<u>Treatment Complications</u>: Just like any other medical procedure, the treatment of complications will be your responsibility. This may mean that if you have a serious complication or side effect and have

health insurance, you could incur additional co-pays, deductibles, and co-insurances. If you have no insurance, the treatment of complications could mean incurring significant out of pocket expenses.

Insurance Coverage for this Procedure: By signing this form, you understand that there is no or limited insurance coverage for this procedure. This means that all costs for this procedure that you have been quoted by our office <u>are unlikely</u> to be reimbursed at a later date by a health insurer.

To the Physician: I attest that I have explained the risks, benefits and alternatives of this procedure to this patient/representative.

Physician Signature

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Date_____

To the patient: I have been given an opportunity to ask questions about my condition, alternative forms of treatment, risks of non-treatment, the procedure(s) to be used, risks and hazards involved, and other disclosures and information contained in this form. I have sufficient information to give this informed consent. My physician has answered my questions to my satisfaction.

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Patient or Guardian Signature		Date
Witness	Relationship	Date
(if applicable)		