



Informed Consent for Orthobiologic Procedures

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 and treatment of your pain. There is **No** guarantee that a procedure will improve or 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, you will be reevaluated to determine if further treatment is necessary. Your provider will explain the details of the procedure listed below. Tell the provider if you are taking any blood thinners such as Plavix, Aspirin, Coumadin, Lovenox, and Heparin, as these can cause excessive bleeding and a procedure may not be able to be performed. Alternatives to the procedure include medications, physical therapy, acupuncture, surgery, etc. Benefits include decreased/elimination of pain, and increased function.

Platelet-rich Plasma (PRP) is a fraction of your whole blood which contains a high concentration of platelets. Platelets are known to contain large quantities of growth factors which can decrease inflammation and stimulate the healing of certain damaged tissues. Research has shown PRP to be a safe and effective procedure. In some cases, multiple procedures are necessary to obtain the desired result. It requires your provider to take blood from one of your veins and sterilely separate the components in a centrifuge, to obtain the PRP. The PRP is then injected into and/or around the area that is being treated, at that same visit.

Bone Marrow Aspirate Concentrate (BMAC) is a fraction of your own bone marrow, which contains a high concentration of platelets as well as stem cells. Platelets are known to contain large quantities of growth factors which can decrease inflammation and stimulate the healing of certain damaged tissues. Research has shown BMAC to be a safe and effective procedure. In some cases, multiple procedures are necessary to obtain the desired result. It requires your provider to take bone marrow from your bones and sterilely separate the components in a centrifuge, to obtain the BMAC. The BMAC is then injected into and/or around the area that is being treated, at that same visit.

An extensive discussion was conducted of the natural history of the disease and the various surgical and non-surgical treatment options available. A risk/benefit analysis was discussed reviewing the advantages and disadvantages of the selected intervention at this time. A full explanation was given of the nature and the purpose of the procedures, 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 which include but are not limited to:

- Increased pain and allergic reaction from local anesthetics, components used to process the blood/bone marrow and materials containing latex
- Damage or infection from the harvest of the tissue, or the injection of the final product into the area being treated. This may result in the need for further treatment (medications, surgery, hospitalization), possibility of severe sickness, and the possibility of death
- Bleeding into the area injected causing pain, and possible need for further treatment
- Numbness of the area injected
- Specific to BMAC harvest is the possibility of pain, continued bleeding, bone infection, nerve injury, retention of broken needle/trocar
- Potential spread of malignancy



Procedure and site: _____

The incidence of serious complications listed above requiring treatment is low, but still may occur. Your provider believes the benefits of the procedure outweigh its risks or it would not have been offered to you. 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 this information, that there are risks involved with this procedure, to include rare complications which may have not been specifically mentioned above. The risks have been explained to my satisfaction and I accept them and consent to the agreed upon procedure. I herein authorized Dr. Laughlin to perform this procedure. I also understand that one of the greatest risks involved with orthobiologic procedures involves various medications taken, allergies, and my general medical condition. I agree that I have informed the doctor of any blood thinning medications, all current medications, changes to medications, allergies and medical conditions prior to the procedure. I agree that all of my questions have been addressed to my satisfaction.

I have disclosed any history of malignancy, and confirm that to my knowledge, I do not have any active malignancy at this time.

I understand that the orthobiologic procedures that have been presented to me are considered off-label use (experimental), and are not FDA approved for their proposed use. I understand that all kits used to process the orthobiologic are FDA approved via 510(k) clearance.

_____ X _____	_____	_____
Patient's Name	Patient's Signature	Date

_____ X _____	_____	_____
Witness's Name (Optional)	Witness's Signature	Date

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

_____ X _____	_____	_____
Matthew Laughlin, DO	Signature	Date