I'm Interested in Participating

Our mission is focused on patient outcomes, and patients who are active and involved in their care are truly the driving force which shapes the future of healthcare and brings life to everything we do.

We appreciate your interest, and would be happy to help you understand the Registry and your potential involvement. Our program allows you to participate via online surveys, which can be completed in the comfort and privacy of your home or office.

The Registry office is a service-oriented team focused on providing support to our participating physicians and patients. If your physician is participating in the IOF Registry, he/she will determine your candidacy in this program and, if appropriate, have you fill out some forms. This includes a Consent Form, Demographics, and other Questionnaires as it relates to your condition. You will be asked for an email address in order for us to send follow-up surveys via an online portal. Follow-up survey intervals will be emailed to you at 1, 3, 6, 12, 18, 24 months and every year thereafter up to 20 years.

The Registry is voluntary, and we will always respect your decision. No identifiable information we collect will ever be distributed or sold to 3rd parties.

303-469-4431 | 303-379-1721 *fax*

403 Summit Boulevard #104 | Broomfield, CO 80021

www.interventionalorthopedics.org

Behind Every New Treatment are Clinical Research Volunteers Like You

Improving patient health through Registry Participation

Join other participants to advance medical research on the latest non-invasive treatments in regenerative orthopedics. Our Registry is specific to patients who have been treated with their own platelets or stem cells defined as **interventional percutaneous orthopedic treatments**, which is the development of the use of needle-based procedures performed through sophisticated guidance techniques.

At Interventional Orthopedics Foundation ("IOF"), research is a major effort, and we take a research approach to seek new and better methods of care to enable physicians and patients to succeed.

Interventional Orthopedics Foundation

303-469-4431
303-379-1721 *fax*

What is a Registry?

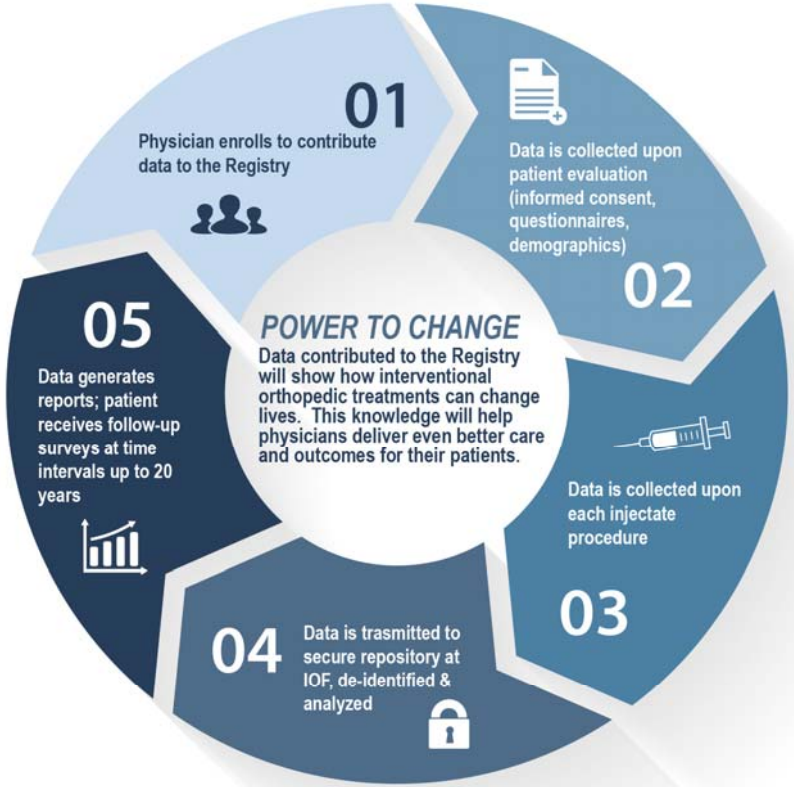
The IOF Registry is a confidential database established to provide physicians with valuable information to assist in making long-term decisions regarding interventional percutaneous orthopedic treatments, such as platelet rich plasma (PRP), bone marrow concentrate, and mesenchymal stem cells (MSCs).

The Registry was established to facilitate research initiatives and promote the development of improved treatments. Along with clinical information collected at the time of your procedure such as types of injectates used (i.e., stem cells and platelet rich plasma); patient outcomes and perspectives are crucial to understanding how we can further ensure safety and improve the care delivered. The Registry employs procedures that ensure the most stringent confidentiality of participants.

The IOF Registry allows participating patients the opportunity to report their health status relating to:

- Quality of Life
- Joint function and pain
- Activity levels
- Long-term procedure success

How Does the Registry Work?



How Can My Participation Promote Research?

One of the largest obstacles in registry research is finding a sufficient number of volunteers to participate. By establishing a database of thousands of people and promoting its use to the interventional orthopedics community, the Registry will help advance state-of-the-art therapies in regenerative medicine. Through the voluntary participation of Registry members, questions about percutaneous orthopedic procedures can be answered, enabling a more thorough understanding of these non-invasive treatment options.

Interventional Orthopedics Foundation
Patient Registry Database

PATIENT CONSENT FORM

You are being asked to participate in a **Registry Database** for research purposes. The purpose of this Consent Form is to help you decide if you want to be in the database. By signing this form you will agree that you are electing to have an "investigational or experimental procedure" referred to as "percutaneous orthopedics" which involvces the use of STEM CELLS and PLATELET RICH PLASMA (PRP) and other injectates as recommended by your physician. This means that these procedures are not currently the standard of care in the medical community.

PURPOSE OF THE REGISTRY

This Registry was designed to assure that the benefits and knowledge gained by studying clinical outcomes associated with the use of percutaneous orthopedic procedures outweigh the potential risks to the patients. The primary objective of this Registry is to observe the improvement in subject-reported clinical outcomes for these procedures used to treat musculoskeletal disorders. Secondary objectives include evaluating post-operative complications, adverse events, re-injections, and surgical intervention.

This Registry allows for the long-term tracking of your health. By your participation in the Registry, you grant to the IOF the authorization to access, review and share your treatment, procedure and follow up data. IOF will maintain the privacy of your confidential medical information in compliance with all local and international laws including, but not limited to, the Health Insurance Portability and Accountability Act (HIPPA) of 1996 (P.L.104-191).

COMMUNICATION

You will receive periodic communications by email, phone, or text from the IOF Registry. You will be required to fill out survey tracking forms that detail the status of your medical condition and any new medical conditions or diagnoses since your percutaneous orthopedic procedure. If you report a potential complication, this will be tracked through the IOF Registry and reviewed both by your treating physician and the medical director of Registry. If you would prefer to receive these periodic survey reminders by text, please type the key phrase *IOFRegistry* (one word) and send to 622622. You will not receive text messaging notifications until this action is complete. You can expect the survey reminders to come by email and phone otherwise.

QUESTIONS

Contact Jennifer Rodriquez at jennifer.rodriquez@interventionalorthopedics.org for any of the following reasons:

- if you have any questions about your participation in the Registry,
- if you have questions, concerns or complaints about the Registry

Do not sign this Consent Form unless you have had a chance to ask questions and have gotten satisfactory answers. If you agree to be in this study, you will receive a signed and dated copy of this Consent Form for your records.

CONSENT

I have read this Consent Form (or it has been read to me). All my questions about the study and my part in it have been answered. I freely consent to be in this registry database and participate in the Registry.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this Consent for the purposes described above.

By signing this Consent Form, I have not given up any of my legal rights.

_____
Subject Name (printed)

_____ _____
Signature of Subject Date

_____ _____
Printed Name of Person Conducting the Consent Discussion Position

_____ _____
Signature of Person Conducting the Consent Discussion Date

Interventional Orthopedics Foundation

Patient Registry Database

PATIENT DEMOGRAPHICS

Date Completed: Date of Reinjection:

Physician:

Patient Name First: Middle: Last:

Title (Mr, Mrs, Dr, etc):

Email Address: Alt. Email:

Phone: Mobile:

Office:

Mailing Address:

City, State, Zip:

Country: Country of Birth:

Date of Birth: Age:

Occupation:

Height: ☐ inch. ☐ cm

Weight: ☐ lbs ☐ kg

Gender: ☐ Male ☐ Female

Optional Questions: *(All information on this Form remains confidential, including those listed below)*

Median Annual Income Level (US Dollars):	☐ Under $10,000 ☐ $10,000 to $24,999 ☐ $25,000 to $49,999 ☐ $50,000 to $74,999 ☐ $75,000 to $99,999 ☐ $100,000 and over
Highest Level of Education:	☐ Less than high school ☐ Graduated from high school ☐ Some college ☐ Graduated from college ☐ Postgraduate school or degree
Race:	☐ Caucasian (White) ☐ Black or African American ☐ Asian ☐ Hispanic or Latino ☐ American Indian/Alaska Native ☐ Native Hawaiian or Other Pacific Islander ☐ Other (please specify):

Informed Consent

Has the nature of this procedure been explained to you (the patient) and have you been provided with a written informed consent?	☐ Yes ☐ No Informed Consent Date: _____(dd-mm-yyyy)

Interventional Orthopedics Foundation

Patient Registry Database

PATIENT PAIN SCALE

Date:	
Physician:	
Patient Name:	
Procedure Date (dd-mm-yyyy):	
Joint / Location:	
Laterality:	☐ RIGHT ☐ LEFT
This question is a 0 to 10 scale regarding your pain this week for the area and side of the body/joint location noted above. Marking "0" means NO PAIN and marketing "10" means the WORST POSSIBLE PAIN. This score applies to the area being treated.	INTENSITY OF PAIN (please check the box# that best describes your pain) Right now 0 1 2 3 4 5 6 7 8 9 10

Interventional Orthopedics Foundation

Patient Registry Database

FUNCTIONAL RATING INDEX (FRI)

Date: Physician:

Patient Name:

[redacted]

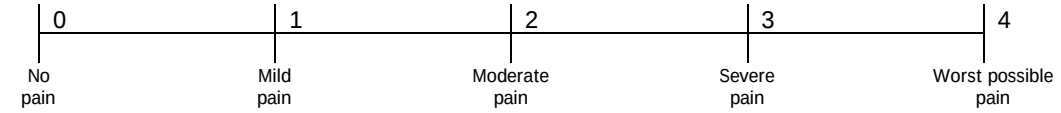
Procedure Date (dd-mm-yyyy):

Joint / Location:

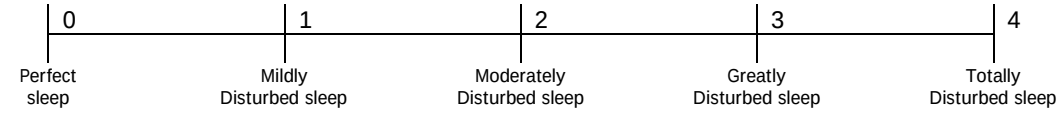
Laterality: ☐ RIGHT ☐ LEFT

In order to properly assess your condition, we must understand how much your **neck and/or back problems** have affected your ability to manage everyday activities. For each item below, **please check the box for which most closely describes your condition right now.**

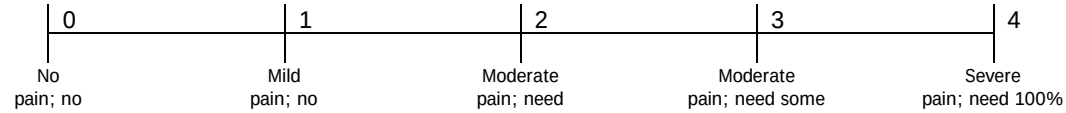
1. Pain Intensity



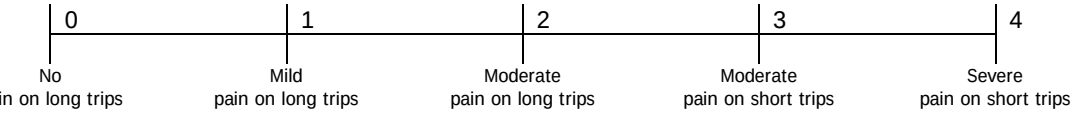
2. Sleeping



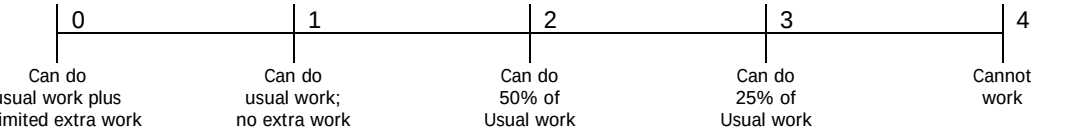
3. Personal Care (washing, dressing, etc.)



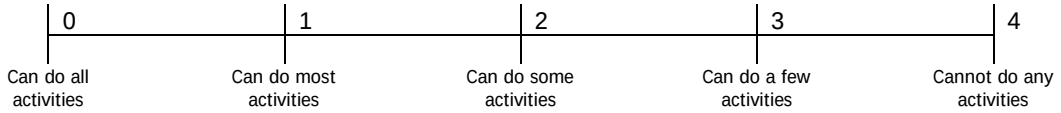
4. Travel (driving, etc.)



5. Work

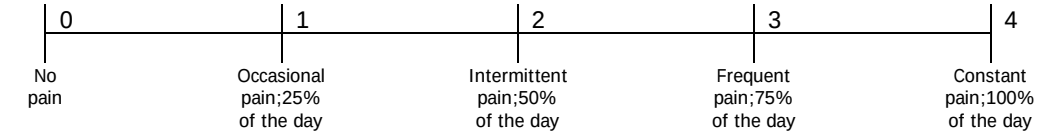


6. Recreation

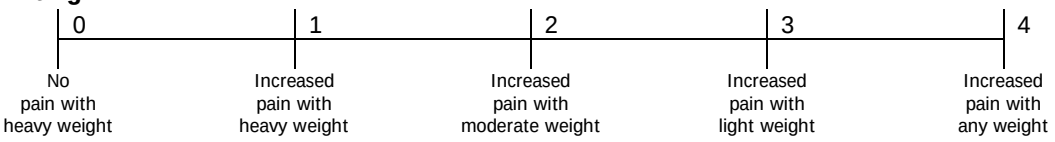


FUNCTIONAL RATING INDEX (FRI)

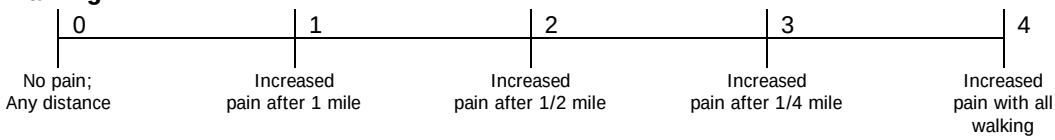
7. Frequency of pain



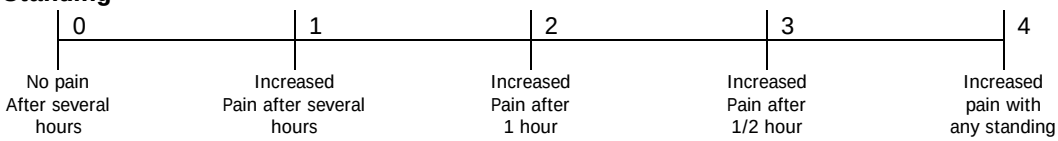
8. Lifting



9. Walking



10. Standing



VERMONT LONGEVITY CENTER

Evan Musman, D.O.

Regenexx®

Patient Name: _____

Advance Beneficiary Notice (ABN)

NOTE: You need to make a choice about receiving these health care items or services.

Insurance will not pay for the item(s) or service(s) that are described below as this global procedure is considered experimental. The fact that your insurance may not pay for a particular item or service does not mean that you should not receive it. There may be a good reason your doctor recommended it. Right now, in your case, **your insurance will not pay for –**

Items or Services: **Regenexx-DDD Procedures for spine applications.**
Because: Insurers consider this type of injection experimental. This is despite peer reviewed medical research that shows that it helps patients with this condition

The purpose of this form is to help you make an informed choice about whether or not you want to receive these items or services, knowing that you will have to pay for them yourself. Before you make a decision about your options, you should **read this entire notice carefully.**

- Ask us to explain, if you don't understand why your insurance won't pay.
  -- The Regenexx-DDD (degenerative disc) procedure consists of a blood draw and the injection of autologous cells back into the affected joints and ligaments and around the irritated nerves.

PLEASE CHOOSE **ONE** OPTION. CHECK **ONE** BOX. **SIGN & DATE** YOUR CHOICE

☐ **Option 1. YES. I want to receive these items or services**

I understand that my insurance will not pay for these items or services. I understand that I can submit insurance on my own behalf to appeal for reimbursement of services.

☐ **Option 2. NO. I have decided not to receive these items or services.**

I will not receive these items or services.

_____ _____

Date **Signature of patient or person acting on patient's behalf**

NOTE: Your health information will be kept confidential. Any information that we collect about you on this form will be kept confidential in our offices. If a claim is submitted to your insurance, your health information on this form may be shared with your insurance. Your health information which your insurance sees will be kept confidential by your insurance.

Evan Musman, D.O., P.C.
AUTHORIZATION FOR PROCEDURE

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 Evan Musman, D.O. as my physician(s), 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.

No Guarantee and Research Disclosure: 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. I also understand that my procedure may be videotaped for research or educational purposes. If used for research purposes, the video will serve as a record of exactly what was performed in the procedure to augment physician notes. Your name will not be used in the research project nor published. If used for educational purposes, your face or name will not be shown to others, just the area where the doctor is working. (If you don't want to be videotaped, just let the doctor or staff know and this will not occur.)

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, including use of general anesthetics, and that these range from minor discomfort to injury to vocal cords, teeth or eyes. If general anesthesia or 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 none of the first two types of anesthesia are used, which is most common for this joint 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.

Financial Disclosure: The physician who is performing your procedure may have a financial interest in the medical practice's lab, where your tissue/blood is being processed. Should you have any questions or concerns regarding this relationship, please discuss them with your physician.

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 nothing to relieve your pain, cure your condition, or otherwise repair your tissues.

Treatment Alternatives: 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.

Risks of Not Receiving Treatment: 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.

Treatment Complications: 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 are unlikely 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_____ 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.

Patient or Guardian Signature_____ Date_____

Witness_____ Relationship_____ Date_____

V P M
VERMONT PAIN MANAGEMENT, PC

Dear Patient,

As you may know, we are always concerned with trying to maximize your outcome from your procedure. Because this procedure involves the ability of your cells to repair tissue and the decade long Regenexx experience has seen that certain medications may interfere with your procedure, we have the following recommendations:

1. **Stop all prescription medications and supplements that can be stopped**. We recognize that some medications may not be safe to abruptly discontinue, so you need to check with your Regenexx doctor. He or she may have you contact the prescribing physician as well. This is for two weeks before and 6 weeks after your procedure.
    a. **Exceptions for supplements (i.e. you can stay on these)** include Glucosamine, Chondroitin, Collagen 2, Hyaluronic Acid, Fish Oil (omega 3s, EPA, DHA), DHEA, Curcumin, Quercitin, Bitter Melon, L-Carnosine, Vitamin C, Vitamin D, and Resveratrol.

2. **These medications have been shown to be particular problems** in our clinical experience or are suspected to be issues based on what is published in the medical research about their impacts on cells or stem cells. **DO NOT STOP ANY PRESCRIBED DRUG WITHOUT SPEAKING WITH A PHYSICIAN**:
    a. Steroid drugs like prednisone, inhaled steroids taken for asthma, or steroid injections like those given for knee or joint arthritis or sciatica. You should be off of these drugs for at least 6 weeks prior to your procedure. Note that this is more than the two weeks noted above.
    b. NSAID drugs like Motrin, Ibuprofen, Aleve, Naprosyn, Celebrex, Voltaren, Cataflam, and others. If you think you will have intolerable pain with stopping these drugs, then please let us know. We can often substitute high dose fish oils or the Regenexx Advanced Stem Cell Support Formula Supplement for these drugs. In fact, one of the ingredients in the Regenexx supplement (Curcumin) was recently shown to be as effective as Ibuprofen for reducing pain and stiffness.
    c. Statin cholesterol lowering drugs like Crestor, Lipitor, Mevacor, Pravachol, Vytorin, Zocor and others. If you have a history of heart disease, you must clear stopping these drugs temporarily with your prescribing cardiologist or internist. If you have no history of heart disease, then while you still may want to consult with your prescribing doctor, you should ask your Regenexx doctor about discontinuing these medications.
    d. ACE Inhibitor Blood Pressure Drugs like Lisinopril, Enalapril, Altace, Accupril, Prinivil, etc.. If you're on these drugs, consult with your prescribing doctor about switching to a different blood pressure drug.
    e. Testosterone Inhibitors like Proscar or Propecia. If you're on these drugs, consult with your Regenexx doctor and/or prescribing doctor about stopping for a while.
    f. Quinolone antibiotics like Floxin, Noroxin, Cipro, Levaquin, etc… These have been associated with tendon ruptures, so consider speaking with your doctor about alternative antibiotics.

3. **Male or Female Hormone replacement** including estrogen, progesterone, testosterone, and growth hormone like Norditropin. You can stay on these hormones.

**** EAT A NO-FAT DIET AT LEAST 6 HOURS PRIOR TO YOUR BLOOD DRAW PROCEDURE.**

****PLEASE CONSUME PLENTY OF WATER 2 HOURS PRIOR TO YOUR BLOOD DRAW PROCEDURE.**

One Kennedy Drive, Suite U1 • So. Burlington, Vermont 05403
Tel 802.861.6100 • fax 802.861.6101 • www.vermontpainmanagement.com

NEW ADULT PATIENT HISTORY INTAKE

Welcome to VERMONT PAIN MANAGEMENT, P.C (Evan Musman, D.O.). To help us establish you with our practice, please provide us with your complete health history.

Name: _____ Date:_____

Date of Birth___/____/_____ Age_____ **RIGHT** or **LEFT** handed?_____ Height: _____ Weight: _____

ALLERGIES (Medications, food, etc.):

_____

_____

Are you allergic to iodine or shellfish? _____ If Yes, what was the reaction? _____

MAIN PAIN COMPLAINTS: (if possible, rank in terms of importance to you)

_____

_____

_____

(Note: we may not be able to address every problem during the course of one visit.)

PRIMARY CARE PHYSICIAN: _____ PHARMACY: _____

CURRENT MEDICATIONS ***LIST ALL*** **PAST MEDICAL, SURGICAL AND TRAUMA HISTORIES**

Medication	Dose	Frequency	Event or Procedure	Date

(if necessary, please attach additional information)

SOCIAL HISTORY

Do you smoke cigarettes? ☐ YES ☐ NO If yes, #_____yrs. #_____ packs per day

Do you use street drugs? ☐ YES ☐ NO If yes, what kind? _____

Do you drink alcohol? ☐ YES ☐ NO If yes, how much? Type_____ &_____ drinks per week

Do you drink caffeinated beverages? ☐ YES ☐ NO If yes, type / how much?_____

PERSONAL AND FAMILY HISTORY

Check those that apply:

	Yourself	Mother	Father	Other		Yourself	Mother	Father	Other
Alcoholism					Glaucoma				
Alzheimer's					Heart Attack				
Elevated Cholesterol					Heart Disease				
Arthritis					High Blood Pressure				
Asthma					Irritable Bowel Syndrome				
Bleeding Disorder					Kidney Disease				
Breast Cancer					Liver Disease/Hepatitis				
Prostate Cancer					Migraines				
Colon Cancer					Pneumonia				
COPD / Emphysema					Other Cancer: _____				
Depression					Stroke				
Diabetes					Suicide				
Drug Abuse					Thyroid Disease				
Epilepsy					Other				

Have you had or do you have?

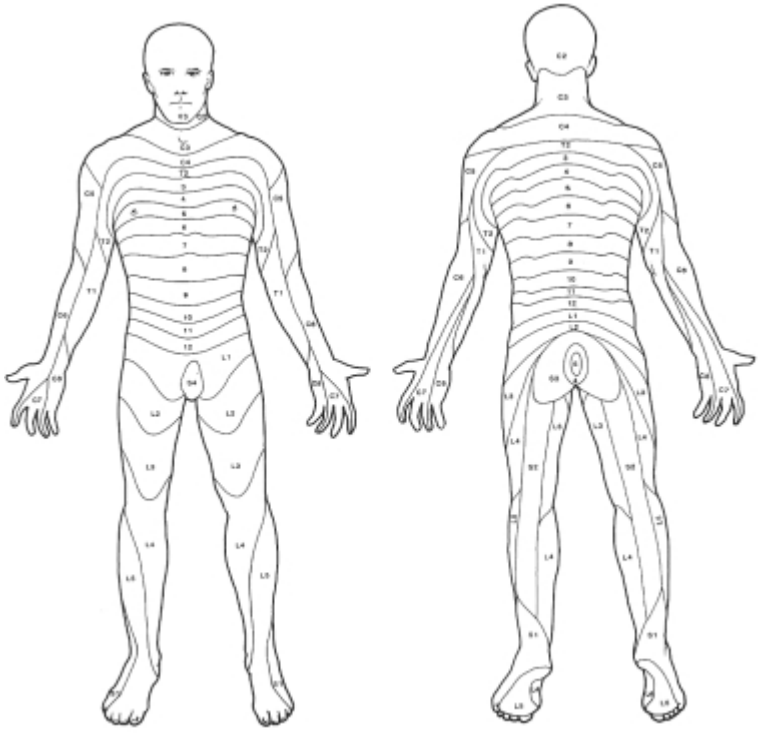
Y	N		Y	N	
___	___	Fatigue/ Feeling tired	___	___	Arthritis: Rheumatoid / Degenerative
___	___	Fever/ Chills	___	___	Swelling in hands or feet
___	___	Unexplained weight-loss	___	___	Stroke or Mini-stroke
___	___	Eye problems (besides glasses)	___	___	Lightheadedness / Dizziness / Headache
___	___	Hearing problems	___	___	Weakness in arms or legs
___	___	Frequent sinus problems	___	___	Skin problems / Rashes
___	___	Chest pain	___	___	Depression / Anxiety / Bipolar
___	___	Shortness of breath	___	___	Infections: HIV / Hepatitis / Urinary
___	___	GERD or Heartburn	___	___	Cancer
___	___	Stomach ulcer	___	___	Do you use a walker or cane?
___	___	Nausea / Vomiting	___	___	Do you use a walker or cane?
___	___	Constipation / Urinary retention			
___	___	Loss of control of bowel or bladder			
___	___	Diabetes / Thyroid problems			
___	___	Kidney problems			
___	___	Bleeding / Bruising problems			

_____

_____

_____

PLEASE NOTE YOUR AREA(s) of PAIN



This history record has been designed to facilitate our patients' continuity of care. This is a confidential record and will be kept in this facility. Information contained here will not be released to anyone without your authorization to do so.

_____

Patient / Guardian signature Date

PATIENT NOTICE OF PRIVACY PRACTICES CONSENT FORM

I have read and fully understand this Notice of Privacy Practices. I understand that Vermont Pain Management, PC may use or disclose my personal health information for the purposes of carrying out treatment, obtaining payment, evaluating the quality of services provided and any administrative operations related to treatment or payment. I understand that I have the right to restrict how my personal health information is used and disclosed for treatment, payment and administrative operations if I notify the practice. I also understand that Vermont Pain Management will consider requests for restriction on a case-by-case basis, but does not have to agree to requests for restrictions.

I hereby consent to the use and disclosure of my personal health information for purposes as noted in Vermont Pain Management's Notice of Privacy Practices. I understand that I retain the right to revoke this consent by notifying the practice in writing at any time.

Patient Name

Signature Date