

RESEARCH PHASE DECLARATION & DISCLAIMER

Use of Cross-Linked Hyaluronic Acid in the Treatment of Nerve Damage & Neuropathy Pain Research Phase

I understand that the use of cross-linked hyaluronic acid in the treatment of nerve damage and neuropathy pain by this office is in its research phase. And that no guarantee, warranty or assurance has been made or implied that it will work and give me the desired pain relief in my particular case.

Based on his prior experience in using this substance where it has been helpful in patients with similar pain problems, Dr. Campa believes it may be helpful for me and is now recommending its use in my case.

I will be given a copy of this document once signed by all parties below.

Patient Name (please print): _____

Signature: _____ Date: _____

NEUROPATHIC PAIN CENTER FOR CLINICAL RESEARCH & TREATMENT
Neuropathy Pain Services

1701 MOON ST. NE ▪ SUITE 100 ▪ ALBUQUERQUE, NM 87112
http://paindiagnosis.net

TEL (505) 508-1543 / FAX (505) 554-2118

INDIVIDUAL PATIENT DISCLOSURE AUTHORIZATION OF INFORMATION FORM

I. AUTHORIZATION TO DISCLOSE AND OBTAIN PROTECTED HEALTH INFORMATION

A. Reason (event) for obtaining / disclosing requested protected health information: Continuity of Medical Care

B. I authorize John A. Campa III, MD to disclose my protected health medical information to:

- **Strike through an item below to decline authorization:**
- Any referring or consulting: physician, attorney, Case Management Nurse
- Hospital, Medical Facility, Pharmacy, Pharmacist providing medications

C. I authorize John A. Campa III, MD to obtain medical information from:

- **Strike through an item below to decline authorization:**
- Any referring or consulting: physician, attorney, Case Management Nurse
- Hospital, Medical Facility, Pharmacy, Pharmacist providing medications

D. I understand this authorization provides that:

- I have the right to access my protected health information to be used or disclosed.
- I may revoke this authorization at any time by contacting your Privacy Officer in writing at: John A. Campa III, MD, c/o Privacy Officer, 1701 Moon St. NE, Suite 100, Albuquerque, NM 87112.
- Information used or disclosed pursuant to this authorization may be subject to redisclosure by the recipient and no longer be protected by HIPAA privacy rules.
- This practice will not condition treatment on my providing authorization for the requested use or disclosure.

PATIENT'S / GUARDIAN SIGNATURE & RELATIONSHIP TO PATIENT

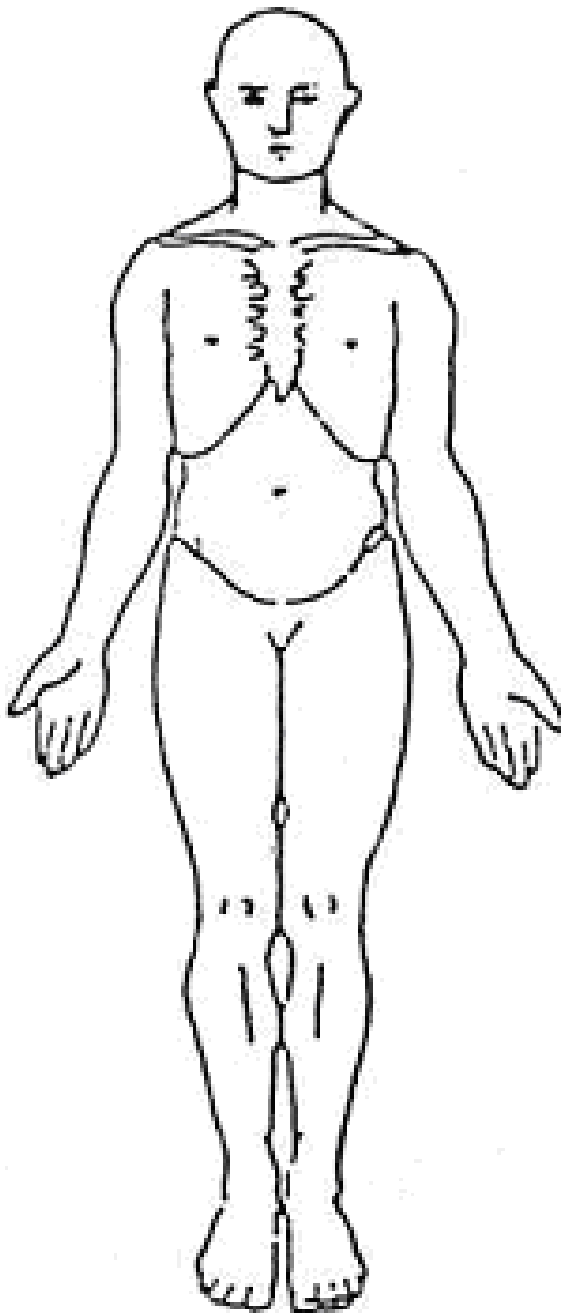
DATE

WITNESS

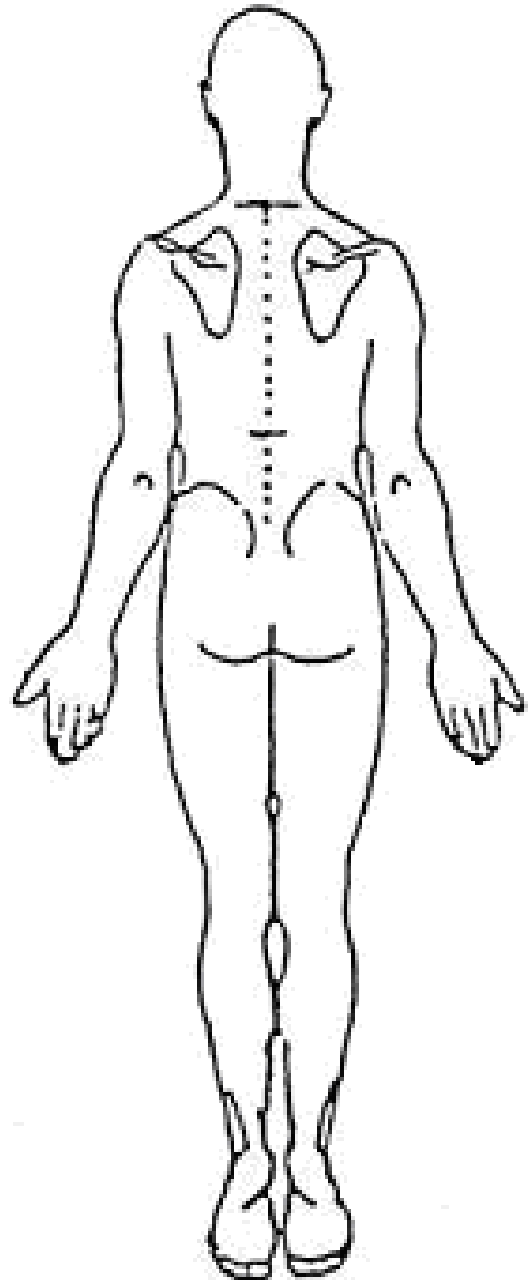
SYMPTOM BODY FIGURE – FOR SHOWING SYMPTOMS OR PAIN

Patient: _____ Date: _____

- Place a “X’s” your symptom or pain is constant and “Y’s” where it shoots to.
- Place “O’s” where the symptom or pain is most severe.
- Write any comments in the white space around the figures you believe would be helpful to the doctor, such as areas of numbness, tingling or weakness.



FRONT



BACK

KEY: 'X' = CONSTANT 'Y' = RADIATES 'O' = MOST SEVERE

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Patient Information & Medical History

Name: _____ Date: _____

Address: _____ City: _____ State: _____ Zip: _____

Phone: (cell) _____ (home) _____ (work) _____

Married? Y N E-mail: _____ DOB: _____ Age: _____ Sex: F M

Occupation: Retired _____ Last 4 numbers of your SSN: _____

How did you hear about us?: Magazine Newspaper Sign Friend: _____
NM Marketplace Magazine TV: KASA-Ch. 2 KQRE-Ch. 13 Internet Dr. _____

Current Pain Problem - What is your main problem and What part of your body does your problem affect most ?:

It has been present for how long?: _____

How did your problem begin or start?: _____

You pain is: Getting Better Getting Worse About The Same

Was a nerve/EMG test done? Y - N Did it show neuropathy? Y - N

Describe your pain - Circle all that apply - Is your pain?:

constant off & on sharp aching squeezing tight burning tingling numb shooting electric-like cold
worse-night worse-with-weight-bearing pins-needles throbbing pressure

Other words: _____

What is your average Pain Score?:

If zero is no pain & ten (10) is the worst pain you can imagine, from 0 to 10, What is your average pain score?: _____

Medical History (circle yes or no, and explain yes answers)

Are you?: Right Handed Left Handed Both

How tall are you?: _____

Patient Information & Medical History
- continued.

- Yes No Do you have control of your bowels & bladder?
If not, is this due to you neuropathy? No Yes Don't-know
- Yes No Are you allergic to Local Anesthetics like Lidocaine or Xylocaine or metals or egg whites?
- Yes No What medications are you allergic to?
- Yes No Do you have a history of severe, life-threatening allergic/anaphylactic reactions or other multiple severe allergies? What are they: _____
- Yes No Have you had a serious reaction to moisturizing creams or other hyaluronic acid products?
- Yes No Have you had lab work that included: CBC-Complete Blood Count, PT, PTT ?
If so, when were the last tests done ? _____
- Yes No Do you currently have an active inflammation or infection in treatment area?
- Yes No Do you have a serious preexisting disease such as diabetes, congestive heart failure, uncontrolled coronary artery disease, Rheumatoid arthritis, lupus, Hepatitis-C, HIV-AIDS or any other or have you undergone transplant surgery?
- Yes No Do you suffer from any disease that affects your nerves and causes a generalized weakness of muscle strength (i.e. Myasthenia gravis, Eaton-Lambert syndrome)?
- Yes No Do you have any severe acne scars or other non-stretchable scars, or widened surgical scars?
- Yes No Do you have a history of large, raised or thick scars or keloid scars?
- Yes No Are you under the care of a physician?
If yes, name: _____
- Yes No Are you pregnant or breastfeeding?

Please circle diseases or medical problems below that you have or have had:

Diabetes Shingles-PHN Neuropathy HBP-High Blood Pressure RA-Rheumatoid Arthritis Migraine
SLE-Lupus Scleroderma Hepatitis-C HIV-AIDS Transplant surgery Heart Disease
Stroke-TIAs Epilepsy-Seizures MS-Multiple Sclerosis Myasthenia Gravis Low-High Thyroid
Vitamin Deficiency-B12 Anemia Sickle Cell Lyme Bleeding-Clotting-Problem DVT
PE-Pulmonary Embolism Cancer-Type: _____

Other unlisted problems?: _____

**Patient Information & Medical History
- continued.**

Fractures: _____

Are you taking drugs that suppress your immune system ? Y - N

Please circle medications you are taking:

Hydrocodone/APAP Oxycodone Hydromorphone Morphine Tramadol Insulin Metformin
Gabapentin Lyrica Cymbalta Vit. D B12 Folic Acid Coumadin-Warfarin Heparin Lovenox

List other medications you are taking:

List Surgeries You Have Had:

FAMILY HISTORY:

Please circle diseases or medical problems below that members of your **FAMILY** have:

Diabetes Shingles-PHN Neuropathy HBP-High Blood Pressure RA-Rheumatoid Arthritis Migraine

SLE-Lupus Scleroderma Hepatitis-C HIV-AIDS Transplant surgery Heart Disease

Stroke-TIAs Epilepsy-Seizures MS-Multiple Sclerosis Myasthenia Gravis Low-High Thyroid

Vitamin Deficiency-B12 Anemia Sickle Cell Lyme Bleeding-Clotting-Problem DVT

PE-Pulmonary Embolism

Cancer-Type: _____

Comments:

I ATTEST THE ABOVE INFORMATION TO BE TRUE, KNOWING MY PHYSICIAN RELIES ON THIS INFORMATION TO PROVIDE SAFE AND EFFECTIVE TREATMENT.

I UNDERSTAND THAT THE USE OF CROSS-LINKED HYALURONIC ACID IN THE TREATMENT OF NERVE DAMAGE AND NEUROPATHY PAIN IS IN ITS RESEARCH PHASE AND, AS SUCH, NO GUARANTEE, WARRANTY OR ASSURANCE HAS BEEN MADE OR IMPLIED AS TO THE RESULTS AND SUCCESS OF THE TREATMENT.

Patient Signature _____

Date: _____

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Patient Current Medical History & Usage of Blood Thinning Substances

Name: _____ **Date:** _____

- Yes No Do you bruise easily or do you have a bleeding - blood clotting disorder ?
- Yes No Are you currently taking: aspirin, steroids or non-steroidal anti-inflammatory drugs ?
Like: Ibuprofen, Nuprin, Advil, Motrin, Naproxen, Naprosyn
- Yes No Are you using blood thinners like Plavix, Clopidogrel, Heparin or Coumadin ?
- Yes No Are you pregnant or planning to become pregnant soon or breastfeeding ?
- Yes No Have you had Bell's Palsy ? When ? _____
- Yes No Are you taking any medicines for immune system suppression ?
- Yes No Are you a smoker?
- Yes No Do you use alcohol?

Circle any of the following you are currently taking as they can contribute to bruising or bleeding:

Bilberry, Chamomile, Chondroitin, Clove, Echinacea, Ephedra, Vitamin E, Valerian
Fish oil, Garlic, Garlic capsules, Ginger, Ginko Biloba, Ginseng, Glucosamine
Grape seed, Herbal teas, Horseradish, Kava, Licorice, Willow bark, St. John's Wort Goldenseal,
Milk Thistle, Saw Palmetto

Date last taken: Today / _____

I ATTEST THE ABOVE INFORMATION TO BE TRUE, KNOWING MY PHYSICIAN RELIES ON THIS INFORMATION TO PROVIDE SAFE AND EFFECTIVE TREATMENT.

Patient Signature _____

Date: _____

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**Informed Consent for Treatment with Cross-linked Hyaluronic Acid
Off-Label FDA Use for Chronic Pain**

NOTE: – This Consent will be valid for today's and all follow-up treatments unless changed by physician.

*** Please initial after each statement and sign at bottom of page.**

1. I, _____ (full name), consent to and authorize: **John A. Campa III, MD**, to perform a injection with cross-linked hyaluronic acid to treat my chronic pain. This may require the initial injection of a "test" nerve block with local anesthetic, like Lidocaine or Bupivacaine, to find the best site to later inject the cross-linked hyaluronic acid.

2. The nature and purpose of the treatment has been explained to me and questions I have regarding the treatment have been answered to my full satisfaction. _____(initials).

3. I am fully aware of the risks of complications, adverse reactions or injuries that can occur from this treatment, and I freely assume those risks. _____(initials).

- The known complications may include:

- Redness, swelling, itching, bruising, pain or pressure lasting over a week.
- Nodules or hardening at the injection site.
- Discoloration of the injection site.

4. I also certify that I have none of the known conditions that *could* contraindicate treatment or have made the physician aware of theses conditions. These conditions include hypertrophic (thick, raised) scars, a history of auto-immune disease (like Lupus, Scleroderma, Rheumatoid Arthritis), or immune system suppressing therapy.

5. I am not pregnant or breast-feeding. _____(initials)

6. I have no known allergy to moisturizing creams or other hyaluronic acid products.
_____(initials).

7. I agree that any pictures taken of my **treatment site** may be used for publication and teaching purposes, however, my name will not be disclosed and complete confidentiality of my name will be maintained. _____(initials).

**Informed Consent for Treatment with Cross-linked Hyaluronic Acid
Off-Label FDA Use for Chronic Pain - continued.**

8. I agree to adhere to all safety precautions and post-treatment instructions, including:
- ❖ Avoid prolonged sun or UV exposure.
 - ❖ Avoid saunas or steam baths for 2 weeks after injection.
 - ❖ For facial injections - no make-up for at least 12 hours after injection, other than concealer.
 - ❖ For first 24 hrs., avoid strenuous exercise, extensive sun or heat exposure, and alcoholic drinks. Exposure to any of these may cause temporary redness, swelling an/or itching at the injection sites.

9. I am informed and understand that the use of injectable, cross-linked hyaluronic acid is FDA approved for use in cosmetics as a wrinkle filler. Its use for chronic pain is an FDA off-label use, meaning: as of this date, not recognized by the FDA. _____(initials)

10. I understand that the use of cross-linked hyaluronic acid in the treatment of nerve damage and neuropathy pain is in its research phase and, as such, no guarantee, warranty or assurance has been made or implied as to the results and success of the treatment.
_____ (initials)

11. I certify that I have read this entire informed consent and that I understand and agree to the information stated in this form. _____(initials)

I understand that the use of cross-linked hyaluronic acid in the treatment of nerve damage and neuropathy pain is in its research phase and, as such, no guarantee, warranty or assurance has been made or implied as to the results and success of the treatment.

Patient Name (please print): _____

Signature: _____

Date: _____

Witness Signature: _____

Date: _____

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AFTER CARE INSTRUCTIONS FOR PATIENTS RECEIVING CROSS-LINKED HYALURONIC ACID
OFFICE ANSWERING SERVICE (505) 857 - 3766

**** YOU MUST TELL ANSWERING SERVICE YOU HAD A PROCEDURE DONE SO THEY WILL CONTACT ME. ****

SWELLING & BRUISING

1. Swelling or bruising may occur. Apply ice for 15 min., every four hours to treated area for the first 24 hours.
2. You may also apply the topical cream Arnica Montana (available over the counter) to the affected area, every four hours as needed.

INJECTION RELATED PAIN & SWELLING

1. For SEVERE pain or swelling - Call the office immediately or go to the nearest ER.
2. For minor pain or swelling: Use Tylenol, anti-inflammatory medications, such as Advil, Aleve or Ibuprofen after procedure, only if necessary. Do not use if allergic.
3. You may also apply the topical cream Arnica Montana (available over the counter) to the painful area, every four hours as needed.

INFECTION

1. If infection after the procedure is suspected, contact us at: (505) 508-1543 for further instructions.
- You may need to come to the office to have the area examined, and possibly receive a prescription for an antibiotic.
2. Signs and symptoms of infection include: Fever, redness, tenderness, warmth and swelling at the treatment site.

WHAT TO AVOID

1. For Facial injection: for the first 12 hrs.: Other than "concealer", avoid make-up.
2. For first 24 hrs.: Avoid strenuous exercise, extensive sun or heat exposure, and alcoholic drinks, as these may cause temporary redness, swelling and/or itching at the injection sites.
3. For 2 weeks: Avoid saunas, steam baths, and laser to the treated areas.

**AFTER CARE INSTRUCTIONS AFTER RECEIVING CROSS-LINKED HYALURONIC ACID
- continued.**

DURATION

The results of treatment with cross-linked hyaluronic acid may last from 6 weeks to 6 months, and more treatments may be needed to maintain improvement in your pain control.

I, _____ hereby certify that I understand the importance of the above post-treatment instructions. If not followed exactly, I may cause some of the adverse reactions listed on the consent form.

I understand that the use of cross-linked hyaluronic acid in the treatment of nerve damage and neuropathy pain is in its research phase and, as such, no guarantee, warranty or assurance has been made or implied as to the results and success of the treatment.

Patient Signature _____

Date: _____