

Informed Consent for Treatment with Human Cellular & Tissue-Based Products (HCT/Ps)

Elective · Experimental / Investigational Procedure — Please Read This Entire Document Carefully

Practice / Clinic

Provider

Product / HCT/P Being Used

Patient Full Name

Date of Birth

Date

Time

AM / PM

Condition / Area Being Addressed

1. Purpose & Nature of This Document

The purpose of this document is to provide written information regarding the risks, benefits, and alternatives to the elective and experimental/investigational procedure involving the administration of Human Cellular and Tissue-Based Products ("HCT/Ps"). This consent supplements — and does not replace — the discussion(s) you have had with your physician, nurse practitioner, or physician assistant, and documents your understanding of the nature of the products to be used and the speculative benefits that may be achieved. **Please read this document carefully and ask any questions before signing.**

I have been advised and consulted about the use of HCT/Ps. The HCT/Ps to be used are derived from the umbilical cord tissue of live, healthy birth babies, donated voluntarily following normal delivery. The product is delivered via intravenous (IV) infusion and/or by direct injection into an affected joint or tissue (for example: knee, ankle, shoulder, elbow, wrist, hip, sacroiliac joints, and/or the facet joints of the lumbar, thoracic, or cervical spine), at the medical professional's clinical discretion. I understand these products are intended and marketed for limited regulatory uses, and that the use described to me — while determined by my provider to potentially be of benefit in my case — is **"off-label" and is not an FDA-approved use.**



Initial

FDA STATUS. I understand that this is an **experimental/investigational procedure that is NOT approved by the U.S. Food and Drug Administration (FDA)**. The FDA has not approved any human tissue-derived product for therapeutic use other than cord blood-derived hematopoietic progenitor cells (blood-forming stem cells) for certain specified indications. I understand the practice and its medical staff make **no representation or guarantee** that this procedure will be effective in my case, regardless of any information I may have received from other patients, testimonials, advertising, or any other source.

2. Protocols

The injectable/infusible material is a product derived from an immuno-privileged site (umbilical cord tissue); as a result, patient rejection is rare but not impossible. Human tissue-derived products have been used on an experimental/investigational basis for several years in orthopedics, sports medicine, pain management, podiatry, and wound care; however, such use is **not widespread or universally accepted** in medicine. There is currently no universally accepted evidence that the use of these products is appropriate for my condition, or that it is more cost-effective or beneficial than other accepted treatments. The product has been procured from a tissue bank that tests the tissue for safety and uses donor serology panels and other testing intended to screen for bacterial and fungal contaminants.

3. Donor Screening & Laboratory Testing

The donated umbilical cord tissue has been determined eligible for use by a licensed physician retained by the tissue bank. Review of donor records includes the donor's medical history, a risk-behavior assessment, and review of medical records and physical examination data. All laboratories performing testing are registered with the FDA and certified to test human specimens under the Clinical Laboratory Improvement Amendments (CLIA) Act of 1988 and 42 CFR Part 493.

Donor tissue is deemed qualified only if pre-screening results specify the donor to be free from risk factors and active infections of applicable communicable disease agents as required by the FDA, and results are negative and/or non-reactive for: Hepatitis B and C Viruses (HBV/HCV); Human Immunodeficiency Viruses Types I & II (HIV I/II Ab); Nucleic Acid Testing (NAT) for HIV and Hepatitis B and C; Hepatitis B Core Antibody (HBc Ab); Hepatitis B Surface Antigen (HBsAg); Human T-Cell Lymphotropic Viruses I & II (HTLV I/II); and Rapid Plasma Reagin (RPR) for syphilis. Each lab maintains records of the donor and lot number for post-procedure tracking. **Despite this screening, no testing can eliminate 100% of the risk of transmission of known or unknown pathogens.**

4. Indications & Procedure

This administration is being provided in my case to address one or more of the following, despite the fact that the FDA has not evaluated the appropriateness of HCT/Ps for any of these: joint deterioration, arthritic conditions, soft-tissue injury and inflammation, autoimmune-related complaints, and/or associated pain. After the skin surface is cleaned, the target joint and/or adjacent tissue may be entered with a needle and syringe, or the product may be introduced intravenously, depending on the medical professional's judgment.

5. Potential Outcomes & Benefits

Potential outcomes **may** include relief or reduction of pain, increased circulation, increased exercise tolerance, improved pain threshold, increased range of motion, improved joint function, or other structural improvements; **however, no beneficial result is or can be guaranteed.** A mild inflammatory reaction following administration is expected and is believed to be part of the body's response.

6. Adverse Reactions

While serious adverse clinical reactions to this type of product are reported to be rare, an adverse reaction is not impossible, and — as with any injection or infusion — infection is possible. If any signs of infection or an adverse reaction occur, **I agree to contact my provider immediately.** Adverse reactions or outcomes that potentially involve the use of this product must be reported.

7. Risks

Initial

I understand and accept that this procedure includes one or more injections and/or an IV infusion, and that the products used were **not developed or FDA-approved for this purpose**. I understand this use is **NOT approved by the FDA for the diagnosis or treatment of ANY condition**, including the condition being addressed in my case. No procedure is risk-free. The material risks below have been discussed with me. By initialing, I attest I have read and understood them and that there may be additional risks not itemized here and not foreseeable.

- Allergic/adverse reaction to bandages, tape, gauze, or skin-cleaning agents; itching at the injection site
- Numbness, tingling, or unpleasant sensation in the treated area
- Soft-tissue swelling, bruising, or hematoma formation
- Vasovagal reaction (fainting/dizziness), nausea, or vomiting
- General disappointment, no improvement, or unsatisfactory result
- Temporary increased muscle spasm; stiffness; slow recovery
- Trauma to nerves, including temporary or permanent nerve paralysis
- Temporary injection or post-injection discomfort or pain
- Infection (rate of occurrence reported to be rare)
- Transmission of communicable, infectious, or genetic disease — bacterial, fungal, or viral; known or unknown
- Immune rejection, or allergic reaction to the product or any cryoprotectant/excipient it may contain
- Worsening of an existing, undisclosed joint or skin infection
- Breakage of equipment, including vial or needle
- Recurrence of original symptoms; damage or injury to adjacent tissues, structures, or nerves
- Discoloration or injury to blood vessels; vein irritation/swelling if injected
- Tendon scarring with pain on motion; potential tendon rupture if inadvertently injected
- Minor bleeding, fluid accumulation, edema, or swelling post-procedure
- Weak grip (wrist/elbow); pneumothorax (chest-wall/thoracic); spinal cord injury (back injections)
- Delay of other, more widely-accepted or less costly treatments
- Risks that are unknown, unforeseeable, or not itemized here

Initial

I understand that while measures to ensure the safety of the product have been taken by the supplier, **current technology cannot preclude the transmission of certain diseases, known or unknown**, and that neither the supplier nor the medical professional performing this procedure can make any claim concerning the biologic properties and safety of the product, despite the tissue bank confirming it collected, processed, screened, tested, stored, and distributed the product in compliance with applicable regulations.

8. Assumption of Risk

I understand that I am electing an experimental/investigational procedure as an alternative to more widely-accepted forms of treatment, and that if this procedure is not effective, **I may be delaying recovery I might have obtained from other, more accepted, and potentially less costly treatments**. Having been informed of the possibility of complications from both known and unknown causes, **I freely and knowingly assume all such risks**. I understand that if I am unwilling to accept all risks associated with this procedure, I have been advised to refuse it.

9. Alternatives to Treatment

Initial

I have been advised of alternatives to this procedure, some of which may be less costly, including:

- **Doing nothing**, which may lead to continuation or worsening of my condition.
- **Conservative therapy** such as physical therapy, chiropractic, or rehabilitation.
- **Other experimental therapies** such as laser or shockwave therapy.
- **Oral pain or anti-inflammatory medication**, which may carry risks of addiction, liver or kidney injury, gastrointestinal bleeding, and other effects.
- **Conventional injections**, such as corticosteroid or other accepted joint injections.
- **Surgery**, including arthroscopic or joint-replacement procedures, each carrying its own material risks including blood clot, dislocation, fracture, heart attack, infection (including MRSA), implant failure, neurovascular damage, stroke, and death.

Initial

Alternative treatments, prescriptions, and therapies — and their benefits, costs, material risks, and disadvantages — have been explained to me in terms I understand, along with the probable consequences of declining recommended or alternative therapies.

10. Patient Representations

Initial

I represent that I have **not** been advised that I have an intra-articular infection in the joint or a skin infection in the areas to be treated, and that I have **not** been informed that I am HIV positive or otherwise immunocompromised. I further represent that I am **not pregnant or lactating**, and that I am **not** taking blood-thinning medication such as Coumadin/Warfarin (or, if I am, that I have disclosed this to the medical professional).

Initial

I have informed the provider of my known allergies and all medications I currently take (prescription, over-the-counter, herbal, supplements, aspirin, and recreational drug or alcohol use), and I have been advised whether to take or hold any of these before, the day of, or after the procedure.

Initial

Truthful disclosure. The information I have provided is complete, accurate, and truthful to the best of my knowledge. **I understand the practice is relying on my answers to determine my eligibility, and that failure to disclose relevant medical information may increase my risk and is my responsibility.**

11. Financial Terms

Initial

I understand this procedure is **elective and experimental/investigational**, is therefore **NOT covered by insurance**, and will not be billed to my insurance. Payment in full is required at the time of service, and **THOSE PAYMENTS ARE NON-REFUNDABLE** regardless of outcome, including no improvement or dissatisfaction. Any expense for care I elect to receive outside of this office is my sole financial responsibility.

12. Acknowledgments

Initial

No representations or guarantees about the results of this procedure have been made; it is **not represented as a cure** or beneficial method of treatment for any condition, nor to provide immunity against re-occurrence of any condition.

Initial

No one can be fully aware of all possible side effects and complications; this procedure involves potential risks and adverse reactions identified herein and potentially others not reasonably anticipated, as with any injection or surgical procedure.

Initial

I have been advised of what to expect post-procedure (recovery time, activity level, and the potential need for additional procedures). If I receive a local anesthetic or have an extremity joint injected that is required to operate a vehicle, I will **not** operate a motor vehicle or dangerous machinery afterward and will be accompanied by a responsible adult as necessary.

Initial

I understand that viewing the practice's website, advertising, or marketing does not by itself establish a doctor-patient relationship, and that all such content is **educational/informational only and is not medical advice or a promise of outcome.**

13. Authorization, Release & Voluntary Consent

The provider has answered all of my questions regarding this experimental/investigational procedure, and I understand the procedure to my complete satisfaction. I knowingly authorize and direct the physician(s) and/or Nurse Practitioner or Physician Assistant named below to perform, and/or assist as necessary in performing, the administration of HCT/Ps on the joints and/or related tissues listed below. I further authorize them to do any other procedure that, in their judgment, may be necessary or advisable should unforeseen circumstances arise.

Physician (M.D./D.O.)

NP / PA Assisting (if any)

Joints and/or tissues to be treated

My consent and authorization for this elective and experimental/investigational procedure is **strictly voluntary**. I have been informed of alternative options and have expressly chosen treatment using HCT/Ps. I understand medicine is not an exact science and that no guarantee has been given or implied as to results. **To the fullest extent permitted by law, I knowingly and voluntarily assume all risks of this procedure and release, waive, and hold harmless the practice, its providers, owners, employees, affiliates, and the product supplier from any and all claims, liabilities, costs, and damages arising out of or related to this elective procedure, except those caused by gross negligence or willful misconduct.** I understand I may ask questions, request more time, or decline this procedure at any time prior to its administration.

Dispute Resolution & Governing Law

Any dispute arising out of or relating to this consent or the procedure shall be resolved by binding arbitration administered by JAMS or the American Arbitration Association under its applicable rules, in the county and state of the treating practice's principal location, and shall be governed by the laws of that state without regard to conflict-of-law principles. **By initialing, I acknowledge I am agreeing to resolve disputes through arbitration and am waiving the right to a jury trial.**



Initial

Patient acknowledges and agrees to the arbitration and jury-trial waiver above.

14. Consent to Contact & Privacy

Initial

I consent to be contacted by the practice by phone, text/SMS, and email regarding my care, appointments, and follow-up. I acknowledge I have been offered a copy of the practice's Notice of Privacy Practices. Message/data rates may apply; I may opt out of non-essential messages at any time.

15. Capacity & Final Certification

I certify that I am at least 18 years of age (or an authorized legal representative), that I am of sound mind and legally competent to execute this consent, that I am not impaired by any substance affecting my judgment, that I have read this entire document, understand its terms and conditions in their entirety, and that all blanks were filled in prior to my signature below.

Patient Signature

Patient Printed Name

Date & Time (AM / PM)

If signed by a Legal Representative — Printed Name & Relationship to Patient

Certification to be Completed by the Medical Professional

I certify that I have explained to the patient the nature, purpose, anticipated benefits, material risks, complications, and alternatives to the proposed administration of HCT/Ps sourced from the umbilical cord of live, healthy birth babies. I have answered all questions fully. I believe that the [circle one] **patient / legal representative** fully understands what I have explained, and that consent was given knowingly and voluntarily.

Medical Professional Signature

Date

Medical Professional Printed Name

☐ Copy Given to Patient

☐ Original Placed in Chart