Informed Consent for Injection of Dynacord Cellular Exosomes

Product Being Used: <u>Human Umbilical Cord Mesenchymal Stem Cell-derived Exosomes</u>

Lot #: _____

Purpose: The purpose of this document is to provide written information as of_____ , 2025 at regarding the risks, benefits, and alternatives to the elective procedure of cellular Exosomes injection(s). This consent is intended to supplement the discussion you have had with your Doctor, and/ or your Doctor's Nurse Practitioner or Physician's Assistant. It is important that you fully understand this information - **so please read this document carefully.**

I, _____, have been advised and consulted about the use of injected Exosomes. I understand the Dynacord exosomes are intended for research use only; however in my case, it has been determined that injection of this product may be beneficial in the treatment of my condition. The procedure involves the injection of exosomes, which are derived from the umbilical cord tissue of live healthy births, via intravenous therapy or through direct injection into an affected joint such as the knee, ankle, shoulder, elbow, wrist, hip, sacroiliac joints, and/or the facet joints of the lumbar, thoracic or cervical regions of the spine.

Protocols: The injectable is a sterile product that is derived from an immune-privileged site (umbilical cord) and as a result, patient rejection is extremely rare. Human tissue derived products have been used experimentally for years in orthopedic and sports medicine, as well as in pain management, podiatry, and wound care. The above-described injectable ("Injectable") used by this office for the procedure has been procured from DynaCord, which is the only FDA Master Drug File classification that thoroughly tests the tissue for safety in clinical procedures and utilizes extensive donor serology test panels and other stringent testing to ensure that the product is free of bacterial and fungal contaminants.

Donor Screening: The donated umbilical cord vesicles have been determined to be eligible for review of donor records includes analysis of the donor medical history, performance of a risk behavior assessment, review medical records and recent physical examinations. This review allows the tissue bank to determine whether the donor is free from risk factors or whether there is clinical evidence of infection due to relevant communicable diseases and other exclusionary disease conditions. Where such potential for infection due to communicable diseases exists, the tissue is rejected. All labs performing the tests are registered with the Food and Drug Administration (FDA) and certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments (CLIA) Act of 1988 and 42 CFR part 493. An allograft of donated human tissue is deemed qualified for transplantation by a tissue bank if it meets the following criteria: 1) the results from the donor pre-screening lab tests specify the donor to be free from risk factors and active infections of applicable communicable disease agents and diseases as required by the FDA, and 2) donor results from the pre-screening lab tests must be negative and/or non-reactive for the following applicable communicable disease agents determined by the following: testing for Hepatitis B and C Viruses (HCV/HBV); testing for Human immunodeficiency viruses Types I and II (HIV 1/11 AB); Nucleic Acid Testing (NAT) for HIV, and Hepatitis B and C;

Core Antibody Testing for Hepatitis B (HBC AB); Testing for Hepatitis B Surface Antigen (HBS AG); Human T-Cell Lymphotropic Viruses I and II (HTLV-1/2) and testing for Reactive Plasma Reagin (RPR) (which tests for non-specific antibodies that may indicate a syphilis infection). The tissue bank that provides vesicles our office uses for this procedure has informed this office that the vesicles and donor have met the above requirements. By law, the laboratories performing human specimen tests are certified and meet the requirements as determined by the Centers for Medicare and Medicaid (CMS), per CLIA and 42 CFR part 493, and the FDA. Each lab is additionally required to maintain appropriate records of the donor with allograft ID number (lot number) for purposes of tracking the allograft post treatment.

___**Indications & Procedure:** I have been informed that the indications for this injection are joint deterioration diseases, arthritic diseases, soft tissue injury and inflammation, autoimmune disorders and/or pain associated with the foregoing. I understand that after my skin surface has been thoroughly cleaned, my joint(s) and/or adjacent muscles and ligaments will be entered with a needle attached to a syringe. At that point, the injectable exosome substance may either be introduced intravenously or directly into my joint space, or the area adjacent to the joint, depending on the medical professional's professional judgment.

Anticipated Outcomes & Benefits: From this procedure, anticipated outcomes and benefits may include relief from pain or pain reduction, increased circulation, increased exercise tolerance, improved pain threshold, increased range of motion, improved joint function, or other structural improvements, but these or any other beneficial result is not and cannot be guaranteed. Post injection, a mild inflammatory reaction is expected and desired for it is this inflammation that is believed to facilitate the healing process.

Adverse Reactions: No adverse clinical reactions to this tissue product have been reported, but it is not impossible for an adverse reaction to happen. As is the case with any injection, infection is possible. If any signs of infection or an adverse reaction occur, you agree to contact your provider immediately. Adverse reactions or outcomes that potentially involve the use of this tissue product must be reported.

___**Risks**: I understand and accept that the procedure to which I am consenting is one or more injections of joints or surrounding tissue and that the products used were developed. Before undergoing any procedure, understanding the potential risks is essential, as no procedure is risk free. The following risks are recognized, but there may also be risks not itemized here that are not foreseen by doctors. By my initials on this paragraph, I attest that the most likely material risks and complications from a joint injection have been discussed with me. These risks commonly include but are not limited to:

allergic or adverse reactions to bandages, tape, gauze, or agents used to clean the skin; itching at the injection site; numbness; soft tissue swelling, bruising, or hematoma formation; vasovagal reaction (i.e., fainting or dizziness) or nausea or vomiting; general disappointment; temporary increased muscle spasm; trauma to nerves including temporary or permanent nerve paralysis; temporary injection and post-injection discomfort or pain; infection (though rate of occurrence is extremely rare); transmission of communicable, infectious or genetic diseases including bacterial, fungal or viral transmission; immune rejection or allergic reaction to injection or DMSO contained in injectable; worsening of existing infections if injection is unknowingly performed on patient with existing and undisclosed joint infection; breakage of equipment including vial/needle; recurrence of symptoms or unsatisfactory result; damage to associated structures; injury to adjacent tissues or nerve injury; discoloration or injury to blood vessels;

irritation and swelling if a vein is injected; tendon scarring resulting in pain on motion; potential rupture of tendon if it is in path of injection and inadvertently injected; minor bleeding post-injection; fluid accumulations, minor edema, or swelling post-injection; weak grip (in wrist/elbow injections); pneumothorax (with chest wall or thoracic area injections); spinal cord injury (with back injections); slow recovery; stiffness; tingling or unpleasant feeling in the area that was injected.

___**Alternatives:** I have been advised of alternatives to the injection of cellular vesicles, which include: 1) Doing nothing, which typically leads to further joint degeneration, restricted mobility and pain. 2) Continued conservative therapy, which in my case has been demonstrated to be ineffective; 3) Taking oral pain medication or anti-inflammatory agents, which are not likely to correct the underlying problem and/ or, depending on the medication, carry a risk of addiction, liver failure, gastro-intestinal bleeds, and death. 4) Joint replacement surgery, which carries risks similar to this procedure as well as blood clot, leg length discrepancy, joint dislocation, fracture, heart attack, infection including staphylococcus infections and MRSA, implant failure or prosthetic loosening, neurovascular damage, re-operation, stroke and death.

_____**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.

__**Derivation:** I understand and accept that the procedure to which I am consenting is an intravenous or direct joint injection of cellular vesicles derived from umbilical cord tissue of a live healthy birth, and the details of this treatment including anticipated benefits, material risks and disadvantages have been explained to me in terms I understand.

___**Personal health disclosures:** By initialing here, I represent that I have **not** been advised by any healthcare provider that I have an intra-articular infection in the joint or skin infection in the areas to be injected, that I have **not** been informed by any healthcare provider that I am HIV positive or otherwise immunocompromised. I additionally state that I am **not** pregnant or lactating, and that I am **not** on any blood thinning medications such as Coumadin/Warfarin (and that if I am taking blood thinners, that I have advised the medical professional of the same).

___**Allergies:** I have informed the doctor of my known allergies, as well as all medications I am currently taking, including prescriptions, over-the-counter remedies, herbal therapies and supplements, aspirin, and other recreational drug or alcohol use, and I have further been advised as to whether I should take any or all of these medications prior to the injection, the day of the injection, or in the days after the injection.

___**Insurance:** I understand that the injection of cellular vesicles is a form of treatment that is considered by insurance companies and others to be experimental, and thus it is not covered by insurance.

___**Experimental treatment:** I understand that the injection of cellular vesicles, because no one can be fully aware of all possible side effects and complications of this treatment, involves both potential risks and adverse reactions identified herein and potentially others, which may not be reasonably anticipated.

_____**Complication waiver:** I understand and accept that there are potential complications, which exist with any injection or surgical procedure.

__**Results waiver:** I am aware that no guarantees about the results of this procedure have been made. I understand that the injection of cellular vesicles is not being represented as a cure for any medical condition nor has it been represented to provide immunity against re-occurrence of any condition.

___**Operation of vehicle:** I have been advised of what to expect post-injection, including but not limited to estimated recovery time, anticipated activity level, and the potential need for additional procedures, and I have also been informed that if I am to receive a local anesthetic and/or other pain management agents, or have an extremity joint injected that I am required to use for operation of a motor vehicle, that I will not operate a motor vehicle or dangerous machinery after performance of the injection and that I will be accompanied to and from the office by a responsible adult, as necessary for the procedure, unless the local anesthesia or joint injection is unrelated to cognitive and motor functions and does not impact my ability to operate such vehicles or machinery.

____I understand this experimental treatment and procedure to my complete satisfaction and have no unanswered questions. I further authorize the physician(s) and his or her associated medical professionals to do any other procedure that in their judgment may be necessary or advisable should unforeseen circumstances arise during the procedure.

_My consent and authorization for this elective and experimental procedure is strictly voluntary. I have been informed of the possibility of complications as detailed above, from both known and unknown causes, and freely and knowingly assume those risks. I understand that if I am not willing to accept all risks associated with this procedure that I have been advised to refuse this treatment. I agree to adhere to all safety precautions and instructions before and after the treatment. I have been instructed in and understand post treatment instructions and have been given a written copy of them. I understand that medicine is not an exact science and acknowledge that no guarantee has been given or implied by anyone as to the results that may be obtained by this experimental treatment. I also understand this procedure is "elective" and "experimental" thereby rendering it non-covered by insurance and that payment is my responsibility. Any expense that may be incurred for medical care I elect to receive outside of this office to include but not limited to treatment that I deem necessary as a result of dissatisfaction with the injection of cellular vesicles will be my sole financial responsibility. Payment in full for all treatments provided pursuant to this informed consent is required at the time of service and **THOSE PAYMENTS ARE NONREFUNDABLE.** I understand that to receive cellular vesicle injection treatment, I must comply with all stipulations outlined in this consent form; if I do not agree then I will not be able to proceed with treatment. I consent to the diagnosis, treatment plan, and cellular vesicle injection, after having been advised of alternative treatments, the known material risks of the diagnosis and experimental treatment to be used, and understand and knowingly accept the consequences of my decision to either accept or reject the offer of cellular vesicle injection. I certify that I have read this entire document, understand the terms and conditions of this agreement in their entirety, that I am capable of executing this informed consent and that all blanks were filled in prior to executing my signature below.

Print Name

Signature

Date