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Informed Consent for Allograft Cellular Therapy

Purpose: The purpose of this document is to provide written information as of_____, 20____ date at _____am/pm regarding the risks, benefits, and alternatives to the elective procedure of Allograft Cellular Therapy (hereafter, referred to as "ACT Injection"). This is supplementary to the discussion you have had with the doctor, and/or the doctor's Nurse Practitioner or Physician Assistant. It is important you fully understand this information – so please read this document carefully.

I, _____, have been advised and consulted about the treatment known as Allograft Cellular Therapy ("ACT Injection"). The procedure involves the injection of cells, derived from the umbilical cord of live healthy birth babies, via IV or directly into the knee, ankle, shoulder, elbow, wrist, hip, and sacroiliac joints, as well as the facet areas of the lumbar, thoracic or cervical regions. ACT Injection is a new treatment used to help improve joint function, stimulate repair, and decrease the pain associated with certain forms of arthritis.

____ By initialing here I understand that this is an experimental treatment that is NOT FDA approved. The FDA has not approved any stem cell-based products for use, other than cord blood derived hematopoietic progenitor cells (blood forming stem cells) for certain indications. Protocols: The injectable is a sterile, minimally manipulated, allograft (an allograft is a tissue graft from a donor of the same species as the recipient), derived from an immuno-privileged site (Umbilical cord blood) which produces high concentrations of mesenchymal stem cells, which as a result of its source bears no antigens, and thus patient rejection is extremely rare. The product is intended for homologous use to replace or supplement damaged or inadequate integumental tissue. Umbilical cord derived stem cells have been used for years for orthopedic and sports medicine, as well as pain management, podiatry, and wound care. The above-described injectable ("Injectable") used by this office for the procedure has been procured from a tissue bank which 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 blood has been determined to be eligible for transplantation by a Licensed Physician who is in charge of so doing on behalf of the tissue bank. Review of donor records include donor medical history and risk behavior assessment, medical records, and recent physical examination, and indicate to the tissue bank that the donor is free from risk factors for and clinical evidence of infection due to relevant communicable diseases and other exclusionary disease conditions. 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) 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 Immuno-Deficiency Viruses Types I and II (HIV I/II 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 I/II); and testing for Reactive Plasma Reagin (RPR) (which tests for non-specific 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 Immuno-Deficiency Viruses Types I and II (HIV I/II 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 I/II); and testing for Reactive Plasma Reagin (RPR) (which tests for non-specific antibodies that may indicate a syphilis infection). The tissue bank that provides the injectables our office uses for this procedure has informed this office that the injectable 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 requires patient records to be properly maintained by storing the 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 may either be done intravenously or injected into my joint space, or the area adjacent to the joint, depending on the medical professional's diagnosis and other factors. 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 cannot be guaranteed. Post injection, a mild inflammatory reaction is expected – and desired – in order 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. If any signs of infection or reaction occur, 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. 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 may include:

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.

____ While great measures to ensure the safety of the allograft product have been taken by the supplier, I understand that current technologies cannot preclude the transmission of certain diseases known or unknown, and that neither the supplier of the injectable nor the medical professional performing this procedure can make any claims concerning the biologic properties and safety of allograft tissues despite the tissue bank confirming it has collected, processed, screened, tested, stored, and distributed the product in compliance with all current FDA regulations concerning HCT/Ps.

____ Alternatives: I have been advised of alternatives to ACT injection, which include: 1) Doing nothing, which typically leads to further joint degeneration, restricted mobility and pain. 2) Taking oral pain killers or anti-inflammatory agents which do not correct the underlying problem and carry a risk of addiction, liver failure, gastro-intestinal bleeds, and death. 3) 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, material risks and disadvantages – have been explained to me in terms I understand, along with the probable consequences of declining recommended or alternative therapies.

____ I understand and accept that the procedure to which I am consenting is an intravenous or joint injection involving cells derived from the umbilical cord blood of a live healthy birth baby, and the details of this treatment including anticipated benefits, material risks and disadvantages have been explained to me in terms I understand.

____ By initialing here, I represent that I have not been advised 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 that I am HIV positive or otherwise immuno-compromised, 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 same).

____ 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.

____ I understand that Allograft Cellular Therapy is considered by insurance companies and others to be experimental, and thus it is not covered by insurance; and that no one can be fully aware of all possible side effects and complications of this protocol.

____ I understand and accept that there are complications, which exist with any injection or surgical procedure

____ I am aware that no guarantees about the results of this procedure have been made. I understand that Allograft Cellular Therapies are not warranted to cure any medical conditions nor provide immunity against re-occurrence of such conditions.

____ I have been advised of what to expect post-injection, including but not limited to estimated recovery time, anticipated activity level, and possibility of additional procedures, and I have also been informed that if I am to receive a local anesthesia and/or other pain management agents, or have an extremity joint injected which joint I am required to use for operation of a motor vehicle, that I will not operate a motor vehicle or dangerous machinery after same, and 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.

____ The doctor or _____ has answered all of my questions regarding this treatment, and I understand the procedure to my complete satisfaction and have no unanswered questions, and I now authorize and direct _____, M.D. and/or his Nurse Practitioner or Physician Assistant_____, to perform, and/or assist as necessary, the injection on the following joints: _____. 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 procedure is strictly voluntary. I have been informed of the possibility of complications as detailed above, from both known and unknown causes, and freely assume those risks. I understand that if I am not willing to accept all risks associated with this procedure then I should not have 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 treatment. I also understand this procedure is "elective" and not covered by insurance and that payment is my responsibility. Any expense which may be incurred for medical care I elect to receive outside of this office, such as, but not limited to dissatisfaction of my treatment outcome will be my sole financial responsibility. Payment in full for all treatments is required at the time of service, and is

nonrefundable. I understand that to receive homologous ACT 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 ACT Injection, after having been advised of alternative treatments, the known material risks of the diagnosis and treatment to be used, and the consequences if these diagnostic and treatment procedures were to be withheld or refused. I certify that I have read this entire document, and understand this treatment agreement and that all blanks were filled in prior to executing my signature below.

Patient Sign: _____

Print Patient Name: _____

Witness: Sign: _____

Print Witness Name_____

Office Agent Sign: _____

Print Office Agent Name _____

CERTIFICATION TO BE COMPLETED BY MEDICAL PROFESSIONAL

I certify that I have explained to the patient the nature, purpose, anticipated benefits, material risks, complications, and alternatives to the proposed joint injection(s) utilizing stem cells 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.

Date _____ _____ Signature

James T. Skeen

___ (Initial) Copy Given to Patient ___ (Initial) Original Placed in Chart