Informed Consent for A2M Therapy

Regenerative Medicine of Raynham LLC, 575 South Street West #2B, Raynham, MA 02767

Product Being Used: Alpha 2 Macroglobulin

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 Alpha 2 Macroglobulin (hereafter, referred to as "A2M 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 ("A2M Injection"). The procedure involves the injection of A2M directly into the treatment area. A2M Injection is a treatment used to help improve joint function, stimulate repair, and decrease the pain and discomfort associated with certain conditions.

____ By initialing here, I understand that this is an experimental treatment that is **NOT FDA approved**.

Protocols: The injectable is a sterile, autologous product derived from the patient's own blood. A2M has 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 produced in a closed system to ensure that the product is free of bacterial and fungal contaminants.

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, neuropathy 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 will be placed into the treatment area, 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.

Adverse Reactions: No adverse clinical reactions to this 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 product must be reported to the provider.

____ **Risks:** I understand and accept that the procedure to which I am consenting is one or more injections of treatment area. 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 A2M 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); 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 A2M product have been taken by the provider, 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 A2M.

____ **Alternatives:** I have been advised of alternatives to A2M injection, which include: 1) Doing nothing, which typically leads to further 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 injection involving A2M derived from my own blood 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 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 A2M 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 A2M 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 _____, DC/M.D. and/or his Nurse Practitioner or Physician Assistant_____, to perform, and/or assist as necessary, the injection on the following areas: _____. 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 A2M 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 A2M 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.

Sign: _____

_____

Print: Patient Name:

Sign: _____

_____

Print: Office Agent:

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 injection(s) utilizing A2M sourced from the patients' blood.

I have answered all questions fully.

I believe that the [CIRCLE ONE] patient / legal representative fully understands what I have explained.

_____ _____

Signature Date

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