REGENERATIVE ORTHO MEDICAL INSTITUTE

Regenerative Ortho and Medical Institute, LLC
1724 33rd Street, Suite 200 · Orlando, FL 32839
Ph: (321) 999-7335 · Fax: (321) 999-7455 · orthoregenmed.com

Informed Consent for Stem Cell Therapy

PREPARED IN ACCORDANCE WITH SECTION 458.3245, FLORIDA STATUTES

PATIENT FULL NAME | DATE OF BIRTH | CHART / MRN #

PHONE | EMAIL (OPTIONAL) | DATE OF CONSENT DISCUSSION

THIS NOTICE MUST BE PROVIDED TO YOU UNDER FLORIDA LAW. This physician performs one or more stem cell therapies that have not yet been approved by the United States Food and Drug Administration. You are encouraged to consult with your primary care provider before undergoing any stem cell therapy.

1. Purpose of this form

This form explains the stem cell therapy your physician has recommended, so that you can make an informed decision about whether to proceed. Please read it carefully and ask any questions before signing. Your physician will review each section with you. You may take as much time as you need, and you may decline or postpone treatment at any time before the procedure begins.

2. Nature and character of the proposed treatment

Stem cell therapy involves placing human cells or tissue-based products that contain living stem cells into or around an injured or painful area of the body, most often by injection. Under Florida law, this therapy may be offered for **orthopedic, wound care, or pain management** conditions. The procedure is usually performed in the office, may use ultrasound or other imaging to guide the needle, and typically takes less than one hour. Local anesthetic may be used to numb the area. Your specific treatment plan is described below.

DIAGNOSIS / CONDITION BEING TREATED | BODY AREA(S) TO BE TREATED

☐ Right ☐ Left ☐ Bilateral ☐ Not applicable

PRODUCT NAME | MANUFACTURER / TISSUE BANK | LOT / DONOR ID #

Source of cells

☐ Umbilical cord / Wharton's Jelly tissue (afterbirth perinatal)
☐ Placental or amniotic tissue (afterbirth perinatal)
☐ My own cells (autologous adult stem cells)
☐ Donor adult stem cells (allogeneic)

Method of administration

☐ Ultrasound-guided injection
☐ Fluoroscopy-guided injection
☐ Landmark-guided injection
☐ Other (describe below)

NUMBER OF PLANNED TREATMENTS | ANESTHESIA (E.G., LOCAL ONLY) | OTHER DETAILS

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3. FDA status

The stem cell therapy proposed for you **has not yet been approved by the United States Food and Drug Administration (FDA)** for the treatment of your condition. This means the FDA has not determined that it is safe and effective for this use. Florida law permits physicians to perform this therapy for orthopedic, wound care, and pain management purposes when the requirements of Section 458.3245, Florida Statutes, are met. Stem cell therapy is not a substitute for FDA-approved treatments.

4. Source and handling of the cells

ROMI uses stem cells only from facilities that, as required by Florida law:

- are registered with and regulated by the FDA;
- are certified or accredited by the National Marrow Donor Program, the World Marrow Donor Association, the Association for the Advancement of Blood and Biotherapies (AABB), or the American Association of Tissue Banks (AATB);
- follow current good manufacturing and tissue practices and donor screening and testing requirements under federal law (21 C.F.R. Part 1271); and
- supply cells that contain viable (living) cells upon post-thaw analysis.

ROMI does not use cells or tissues derived from a fetus or an embryo after an abortion.

Accreditation of the supplying facility

☐ AATB ☐ AABB ☐ NMDP ☐ WMDA

5. Anticipated results

The goal of treatment is to reduce pain and improve function in the treated area. Some patients notice improvement over several weeks to several months; others experience little or no improvement. Results vary from person to person and depend on factors such as the type and severity of the condition, age, overall health, and activity level. More than one treatment may be recommended. **No result is guaranteed**, and stem cell therapy does not cure arthritis or reverse structural damage such as bone-on-bone joint loss.

6. Anticipated benefits

- Possible reduction in pain and inflammation.
- Possible improvement in movement, strength, and day-to-day function.
- A minimally invasive option that may delay or reduce the need for more invasive treatment in some patients.
- Typically a short recovery period compared with surgery.

7. Recognized serious possible risks and complications

As with any injection-based procedure, risks exist. Your physician will discuss the risks that apply to you. These include, but are not limited to:

- **Common:** pain, swelling, stiffness, bruising, or a temporary increase in symptoms at the injection site, usually lasting a few days.
- **Less common:** infection; bleeding or hematoma; allergic or sensitivity reaction to the product, local anesthetic, or skin preparation; lightheadedness or fainting (vasovagal reaction).
- **Rare but serious:** injury to nearby nerves, blood vessels, tendons, or other structures; joint infection requiring further treatment or surgery; an immune reaction to donor cells; and, despite donor screening and testing, transmission of an infectious disease.
- **No benefit or worsening:** the treatment may not relieve your symptoms, and your condition may stay the same or worsen.

- **Unknown long-term risks:** because this therapy is not FDA-approved, its long-term effects are not fully known. Theoretical risks, such as abnormal tissue growth, have been raised in medical literature.
- Risks associated with imaging guidance, sedation, or anesthesia, if used.

8. Recognized alternative forms of treatment, including nontreatment

You do not have to have stem cell therapy. Other options, each with its own possible benefits and risks, include:

Alternative	Possible benefits	Possible risks / limitations
No treatment / observation	Avoids procedure risks and cost; some conditions improve on their own.	Symptoms may continue or worsen; condition may progress.
Activity modification and physical therapy	Improves strength, flexibility, and function; low risk.	Requires time and effort; may not fully relieve pain; temporary soreness.
Bracing, supports, or assistive devices	Reduces load on the painful area; non-invasive.	Limited relief; skin irritation; muscle weakness with long-term use.
Oral or topical medications (e.g., anti-inflammatories, pain relievers)	Can reduce pain and inflammation quickly.	Stomach, kidney, liver, cardiovascular, or bleeding side effects; relief is often temporary.
Corticosteroid injection	Often fast, short-term relief of pain and inflammation; FDA-approved medications.	Temporary relief; flare, infection, elevated blood sugar; repeated injections may affect tissue.
Hyaluronic acid injection (knee)	May reduce knee osteoarthritis pain for several months.	Variable benefit; injection-site pain or swelling; infection (rare).
Platelet-rich plasma (PRP)	Uses your own blood; may reduce pain in some conditions.	Variable evidence; injection-site pain; infection (rare); usually self-pay.
Surgery	May correct structural problems and provide lasting relief when appropriate.	Anesthesia and surgical risks (infection, blood clots, nerve injury); longer recovery and rehabilitation.

9. Consultation with your primary care provider

You are encouraged to consult with your primary care provider before undergoing any stem cell therapy.

☐ I have consulted with my primary care provider about this therapy.

☐ I have not consulted with my primary care provider, and I choose to proceed. I understand I am encouraged to do so.

PRIMARY CARE PROVIDER NAME (OPTIONAL) _____ PHONE (OPTIONAL) _____

10. Health information

I confirm that I have told my physician about my complete medical history, including:

☐ All current medications and supplements, including blood thinners

☐ Allergies (including to medications, latex, or local anesthetics)

☐ Current or past cancer, or active infection

☐ Conditions or medications that weaken the immune system

Pregnancy:

☐ I am not pregnant or breastfeeding ☐ I am pregnant or breastfeeding ☐ Not applicable

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11. Financial responsibility

Stem cell therapy is not FDA-approved and is generally **not covered by health insurance or Medicare**. It is provided on a self-pay basis. Before treatment, I have received a written good-faith estimate of the expected charges. I understand that I am responsible for payment as described in that estimate, and that any related office visits, imaging, or other services may be billed separately.

☐ I received a written good-faith estimate before scheduling this treatment.

12. Patient acknowledgments

Please initial each statement.

_____ INITIALS — I have read this form, or it has been read to me, in a language I understand.

_____ INITIALS — My physician has explained the nature and character of the proposed treatment, its anticipated results, and its recognized serious possible risks, complications, and anticipated benefits.

_____ INITIALS — I understand that the proposed stem cell therapy has **not yet been approved by the United States Food and Drug Administration**.

_____ INITIALS — Recognized alternative forms of treatment, including nontreatment, and their risks and benefits have been explained to me.

_____ INITIALS — I have been encouraged to consult with my primary care provider before undergoing any stem cell therapy.

_____ INITIALS — I have had the opportunity to ask questions, and all of my questions have been answered to my satisfaction.

_____ INITIALS — I understand that no guarantee or assurance has been made about the results of this treatment.

_____ INITIALS — My decision is voluntary. I may withdraw this consent at any time before the procedure begins without affecting my access to other care at ROMI.

_____ INITIALS — I have been offered a copy of this signed form.

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13. Consent and signatures

By signing below, I consent to the stem cell therapy described in this form, to be performed by Michael Magee, MD, and the clinical staff assisting him at Regenerative Ortho and Medical Institute.

SIGNATURE OF PATIENT | DATE | TIME

PRINTED NAME OF PATIENT | PATIENT DATE OF BIRTH

If signed by a legal representative:

SIGNATURE OF LEGAL REPRESENTATIVE | PRINTED NAME

RELATIONSHIP / LEGAL AUTHORITY | DATE

Interpreter (if used): I have accurately interpreted this form and the physician's explanation for the patient.

INTERPRETER SIGNATURE | PRINTED NAME | LANGUAGE | DATE

WITNESS SIGNATURE | PRINTED NAME | DATE

Physician attestation

I have personally explained to the patient (or the patient's legal representative) the nature and character of the proposed stem cell therapy, that it has not yet been approved by the United States Food and Drug Administration, its anticipated results, its recognized serious possible risks, complications, and anticipated benefits, and the recognized possible alternative forms of treatment, including nontreatment. I have encouraged the patient to consult with his or her primary care provider and have answered the patient's questions.

PHYSICIAN SIGNATURE | PRINTED NAME | DATE

For office use: Original to patient chart · Copy offered to patient · Product label / lot sticker attached to procedure note.