



## Informed Consent for Clinical Research

### Study Title: Evaluation of Regenerative Medicine Treatment Outcomes with Amniotic Fluid for Musculoskeletal Conditions

1. **Purpose:** Healthcare practices are often faced with patients whose source of pain may be the result of an inflammatory or degenerative response caused by trauma or disease. By treating the patient with a regenerative medicine, the clinician may see improved response to traditional pain management therapy and existing protocols. A cytokine and stem-cell rich amniotic-tissue derived product may prove to be an ideal non-steroidal and potentially regenerative therapy for use by the physician due to its unique characteristics.

We would like to enroll you as a participant in a research study with the purpose of evaluating an amniotic-derived stem cell rich tissue substance. Outcomes will be compared to the literature results of the current gold standard for joint and soft tissue injections, cortisone.

The injection substance is derived from the amniotic fluid of live consenting donors and there is nothing embryonic (fetal). The tissue is regulated by the FDA and it is processed according to the FDA's Current Good Tissue Practices (CGTP) in an ISO certified lab. The tissue substance has been used in this country over 10,000 times for joints and soft tissues. The risk profile to date has been excellent with minimal adverse effects reported. Having said this, any procedure has risks associated with it as outlined below.

The objective of this study is to evaluate the Amniotic Fluid tissue product for all types of musculoskeletal conditions by evaluating: 1) Pain Relief and 2) Functional outcomes

2. **Procedure:** You will receive an injection of the amniotic product along with numbing medicine with the specific technique according to the clinic provider.

Your injection protocol will be decided according to your condition and what the participating provider feels is in your best interest to alleviate pain.

Your research data will be completely confidential and blinded. We will be following you post-procedure for at least twelve months. Follow up time-frames are at 4 wks, 12 wks, 24 wks, and 36 wks and 52 wks.

3. **Risks and Discomforts:** Risks of these treatments include but are not limited to: infection, bleeding, allergic reactions, nerve injury, lidocaine complication (such as heart attack), blood clots, pneumonia, and failure to alleviate your pain. Your treating physician will address these issues should they occur and if serious enough, direct you to an emergency room.

4. **Nature, Purpose, Alternatives:** My physician has explained to me the nature, purpose, and consequences of each intervention as well as significant risks involved, possible complications, and



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possible alternative treatments. In addition, I have read this form, or it has been explained to me. I understand the risks and intend to enter this study and have the non-randomized procedure.

5. **Benefit:** There is no monetary benefit to you from participating in this study. As our knowledge of musculoskeletal pain treatment evolves, we may be able to improve treatments and increase pain reduction for people with the same type of pain problem.

6. **Alternatives:** You may decide not to participate in this study at any time. If so, there will be no prejudice to the care you will receive and you will be given the care you need, regardless of your decision to participate. If you have any questions about this study or your rights as a research subject, please contact R3 Stem Cell at (844) GET-STEM. You may also email Solutions IRB at [participants@solutionsirb.com](mailto:participants@solutionsirb.com) or call (855) 226-4472.

Subject's Statement: I understand the purpose of the study, and the potential risks and benefits of taking part in the study. I have had a chance to ask questions and all have been answered. I give my free and informed consent to be a participant in this study by signing but have not given up any of my legal rights.

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PATIENT

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DATE AND TIME

The patient and I have discussed the research project, procedure, the risks, complications, and alternatives. To the best of my knowledge, the patient understands the research and procedure and consents to it.

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PHYSICIAN'S SIGNATURE

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DATE AND TIME



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