

## **CONSENT FOR AMNIOTIC FLUID THERAPY**

I hereby acknowledge and understand that, by signing this voluntary care patient consent form, I am acknowledging that I am a patient of Lifecare Chiropractic and I am giving informed consent to their care and diagnosis, and to the performance and treatment of stem cell therapy procedures/treatments as administered and/or supervised by Dean Dabbah, MD.

I also understand that the procedures/treatments are thought to be a medically acceptable alternative procedure/treatment that include the use of amniotic fluid therapy which is considered a Human Allograft and is registered and regulated by the United States Food & Drug Administration (FDA) FEI # 3010398923.

Stem cell therapy is harvested from healthy, screened volunteered donors at the time of scheduled cesarean section, in the United States, and processed with the highest level of scrutiny and oversight by using ISO 13485 designed Standard Operating Procedures & Guidelines based on FDA 21 CFR Part 1271 and Section 361 of the Public Health Service Act and promulgated by the American Association of Tissue Banks (AATB). This product is minimally manipulated and classified as a FDA 361 HCT/P tissue.

Both the FDA and AATB are dedicated to ensuring a uniform high-quality control standard with a primary focus on ensuring that human tissues intended for “transplant” by way of implantation or transplantation are safe and free from infectious or communicable diseases. The Joint Commission standard QC.5.310.7 is followed for tracking of this specimen. Communicable disease testing has been performed by a laboratory registered with the FDA to perform donor testing and certified to perform such testing on this human specimen in accordance with Clinical Laboratory Improvement Amendments (CLIA) and 42 CFR Part 493.

Although the risks of using stem cell therapy is exceptionally low (especially considering that there have been no adverse side effects reported since amniotic fluid therapy was first used in 1910), as with any medical treatment, there is always a risk; therefore, it must be understood that transmission of diseases, side effects or possible complications cannot be 100% ruled out. Potential risks include infection, inflammation, pain, and inadequate screening of donors. If I have had surgery on the site of my symptoms, there is a smaller chance that I can be helped. This product cannot reverse post-operative scarring, realign crooked joint deformities, or guarantee the change of speed, smoothness, or range of joint movement. Stem cell therapy has not been shown to worsen any medical condition.

The amniotic fluid is a rich source of collagen, as well as other proteins, cytokines, carbohydrates, hyaluronic acid, exosomes, and growth factors needed for repairing tissues and cells. It contains anti-inflammatory and antimicrobial components and has not been known to be rejected by any recipients. In recognizing that research on RELeV amniotic fluid therapy is ongoing and has not produced standard treatment protocols nor guaranteed results or outcomes in any disease or health care issue, I acknowledge that it has been explained to me that there is no guarantee or assurance that I will realize desired health care results, outcomes, "cures" or recovery from these procedures/treatments. The use of these types of products is still considered experimental. The producer of RELeV amniotic fluid therapy does not want to falsely feed my hopes but also does not want to withhold my access to a safe, ethically processed, quality product that has years of experience exceeding US regulatory standards.

Furthermore, I acknowledge and consent to RELeV amniotic fluid therapy treatment as deemed medically safe to treat me as the undersigned consenting Patient. I have decided to consider this elective therapy as potentially medically beneficial to assist my condition.

In the unlikely event that staff or associates are exposed to any of the undersigning patient's blood or bodily fluids during procedure/treatment of consenting patient, for the safety of all parties, I consent in advance and upon request to testing for HIV, Hepatitis B virus, or Hepatitis C virus.

For HIPPA and other educational and patient service purposes, I consent to releasing my treatment and outcome status and testimony, for publication, for medical, scientific, product development or educational purposes, including but not limited to New Life Medical Services and its administrative and/or executive supportive staff. Furthermore, I consent, if requested by my physician, to medical or health care observers and trainers being present during my procedure.

I, \_\_\_\_\_, hereby give my consent for stem cell therapy to be performed by Dean Dabbah, MD and acknowledge and confirm that I am mentally capable of giving informed consent to the provision of the diagnosis, care and/or treatment described herein and I am not subject to duress or undue influence. I fully comprehend the above disclaimers and details as they relate to, and reference, the elective stem cell therapy that I am receiving today. Furthermore, Dean Dabbah, MD has discussed, in detail, the above referenced procedure/treatment and has explained possible adverse side effects, complications, risks and outcomes while also answering any questions I have had regarding the same. I disclaim any right to all tort claims or any other legal action, including but not limited to any medical or other health related claim, against Lifecare Chiropractic and Dean Dabbah, MD unless the action or omission by Lifecare Chiropractic and Dean Dabbah, MD constitutes willful or wanton misconduct.

Furthermore, I have been provided a copy of post procedure instructions. In understanding and agreeing with the aforementioned, I have no further questions or require further explanation and agree to the application of the procedure to be performed by Dean Dabbah, MD.

Signature / or Guardian \_\_\_\_\_ Date: \_\_\_\_\_

Witness: \_\_\_\_\_ Date: \_\_\_\_\_