Informed Consent for Stem Cell Therapy

The undersigned patient/guardian does hereby acknowledge and confirm that they have received a consultation regarding Stem Cell and that consultation shall not serve in any capacity as a replacement for their primary care physician/provider. The consultation is to discuss, without guarantee, the possibility that the infusion/injection therapy could provide some therapeutic benefit to the patient. It is further understood that the program designed for you, including any procedures or modalities (intravenous therapies, hyperbaric oxygen therapy, etc.) are not to be construed as treatments or remedies to diagnose, treat, cure, or prevent any disease or injury.

Advanced Medical Physicians is not offering Stem Cell Therapy as a cure for any condition, disease or injury. No statements or implied treatments on this document have been evaluated or approved by the FDA.

The FDA recently re-confirmed, there is only one registered stem cell product, and while there is enormous promise in stem cell therapies, and thousands of ongoing experimental applications trying to establish efficacy, these are not at the point where they would meet the scientific standard.

The FDA has stated:
Stem cells, like other medical products that are intended to treat, cure or prevent disease, generally require FDA approval before they can be marketed. 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.

http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194655.htm

"There is a potential safety risk when you put cells in an area where they are not performing the same biological function as they were when in their original location in the body." Cells in a different environment may multiply, form tumors, or may leave the site you put them in and migrate somewhere else.

http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm286155.htm

Stem cell therapies have enormous promise, but the science in each use is still in the developmental stage. Professional judgment and expertise is needed in using stem cells for any therapeutic use, and we urge anyone embarking on the use of stem cell therapies to consult the national health data bases to evaluate current information from clinical trials and the FDA websites on human tissue should also be consulted to get its current evaluation of any therapy.

It is the consultant's obligation to provide you with the information you need in order to decide whether to consent to the special procedure(s) being recommended to you.

Your signature on this document shall serve as verification that you have received that information and have given your consent to the procedure. You should therefore read this and any attached information carefully and ensure that all your concerns have been addressed by the consultant sufficiently before you give consent.

You understand if a chiropractor consulted with you regarding your neuromusculoskeletal condition, you are being referred to licensed medical professionals for stem cell therapy and the protocols will be up to their professional medical opinion.

Referral for the following procedure has been recommended:

Upon your authorization and consent, this Joint Injection and/or Intravenous Stem Cell Therapy will be performed on you by a Licensed Physician Assistant. All invasive procedures carry the risk of unsuccessful results, complication, injury, or even death from both known and unforeseen causes, and no warranty or guarantee is made as to results or cure. You have the right to be informed of the nature of the procedure and it's actual or potential risks, benefits, and side effects, as well as any reasonable alternative(s) and the side effects of such alternative(s). You also have the right to give or refuse consent to any proposed procedure or therapy at any time prior to its performance.

Stem cells arrive frozen, and once received they must be injected that day. By signing below you are acknowledging that there is no refund if you do not keep your appointment.

Therefore, as stated above, your signature on this form indicates that:

1. You have read and understand the information provided in this form and any attachment to this form.
2. The procedure has been adequately explained as set forth above, along with risks, benefits, and other information described on this form.
3. You have had the chance to ask any and all questions regarding this procedure.
4. You have received all of the information you desire concerning the procedure.
5. You authorize and consent to the performance of the procedure with complete understanding of it and its risks and benefits.

Date:_____Time:_____AM/PM

Signature_____

Patient/Parent/Conservator/Guardian

Printed Name & Relationship:

_____