**ACKNOWLEDGMENT OF CONSENT TO PARTICIPATE IN**

**THE CELL SURGICAL NETWORK RESEARCH PROGRAM**

**Cell Surgical Network has been granted approval by the Institutional Review Board of the International Cellular Medicine Society for a Clinical Intervention Study. This document is a portion of the consent patients sign prior to acceptance into the research study of autologous stem cells and growth factors.**

**STUDY TITLE AND NUMBER:**

**AUTOLOGOUS ADIPOSE DERIVED STROMAL VASCULAR FRACTION DEPLOYMENT #CSN111**

**PURPOSE OF THIS RESEARCH STUDY**

Many subjects may benefit from autologous cell therapy for various medical problems. Recent medical studies have shown that some subjects can be helped by cell therapy. Stromal vascular fraction contains adult mesenchymal stem cells. Our practice offers the stromal vascular fraction deployment research program to candidates who meet the other medical screening criteria we have established and who have agreed to comply with all requirements of the research program. This research program is designed to study the safety, tolerability, and effects of autologous adipose derived stromal vascular fraction deployed into subjects during a single outpatient visit and allow subjects to be followed for several years to evaluate for short term or long term adverse effects.

You are being asked to be included in this study since you have been diagnosed with a degenerative or inflammatory condition. It is appropriate for subjects to ask any questions they may have. To determine whether you are an appropriate candidate for stromal vascular fraction deployment research, we will ask you to disclose all of your medical history and conditions, possibly obtain blood and other testing, and comply with the treatment and monitoring programs. You are not a candidate for stromal vascular fraction deployment research if you have actively growing cancer.

**POSSIBLE BENEFITS**

The potential benefits of stromal vascular fraction deployment for eligible patients may include improvement in certain chronic degenerative diseases. Although some benefits often occur, some patients will experience all of them, some will experience some of them and some patients will not experience any of them. Also, the degree of benefit varies. *We do not know the long term effects of stromal vascular fraction deployments. We do not know if a stromal vascular fraction administration will be effective 5-1O years after it is administered, and we know of no large study that* has *conclusively reviewed patients for cancer, or any long term side effect 5-10 years after* a *stromal vascular fraction deployment.*

**POSSIBLE RISKS OR DISCOMFORT**

The potential risks of stromal vascular fraction deployment include, but are not limited to complications of liposuction (bleeding, bruising, discomfort, infection, scar, unwelcome cosmetic effects, reaction to local anesthesia, damage to internal organs), local reactions to intravenous infusion of stromal vascular fraction (you may experience pain, bruising, vein thrombosis, swelling, hematoma, or bleeding at the puncture site), side effects of intra-arterial injection of stromal vascular fraction, (such as embolization, "clots", damage to arteries and organs, immediate or delayed uncontrolled bleeding from the puncture site are conceivable possibilities), side effects of intra-venous injections of stromal vascular fraction (such as joint pain, swelling, bleeding, infection), and side effects of stromal vascular fraction injection into soft tissue (such as swelling, pain, bleeding, or damage to nerves or internal organs). There are also unknown long term effects of autologous stromal vascular fraction therapy.

If you have an active tumor or cancerous tumor that is present but you are not aware of its existence, we do not know how it would be affected - it could conceivably be made more aggressive.

**AVAILABLE TREATMENT ALTERNATIVES**

Many diseases being treated by stromal vascular fraction deployment may be relieved by other means and your study doctor can discuss these with you. Some symptoms may resolve naturally without medical intervention. Even if you are a candidate for stromal vascular fraction deployment research, you may experience no improvement and therefore would not be harmed by **not** receiving the deployment.

**WOMEN**

Stromal vascular fraction deployment represents potential unknown risks to women who are pregnant or who may become pregnant after deployment. There are also unknown risks to an embryo or fetus. Anesthesia that accompanies this procedure may be harmful to an unborn baby.

I **know the practice of medicine and surgery is not an exact science and, therefore, reputable practitioners cannot properly guarantee outcomes. I acknowledge that no guarantee or assurance (expressed or implied) has been made by anyone regarding the Stromal Vascular Fraction** **deployment procedure that** I **have herein requested and authorized.**