**Consent to Participate in Autologous Adipose Derived Stromal Vascular Fraction with Platelet Rich Plasma (SVF-PRP) Deployment Protocol or Registry**

I, , do hereby request and authorize Dr. Ryan Welter, his associate doctors and/or assistants as may be selected by him to perform the following procedure:

# Purpose of This Protocol

I understand the purpose of this protocol is to treat (insert condition below):

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. Autologous adipose derived stromal vascular fraction with platelet rich plasma (SVF-PRP) contains adult mesenchymal stem cells. Our practice offers the autologous adipose derived SVF-PRP deployment protocol to candidates who meet the other medical screening criteria we have established and who have agreed to comply with all requirements of the protocol. This protocol is designed to study the safety, tolerability, and effects of autologous adipose derived SVF-PRP deployed into subjects. The protocol consists of a single out-patient visit and allows subjects to be followed for several years to evaluate for short term and long term adverse effects.

You are being asked to be included in this protocol since you have been diagnosed with a applicable condition. It is appropriate for subjects to ask any questions about this informed consent form and you may even take this form home for consideration before signing. To determine whether you are an appropriate candidate for autologous adipose derived SVF-PRP deployment, 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 protocols. If you do not completely disclose your medical history and conditions, obtain testing that we recommend and comply strictly with the protocol, you could be exposed to serious medical risks, including cancer, disability and death. You are not a candidate for autologous adipose derived SVF-PRP deployment if you have an actively growing cancer or are being treated for cancer.

Initials

# POSSIBLE BENEFITS

The potential benefits of autologous adipose derived SVF-PRP deployment for eligible patients may include improvement in certain medical conditions. Results and degree of benefit vary by patient. We do not know the long- term effects of autologous adipose derived SVF-PRP. We do not know if autologous adipose derived SVF-PRP will be effective 5-10 years after it is administered. We are not aware of any large study that has conclusively reviewed patients for cancer, or any long term side effects 5-10 years after a autologous adipose derived SVF-PRP deployment.

# POSSIBLE RISKS OR DISCOMFORT

The potential risks of autologous adipose derived SVF-PRP include, but are not limited to complications of liposuction (bleeding, discomfort, infection, scar, subcutaneous fibrosis, unwelcome cosmetic effects, reaction to local anesthesia, internal organ injuries), local reactions to intravenous infusion of autologous adipose derived SVF-PRP (pain, bruising, vein thrombosis, swelling, hematoma, or bleeding at the puncture site), side effects from intra-arterial injection of autologous adipose derived SVF-PRP, (such as embolization “clots”, damage to arteries and organs, immediate or delayed uncontrolled bleeding from the puncture site are conceivable possibilities), and side effects of autologous adipose derived SVF-PRP 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 adipose derived SVF-PRP therapy.

As with any other medications or surgical measures, other possible risks could include life-threatening reactions that might require resuscitative medications or measures (chest compressions, electric shock, CPR in general, and/or 911 call).

We do not currently know how autologous adipose derived SVF-PRP deployment would affect any undetected active tumor or cancerous tumor that is present at the time of deployment. It is possible that autologous adipose derived SVF-PRP deployment could increase the aggressiveness of an active or cancerous tumor.

# AVAILABLE TREATMENT ALTERNATIVES

Many diseases being treated by autologous adipose derived SVF-PRP deployment may be relieved by other treatments and your study doctor can discuss these with you. Some symptoms may resolve naturally without medical intervention.

Initials

# FINANCIAL CONSIDERATIONS

I have been informed that my participation in this protocols and/or the registry for autologous adipose derived SVF- PRP deployment is patient funded and therefore, I am responsible for the cost of the procedure. In addition, I am responsible for extra costs due to any complications related to the procedure that are not covered by medical insurance.

By participating in this study, I will not be entitled to any remuneration from any patents or latter company profits.

# CONSENT OF AUTHORIZATION

I authorize Dr. Ryan Welter, his associate doctors, assistants, nurses, radiologists, anesthesiologists, and/or technologists of Regeneris Medical to employ the procedure on me. I also authorize the operating surgeon to perform any other procedures, which he may deem necessary or desirable in attempting to improve the conditions encountered during the procedure.

Initials

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encountered during the procedure. Initials

My participation in this protocol is voluntary and may be withdrawn at any time without penalty. My participation may also be withdrawn at any time by Regeneris Medical for any reason without my consent.

Initials

I am willing to provide a written and / or video testimonial about my experience at Regeneris Medical as it pertains to my autologous adipose derived SVF-PRP treatment.

Yes ( ) No ( ) Initials

I understand that taking photographs/video recording is part of the nature of this study. I therefore authorize Dr. Ryan Welter, his associate doctors and/or assistants, photographers and technicians to take photographs necessary before, during and after the procedure to be used in my medical records.

Yes ( ) No ( ) Initials

Regeneris Medical would like to share de-identified photographs / video recordings to be presented and/or published discreetly in professional journals or medical textbooks; or any form of publication by Regeneris Medical without any further consent, authorization or release by me. Do you consent to Regeneris Medical sharing and/or presenting de-identified photos?

Yes ( ) No ( ) Initials

Regeneris Medical would like to add safety and efficacy data collected from your visits to an online registry database for autologous adipose derived SVF-PRP protocols. Participating in this registry will not change your treatment nor will not participating in this registry change your treatment. Your participation is completely voluntary. Data entered into this registry will be de-identified and used to monitor safety and efficacy for autologous adipose derived SVF-PRP protocols. Do you consent to participate in this de-identified registry?

Yes ( ) No ( ) Initials

For women: stromal vascular fraction with PRP 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. Thus, a mandatory pregnancy test is required for all women of childbearing age unless she has had a hysterectomy or are post-menopausal for a year or longer.

I have been advised by Dr. Ryan Welter to undergo a pregnancy test prior to this procedure. Initials

I am advised that in case of emergency my medical team will provide resuscitative procedures. Initials

# I know the practice of medicine and surgery is not an exact science and therefore, physicians cannot guarantee outcomes. I acknowledge that no guarantee or assurance (expressed or implied) has been made by anyone

**regarding Stromal Vascular Fraction with Platelet Rich Plasma Deployment. The effects and nature of adipose derived SVF-PRP deployment, the risks involved, the possible complications, and the possible consequences as well as alternatives have been fully explained to me. I have been given an opportunity to ask any questions concerning the type of procedure and fully understand the responses. I have been given information and instruction sheets pertaining to the proposed procedure. It is my responsibility to read these and abide by the recommendations.**

Initials

By signing this consent, I acknowledge that I,

1. Have read this form (or it was read to me) carefully.
2. Have asked any question that I wished
3. Have received satisfactory answers to all my questions and requests for additional information
4. Will disclose my medical history and conditions truthfully and completely to the practice.
5. Will inform the practice promptly of any change in my health, any signs and symptoms or any complication of this treatment.
6. Have voluntary agreed to participate in the protocol.

I will receive a copy of this signed and dated consent.

Signature of Patient Date

Printed Name of Patient Date

Signature of Person Explaining Consent Date

Printed Name of Person Explaining Consent Date

For any questions about the protocol or this form: Please contact:

Ryan Welter, M.D., Ph.D Regeneris Medical

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[www.regenerismedical.com](http://www.regenerismedical.com/) Initials