Sculptra Information and Consent Form

Name of Patient: _____ Date: _____

Georgia law requires that your physician obtain your informed consent to medical and surgical treatment. In keeping with the Georgia state law, you are being asked to sign a confirmation that we have discussed the nature of your condition, your contemplated operation or medical procedure, the general nature of the proposed treatment/surgery, the request of the proposed treatment/surgery, the prospects for success, the reasonable therapeutic alternatives to the treatment/surgery, and the risks of such alternatives. Your physician has discussed with you the common problems or risks. We wish to inform you as completely as possible. You are also being asked to sign a confirmation that you have been given the opportunity to ask whatever questions you had and that your questions have been answered in a satisfactory manner. Please read the form carefully. Ask about everything you do not understand and we will be pleased to explain it.

Diagnosis – A natural, youthful face is full and not tight. Age related changes of the lips and mouth include atrophy of the lips and atrophy of the corners of the mouth resulting in downturn. Another early sign of aging is the development of nasolabial lines. Although the upper face can easily be rejuvenated with Botox, the lower face is less amenable to this treatment. In order to treat the entire aging face, a combination of Botox and injectable fillers is often needed for optimal results.

Sculptra – Sculptra is a safe, synthetic, and biocompatible material that is injected below the surface of the skin. It's made up of microspheres (a spherical shell that is usually made of a biodegradable or resorbable plastic polymer, that has a very small diameter usually in the micrometer or nanometer range, and that is often filled with a substance, as a drug or antibody, for release as the shell is degraded) of poly-L-lactic acid forty to sixty microns in size. Because poly-L-lactic acid is the main ingredient in Sculptra, patients don't require a test for allergic reactions.

Sculptra is approved to treat lipoatrophy, the progressive facial decomposing seen on most HIV patients, but it is used "off-label" for cosmetic purposes.

The results of Scultpra are not immediate. At your first treatment visit, it may appear that Sculptra worked immediately because of swelling from the injections and the water used to dilute Scultpra. a few days following the treatment, when the swelling goes down and the water is absorbed by your body, you may look as you did before your treatment. Sculptra takes time to gradually correct the depression in your skin. Your doctor will decide the appropriate number of treatment sessions and the amount of Sculptra you will need at each session. Multiple sessions are often required and patients with severe facial fat loss may require 3 to 6 treatments.

Side Effects – Side effects of Sculptra may include: delayed appearance of small bumps under the skin in the treated area, bleeding, tenderness or discomfort, redness, bruising, or swelling may occur at the site of injection.

You may also experience any of the following: Poor cosmetic result, extrusion, infection, unequal lips, folds, or other areas, possible further surgery, swelling, granuloma formation (lumps), allergic reaction, firm hard areas on lips, folds, or lines, inadequate augmentation. The augmentation cannot be called permanent. Re-absorption of implant will probably occur.

The practice of medicine and surgery is not an exact science, and, therefore, reputable practitioners cannot guarantee results. The results of the injections may not last for as long or as well as expected. There are no promises or guarantees regarding the degree of improvement when using Sculptra.

2. <u>This augmentation material is not yet FDA approved for lip augmentation or correction of depressions and lines in non-HIV patients. The effects on the body are unknown at this time. Long-term effects are unknown.</u>

Postoperative Care –

- Ice packs may be used during the first 24 hours- 10 minutes on, 10 minutes off.
- Massage the injected site vigorously twice daily for the first week.
- Elevate the head with two pillows while sleeping during the first few days to minimize swelling.
- Aspirin, NSAIDs, and alcohol should be avoided for the first few days after treatment.
- Tylenol may be used for pain control.
- Exaggerated movements of the areas augmented should be avoided for the first several days.
- Avoid hot foods or gum chewing for the first several hours as mouth trauma may occur in the anesthetized areas.

Notify Dr. Kavali for significant swelling, bleeding, eye pain, vision loss, dusky discoloration, excessive pain, or fever.

Drugs, Pregnancy and Allergies – You should not be pregnant, nursing an infant, a history of a bleeding disorder, abnormal scarring or autoimmune disease. You should not be taking any of the following medications: immunosuppressants or blood thinners. Also, you should have told your physician if you have a history of oral herpes simplex (cold sores).

Alternatives – As explained, not all wrinkles will respond to soft sculptra. Other alternatives are dermabrasion; chemical peeling; laser resurfacing; face-lifting, browlifting, necklifting, and other surgical resection of the frown muscles of the frown muscles of the brow; treatments with Retin-A or Renova or alpha hydroxy acids may also produce some benefits.

Follow-Up Suggested by the Doctor – I agree to follow up with my doctor as scheduled by her office and as recommended by Dr. Kavali. I agree to inform Dr. Kavali of any problem that I am having and to allow her to see me at that time

Consent –

I voluntarily request treatment by Dr. Kavali, MD using Sculptra which has been explained to me, and my questions regarding such treatment, its alternative, its complications and risk have been answered by the doctor, her staff, and/ or written information. The information which I have been given has been in terms clear to me and I understand the risks and complications of the treatments. My questions have been fully and completely answered for me and I have read this document and understand its contents. I hereby give my unrestricted informed consent for the procedure.

Date: _____ Time: _____ AM / PM

I UNDERSTAND THAT USE OF THIS PRODUCT HAS NOT BEEN CLEARED BY THE FDA FOR THIS INDICATION.

Signature of Patient _____

Signature of Patient Representative _____

Witness _____ Witness _____

I have provided and explained the information set forth herein and answered all questions of the patient or the patient's representative concerning treatment/surgery.

Signature of Physician _____

Order by priority when consenting to medical/surgical procedure (except for care and treatment of any mentally retarded person who is a resident of certain state operated facilities).

1. Any competent adult, age 18 or older, for himself.

2. The judicially appointed curator of a patient, if one has been appointed.
3. An agent acting pursuant to a valid mandate (power of attorney), specifically authorizing the agent to make health care decisions.
4. The patient's spouse not judicially separated.
5. An adult child of the patient.
6. Any parent whether adult or minor for his/her minor child.
7. The patient's sibling.
8. The patient's other ascendants or descendants.
9. Any person temporarily standing in loco parentis, whether formally serving or not, for the minor under his care, and guardian for his ward.

If there is more than one person within the same class above, then the consent of the majority of those members of the class available for consultation is required.

DO NOT SIGN THIS FORM UNLESS YOU HAVE READ IT AND FEEL THAT YOU UNDERSTAND IT. ASK ANY QUESTIONS YOU MIGHT HAVE BEFORE SIGNING THIS FORM. DO NOT SIGN THIS FORM IF YOU HAVE TAKEN MEDICATIONS WHICH MAY IMPAIR YOUR MENTAL ABILITIES OR IF YOU FEEL RUSHED OR UNDER PRESSURE.

_____ _____

Signature of Patient or Other Person Authorized to Sign **Date**

_____ _____

Signature of Witness **Date**

I have informed the patient of the available alternatives to soft tissue augmentation, and of the potential risks and complications that may occur as a result of this treatment.

_____ _____

Physicans Name, MD **Date**