Informed Consent for Sculptra Therapy

Patient Name: _____ Date: _____

Sculptra therapy is the injection into the skin and underlying tissues of poly-L-lactic acid. Sculptra therapy is designed to help correct skin depressions, such as creases, wrinkles, folds, scars, hollow eye rings, degenerative skin aging, and facial lipoatrophy (loss of fat)

Sculptra is a poly-L-lactic acid implant in the form of a sterile apyrogenic suspension. Poly-L-lactic acid is a biocompatible (does not harm the body), biodegradable (broken down or metabolized by the body), synthetic polymer from the alpha-hydroxy-acid family (fruit acids). Poly-L-lactic acid has been used medically for many years in dissolvable stitches, and does not require pre-treatment skin testing for allergies.

Dr. Hensel has informed me that depending on the area and condition treated, the volume of Sculptra used and the injection technique, the effect of a treatment with Sculptra may last from 1 to 2 years, but that in some cases the duration of the effect can be shorter or longer. Most areas of treatment will require 2 to 6 sessions, usually at 6 to 8 week intervals, for optimal correction. Because individual responses to Sculptra therapy may vary, the exact number of treatment sessions required cannot be predicted with complete accuracy. Additionally, in order to maintain the desired degree of correction, intermittent "touch-up" treatments may be needed.

After each injection session, tissue volume in the treated area will gradually build up over the following weeks and months, as your body produces new collagen (neocollagenesis). At the time of your return visit for your next session of Sculptra therapy, your response to the previous treatment will be assessed and additional treatments can be performed if needed and agreed upon to optimize your correction. Sculptra therapy does not treat or cure the underlying cause or disease of tissue or fat loss; rather it is designed to improve the appearance of the affected area(s).

I have been educated on some of the features, benefits, and possible risks involved with using Sculptra and have had my questions answered to my satisfaction. Some of these possible risks include:

- After the injection(s) some common injection-related reactions probably will occur, these may include swelling, redness, pain, itching, discoloration and tenderness at the injection site. These typically resolve spontaneously, usually within 1 to 15 days after injection.
- Because Sculptra therapy injections are administered in a solution containing water, there will be an initial swelling (edema) that will be noticeable for at least several hours and perhaps as long as several days. This effect is temporary, and does not affect the long-term tissue response.
- Small bumps under the skin, termed micro-nodules, which may be non-visible or visible, may be felt in the areas of treatment. Usually, these bumps may only be felt when pressing on the skin. Micro-nodules typically last from 6 to 12 months, and may spontaneously disappear. They usually do not require treatment, and usually do not have any symptoms.
- Induration, or a feeling of fullness or thickness, can be felt in the injection area. This is a normal response of the treated tissue to the process of inflammation and neocollagenisis. Simply massaging the treated areas gently 3 to 5 times per day for 3 to 5 minutes, for 3 to 5 days after the injection can help minimize induration.
- Visible bumps may occur in rare instances, and they may be associated with redness, tenderness, skin discoloration or textural alteration. These bumps, which may be termed granulomas, may or may not require treatment, including but not limited to, injections, freezing, or excision.
- Other rarely reported adverse events include: injection site abscess, allergic reaction, skin hypertrophy and/or atrophy, malaise, fatigue, and edema.
- Sculptra therapy is contraindicated (not allowed) in pregnancy or during breast feeding. If you believe you may be pregnant or are breastfeeding, please inform the provider prior to injection.
- Sculptra therapy has been approved by the United States Food and Drug Administration (FDA), for the restoration and/or correction of facial fat loss (lipoatrophy) in people with HIV and for aesthetic (cosmetic) use. Sculptra therapy (New-Fill) has been performed since 1999 in more than 150,000 patients in more than 30 countries, principally for cosmetic use.

Initial _____

- The use of anti-inflammatory drugs, anti-clotting agents or aspirin might cause bleeding or increased bruising at the injection site. If you've previously had facial herpes simplex at the injection site, the injection might provoke an outbreak. If any of these conditions apply to you, please inform your provider.
- Any injection, for any reason, carries a small risk of infection. If the needle accidentally punctures a blood vessel, this may result in temporary discoloration of the treated area, scabbing, shedding and shallow scarring.
- Allergic reactions are rare. An allergic reaction can manifest itself by prolonged redness, itching, swelling or a hardening of the skin around the injection site. The reactions can last for as long as 3 to 4 months and in rare cases, more than a year. Please make sure you inform us of all known allergies and sensitivities.

Initial _____

The use of and indication for Sculptra has been explained to me, and I have had the opportunity to have my questions answered to my satisfaction. **Dr. Hensel** has provided me with this informed consent and I have been given the time and opportunity to review it with any other individuals of my choice.

I have been told that I can reasonably expect the foregoing benefits of Sculptra, but that no results can be guaranteed or assured, and no such guarantees or assurances have been given to me. Additionally, I understand that the practice of medicine is not an exact science, and positive outcomes cannot be guaranteed, nor can promises or guarantees be made regarding potential negative outcomes. I have had appropriate alternative treatments to Sculptra therapy explained to me including other fillers, surgical procedures and topical treatments.

I have been informed that Sculptra needs to be reconstituted (prepared) prior to my appointment, and if I cancel with less than 24 hours notice prior to my appointment, I will be charged the full price of the vial. I agree to this financial policy.

By signing this Informed Consent, I agree to being treated with the Sculptra as described above. I acknowledge that I understand the procedures and the risks and that it has been explained to me to my satisfaction, and I agree to hold **Dr. Hensel** harmless from the described risks on the condition that the injections of Sculptra are administered in accordance with appropriate guidelines.

_____ _____

Physician/Provider Signature & Date Patient/Guardian Signature & Date

PHOTOGRAPHIC RELEASE CONSENT

I give permission to **Dr. Hensel** to take photographs of my treatment areas for diagnostic purposes and to document for the medical record my response to Sculptra therapy. I agree that these photographs are the property of **Dr. Hensel** and I give my permission to use these photographs for teaching purposes, for use in scientific publications, books, journals, lectures, seminars and electronic media. It is understood that in any such publication I shall not be identified by name, and that appropriate measures shall be made to protect my identity. I understand that I will not receive any compensation for the use of my photographs for scientific and teaching/educational purposes.

_____ _____

Physician/Provider Signature & Date Patient/Guardian Signature & Date