

Informed Consent for Sculptra Therapy

Patient Name: _____

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 nucleogenesis. 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.
- A full session may require 2-4 treatments spaced 1-2 months apart. Maintenance treatments may be required yearly. Study results show long lasting effects of 2+ years

I voluntarily request treatment by 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 clinician, 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.

Signature

Date:
