INFORMED CONSENT FOR TREATMENT WITH INJECTABLE FILLERS BETWEEN THE PATIENT AND [COMPANY NAME]

My signature and initials after each statement below constitutes my acknowledgment that:

The injection will utilize a stabilized hyaluronic acid product to smooth moderate to severe facial wrinkles and folds around the nose and mouth or shape facial contours. Facial filler injections are customized for every patient, depending on his or her particular needs. These can be performed in areas involving the face and eyelid region, forehead, and lips. Fillers cannot stop the process of aging. They may, however, temporarily diminish the look of wrinkles and soft tissue depressions. Filler injections may be performed as a singular procedure, in combination with other treatments such as BOTOX®. Filler injections may require regional nerve blocks or local anesthetic injections or topicals to diminish discomfort. Soft tissue fillers produce temporary swelling, redness, and needle marks, which resolve after a few days.

Continuing treatments are necessary in order to maintain the effect of fillers over time. Most patients need one or possibly two treatments to achieve optimal wrinkle smoothing. Fillers, once injected, will be slowly absorbed by the body. The length of effect for filler injections is variable, but can last as long as 9 months to 1 year. Subsequent alterations in face and eyelid appearance may occur as the result of aging, weight loss or gain, sun exposure, or other circumstances not related to filler injections. Future surgery or other treatments may be necessary. Filler injection does not arrest the aging process or produce permanent tightening of the skin or improvement in wrinkles.

- I, ______, consent to and authorize ______, to perform with injectable fillers with the goal of improving the appearance of scars and/or wrinkles, or to have my lips augmented (made larger). The fillers to be used include Hylaform, Restylane, Collagen, and/or Juvederm Volbella, Voluma, Vollure, Lyft, Silk, Refyne, Defyne Kysse, Contour, Radiesse Plus, Belotero Balance Plus, Versa Lips. ______
 - The area to be treated _______
 - The filler to be used______
- 2. The nature and purpose, possible benefits and risks of the treatment have been explained to me, and questions I have regarding the treatment have been answered, to my satisfaction and I accept them and consent to receive the treatment. I agree that I have been given an opportunity to ask questions before I sign and my questions have been answered to my satisfaction, and I have been told that I can ask other questions at any time
- 3. Alternative forms of management include not treating the skin wrinkles or soft tissue depressions by any means. Improvement of skin wrinkles and soft tissue depressions may be accomplished by other treatments including, without limitation: laser treatments, chemical skin-peels, or other skin procedures, alternative types of tissue fillers, or surgery such as a blepharoplasty, face or brow lift when indicated. Risks and potential complications are associated with alternative forms of medical or surgical treatment. Other options not mentioned here may exist.
- 4. I am fully aware of the risks of complications or injuries that can occur from this treatment, both from known and unknown causes and I freely assume those risks. I understand that the treatment is not an exact science, and I acknowledge that no guarantees have been made to me concerning the results or outcome of the treatment.

I understand that, the known complications could include, without limitation:

- Bleeding and bruising: It is possible, though unusual, to have a bleeding episode from an injection. Should you develop post-injection bleeding, emergency treatment or surgery may be necessary. Bruising in soft tissue may also occur. Aspirin, anti-inflammatory medications, platelet inhibitors, anticoagulants, Vitamin E, ginkgo biloba, and other herbs and homeopathic remedies may increase the risk of bleeding and bruising. Do not take any of these products for seven days before or after injections of dermal fillers unless you have been advised to do so by your cardiologist or primary care physician.
- **Swelling:** Swelling (edema) is a normal occurrence following the injection of dermal fillers. It usually decreases after a few days, but if it is slow to resolve, medical treatment may be necessary.
- **Erythema** (skin redness): Erythema occurs in the skin after injections. It can be present for a few days after the procedure.
- Needle marks: Visible needle marks from injections occur normally and resolve in a few days.
- Acneiform skin eruptions: Acne-like skin eruptions can occur following the injection of dermal fillers. These generally resolve within a few days.
- Skin lumpiness: Lumpiness can occur following the injection of dermal fillers. This tends to smooth out over time. In some situations, however, it may be possible to feel the injected tissue filler material for long periods of time.
- Visible tissue filler: It may be possible to see dermal fillers through the skin if it is injected into an area where the skin is thin.
- Asymmetry: The human face is normally asymmetrical in its appearance and structure. It may not be possible to achieve or maintain exact symmetry with tissue filler injections. There can be variations from one side to the other, even after injections of dermal fillers, that may require additional injections.
- Under/Over Correction: The injection of soft tissue fillers to correct wrinkles and soft tissue contour deficiencies may not achieve the desired outcome. The amount of correction may be inadequate or excessive. It may not be possible to control the process of injection of tissue fillers due to factors attributable to each patient's situation. If under correction occurs, you may be advised to consider additional injections of tissue filler materials.
- **Pain:** Discomfort associated with injections of dermal fillers is normal and usually of short duration.
- Skin sensitivity: Skin rash, itching, tenderness and swelling may occur following injections of filler products. <u>After treatment, you should avoid exposing the treated area to excessive sun,</u> <u>ultraviolet lamps, and extremely hot or cold temperatures until any initial swelling or redness</u> <u>has gone away</u>. You should also avoid strenuous exercise, and avoid alcoholic beverages for the first 24 hours after treatment. If you undergo laser treatment, chemical peels or any other skin procedure after treatment with dermal fillers, there is a risk of an inflammatory reaction at the implant site.
- Accidental intra-arterial injection: Dermal fillers can accidentally be injected into arteries and block blood flow. This could cause necrosis in facial skin and other structures, loss of vision or other consequences. This is a very serious, but rare, occurrence. The risk and consequences of accidental intravascular injection of filler is unknown and not predictable. I understand that dermal fillers made from hyaluronic acid may be dissolved by hyaluronidase if my condition warrants.
- **Damage to deeper structures:** Deeper structures, such as nerves and blood vessels, may be damaged during injections of dermal fillers. Injury to deeper structures may be temporary or permanent.
- **Infection:** Bacterial, fungal and viral infections can occur following injection with dermal fillers. The reactivation of the herpes simplex virus, commonly referred to as a cold sore, is one such infection. This can occur both in individuals who have had prior cold sores and in those who have

not. Please ask your provider for a Valtrex prescription if you plan to have an injection in an area where you have had a prior cold sore. Should any other type of skin infection occur, additional treatment, including antibiotics, may be necessary.

- Allergic reactions and hypersensitivity: As is the case with the use of all biologic products, allergic and anaphylactic reactions may occur as a result of an injection with dermal fillers. You should not have injections with dermal fillers if you have a history of multiple severe allergies, a history of anaphylaxis or allergies to gram-positive bacterial proteins. Allergic reactions may require additional treatment.
- **Scarring:** It is possible that injections with dermal fillers could promote excessive scar formation, so you should not receive these injections if you have a history of keloid formation or other forms of excessive healing at scar sites.
- **Granulomas:** Granulomas are masses that the body forms that are akin to scar tissue. Rarely, these may occur in the skin and deeper tissues after an injection with dermal fillers. Should a granuloma develop, additional treatments, including surgery, may be necessary.
- Skin Necrosis: It is very unusual to experience death of skin and deeper soft tissues after injections. Skin necrosis can produce unacceptable scarring. Should this complication occur, additional treatments, or surgery may be necessary.
- Skin disorders: In rare instances, granuloma, abscess, localized necrosis and urticaria have occurred after injections of dermal fillers into areas with active inflammation or infection (e.g. cysts, pimples, rashes or hives). Fillers should not be used in areas with active inflammation or infections (e.g., cysts, pimples, rashes or hives).
- Antibodies to dermal fillers: If antibodies to dermal fillers form in your body, they could reduce the effectiveness of this material or produce a reaction in subsequent injections. The health significance of antibodies to hyaluronic acid tissue fillers is unknown.
- Anesthetic reactions: It is possible to have a reaction to the anesthetic applied before injection or the lidocaine anesthetic mixed with dermal fillers. Such reactions include light-headedness, rapid heart rate (tachycardia) and fainting. Medical treatment of these conditions may be necessary.
- **Migration of Filler**: The filler substance may migrate from its original injection site and produce visible fullness in adjacent tissue or other unintended effects.
- Unsatisfactory Result: Filler injections alone may not produce an outcome that meets your expectations for improvement in wrinkles or soft tissue depressions. There is the possibility of a poor or inadequate response from filler injection(s). Additional injections may be necessary. Surgical procedures or other treatments may be recommended in additional to additional treatments.
- 5. I also certify that I have none of the known conditions that would contraindicate treatment. These conditions include a history of excessive scarring (e.g., hypertrophy scars and keloid formations) and

pigmentation disorders, a history of any autoimmune disease, Vascular disease, HIV disease, immune therapy or psychiatric disease, severe allergies marked by a history of anaphylaxis or history or presence of multiple severe allergies, a history of allergies to Gram-positive bacterial proteins, an allergy to lidocaine, as this is pre-mixed with Restylane® and Juvéderm® fillers, pregnancy, breastfeeding, and active skin infection or inflammation at the site of injection. I am not pregnant, breast-feeding, and I have no known allergy to Hyaluronic acid, anesthetic agents, latex gloves [should they be used] or bovine source collagen or any of the above contraindications.

6. The following are important treatment considerations for you to discuss with us and understand in order to help avoid unsatisfactory results and complications. Please inform us prior to treatment:

- □ If you are using substances that can prolong bleeding, such as aspirin or ibuprofen, or herbal supplements (e.g., Vitamin E, ginkgo biloba), as with any injection, you may experience increased bruising or bleeding at the injection site
- □ If you are on immunosuppressives or therapy used to decrease the body's immune response, as there may be an increased risk of infection
- □ If laser treatment, chemical peeling, or any other procedure based on active dermal response is considered after (or before) treatment with tissue fillers, as there is a possible risk of an inflammatory reaction at the treatment site

There are many medications that are not approved for specific use by the FDA. The following medications identified above have not been approved by the FDA: Juvederm Ultra 2, 3 or 4

- 7. Dermal fillers are approved for specific uses in people aged 22 and older. Those uses include:
 - Correcting moderate-to-severe facial wrinkles and skin folds.
 - Increasing fullness of lips, cheeks, chin, under-eye hollows, jawline, and back of the hand
 - Restoring facial fat loss in people with human immunodeficiency virus (HIV)
 - Correcting acne scars on the cheek
 - Infraorbital hollows
- 8. This could mean that they may not meet FDA approval requirements for safety, effectiveness, and quality. However, it could also mean that the manufacturer has not yet applied for FDA approval. By initialing and signing this consent, I acknowledge that I have been informed about the lack of FDA approval for anything other than the above purposes relating to the medications discussed in this paragraph and I understand and accept that the risks and wish to receive the medication(s).
- 9. I certify that I have read this entire informed consent and that I understand and agree to the information stated in this form. I certify that I am a competent adult of at least 18 years of age, or that if I am a minor under the age of 18, I understand that the consent of my parent/legal guardian will also be required before treatment. This informed consent is freely and voluntarily executed and shall be binding upon my spouse, relatives, legal representatives, heirs, administrators, successors, and assigns. I agree that any picture taken of my treatment site may be used for publication and teaching purposes, however, my name will not be disclosed and all reasonable attempts to maintain complete confidentiality of my name will be maintained. LC Aesthetic providers maintain the right not to treat minors even with adult consent
- 9. Furthermore, I completely and totally indemnify [COMPANY NAME] and its owner[s], agents, employees, shareholders and [independent] contractor's from any and all liability in relation to the performance of this procedure[s]. Any and all complications should be seen in the emergency room or by your local physician.. [COMPANY NAME] providers and its employees maintain the right, under all circumstances and without penalty, to not perform the procedure should such decision be made by them.
- 10. No guarantee, warranty or assurance has been made as to the treatment results. I acknowledge that I may be disappointed with the results of the procedure. The procedure may result in unacceptable visible deformities, loss of function and/or loss of sensation. I agree that this constitutes full disclosure, and that it supersedes any previous verbal or written disclosures.
- 11. I understand that the results are of temporary nature, and more treatments will be needed to maintain improvement. I agree to adhere to all safety precautions described here including:
 - Avoiding prolonged sun or UV exposure
 - Avoiding saunas for two weeks after injection

- Avoiding steam baths for two weeks after injection
- Make up should be avoided for at least 12 hours after injection

This agreement is non-transferable and may not be altered by anyone without the express written consent of [COMPANY NAME]. Further, this agreement does not expire. This agreement does not expire.

12. I agree to pay ______ for the above mentioned services. _____

My signature below evidences my voluntary agreement to receive this treatment from [COMPANY NAME] (the "Practice"), and that I am the patient or am authorized to act on behalf of the patient to sign this consent form. By signing below, I agree that I have read, understand, and agree to all of the statements contained in this consent form. I understand that my agreement is effective on the date signed below and that I may revoke my agreement in writing. My revocation will not be effective for actions already taken by the Practice or that are in progress and will only be prospectively effective.

Patient Name (please print)		
Signature	Dat	e