[INSERT PRACTICE LOGO]
(dental practice to insert)

[INSERT PRACTICE NAME & ADDRESS]
[INSERT PRACTICE PHONE]
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INFORMED CONSENT FOR GUM BUILDER^{tm} TREATMENT FOR GUM RECESSION AND TEETH HYPERSENSITIVITY

Patient's First Name _____ Patient's Last Name _____

Provider's First Name _____ Provider's Last Name _____

PROCEDURE INFORMATION

I hereby consent to undergo the Gum Builder^{tm} treatment, a therapeutic procedure performed by _____. The Gum Builder^{tm} procedure uses Radiesse® dermal filler which consists of tiny, smooth, calcium hydroxylapatite (CaHA) microspheres suspended in a sodium carboxymethylcellulose gel carrier. Upon injection, it initially acts as a filler. It is easily malleable, can be used to shape and contour the gingiva and face. Once injected, Radiesse® dermal filler starts the process known as neocollagenesis, stimulating the steady, ongoing growth of the body's collagen and elastin in the gingiva which may result in gum tissue regeneration and a decrease in teeth hypersensitivity especially caused by gum recession. It is FDA cleared for use in periodontal defects as well as the correction of moderate to severe facial wrinkles and folds.

TREATMENT DESCRIPTION

The injection will utilize Radiesse® intra-orally in the soft tissues to stabilize gum recession and reduce hypersensitivity. Fillers cannot stop the process of aging. Filler injections may be performed as a singular procedure, in combination with other treatments or as an adjunct to a surgical procedure. Filler injections may require regional nerve blocks or local anesthetic injections to diminish discomfort. Soft tissue fillers produce temporary swelling, redness, and needle marks, which resolve after a few days. Continuing treatments are necessary to maintain the effect of fillers over time. Once injected, fillers will be slowly absorbed by the body. The length of effect for injections is variable.

RISKS AND SIDE EFFECTS

Every procedure involves a certain amount of risk and you must understand these risks and the possible complications associated with them. In addition, every procedure has limitations. An individual's choice to undergo this procedure is based on the comparison of the risk to the potential benefit. Although the majority of patients do not experience the following, you should discuss each of them with your provider to make sure you understand the risks, potential complications, limitations, and consequences of facial filler injections. Problems associated with the use of tissue fillers can relate to normal occurrences following tissue filler injections, or potential complications following tissue filler injections.

- **BLEEDING AND BRUISING:** It is possible, though unusual, to have a bleeding episode from a filler injection or local anesthesia used during the procedure. Bruising in soft tissues may occur. Should you develop post-injection bleeding, it may require emergency treatment or surgery. Aspirin, anti-inflammatory medications, platelet inhibitors, anticoagulants, Vitamin E, ginkgo biloba, and other "herbs / homeopathic remedies" may contribute to a greater risk of a bleeding problem. Do not take any of these for seven days before or after filler injections.
- **SWELLING:** Swelling (edema) is a normal occurrence following the injections. If it happens, it decreases after a few days. If swelling is slow to resolve, medical treatment may be necessary and please contact our

office.

- **PAIN:** Discomfort associated with injections is normal and usually of short duration.
- **SKIN AND GUM SENSITIVITY:** Skin rash, itching, tenderness, and swelling may occur following injections. After treatment, if you have other treatments in the same area, the gum may not heal completely and there is a possible risk of an inflammatory reaction at the injection site.
- **INFECTION:** Although infection following injection of tissue fillers is unusual, bacterial, fungal, and viral infections can occur. Herpes simplex virus infections around the mouth can occur following a tissue filler treatment. This applies to both individuals with a history of Herpes simplex virus infections and individuals with no known history of Herpes simplex virus infections in the mouth area. Specific medications must be prescribed and taken both before and following the treatment procedure to suppress an infection from this virus. Should any type of skin or gum infection occur, additional treatment including antibiotics may be necessary.
- **UNDER/OVER CORRECTION:** The injection of soft tissue fillers 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.
- **LUMPS:** Lumpiness can occur following the injection of fillers. This tends to smooth out over time. In some situations, it may be possible to feel the injected tissue filler material for long periods.
- **GRANULOMAS:** Painful masses in the skin, gingiva, and deeper tissues after a filler injection are extremely rare. Should these occur, additional treatments including surgery may be necessary. Fillers should not be used in areas with active inflammation or infections (e.g., cysts, pimples, rashes, or hives).
- **MIGRATION OF FILLER:** The filler substance may migrate from its original injection site and produce visible fullness in adjacent tissue or other unintended effects.
- **SKIN/GINGIVAL NECROSIS:** It is very unusual to experience the death of skin and deeper soft tissues after injections. Skin or gingival necrosis can produce unacceptable scarring. Should this complication occur, additional treatments, or surgery may be necessary.
- **ALLERGIC REACTIONS OR HYPERSENSITIVITY:** As with all biological products, allergic and systemic anaphylactic reactions may occur. Fillers should not be used in patients with a history of multiple severe allergies, severe allergies manifested by a history of anaphylaxis, or allergies to gram-positive bacterial proteins. Allergic reactions may require additional treatment.
- **DRUG AND LOCAL ANESTHETIC REACTION:** There is the possibility that a systemic reaction could occur from either the local anesthetic or epinephrine used for sensory nerve block anesthesia when tissue filler injections are performed. This would include the possibility of light-headedness, rapid heartbeat (tachycardia), and fainting. Medical treatment for these conditions may be necessary.
- **ACCIDENTAL INTRA-ARTERIAL INJECTION:** It is extremely rare that during injection, fillers could be accidentally injected into arterial structures and produce a blockage of blood flow. The risks and consequences of accidental intravascular injection of fillers are unknown and not predictable. I understand that if this occurs, hyaluronidase (dissolving agent) cannot be used for Radiesse. The provider will need to flood the area with saline and massage the area to break up the product and restore blood flow. If blood flow is not restored, I understand that I will need to be referred to a medical or dental specialist. I also understand that additional medications may need to be taken such as antibiotics and/or steroids.

- **SCARRING:** Fillers should not be used in patients with known susceptibility to keloid formation or hypertrophic scarring.
- **UNSATISFACTORY RESULT:** Filler injections alone may not produce an outcome that meets your expectations for improvement in periodontal defects. 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 addition to additional treatments.
- **UNKNOWN RISKS:** The long-term effect of facial fillers beyond one year is unknown. The possibility of additional risk factors or complications attributable to the use of facial filler as a soft tissue filler may be discovered.

ALTERNATIVE TREATMENTS

____ Alternatives to the procedures such as gum surgery and doing nothing and options that I have volunteered for have been fully explained to me.

DENTAL LOCAL ANESTHESIA

____ Local anesthesia will be administered to numb the treatment area before your gum builder procedure. While local anesthesia is generally safe, I am aware of the following risks which may include but are not limited to: temporary numbness, tingling, or altered sensation in your lips, tongue, teeth or surrounding tissue, which typically resolves within a few hours, injection site soreness, swelling or bruising which is common and usually mild, rare cases of a hematoma, which is a collection of blood under the tissue, nerve injury which is uncommon and may result in prolonged or permanent altered sensation, infection at the injection site, allergic or adverse reactions to the anesthetic agent, ranging from mild skin reactions to, in very rare cases, a systemic response requiring immediate medical attention. I understand that if I experience unusual symptoms after the procedure, I will contact my provider promptly.

PREGNANCY AND ALLERGIES

____ I am not aware that I am pregnant and I am not trying to get pregnant, I am not lactating (nursing). I do not have any significant neurologic disease including but not limited to myasthenia gravis, multiple sclerosis, lambert--eaton syndrome, amyotrophic lateral sclerosis (ALS), and Parkinson’s. It is not known if Hyaluronic Acid Filler or its breakdown products can be excreted in human milk. It is not recommended that pregnant women or nursing mothers receive Hyaluronic Acid Filler or other facial filler treatments.

PAYMENT

____ I understand that this is an "elective” procedure and that payment is my responsibility and is expected at the time of treatment.

RIGHT TO DISCONTINUE TREATMENT

____ I understand that I have the right to discontinue treatment at any time.

RESULTS

____ The procedure has been fully explained to me. I also understand that any treatment performed is between myself and the healthcare provider who is treating me and I will direct all post-operative questions or concerns to the treating provider. I accept the risks and complications of the treatment, I may need to see a specialist in the event of a complication, and I understand that no guarantees are implied as to the outcome of the

procedure. I also certify that if I have any changes in my medical history, I will notify the healthcare professional who treated me immediately. I have read the above and understand it. My questions have been answered satisfactorily. I also state that I read and write in English.

AGREEMENT

By signing this form, you agree that I have read this form carefully and considered the side effects, risks and uncertainty of the outcome and decided the treatment is still in my best interests. If there was a treatment fee, I understand that the initial treatment of side effects and complications is included in the cost of the procedure and therefore no refunds are issued due to any of the above occurring. If additional complication treatment is needed, I am solely responsible for any costs incurred from the provider, or outside healthcare facilities or specialists should I have any side effects or complications. I have discussed all the details of the treatment plan, past treatments and my medical history with my provider. I understand photographs are taken and may be stored for 7 years as part of my clinical record. **Initial** ___

Patient: please type your initials to agree to aforementioned ____

Patient Signature: _____

To be completed by the Provider

Provider's Email: _____

Health History Completed? ■ Y / ■ N

Dental / Head and Neck Examination Completed? ■ Y / ■ N

I am the treating healthcare professional. I discussed the above risks, benefits, and alternatives with the patient. The patient had an opportunity to have all questions answered and was offered a copy of this informed consent. The patient has been told that I am responsible for their treatment and post treatment should there be any complications. The patient has been instructed to contact me or my office should they have any questions or concerns after this treatment procedure.

Provider First Name: _____

Provider Last Name: _____

Provider Signature: _____