INFORMED CONSENT FOR FILLER INJECTION (JUVEDERM PRODUCTS, RESTYLANE PRODUCTS)

PATIENT NAME_____

(PLEASE REVIEW PRIOR TO YOUR PROCEDURE)

INSTRUCTIONS
This is an informed-consent document which has been prepared to help your healthcare provider inform you concerning a soft tissue filler injection, its risks, and alternative treatments. It is important that you read this information carefully and completely. Please initial each page, indicating that you have read the page and sign the consent for this procedure as proposed by your healthcare provider.

ALTERNATIVE TREATMENTS-Alternatives include not performing the treatment at all. Other alternative treatments which vary in sensitivity, effect and duration include animal derived filler products, dermal fillers derived from the patient's own fat tissues, synthetic plastic permanent implants or toxins that can paralyze muscles that cause some wrinkles.

Disclaimer of "Off-Label" use - Each filler is FDA approved for use in the specific areas of the face. However, once a product is FDA approved, it may be used in other areas of the face and body as determined by a medical professional. Therefore, any filler injection may include off-label use in an effort to give the best result possible.

RISKS OF DERMAL FILLERS-Every procedure involves a certain amount of risk, and it is important that you understand the risks involved. An individual's choice to undergo this procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not experience the following complications, you should discuss each of them to make sure you understand the risks, potential complications, and consequences of dermal fillers.

Pain -Dermal fillers are injected into the skin using a fine needle to reduce injection discomfort. You may choose to anesthetize the treatment area either topically, with a local block or both. Please consult your medical professional about pain management. Tenderness is seen occasionally and is usually temporary, resolving in 2 to 3 days.

Skin Disorders - It is common to have a temporary redness and swelling following a treatment. This will usually subside in the first few hours after a session, but may last for several days to a week. Minimize exposure of treated areas to excessive sunlight, UV lamp exposure, and extreme cold weather until any swelling and redness have disappeared. Avoid use of alcohol for the next 24 hours. While very rare, scarring can occur following treatment. Also, dermal fillers should not be used in patients with a known potential for keloid formation or heavy scarring. Some fillers may produce nodules under the skin which might be seen or felt by the patient. In rare cases, an inflammatory granuloma may develop, which could require surgical removal of the filler.

Bleeding and bruising - Pinpoint bleeding is rare, but can occur following treatments. Bruising is seen on occasion following treatments. Rarely, bruising can last for weeks or months and might even be permanent. Patients using Aspirin, Ibuprofen, Advil, Motrin, Nuprin, Aleve, garlic, Gingko Biloba, Vitamin E, or blood thinners have an increased risk of bleeding or bruising at the injection site.

Unsatisfactory results - There is the possibility of a poor or inadequate response from dermal fillers. There might be an uneven appearance of the face with some areas more affected by the filler than others. In most cases this uneven appearance can be corrected by more injections in the same or nearby areas. In some cases, though, this uneven appearance can persist for several weeks or months. The practice of medicine and surgery is not an exact science. Although, good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained. The use of laser treatments on top of the injection sites carries the risk of lessening or loss of the implant.

Allergic reactions - Dermal fillers should not be used in individuals with a known previous history of reactions. In rare cases, local allergies to tape, preservatives used in cosmetics or topical preparations have been reported. Systemic reactions (which are more serious) may result from prescription medicines.

Infection - Although infection following dermal filler injections is unusual, bacterial, fungal, and viral infections can occur. Additional treatments or antibiotics may be needed. Most cases are easily treatable but, in rare cases, permanent scarring in the area can occur. If you have a history of herpes simplex in the area to be treated, we recommend prophylactic antibiotics before and after injection around the mouth.

Swelling - Some swelling (edema) is common after any injection and tend to resolve in a few hours. In some cases, swelling may last for a few days and rarely, there may be prolonged swelling lasting a few weeks or months.

Lumps and tissue irregularities - Some lumps or irregularities are possible but usually resolve with time or gentle massage. In rare cases, long-term lumps (granulomas) may occur requiring treatment.

Need for reversal of injection - If you are not satisfied with the result, some fillers can be "undone" with an injection of hyaluronidase. Radiesse and Sculptra CANNOT be undone.

Damage to deeper structures- Deeper structures such as nerves, blood vessels, and the eyeball may be damaged during the course of injection. Injury to deeper structures may be temporary or permanent. This may results in skin loss causing wounds, scar, and deformity. Blindness is possible.

Migration of filler - The product may migrate from its original injection site to other areas and produce unintended effects.

Eye Disorders- Functional and irritative disorders of eye structures may rarely occur following filler injections.
Asymmetry - The human face and eyelid region is normally asymmetrical with respect to structural anatomy and function. There can be a variation from one side to the other in terms of the response to filler injection.

Pain- Discomfort associated with filler injections is usually short duration.

Skin disorders- Skin rash and swelling may rarely occur following filler injection.

Unknown risks-The long term effect of filler on tissue is unknown. There is the possibility of additional risk factors may be discovered.

Unsatisfactory result-There is the possibility of a poor or inadequate response from filler injection. Additional filler injections may be necessary. Surgical procedures or treatments may be needed to improve results after filler injection.

Long-term effects- Subsequent alterations in appearance may occur as the result of aging, weight loss of gain, sun exposure, or other circumstances not related to filler injections. Filler injection does not arrest the aging process or produce permanent tightening of the skin. Future surgery or other treatments may be necessary.

Pregnancy and nursing mothers- Animal reproduction studies have not been performed to determine if filler injections could produce fetal harm. It is not known if filler material can be excreted in human milk.

Blindness- Blindness is extremely rare after filler injections. However, it can be caused by internal bleeding around the eyeball or due filler material traveling in a blood vessel to the eye.. The occurrence of this is very rare.

ADDITIONAL TREATMENT NECESSARY
There are many variable conditions in addition to risk and potential complications that may influence the long term result of filler injections. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with filler injections. Other complications and risks can occur but are even more uncommon. Should complications occur, additional surgery or other treatments may be necessary. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained.

FINANCIAL RESPONSIBILITIES
The cost of injection may involve several charges. This includes the professional fee for the injections, follow up visits to monitor the effectiveness of the treatment, and the cost of the material itself. It is unlikely that injections to treat cosmetic problems would be covered by your health insurance. Additional costs of medical treatment would be your responsibility should complications develop from filler injections.

DISCLAIMER
Informed-consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s). The informed-consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances.

However, informed consent documents should not be considered all-inclusive in defining other methods of care and risks encountered. Your provider may provide you with additional or different information which is based on all of the facts pertaining to your particular case and the state of medical knowledge.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

DURATION OF RESULTS
While exact duration of filler effects cannot be promised, typical results are as follows:

BELOTERO BALANCE - 3 months
JUVEDERM PRODUCTS - 6months
RADIESSE - 12 months
RESTYLANE PRODUCTS - 6 months
SCULPTRA - 1 to 2 years
VOLUMA - 12 months

It is important that you read the above information carefully and have all of your questions answered before signing the consent.

CONSENT FOR DERMAL FILLER TREATMENT
I hereby authorize your employees and assistants as may be selected to perform the following procedure or treatment:

Soft Tissue Filler Injection
JUVEDERM PRODUCTS, RESTYLANE PRODUCTS

I have received the following information sheet:
INFORMED-CONSENT for FILLER INJECTION

I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.
I consent to the photographing or televising of the procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.
For purposes of advancing medical education, I consent to the admittance of observers to the treatment room.
IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:

- THE ABOVE TREATMENT OR PROCEDURE TO BE UNDERTAKEN
- THERE MAY BE ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT
- THERE ARE RISKS TO THE PROCEDURE OR TREATMENT PROPOSED

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-5). I AM SATISFIED WITH THE EXPLANATION.

_____
Patient Name (Please Print)

_____ Date_____
Patient Signature

_____Date_____