## <u>Laser Light Skin Clinic</u> Patient Consent – Injections, Including Botox and Filler

(botulism toxin type a) (abobotulinum toxin type a) (incobotulinum toxin type a)

**Note**: This consent form may contain words that you do not understand. Please ask the staff of Laser Light Skin Clinic to explain any words or information that you do not clearly understand.

Facial lines and wrinkles are caused by several factors, including aging, exposure to the sun, heredity and genetics, muscles forming facial expression, gravity, and other factors. The use of facial muscles can create frowns, forehead and neck lines, and skin sagging, droopiness, wrinkles, jowls, and smile lines (commonly called crow's feet). A number of medical, non-medical, surgical, and non-surgical alternatives and techniques are available for skin tightening, including non-surgical cosmetic treatments. The objective of those treatments is to provide a younger, tighter, and firmer appearance. Some non-surgical treatments utilize heat, which causes natural collagen within your skin to shrink and, therefore, 'tighten'. This heating may also stimulate your skin to produce new collagen fibers, which further improves the appearance and tone of your skin. Other non-surgical techniques and treatments are based on injections into muscles, infra-red energy, radio frequency technology, laser skin tightening, and application of creams and gels. Many of the non-surgical techniques and treatments are minimally invasive and require little or no recovery time. There is, however, a limit to how much your skin can shrink and tighten. Where excessive sagging exists, a surgical procedure, such as a face lift, may produce better or more desirable results.

Injection of neurotoxins and filling agents for the treatment of facial aesthetics has increased during the past several decades. Injectable neurotoxins and soft tissue stimulators and fillers are available. Injectable agents carry risks of complications. Although most adverse events are minor and temporary, more serious complications can occur. The most common complications are pain, bruising, and swelling. Pain varies and depends on patient sensitivity. Other reactions may include nausea, fatigue, malaise, flu-like symptoms with mild fever, rash, headaches, redness, tenderness, itching, numbness, dizziness, skin irritation, drooping of eyelids, drooping of eyebrows, and eruptions at sites that are distant from the injection site. The risk of infection is low, but possible. For treatments of the neck, you may encounter difficulty swallowing. In most cases, infections are treatable, but in rare cases a permanent scarring in the area can occur. More serious complications include respiratory problems (such as bronchitis or sinusitis), allergic reactions, and botulism. Aesthetic complications may include loss of facial expression, scarring, and incomplete muscle paralysis. Spread of toxins to other sites may also cause unintended paralysis of neighboring areas.

Another risk when injecting toxins around the eyes includes corneal exposure because people may not be able to blink the eyelids as often as they should to protect the eye. This inability to protect the eye has been associated with damage to the eye as impaired vision, or double vision, which is usually temporary. This reduced blinking has been associated with corneal ulcerations. There are medications that can help lift the eyelid. These side effects can last for several weeks or longer.

Prior to any treatment, we encourage you to review information contained in pamphlets and materials that are available; review information that is available on the Internet; ask questions of Laser Light Skin Clinic physicians and medical personnel; or obtain information from other sources.

Botox treatment will involve several injections of a small amount of btxa/abx/xco, a purified toxin, into a specific muscle, which causes weakness of that muscle. The injections will relax the muscle, casing the lines that the muscle actions have created. These types of injections cause the muscles to halt their function (be paralyzed), which should improve the appearance of wrinkles in the area of the injection. This paralysis is temporary, and re-injection is usually necessary within three or four months to achieve the same effect. A particular treatment may not be effective for that length of time, may not work as well or for as long as expected or hoped for, or may not work at all. Also, more than one injection may be needed to achieve satisfactory results.

Cosmetic treatments, including treatments involving injections of botox and fillers, are not an exact science. The results might include an uneven appearance of the face, with some muscles more affected by the injections than others. In some cases this uneven appearance can persist for several weeks or months. Antibodies may develop, making treatment ineffective.

Not all facial wrinkles, lines, creases, and folds are caused by muscle activity alone. Therefore, other alternatives for treatment may be available and, in some cases, preferable. They include topical treatments (tretinoin, alpha hydroxyl acids, vitamin C); surgical facelift; injections of "filler" such as collagen or fat; chemical or laser peel; forehead or brow lift; surgical removal of the frown muscle; blepharoplasty (eyelid skin removal); and other treatments or procedures. These alternative procedures may improve the appearance by removing, tightening, or repositioning skin. Risks include skin irritation, infection, bleeding, discomfort, numbness, prolonged redness, scarring, swelling, nerve damage, blindness, and even death. Recovery time may take 1-2 weeks or longer for some of the alternative treatments.

This description of risks, concerns, alternatives, and treatment results is not intended to be inclusive of all possible risks associated with injections. There are both known and unknown side effects associated with any medication or procedure.

If you are pregnant or nursing, or if you become pregnant during the course of treatments, please notify your physician before a treatment occurs. You should not have an injection if you are pregnant or nursing. Also, you should not have an injection if you have any significant neurological disease, such as Myasthenia Gravis.

Following an injection, you should not recline, manipulate the treatment area, or vigorously move about for at least four hours. You should not use the muscles that were injected for the next four hours (such as trying to frown, squint, or raise your eyebrows). You must follow all post-treatment and after-care instructions.

Laser Light Skin Clinic does not guarantee the results of any treatment. You may not be satisfied with the results.

## **Patient Acknowledgement and Consent**

I have read the information set forth above regarding my proposed treatment, and I have had the opportunity to ask questions of the staff of Laser Light Skin Clinic regarding my proposed treatment and to receive answers that are satisfactory to me. I consent to the treatment, as well as any related treatments that my physician considers necessary and appropriate in connection with the injection treatment.

I voluntarily request that Laser Light Skin Clinic treat my condition (facial lines and wrinkles resulting from muscle action) with btxa/abx/xeo. I accept the uncertainties, risks and limitations of this procedure.

I give my consent to being photographed for medical purposes and medical training purposes.

I agree to accept full financial responsibility and pay the charges for the treatment and course of treatment.

I agree to follow-up with Laser Light Skin Clinic within two weeks after my first treatment.

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I acknowledge that a copy of the package insert was made available to me. I understand that at each subsequent visit for Botox/Dysport/Xeomin injections, I have the opportunity to review insert.

## **Black Box Warning:**

Distant spread of toxin effect. Postmarketing reports indicate that the effects of BOTOX®, COSMETIC DYSPORT®, XEOMIN ®, and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include asthenia, generalized muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence, and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity, but symptoms can also occur in adults treated for spasticity and other conditions particularly in those patients who have underlying conditions that would predispose them to these symptoms. In unapproved uses, including spasticity in children and adults, and in approved indications, cases of spread of effect have occurred at doses comparable to those used to treat cervical dysphonia and at lower doses.

Print Patient Name	Patient Signature
Print Witness Name	Witness Signature