## INFORMED CONSENT FOR NEUROTOXIN INJECTION (BOTULINUM TOXIN TYPE-A AS BOTOX, DYSPORT, JEUVEAU, AND XEOMIN) between the patient and [COMPANY NAME].

## FOR THE TEMPORARY TREATMENT OF SUPERFICIAL FACIAL WRINKLES

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

Botox® is the botulinum toxin and works by paralyzing nerves and muscles.

- 1. I, \_\_\_\_\_\_\_, consent to and authorize \_\_\_\_\_\_\_ to perform a treatment of facial wrinkles with Botox. \_\_\_\_\_\_
- 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. I understand surgery, medications, no treatment, or other treatment alternatives may be as effective or more effective in reducing the appearance of wrinkles. 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:

- Redness, swelling/edema, itching, pain or pressure lasting more than one week
- Nodules or induration at the injection site
- Discoloration of the injection site
- Poor effect
- Allergic reactions
- Bruising
- Facial asymmetry
- Paralysis leading to droopy eyelid and double vision
- Some patients may experience weakness or flu-like symptoms
- Visual problems
- Dry Eyes
- Some patients may develop antibodies to Botox
- Post treatment bacterial, viral and/or fungal infection requiring further treatments
- Facial asymmetry (one side looks different than the other)
- Paralysis of a nearby muscle leading to: droopy eyelid (in approximately 1-2% of injections, this usually lasts 2-3 weeks), double vision, inability to close eye, dry eye, difficulty whistling or drinking from a straw
- Loss of vision, this is extremely rare, however, it can be caused by internal bleeding around the eyeball or needle stick injury

- Permanent loss of muscle tone with repeated injection
- Occasional numbress of the forehead lasting up to 2-3 weeks
- 5. I also certify that I have none of the known conditions that would contraindicate treatment. These conditions include hypertrophy scars, a history of any autoimmune disease, immune therapy, any significant neurological disease (including but not limited to: Eaton-Lambert syndrome, amyotrophic lateral sclerosis (ALS), or myasthenia gravis, an infection, skin condition, or muscle weakness at the site of the injection, pregnancy or nursing. I am not pregnant, breast-feeding, and I have no known allergy to Botox®/Dysport® or the toxin ingredients (including lactose, sucrose, saline) to human albumin or to eggs.
- 6. There are many medications and injectable fillers that are approved for specific use by the FDA, but some proposed uses may be "Off-Label", that is, not specifically approved by the FDA. Botox® is FDA approved for use on the forehead lines, glabellar lines, and crow's feet. The above medication has not been approved by the FDA for any use other than as described above. 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 medication discussed in this paragraph and I understand and accept that the risks and wish to receive the medication(s).
- 7. 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 complete confidentiality of my name will be maintained.
- 8. 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.
- 9. I will hold [COMPANY NAME] and its owner[s], agents, employees and shareholders completely harmless from all and any litigation or claims made should I have any adverse reaction to Botox® or reaction to Botox®. Further, I hold all providers completely harmless from any and all litigation, malpractice suits or claims made in relation to my receiving Botox®. 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. If you are planning a LASIK® procedure, please inform the provider as your Botox® may be deferred.
- 11. I am aware that when small amounts of purified botulinum toxin (Botox®) are injected into a muscle it causes weakness or paralysis of the muscle. This appears in 3-10 days and usually last 3-4 months but can be shorter or longer. In a very small number of individuals, the injection does not work as satisfactorily or for as long as usual. I understand that I will not be able to "frown" while the injection is effective but that this will reverse after a period of months at which time re-treatment is appropriate. 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:
  - No laying down or reclining for four hours after injection
  - No scratching or rubbing the injected area
  - No bending forward for four hours

• Make up should be avoided for one to two 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.

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.

Date:

Patient Name (please print)	
Signature	Date
Witness Signature	_Date

(If applicable) Patient Parent/Guardian Signature:

Patient's Parent/Guardian Printed Name: