Botulinum Toxin Type A: BOTOX Cosmetic & Dysport Consent Form

BOTOX Cosmetic is indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugators and/or procerus muscle activity in adult patients ≤ 65 years of age.

BOTOX Cosmetic (onabotulinumtoxin A) for injection, is a sterile, vacuum-dried purified botulinum toxin type A, produced from fermentation of Hall strain Clostridium Botulinum Type A grown in a medium containing casein hydrolysate, glucose, and yeast extract, intended for intramuscular use. BOTOX Cosmetic blocks neuromuscular transmission by binding to acceptor sites on motor nerve terminals, entering the nerve terminals, and inhibiting the release of Acetylcholine, this inhibition occurs as the neurotoxin cleaves SNAP-25, a protein integral to the successful docking and release of Acetylcholine from vesicles situated within nerve endings. When injected intramuscularly at therapeutic doses, BOTOX Cosmetic produces partial chemical denervation of the muscle resulting in a localized reduction in muscle activity.

Dysport (abobotulinumtoxin A) is an Acetylcholine release inhibitor and a neuromuscular blocking agent indicated for temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and corrugators muscle activity in adult patients < 65 years of age.

The effects of Dysport and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with boulinum toxin effects. 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, particularly in those patients who have underlying conditions that would predispose them to these symptoms.

Dysport is contraindicated in patients with known hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation. This product may contain trace amounts of cow's milk protein. Patients know to be allergic to cow's milk should not be treated with Dysport. Dysport is contraindicated for use in patients with infection at the proposed injection site(s).

There are no adequate and well-controlled studies in pregnant women. Dysport should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known whether Dysport is excreted in human milk.

I _____ (client name) authorize Dr. Michael Miller to perform injection procedures of BOTOX Cosmetic and/or Dysport injections on the following areas:

- ☐ Glabellar Complex (area between eyebrows) (Corrugator Supercilli, Depressor Supercilli, Procerus) Initials:_____
- ☐ Frontalis (forehead lines) Initials:_____
- ☐ Orbicularis Oculi (area lateral to the eye—Crow's Feet) Initials:_____
- ☐ Other _____ Initials:_____

Client initials:

_____ I understand the details of the Botulinum Toxin Type A injection procedures which have been explained to me.

_____ The alternative methods, their benefits and their disadvantages have been explained to me.

_____ I understand that the FDA has only approved the cosmetic use of BOTOX Cosmetic and Dysport for frown lines between the eye brows (Glabellar Complex). Any other cosmetic use is considered "off label".

_____ I understand and accept the possible risks and complications of BOTOX Cosmetic and Dysport injections.

Including but not limited to:

- Paralysis of a nearby muscles that could interfere with opening of the eye(s)
- Local numbness
- Headache, nausea, or flu-like symptoms
- Swallowing, speech, or respiratory disorders
- Swelling, bruising, or redness at the injection site
- Disorientation and double vision
- Temporary asymmetrical appearance
- Abnormal or lack of facial expression
- Inability to smile when injected in the lower face
- Facial pain
- Product ineffectiveness

_____ I understand and accept that the long-term effects of repeated use of BOTOX Cosmetic and Dysport injections are unknown. Possible risks and complications that have been identified, but are not limited to:

- Muscle atrophy
- Nerve irritability
- Production of antibodies with unknown effect to general health

_____ I understand and accept the extremely rare complications, including the remote risk of death or serious disability that exists with this procedure.

_____ I am aware that smoking during the pre and post care of injections of Botulinum Toxin Type A injection procedures could increases chances of complications.

_____ I have informed the doctor of all known allergies I have.

_____ I have informed the doctor of all medications I am currently taking, including prescriptions, over the counter medications, natural (herbal), homeopathics, and any other.

_____ I have been advised whether I should take any or all of the medications on the days surrounding Botulinum Toxin Type A injection procedures.

_____ I am aware and accept that no guarantees regarding the result of Botulinum Toxin Type A injection procedures.

_____ I have been informed of what to expect post-treatment, including but not limited to procedures I can do if I wish to maintain the appearance of the Botulinum Toxin Type A injection procedures.

_____ I am not currently pregnant or nursing, and I understand that should I become pregnant while using BOTOX Cosmetic and Dysport there are risks, including fetal complications.

_____ If pre and post-treatment photos and/or video are taken of the treatment for medical record purposes, I understand that these photos will be protected by regulations regarding client confidentiality.

_____ The doctor has answered all my questions regarding this procedure.

_____ I have been advised to seek immediate medical attention if swallowing, speech, or respiratory complications arise.

_____ I certify that I have read and understand this agreement and that all spaces for initials were filled in prior to my signature.

Client Signature: _____ Date: _____

I certify that I have explained the nature, purpose, benefits, risks, rare complications, and alternatives of the proposed Botulinum Toxin Type A injection procedures. I have answered fully, and I believe that the patient fully understands what I have explained.

Doctor Signature: _____ Date: _____