Appendix 4

Consent Forms

4A. Botulinum Toxin Treatment of the Face and Neck

This consent form is designed to provide the information necessary when considering whether or not to undergo botulinum toxin treatment for facial and neck wrinkles with Botox®.

Injection of botulinum toxin (Botox) causes weakness of targeted muscles, which can last approximately 3–4 months. Injection of small amounts of Botox relaxes the treated muscles and can reduce facial wrinkles such as frown lines. Botox solution is injected with a small needle into the targeted muscles. Effects are typically seen in a few days and can take 1–2 weeks to fully develop.

Botox is approved by the Food and Drug Administration for the temporary treatment of moderate to severe dynamic frown lines in adults aged 18–65 years and is used off-label for all other cosmetic treatment areas.

The risks, side effects, and complications in treatment with Botox on facial and neck areas include, but are not limited to the following:

- Localized burning or stinging pain during injection
- Bruising
- Redness
- Tenderness
- Swelling
- Infection
- Numbness or dysesthesia
- Headache
- Anxiety
- Vasovagal episode with loss of consciousness
- Facial asymmetry, alteration, or poor aesthetic results
- Inadequate reduction of wrinkles or lack of intended effect
- Blepharoptosis (droopy eyelid)
- Eyebrow ptosis (droopy eyebrow)
- Photophobia (light sensitivity)
- Impaired eyelid closure and blink reflex
- Ectropian (lower eyelid exposure)
- Lagophthalmos (incomplete eyelid closure)
- Xerophthalmia (dry eyes)
- Epiphora (tearing)
- Diplopia (double vision) or vision changes
- Eye trauma
- Worsening eye bags
- Lip ptosis with resultant smile asymmetry

- Oral incompetence with resultant drooling and/or impaired speaking, eating, or drinking
- Cheek flaccidity
- Dysarthria (difficulty articulating)
- Dysphagia (difficulty swallowing), necessitating nasogastric tube placement in severe cases
- Hoarseness
- Neck weakness
- Weakening of muscles adjacent to the intended treatment area
- Autoantibodies against botulinum toxin may be present or develop after treatments rendering treatments ineffective (1–2% of patients treated for cosmetic indications per Allergan).
- Extremely rare, immediate hypersensitivity reaction with signs of urticaria, edema, and a remote possibility of anaphylaxis.
- Case reports of side effects due to distant spread from the site of injection have been reported with large doses of botulinum toxin, including generalized muscle weakness, ptosis, dysphagia, dysarthria, urinary incontinence, respiratory difficulties, and death due to respiratory compromise.

Postmarketing safety data suggest that botulinum toxin effects may, in some cases, be observed beyond the site of local injection. The symptoms may include generalized muscle weakness, double vision, blurred vision, eyelid droop, difficulty swallowing, difficulty speaking, 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 related to spread of toxin effects. 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. No definite serious adverse event reports of distant spread of toxin effect associated with dermatologic use of cosmetic botulinum toxin at the labeled dose of 20 units (for frown lines) or 100 units (for underarm sweating) have been reported.

My signature below certifies that I have fully read this consent form and understand the information provided to me regarding the proposed procedure. I have been adequately informed about the procedure including the potential benefits, limitations, and alternative treatments, and I have had all questions and concerns answered to my satisfaction. I understand that results are not guaranteed and I accept the risks, side effects, and possible complications inherent in undergoing Botox treatments.

Patient Name _____

Patient Signature _____ Date _____

4B. Botulinum Toxin Treatment of Underarm Sweating (Axillary Hyperhidrosis)

This consent form is designed to provide the information necessary when considering whether or not to undergo botulinum toxin treatment for underarm sweating, also called primary axillary hyperhidrosis, with Botox®.

Botulinum toxin (Botox) injections can reduce underarm sweating that is not due to an underlying medical condition. Botox is approved by the Food and Drug Administration for the temporary treatment of primary axillary hyperhidrosis. Botox solution is injected with a small needle into the skin to target the sweat glands. Reduced underarm sweating is typically reported 1–2 weeks after treatment and effects last for approximately 6 months or more in some cases.

Before receiving Botox treatment for underarm sweating, you should receive an evaluation from you regular physician to ensure that you do not have an underlying medical condition that is causing the excessive underarm sweating. Also, Botox is not intended as the first treatment to prevent underarm sweating. It is indicated once other therapies such as over-the-counter antiperspirants and aluminum chloride topical antiperspirants have been tried and found ineffective.

The risks, side effects, and complications in treatment with Botox on underarm areas include, but are not limited to the following:

- Localized burning or stinging pain during injection
- Bruising
- Redness
- Tenderness
- Swelling
- Infection
- Numbness or dysesthesia
- Anxiety
- Vasovagal episode with loss of consciousness
- Inadequate reduction of sweating or lack of intended effect
- Autoantibodies against botulinum toxin may be present or develop after treatments rendering treatments ineffective (1–2% of patients treated for cosmetic indications per Allergan).
- Extremely rare, immediate hypersensitivity reaction with signs of urticaria, edema, and a remote possibility of anaphylaxis.
- Case reports of side effects due to distant spread from the site of injection have been reported with large doses of botulinum toxin, including generalized muscle weakness, ptosis, dysphagia, dysarthria, urinary incontinence, respiratory difficulties, and death due to respiratory compromise.

Postmarketing safety data suggest that botulinum toxin effects may, in some cases, be observed beyond the site of local injection. The symptoms may include generalized muscle weakness, double vision, blurred vision, eyelid droop, difficulty swallowing, difficulty speaking, 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 related to spread of toxin effects. 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. No definite serious adverse

event reports of distant spread of toxin effect associated with dermatologic use of cosmetic botulinum toxin at the labeled dose of 100 units for underarm sweating have been reported.

My signature below certifies that I have fully read this consent form and understand the information provided to me regarding the proposed procedure. I have been adequately informed about the procedure including the potential benefits, limitations, and alternative treatments, and I have had all questions and concerns answered to my satisfaction. I understand that results are not guaranteed and I accept the risks, side effects, and possible complications inherent in undergoing Botox treatments.

Patient Name _____

Patient Signature _____ Date _____