

Joseph Walrath, MD  
Oculoplastic Surgery

**Date:** \_\_\_\_\_ **Time:** \_\_\_\_\_

**Diagnosis:**  Blepharospasm       Hemifacial Spasm       Facial Tic       Tearing

**Procedure:** Injection of Botulinum Toxin - LIFETIME CONSENT

Blepharospasm, hemifacial spasm and facial tic are diseases of unknown cause characterized by involuntary movements of the facial muscles. There is no cure; however surgery, oral medication and injection of botulinum toxin (Botox, Dysport, Xeomin) are treatments for the symptoms. I understand that signing this consent form entails no obligation on my part and that I may decide to discontinue this treatment program or select another form of treatment. I understand that oral medication and surgery are alternative forms of treatment.

When injected into a facial muscle in extremely small quantities, botulinum toxin causes temporary weakness of the abnormally acting muscle. When injected into the tear gland, botulinum toxin causes temporary decreased tear production. I understand that this treatment does not cure the basic problem of the involved muscles or tear gland. The duration of the effect varies between patients but averages two to three months.

**SIDE EFFECTS:** I understand that there is a possibility of temporary drooping of the upper eyelid, dryness of the eye requiring eye drops, tearing from the eye due to weakness of the lower lid, difficulty closing the eye, double vision, and sensitivity to light. Other temporary side effects rarely reported are bleeding, puffy eyelid, in-turned eyelid, out-turned eyelid, headache, and lip movement interference causing trouble with speech (less than 1%). As with injections elsewhere, a bruise and discomfort may occur. Very rarely, patients may develop antibodies to botulinum toxin making the injections less effective. Botulinum toxin contains human-derived albumin and carries a theoretic risk of virus transmission. There have been no reports of disease transmission through Botulinum toxin or albumin. There have been rare reports of death, pneumonia and severe allergic reaction after botulinum toxin injection but the relationship of these events to botulinum toxin is not established.

**CONTRAINDICATIONS:** You should not have botulinum toxin if you are pregnant, nursing, or allergic to albumin; if you have an infection, skin condition at the site of the injection; if you have Eaton-Lambert syndrome, Lou Gehrig's disease, or myasthenia gravis; or if you are taking an aminoglycoside antibiotic like gentamicin.

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I understand the above, and have had the risk benefits, and alternatives explained to me. No guarantees about results have been made. I give my informed consent for botulinum toxin injections today as well as for future treatments as needed.

OFF-LABEL FDA IMPLICATIONS: When a drug is approved by the FDA for medical use, the manufacturer produces a "Label" to explain its use. Once a medication is approved by the FDA, physicians may use it "off-label" for other purposes if they are well-informed about the drug, base its use on firm scientific method and sound medical evidence, and maintain records of its use and effect. While the FDA has not approved botulinum toxin specifically for the treatment of tearing, physicians may perform injections for this "off-label" indication. Because it is not FDA-approved, I understand that insurance will not reimburse me for the material cost of the botulinum toxin or the cost of the injection.

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Patient Signature

\_\_\_\_\_  
Dr. Joseph Walrath

\_\_\_\_\_  
Person authorized to consent:

Parent  Guardian  Spouse  POA

\_\_\_\_\_  
Witness