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# BOTOX® TREATMENT INFORMED CONSENT BOOKLET

## INSTRUCTIONS

This Informed Consent Booklet has been prepared by Dr. Chris Eisenhauer to help to inform you about the potential benefits and associated risks of, as well as alternatives to, BOTOX® treatments.

During your consultation and medical assessment, Dr. Eisenhauer will have reviewed with you the potential benefits and associated risks that are outlined in this booklet. He will also have provided you with answers to any questions you may have had about your procedure.

It is important that you carefully read the information contained in this booklet. Only when all of your questions and concerns about the procedures have been addressed should you then initial each page, indicating that you have fully read and understood all the items discussed in this booklet. When you reach the end of the booklet, please sign the consent form for the procedure as proposed by Dr. Eisenhauer. If you have any remaining questions or concerns about the potential benefits and associated risks of, or alternatives to, any BOTOX® treatments outlined in this book, do not initial any pages or sign the consent without first speaking to Dr. Eisenhauer.

## INTRODUCTION

Being fully informed about your condition and treatment will help you make the decision whether or not to undergo BOTOX® cosmetic treatments. This disclosure is not meant to alarm you; it is simply an effort to better inform you so that you may give or withhold your consent for this treatment.

*Clostridia botulina* bacteria produce a class of chemical compounds known as “toxin”. The Botulina Type A Toxin (BOTOX) is processed and purified to produce a sterile product suitable for specific therapeutic uses. Once the diluted toxin is injected, it produces a temporary paralysis (chemodenervation) of muscle by preventing transmission of nerve impulses to muscle. The duration of muscle paralysis generally lasts for approximately three to four months.

BOTOX® has been approved to treat certain conditions involving crossed eyes (strabismus), eyelid spasm (blepharospasm), cervical dystonia (spastic muscle disorder with the neck), and motor disorders of the facial nerve (VII cranial nerve). As of April 2002, BOTOX® has been FDA-approved for the cosmetic treatment of forehead wrinkles caused by specific muscle groups and, more recently, approved for crow’s feet wrinkles as of September 2013. Other areas of the face and body, such as smoker’s lines around the lips and neck bands may be treated in an “off-label” fashion. BOTOX® has also been used to treat migraine headaches, colorectal disorders, excessive perspiration disorders of the armpit and hands, and musculoskeletal pain disorders.

The BOTOX® cosmetic solution is injected with a tiny needle into the skin and muscle. BOTOX® injections are customized for every patient, depending on his or her particular needs. These can be performed in areas involving the eyelid region, forehead, and neck. BOTOX® cannot stop the process of aging. It can, however, temporarily diminish the look of wrinkles caused by muscle groups. BOTOX® injections may be performed as a singular procedure or as an adjunct to a surgical procedure. You should see the benefits develop over the next seven days to two weeks, although complete evaluation of the outcome from treatment is evaluated at two weeks. A decreased appearance of frowning or creasing

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of other lines and/or a change in specific facial grimacing will be the result of this treatment.

## **ALTERNATIVE TREATMENTS**

Alternative forms of management include not treating the skin wrinkles by any means. Improvement of skin wrinkles may be accomplished by other treatments or alternative types of surgery such as blepharoplasty, face or brow lift when indicated. Other forms of eyelid surgery may be needed should you have intrinsic disorders affecting the function of the eyelid such as drooping eyelids from muscle problems (eyelid ptosis) or looseness between the eyelid and eyeball (ectropion). Minor skin wrinkling may be improved through chemical skin peels, lasers, injection of filling material, or other skin treatments. Risks and potential complications are associated with alternative forms of medical or surgical treatment.

## **INHERENT RISKS OF BOTOX (BOTULINA TYPE A TOXIN) INJECTIONS**

Every procedure involves a certain amount of risk and it is important that you understand these risks and the possible complications associated with them. In addition, every procedure has limitations. An individual's choice to undergo a surgical procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not experience these complications, you should discuss each of them with Dr. Eisenhower to make sure you understand risks, potential complications, limitations, and consequences of BOTOX injections. Additional information concerning BOTOX may be obtained from the package-insert sheets supplied by Allergan.

## **SPECIFIC RISKS OF BOTOX (BOTULINA TYPE A TOXIN) INJECTIONS**

### **Incomplete Block**

It is possible to not experience a complete block of desired muscles. Additional injections to reach the desired level of block can be performed until the goal is achieved.

### **Asymmetry**

The human face and eyelid region is normally asymmetrical with respect to structural anatomy and function. There can be a variation from one side to the other in terms of the response to BOTOX injections.

### **Drooping Eyelid (ptosis)**

Muscles that raise the eyelid may be affected by BOTOX should this material migrate downward from other injection areas.

### **Pain**

Discomfort associated with BOTOX injections is usually short of duration.

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### **Migration of BOTOX**

BOTOX may migrate from its original injection site to other areas and produce temporary paralysis of other muscle groups or other unintended effects, BOTOX has been reported to cause swallowing problems in patients treated for spastic muscle disorders of the cervical region (cervical dystonia).

### **Bleeding and Bruising**

It is possible, though unusual, to have a bleeding episode from a BOTOX injection. Bruising in soft tissue may occur. Serious bleeding around the eyeball during deeper BOTOX injections for crossed eyes (strabismus) has occurred. Should you develop post-injection bleeding, it may require emergency treatment or surgery. Aspirin, anti-inflammatory medications, platelet inhibitors, anticoagulants, Vitamin E, ginko biloba, and other "herbs/homeopathic remedies" may contribute to a greater risk of a bleeding problem. Do not take these for ten days before or after BOTOX injections.

### **Damage to Deeper Structures**

Deeper structures such as nerves, blood vessels, and the eyeball may be damaged during the course of injection. Injury to deeper structures may be temporary or permanent.

### **Corneal Exposure Problems**

Some patients experience difficulties closing their eyelids after BOTOX injections and problems may occur in the cornea due to dryness. Should this rare complication occur, additional treatments, protective eye drops, contact lenses, or surgery may be necessary.

### **Unknown Risks**

The long-term effect of BOTOX on tissue is unknown. The risk and consequences of accidental intravascular injection of BOTOX is unknown and not predictable. There is the possibility that additional risk factors may be discovered.

### **Dry Eye Problems**

Individuals who normally have dry eyes may be advised to use special caution in considering BOTOX injections around the eyelid region.

### **Double-Vision**

Double-vision may be produced if the BOTOX material migrates into the region of muscles that control the movements of the eyeball.

### **Eyelid Ectropion**

Abnormal looseness of the lower eyelid can occur following BOTOX injection.

### **Other Eye Disorders**

Functional and irritative disorders of eye structures may rarely occur following BOTOX injections.

### **Blindness**

Blindness is extremely rare after BOTOX injections. However, it can be caused by internal bleeding around the eyeball or needle stick injury. In a period of 10 years of BOTOX administration, complications

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of blurred vision, retinal vein occlusion, and glaucoma have been reported in three patients. The occurrence of eye problems appears very rare.

#### **Allergic Reactions**

As with all biologic products, allergic and systemic anaphylactic reactions may occur. Allergic reactions may require additional treatment.

#### **Antibodies to BOTOX**

Presence of antibodies to BOTOX may reduce the effectiveness of this material in subsequent injections. The health significance of antibodies to BOTOX is unknown.

#### **Infection**

Infection is extremely rare after BOTOX injections. Should an infection occur, additional treatment including antibiotics may be necessary.

#### **Skin Disorders**

Skin rash, itching, and swelling may rarely occur following BOTOX injection.

#### **Neuromuscular Disorders**

Patients with peripheral motor neuropathic disorders (amyotrophic lateral sclerosis, myasthenia graves, and motor neuropathies) may be at greater risk of clinically significant side effects from BOTOX.

#### **Migraine Headache Disorders**

BOTOX has been used to treat forehead muscle groups that are involved with the migraine headache condition. Patients are advised that results of BOTOX treatment for migraine headaches may be variable and improvement in this disorder may not occur following BOTOX treatments.

#### **Unsatisfactory Result**

There is the possibility of a poor or inadequate response from BOTOX injection. Additional BOTOX injections may be necessary. Surgical procedures or treatments may be needed to improve skin wrinkles including those caused by muscle activity.

#### **Long-term Effects**

Subsequent alterations in face and eyelid appearance may occur as the result of aging, weight loss, weight gain, sun exposure, pregnancy, menopause, or other circumstances NOT related to BOTOX injections. BOTOX injection does not arrest the aging process or produce permanent tightening of the eyelid region. Future surgery or other treatments may be necessary.

#### **Pregnancy and Nursing Mothers**

Animal reproduction studies have not been performed to determine if BOTOX could produce fetal harm. It is not known if BOTOX can be excreted in human milk. It is not recommended that pregnant women or nursing mothers receive BOTOX treatments.

#### **Drug Influences**

The effect of BOTOX may be potentiated by amino glycoside antibiotics or other drugs known to interfere with neuromuscular transmission.

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### **Off-Label FDA Issues**

There are many devices, medications, and injectable fillers and botulinum toxins that are approved for specific use by the FDA, but this proposed use is "Off-Label", that is not specifically approved by the FDA. It is important that you understand this proposed use is not experimental and your provider believes it to be safe and effective.

### **HEALTH INSURANCE**

BOTOX® is a cosmetic treatment that poses no medical or healthcare threat. Most health insurance companies exclude coverage for these treatment. However, there are a few exceptions that insurance companies will accept BOTOX as a medical treatment. Talk with Dr. Eisenhower before treatment to determine what your procedure qualifies as.

### **FINANCIAL RESPONSIBILITIES**

You will be responsible for all necessary payments. Additional costs may occur should complications develop from treatment. There are no refunds once a treatment has been performed.

### **DISCLAIMER**

Informed Consent Booklets are used to communicate information about the proposed treatment of a condition along with the disclosure of risk(s) and alternative treatment(s). The informed consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances.

The contents of this booklet and any discussions with Dr. Eisenhower are the material risks, both common and uncommon, that Dr. Eisenhower feels a reasonable person would want to know, understand, and consider when deciding how and if they wish to proceed with the proposed treatment of their condition.

However, Informed Consent Booklets should not be considered all-inclusive in defining other methods of care and risks encountered. Dr. Eisenhower may provide you with additional or different information that is based on all the facts in your particular case and state of medical knowledge.

Informed consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all the facts involved in an individual case and are subject to change as scientific knowledge and technology advance, as practice patterns evolve.

It is important that you carefully read the above information contained on this and all preceding pages and have all of your questions answered by Dr. Chris Eisenhower before signing the consent on the last page of this booklet.

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# CONSENT FOR PROCEDURE AND/OR TREATMENT

**I have received the following information/Informed Consent Booklet for:  
BOTOX®**

1. I hereby authorize Dr. Eisenhower and/or such assistants as may be selected to perform the following procedure and/or treatment: \_\_\_\_\_.
2. I acknowledge that I have been informed about the Off-Label FDA status of BOTOX® and I understand it is not experimental and accept its use.
3. I am not pregnant and I am not breastfeeding. \_\_\_\_\_ Female Patient initial
4. I understand that the procedure is purely elective, that the results may vary with each individual, and multiple treatments may be necessary.
5. I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risk and the possibility of complications, injury, and sometimes death.
6. Before and after treatment instructions have been discussed with me. The procedure, potential benefits and risks, and alternative treatment options have been explained to my satisfaction.
7. I have read and understand all information presented to me before consenting to treatment.
8. For the purpose of advancing medical education, I consent to the admittance of observers to the treatment room.
9. I understand that the signature of the witness (if a non-physician) on this document indicates only that the signing of my own name has been observed and not that the witness has necessarily provided information regarding the procedure.
10. I have had all my questions answered to my satisfaction. I freely consent to the proposed treatment.

**I CONSENT TO THE PROCEDURE AND/OR TREATMENT AND THE ABOVE LISTED ITEMS.  
I AM SATISFIED WITH THE EXPLANATION.**

\_\_\_\_\_  
Patient or Person Authorized to Sign for Patient

\_\_\_\_\_  
Please Print Name

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness

**Patient Initials \_\_\_\_\_ Date \_\_\_\_\_**