

## **INFORMED CONSENT FOR BOTULINUM TOXIN TREATMENT FOR BRUXISM**

The purpose of this informed consent form is to provide written information regarding the risks, benefits and alternatives of the procedure named above. This material serves as a supplement to the discussion you have with your doctor/healthcare provider. It is important that you fully understand this information, so please read this document thoroughly. If you have any questions regarding the procedure, ask your doctor/healthcare professional prior to signing the consent form.

### **THE TREATMENT**

Botulinum toxin (Botox®, Xeomin®, and similar agents) is a neurotoxin produced by the bacterium Clostridium A. Botulinum toxin can relax the muscles on areas of the face and neck which cause wrinkles associated with facial expressions or contraction associated with facial pain or bruxism. Injection of purified botulinum toxin into the muscles of mastication can block the signals that tell these muscles to contract, relieving the involuntary grinding and clenching of teeth. Botulinum toxin is diluted to a very controlled solution and when injected into the muscles with a very thin needle, it is almost painless. The procedure takes about 5- 10 minutes and the results can last up to 3 months. With repeated treatments, the results may tend to last longer.

### **RISKS AND COMPLICATIONS**

Before undergoing this procedure, understanding the risks is essential. No procedure is completely risk-free. The following risks may occur, but there may be unforeseen risks and risks that are not included on this list. Some of these risks, if they occur, may necessitate hospitalization, and/or extended outpatient therapy to permit adequate treatment. It has been explained to me that there are certain inherent and potential risks and side effects in any invasive procedure and in this specific instance such risks include but are not limited to: 1. Post treatment discomfort, swelling, redness, and bruising, 2. Post treatment bacterial, and/or fungal infection requiring further treatment, 3. Allergic reaction, and 4. Flu-like symptoms may occur.

### **PREGNANCY, ALLERGIES & NEUROLOGIC DISEASE**

I am not aware that I am pregnant and I am not trying to get pregnant. I am not lactating (nursing). I do not have any significant neurologic disease including but not limited to myasthenis gravis, multiple sclerosis, Lambert-Eaton syndrome, amyotrophic lateral sclerosis (ALS), and Parkinson's. I do not have any allergies to the toxin ingredients, or to human albumin.

### **ALTERNATIVE PROCEDURES**

Alternatives to the procedures and options that I have volunteered for have been fully explained to me.

### **PAYMENT**

I understand that this is an "elective" procedure and that payment is my responsibility and is expected at the time of treatment.



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**RIGHT TO DISCONTINUE TREATMENT**

I understand that I have the right to discontinue treatment at any time.

**RESULTS**

I am aware that when small amounts of purified botulinum toxin are injected into a muscle it causes weakness or paralysis of that muscle. This appears in 10-14 days and usually lasts up to 3 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 and there are some individuals who do not respond at all. I understand that I will not be able to use the muscles injected as before while the injection is effective but that this will reverse after a period of months at which time retreatment is appropriate. I understand that I must stay in the erect posture and that I must not manipulate the area(s) of the injections for the 24 hours post-injection period.

I understand this is an elective procedure and I hereby voluntarily consent to treatment with botulinum toxin injections for bruxism. The procedure has been fully explained to me. I also understand that any treatment performed is between me and the doctor/healthcare provider who is treating me and I will direct all post-operative questions or concerns to the treating clinician. I have read the above and understand it. My questions have been answered satisfactorily. I accept the risks and complications of the procedure and I understand that no guarantees are implied as to the outcome of the procedure. I also certify that if I have any changes in my medical history I will notify the doctor/healthcare professional who treated me immediately. I also state that I read and write in English.

Patient Name: \_\_\_\_\_ Signature of Patient or Legal Guardian: \_\_\_\_\_ Date: \_\_\_\_\_