

Patient: _____ Date of Birth: _____

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® and Dysport®) 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 facial pain. Treatment with botulinum toxin can cause your facial expression lines or wrinkles to be less noticeable or essentially disappear. Areas most frequently treated are:

- Frown lines, located between the eyes
- Crow's feet
- Forehead wrinkles
- Smoker's lines
- Head and neck muscles

Botox® is diluted to a very controlled solution and when injected into the muscles with a very thin needle, it is almost painless. Patients may feel a slight burning sensation while the solution is being injected. The procedure takes about 15-20 minutes and the results can last up to 3-4 months. With repeated treatments, the results may tend to last longer.

Initial: _____

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. There have been no long-term adverse effects or health hazards related to the use of botulinum toxin thus far. Muscle biopsy specimens have failed to show any evidence of permanent degeneration or atrophy. There are, however, several well known side effects that are temporary. These include the following:

- **Bruising** - Usually at or near the injection site, may be increased with the use of anti-inflammatories, aspirin or aspirin-like products including Vitamin E. This effect generally clears up within 7-10 days. No treatment is necessary.
- **Headache** - Related to the actual injections, is usually mild and transient lasting less than 24 hours. May be relieved with acetaminophen (Tylenol).

- **Pain at the injection site** - Similar to headache above, is usually mild, transient and relieved with acetaminophen.
- **Asymmetry** - May be noticed within first two weeks of therapy when product has not taken full effect. Optimal results are not seen for at least 2 weeks. Any unevenness may be corrected with “touch-up” injections if necessary.
- **Numbness** - Actually a change in sensation noticed by some Botox®/Dysport® patients in the treated areas. Better described as “dullness”, it is usually only noticed for a few days after treatment. Treatment is not necessary.
- **eyebrow or eyelid ptosis(drooping) and double-vision (diplopia)** - Seen in 1-2 % of patients receiving Botox®/Dysport® therapy. It is temporary, lasting 2-4 weeks and is usually mild. May be treated with special eye drops.

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. double vision, 3. a weakened tear duct, 4. post treatment bacterial, and/ or fungal infection requiring further treatment, 5. allergic reaction, 6. minor temporary droop of eyelid(s) in approximately 2% of injections, this usually lasts 2-3 weeks, 7. occasional numbness of the forehead lasting up to 2-3 weeks, 8. transient headache and 9. flu-like symptoms may occur.

Initial: _____

Pregnancy, Allergies & Neurologic Disease

I am not aware that I am pregnant. 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: Myasthenia 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.

Initial: _____

Alternative Procedures

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

Initial: _____

Photographs

I am aware clinical photographs may be taken and used for scientific purposes in publications, presentations and social media. I understand my identity will be protected.

Initial: _____

Payment

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

Initial: _____

Right to Discontinue Treatment

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

Initial: _____

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. The weakening effect gradually begins over 2-7 days and is not complete for two weeks. The results usually lasts up to 3-4 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 should not apply force to the treatment area nor should it be rubbed vigorously or massaged. I understand that I must stay in the erect posture and that I must not manipulate the area(s) of the injections for 4 hours post-injection period.

Initial: _____

I understand this is an elective procedure and I hereby voluntarily consent to treatment with botulinum toxin injections for facial dynamic wrinkles, TMJ dysfunction, bruxism and types of orofacial pain including headaches and migraines. 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.

Patient Name (print): _____ Patient Signature: _____ Date: _____

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.

Provider Name (print): _____ Provider Signature: _____ Date: _____