KC MAASUMI MD, MS
Headache, Migraine & Spine Care

INFORMED CONSENT FOR BOTULINUM TOXIN TREATMENT

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 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. Treatment with botulinum toxin can cause your facial expression lines or wrinkles to be less noticeable or essentially disappear. Areas most frequently treated are: a) glabellar area of frown lines, located between the eyes; b) crow's feet (lateral areas of the eyes); c) forehead wrinkles; d) radial lip lines (smoker's lines), e) 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 are variable but can last up to 3 months. With repeated treatments, the results may tend to last longer.

BOTOX INJECTION FOR CHRONIC MIGRAINE

Botulinum toxin has been approved by the Federal Drug Administration for treatment of chronic migraine. Botulinum toxin does not cure chronic migraine and it may not be effective in some patients. Botox administration is completed by injecting 5 units of the onabotulinumtoxin A into the muscles of the head neck. The benefits resulting from this procedure tends to wear off approximately 3 months where a repeated injection every three months is necessary to maintain the same results. Injections can be done every 12 weeks for the maximal effect. Generally the effect is achieved by the third week.

Common side effects of Botox injections used for chronic migraine may include:

- Temporary and usually mild facial weakness with facial injections
- Temporary and usually mild head or neck weakness with head or neck injections
- Reduction or loss of forehead facial animation due to forehead muscle weakness
- Eyelid droopiness or ptosis
- Temporary pain at the site of injection or ecchymoses at the site of injection
- Temporary dry eye
- Temporary double vision
- It is rare but possible that any injection may lead to infection or allergic reaction.
- Further reduced effectiveness after repeated injection is sometimes seen

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. 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.

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 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.

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

RIGHT TO DISCONTINUE TREATMENT
I understand that I have the right to discontinue treatment at any time.

I hereby indemnify the location/house/facility/meeting room/hotel where this treatment is being performed from any liability relating to the procedures that I have volunteered for.

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 2 – 10 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 re- treatment 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 2 hours post-injection period.

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. I also state that I read and write in English.

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Patient Name (Print) Patient Signature Date

I am the treating doctor/healthcare professional. I discussed the above risks, benefits, and alternatives with the patient. The patient had an opportunity to have all questions answered and was offered a copy of this informed consent. The patient has been told to contact my office should they have any questions or concerns after this treatment procedure.

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Doctor Name (Print) Doctor Signature Date