

## **BOTULINUM TOXIN TYPE A (NEUROMODULATOR) INFORMED CONSENT**

I, \_\_\_\_\_, understand that I will be injected with an FDA-approved neuromodulator, Botulinum Toxin Type A (Botox Cosmetic [onabotulinumtoxinA], Xeomin [incobotulinumtoxinA], Dysport [abobotulinumtoxinA], or Jeuveau [prabotulinumtoxinA-xvfs]), in the area of the glabellar muscles, the frontalis (forehead muscles), lateral canthal lines (crow's feet), or other muscles to paralyze these muscles temporarily. Botulinum Toxin may also decrease perspiration.

Botulinum Toxin Type A is a protein produced by the bacterium *Clostridium Botulinum*. For the purpose of improving the appearance of wrinkles, small doses of the diluted toxin are injected into the affected muscles, blocking the release of a chemical that would otherwise signal the muscle to contract. The toxin thus paralyzes or weakens the injected muscle. The treatment usually begins to work within 24 to 48 hours (although in some areas it may take up to two weeks) and can last up to four months, although results vary. The FDA recommends re-injection no sooner than every 3 months. It is not known whether Botulinum Toxin A can cause fetal harm when administered to pregnant women or can affect reproductive capabilities. It is also not known if Botulinum Toxin A is excreted in human milk. For these reasons, **Botulinum Toxin A should not be used on pregnant or lactating women.**

Botox (onabotulinumtoxinA) injection has been FDA approved for use in the cosmetic treatment for glabellar frown lines, forehead lines, and lateral canthal lines (crow's feet). Xeomin (incobotulinumtoxinA), Dysport (abobotulinumtoxinA), and Jeuveau (prabotulinumtoxinA-xvfs) injections have been FDA approved for use in the cosmetic treatment for glabellar frown lines only. Any other cosmetic uses are considered off-label.

I authorize and direct Dr. Sarah McMillan and Dr. Daniel Liebertz, with associates and assistants of his or her choice, to perform the procedure of Botulinum Toxin Type A injection(s) on me.

The details of the procedure have been explained to me in terms I understand. Alternative methods and their benefits and disadvantages have been explained to me.

- I understand and accept the most likely risks and complications of Botulinum Toxin Type A injection(s) include but are not limited to:
  - Paralysis of nearby muscles that could interfere with opening of the eye(s)
  - Local numbness
  - Headache, nausea, or flu-like symptoms
  - Swallowing, speech, or respiratory disorders
  - Swelling, bruising, or redness at the injections site
  - Product ineffectiveness
  - Disorientation, double vision, or past pointing
  - Temporary asymmetrical appearance
  - Abnormal or lack of facial expressions
  - Inability to smile or asymmetric smile when injected into the lower face
  - Facial pain
- I understand and accept that the long-term effects of repeated use of Botulinum Toxin Type A are as yet unknown. Possible risks and complications that have been identified include, but are not limited to:
  - Muscle atrophy
  - Nerve irritability
  - Production of antibodies with unknown effect to general health

- I understand and accept the less common complications, including the remote risk of death or serious disability, that exists with this procedure.
- I am aware that smoking during the pre- and post-operative periods could increase chances of complications.
- I have informed the physician of all of my known allergies
- I have informed the physician of all medications I am currently taking, including prescriptions, over-the-counter remedies, herbal therapies, and all others.
- I have been advised whether I should take any or all of these medications on the days surrounding the procedure.
- I am aware and accept that no guarantees about the results of the procedure have been made or implied
- I have been informed of what to expect post-treatment, including but not limited to: estimated recovery time, anticipated activity level, and the necessity of additional procedures if I wish to maintain the appearance this procedure provides me.
- I am not currently pregnant or nursing, and I understand that should I become pregnant while using this drug there are potential risks, including fetal malformation.
- If pre- and post-operative photos and/or videos are taken of the treatment for record purposes, I understand that these will be the property of the attending physician.
- I understand that these photos may only be used for scientific or record-keeping purposes.
- The physician has answered all of my questions regarding this procedure
- I have been advised to seek immediate medical attention if swallowing, speech, or respiratory disorders arise.

Additionally,

**The number of units injected is an estimate of the amount of neuromodulator required to paralyze the muscles. I understand there is no guarantee of results of any treatment. I understand the regular charge applies to all subsequent treatments.**

I understand and agree that all services rendered to me are charged directly to me and that I am personally responsible for payment. I further agree in the event of non-payment, to bear the cost of collection, and/or Court cost and reasonable legal fees, should this be required.

By signing below, I acknowledge that I have read the foregoing informed consent and agree to the treatment with its associated risks. I hereby give consent to perform this and all subsequent neuromodulator treatments with the above understood. I hereby release the doctor, the person injecting the neuromodulator and the facility from liability associated with this procedure.

*Patient Signature* \_\_\_\_\_ *Date:* \_\_\_\_\_