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INFORMED CONSENT BOTOX INJECTION (*Botulina* Toxin Type A)

Clostridia botulina bacteria produce a class of chemical compounds known as "toxins". The Botulina Type A Toxin (BOTOX) is processed and purified to produce a sterile product suitable for specific therapeutic uses. Once the 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 months.

BOTOX Cosmetic has been used to treat certain conditions involving crossed eyes (strabismus), eyelid spasm (blepharospasm), and motor disorders of the facial nerve (VII cranial nerve). It has been used in other "off-label" uses for the treatment of facial wrinkles and neck bands caused by specific muscle groups. Certain spastic muscle disorders with the neck and colorectal area have been treated with this agent.

BOTOX Cosmetic injections are customized for every patient, depending on his or her particular needs. These can be performed in areas involving eyelid region, forehead and neck. BOTOX Cosmetic cannot stop the process of aging. It can however, temporarily diminish the look of wrinkles caused by muscle groups. BOTOX Cosmetic injections may be performed as a singular procedure or as an adjunct to a surgical procedure.

- 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 a 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-peels, lasers, injection of filling material or other skin treatments. Risks and potential complications are associated with alternative forms of medical or surgical treatment.
- Every procedure involves a certain amount of risk, and it is important that you understand the risks involved. An individual's choice to undergo this procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not experience the following complications, you should discuss each of them with Dr. McHugh to make sure that you understand the risks, potential complications and consequences of BOTOX Cosmetic injections.
- It is possible, though unusual, to have a bleeding episode from a BOTOX Cosmetic injection. Bruising in soft tissues may occur. Should you develop post-injection bleeding, it may require emergency treatment or surgery. Do not take aspirin or anti-inflammatory medications for seven days before BOTOX Cosmetic injections, as it may contribute to greater risk of a bleeding problem.
- 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.
- Some patients experience difficulties closing their eyelids after BOTOX Cosmetic 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.

- BOTOX Cosmetic may migrate from its original injection site to other areas and produce temporary paralysis of other muscle groups or other unintended areas.
- Muscles that raise the eyelid may be affected by BOTOX Cosmetic, should this material migrate downward from other injection areas.
- Double-vision may be produced if the BOTOX Cosmetic material migrates into the region of muscles that control movements of the eyeball.
- Abnormal looseness of the lower eyelid can occur following BOTOX Cosmetic injection.
- Functional and irritative disorders of eye structures may rarely occur following BOTOX Cosmetic injections.
- 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 Cosmetic injection.
- Skin rash and swelling may rarely occur following BOTOX Cosmetic injections.
- The long term effect of BOTOX Cosmetic on tissue is unknown.
- There is the possibility of a poor or inadequate response from BOTOX Cosmetic injection. Additional BOTOX Cosmetic injections may be necessary. Surgical procedures or treatments may be needed to improve skin wrinkles, including those caused by muscle activity.
- As with all biologic products, allergic and systemic anaphylactic reactions may occur. Allergic reactions require additional treatment.
- Infection is extremely rare after BOTOX Cosmetic injections. Should an infection occur, additional treatment including antibiotics may be necessary.
- Animal reproduction studies have not been performed to determine if BOTOX Cosmetic could produce fetal harm. It is not known if BOTOX Cosmetic can be excreted in human milk.
- The effect of BOTOX Cosmetic may be potentiated by aminoglycoside antibiotics or other drugs known to interfere with neuromuscular transmission.

The cost of BOTOX Cosmetic injection may involve several charges. This includes the professional fee for the injections, follow-up visits to monitor the effectiveness of the treatment and the cost of the BOTOX Cosmetic material itself. BOTOX Cosmetic injections to treat cosmetic problems are not covered by health insurance. Additional costs of medical treatment would be your responsibility should complications develop from BOTOX Cosmetic injections.

Informed consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with the disclosure of risks and alternative forms of 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.

However, informed consent documents should not be considered all-inclusive in defining other methods of care and risks encountered. Dr. McHugh may provide you with additional or different information which is based on all of the facts pertaining to your particular case and the 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 of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

It is important that you read the above information carefully and have all of your questions answered before signing the consent on the next page.

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CONSENT FOR SURGERY/PROCEDURE or TREATMENT

1. I hereby authorize Thomas P. McHugh, MD to perform the following procedure or treatment:

BOTOX INJECTION

I have received the following information sheet:

INFORMED CONSENT for BOTOX Injection

2. I recognize that during the course of the operation and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician to perform such procedures that are in the exercise of his professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure has begun.
3. 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.
4. I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.
5. I consent to the photography or televising of the operation(s) or procedure(s) to be performed, including appropriate portions of my body for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.
6. For purposes of advancing medical education, I consent to the admittance of observers in the treatment room.
7. IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:
 - THE ABOVE TREATMENT OR PROCEDURE TO BE UNDERTAKEN
 - THERE MAY BE ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT
 - THERE ARE RISKS TO THE PROCEDURE OR TREATMENT PROPOSED

I CONSENT TO THE TREATMENT OR PROCEDURE LISTED AND AM SATISFIED WITH THE EXPLANATION.

Signature of Patient or Person Authorized to Sign

Date