GULF COAST PLASTIC SURGERY *Gregory P. Pisarski, MD*

*186 Abner Jackson Parkway ● Lake Jackson, TX 77566 ● (979)297-9289 ● **FAX(979)299-1007***

BOTULINUM TOXIN TYPE A (Dysport)

Consent form

Name:_____ **Date:** _____

INTRODUCTION

This is an informed consent document, which has been prepared to help inform you about Dysport is made from the Botulinum Toxin Type A, a protein produced by the bacteria Clostridium botulinum. For the purpose of improving the appearance of wrinkles, small doses of the 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 5 to 7 days, and can last up to 3 to 4 months. The Food and Drug Administration (FDA) approved the cosmetic use of Botulinum Toxin Type A for the temporary relief of moderate to severe frown lines between the brow and recommends that the procedure be performed no more frequently than once every 3 months.

It is not known whether Botulinum A toxin can cause fetal harm when administered to pregnant women or can affect reproduction capabilities. It is also not known if Botulinum A toxin is excreted in human milk. For these reasons, Botulinum A toxin should not be used on pregnant or lactating women for cosmetic purposes.

DISCLAIMER

Informed consent documents are used to communicate information about the proposed treatment of a disease or condition along with disclosure of risk and alternative forms of treatment. 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 risk encountered. Your physician may provide you with additional or different information that is based on all the facts in your particular case and the state of medical knowledge at the time.

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 changes 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 statement.

Patient's Initials

_____ 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 that the FDA has only approved the cosmetic use of Botulinum A Toxin for frown lines between the brow. Any other cosmetic use is considered "off label".

_____ I understand and accept the most likely risks and complications of Botulinum A Toxin injection(s) that include but are not limited to:

- Paralysis of a nearby muscle, which could interfere with opening the eye(s)
- Local numbness
- Headache, nausea and/or flu-like symptoms
- Abnormal and/or lack of facial expression
- Facial pain
- Swelling, bruising, and/or redness at injection sight
- Disorientation, double vision, and/or past pointing
- Temporary asymmetrical appearance
- Swallowing, speech and/or respiratory disorders
- Inability to smile when injected in the lower face
- Product ineffective

Possible risks and complications that have been identified include but are not limited to:

- muscle atrophy
- nerve irritability to general health
- production of antibodies with unknown effect

_____ I understand and accept that the long-term effects of repeated use of Botox/Dysport are as yet unknown.

_____ 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 postoperative periods could increase chances of complications.

_____ I have informed the doctor of all my known allergies.

_____ I have informed the doctor of all medications I am currently taking, including prescriptions, over-the-counter remedies, herbal therapies, and any other.

_____ I have been advised whether I should take any/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.

_____ The doctor 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.

CONSENT STATEMENT:

I authorize and direct Dr. Gregory Pisarski to perform the following procedure of Botulinum A Toxin injection(s) on _____ for the treatment of dynamic wrinkles.

(patient name)

I understand the potential risk as well as the benefits of Botox/Dysport. I acknowledge that no guarantee has been given by anyone as to the results that may be obtained. If pre/post-operative photos are taken of the treatment for record purposes, I understand that these photos will be the property of the attending physician.

I consent to the photographing of the procedure for medical, scientific or educational purposes provided the pictures do not reveal my identity. For purposes of education, I consent to the admittance of observers during the procedure. I understand: the treatment that will be provided to me and the alternative procedures or methods of treatment. I have also been given specific follow-up instructions and will comply with these.

I certify that I have read and understand this treatment agreement and that all blanks were filled in prior to my signature.

_____	_____	_____
Signature - Patient	Print Name	Date
_____	_____	_____
Signature - Witness	Print Name/Title	Date

I certify that I have explained the nature, purpose, benefits, risks, complications, and alternatives to the proposed procedure to the patient. I have answered all questions fully, and I believe that the patient fully understands what I have explained.

_____	Gregory P. Pisarski, MD	_____
Signature – Physician	Print Name/Title	Date