Affix Patient Label

Name______________________ Date of Birth__________

Informed Consent:

BOTOX ® THERAPY

This information is given to you so that you can make an informed decision about having **Botox® Therapy**.

Reason and Purpose of the Procedure: (Within A Neurology Practice) :

- Prevention of headache in adult patients with chronic migraine
- Treatment of upper limb spasticity in adult patients
- Treatment of cervical dystonia in adult patients to reduce the severity of abnormal head position and neck pain
- Treatment of blepharospasm associated with dystonia in patients greater than 12 years of age

The Medication:

Botox® is a purified toxin produced by the bacterium clostridium botulinum that is injected into specific muscles causing weakness of that muscle. This is not a permanent treatment and repeat injections are given no more frequently than every 3 months.

Side Effects:

No procedure is completely free from side effects. Some side effects are well known. There may be side effects not included in the list that your doctor cannot expect.

Possible Side Effects

- Bruising or swelling: May be eased by applying ice.
- Infection of the injection site: You may need antibiotics.
- Pain: May be treated with over the counter options such as Motrin or Tylenol.
- Flu like symptoms: May be treated with over the counter options such as Motrin or Tylenol.

Other Side Effects – Depends on Location of Injection

- Injections around the eye may cause double vision, dry eye, reduced blinking or drooping eye lids that may persist for a few weeks.
- The toxin could spread to neighboring muscles. As a result, injections in the lower face and neck may cause temporary dry mouth and trouble speaking or chewing. These will subside and require no intervention. If trouble swallowing or breathing occur, seek emergency medical attention.

Possible Allergic Reaction Mild symptoms may be treated with over the counter options such as Benadryl. Severe skin changes or breathing difficulty should result in seeking immediate medical attention.

- Itching
- Rash
- Welts
- Wheezing
- Asthma symptoms

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Who Should Not Get the Injection

- If you are pregnant or breastfeeding
- Have had a previous allergy to botulinum product
- Have a neuromuscular condition, such as ALS (Lou Gehrig's Disease) Myasthenia Gravis, or Lambert-Eaton Syndrome

Risks specific to you:

____

____

____

____

Alternative Treatments:

Other choices:

- Do nothing. You can decide not to have the procedure.
- Medication
- Your doctor can discuss other options with you.

If you choose not to have this treatment:

- You may continue to have frequent headaches, muscle pain or involuntary muscle movements.

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By signing this form I agree:

- I have read this form or had it explained to me in words I can understand.
- I understand its contents.
- I have had time to speak with the doctor. My questions have been answered.
- I want to have this procedure: **Botox® Therapy**
- ____.
- I understand that my doctor may ask a partner to do the procedure.
- I understand that other doctors, including medical residents, or other staff may help with procedure. The tasks will be based on their skill level. My doctor will supervise them.

Provider: This patient may require a type and screen or type and cross prior to the procedure. If so, please obtain consent for blood/products.

Patient Signature ____

Relationship ☐ Patient ☐ Closest relative (relationship) ☐ Guardian

For provider use only:
I have explained the nature, purpose, risks, benefits, possible consequences of non-treatment, alternative options and possibility of complications and side effects of the intended intervention. I have answered questions and patient has agreed to the Botox® Therapy

Provider Signature:__________________________________Date:________________Time:__________

Teach Back

Patient shows understanding by stating in his or her own words:

____ Reason(s) for the Botox® Therapy:____
____
____ Area(s) of the body that will be affected: ____
____ Benefit(s) of the Botox® Therapy____
____
____ Side effects of the Botox® Therapy:____
____ Alternative(s) to the Botox® Therapy: ____
____

or

____ Patient elects not to proceed: ______________________________________ (patient signature)

Validated/Witness:__________________________ Date:________________ Time:______________

1 Boxtox® Prescribing Information, November 2011

2 Aurora SK, Winner P, Freeman MC, et al. OnabotulinumtoxinA for treatment of chronic migraine: pooled analyses of the 56-week PREEMPT clinical program. Headache 2011; 51 (9): 1358-1373.