Holland Bloorview
Kids Rehabilitation Hospital

Client Name:_____

Health Record Number: _____

D.O.B.: _____

CONSENT TO TREATMENT WITH BOTOX ®
(Botulinum Toxin Type A) Injectable

Background and Purpose

Your physician has proposed a course of treatment with BOTOX® (Botulinum Toxin Type A) Injectable in the

_____ .

This treatment was suggested because of hypertonia (increased tone, spasms) in the arms or legs. Alternative treatments of physical therapy, medicine, casts, braces and surgery have been discussed.

BOTOX® contains a very small amount of albumin, a human blood product, which is approved for use by Health Canada.

Treatment Procedures

I understand that BOTOX® will be injected (placed with a needle) into one or more muscles. I understand that the injection treatment may be required every 3-6 months.

I know that Health Canada's labeling for BOTOX® use only reflects treatment for dynamic equinus (toe pointing) with recommended doses of 6 Units/kilogram to a maximum of 200 Units in a 3 month period. I am aware that my/my child's physician may recommend a higher dose to treat my child for hypertonia. I understand that the dose recommended by my/my child's physician has been calculated based on the best available scientific information, the child's weight and the number of muscles being injected.

I have been told that **side effects** may occur, such as:

- soreness, bleeding/bruising at the injection site (estimated in 0.8% or 8 per 1000 patients)
- temporary local weakness close to the injected muscle (estimated in 1%)
- temporary urinary incontinence (estimated in 1%)
- weakness in distal muscles that have not been injected indicating a more generalized spread of the toxin (symptoms can include drooping eyelids, slurred speech, difficulty swallowing, breathing difficulties, or generalized muscle weakness and can range in severity from very mild to severe) (estimate in 0.4% or 4 per1000)

I am aware that in a small number of cases, the use of BOTOX® can lead to difficulty swallowing, talking or breathing, and in very rare cases, the use of BOTOX® has been associated with hospitalizations and death. I have been given information about the signs and symptoms of an adverse reaction to the BOTOX® that can appear as early as one day and as late as several weeks after treatment. I know that I should bring my child to receive immediate medical attention if these signs or symptoms appear in my child. I am aware that the use of BOTOX® has been associated with seizures although it is unclear that BOTOX® is the cause of these seizures. I am aware that BOTOX® causes some weakness in the muscle that is injected and this weakness can take up to 2 years to resolve. Although BOTOX® has been used for over 15 years in children some of the long-term effects of BOTOX® on muscle may still be unknown.

I have been provided with adequate verbal/written information about BOTOX®, given the opportunity to ask questions and give my consent to this treatment.

_____

Signature of Client/Substitute Decider Print Name Relationship

_____

Signature of Witness Date

CON TREAT BOTOX