San Mateo Spine Center
101 S. SAN MATEO DR., SUITE 301*SAN MATEO, CA 94401*TEL 650-558-1802* FAX 650-558-1806

BOTOX CONSENT

Patient Name **Date:**

WARNINGS AND PRECAUTIONS

Lack of Interchangeability between Botulinum Toxin Products

The potency Units of BOTOX® Cosmetic are specific to the preparation and assay method utilized. They are not interchangeable with other preparations of botulinum toxin products and, therefore, units of biological activity of BOTOX® Cosmetic cannot be compared to nor converted into units of any other botulinum toxin products assessed with any other specific assay method.

Please see additional important Safety information on back cover.

BOTOX® Cosmetic (onabotulinumtoxinA) IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Spread of Toxin Effect
Please refer to Boxed Warning for Distant Spread of Toxin Effect.

No definitive serious adverse event reports of distant spread of toxin effect associated with dermatologic use of BOTOX® Cosmetic at the labeled dose of 20 Units (for glabellar lines), 24 Units (for lateral canthal lines), 40 Units (for forehead lines with glabellar lines), 44 Units (for simultaneous treatment of lateral canthal lines and glabellar lines), and 64 Units (for simultaneous treatment of lateral canthal lines, glabellar lines, and forehead lines) have been reported.

Serious Adverse Reactions With Unapproved Use
Serious adverse reactions, including excessive weakness, dysphagia, and aspiration pneumonia, with some adverse reactions associated with fatal outcomes, have been reported in patients who received BOTOX® injections for unapproved uses. In these cases, the adverse reactions were not necessarily related to distant spread of toxin, but may have resulted from the administration of BOTOX® to the site of injection and/or adjacent structures. In several of the cases, patients had pre-existing dysphagia or other significant disabilities. There is insufficient information to identify factors associated with an increased risk for adverse reactions associated with the unapproved uses of BOTOX®. The safety and effectiveness of BOTOX® for unapproved uses have not been established.

Hypersensitivity Reactions
Serious and/or immediate hypersensitivity reactions have been reported. These reactions include anaphylaxis, serum sickness, urticaria, soft-tissue edema, and dyspnea. If such reactions occur, further injection of BOTOX® Cosmetic should be discontinued and appropriate medical therapy immediately instituted. One fatal case of anaphylaxis has been reported in which lidocaine was used as the diluent and, consequently, the causal agent cannot be reliably determined.

Cardiovascular System
There have been reports following administration of BOTOX® of adverse events involving the cardiovascular system, including arrhythmia and myocardial infarction, some with fatal outcomes. Some of these patients had risk factors including pre-existing cardiovascular disease. Use caution when administering to patients with pre-existing cardiovascular disease.

Increased Risk of Clinically Significant Effects with Pre-existing Neuromuscular Disorders
Individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis, or neuromuscular junction disorders (eg, myasthenia gravis or Lambert-Eaton syndrome) should be monitored when given botulinum toxin. Patients with neuromuscular disorders may be at increased risk of clinically significant effects including generalized muscle weakness, diplopia, ptosis, dysphonia, dysarthria, severe dysphagia, and respiratory compromise from onabotulinumtoxinA (see *Warnings and Precautions*).

Dysphagia and Breathing Difficulties
Treatment with BOTOX® and other botulinum toxin products can result in swallowing or breathing difficulties. Patients with pre-existing swallowing or breathing difficulties may be more susceptible to these complications. In most cases, this is a consequence of weakening of muscles in the area of injection that are involved in breathing or oropharyngeal muscles that control swallowing or breathing (see *Boxed Warning*).

Pre-existing Conditions at the Injection Site
Caution should be used when BOTOX® Cosmetic treatment is used in the presence of inflammation at the proposed injection site(s) or when excessive weakness or atrophy is present in the target muscle(s).

Human Albumin and Transmission of Viral Diseases
This product contains albumin, a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases and variant Creutzfeldt-Jakob disease (vCJD). There is a theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD), but if that risk actually exists, the risk of transmission would also be considered extremely remote. No cases of transmission of viral diseases, CJD or vCJD have ever been identified for licensed albumin or albumin contained in other licensed products.

ADVERSE REACTIONS
The most frequently reported adverse reaction following injection of BOTOX® Cosmetic for glabellar lines was eyelid ptosis (3%).

The most frequently reported adverse reaction following injection of BOTOX® Cosmetic for lateral canthal lines was eyelid edema (1%).

The most frequently reported adverse reactions following injection of BOTOX® Cosmetic for forehead lines with glabellar lines were headache (9%), brow ptosis (2%) and eyelid ptosis (2%).

DRUG INTERACTIONS
Co-administration of BOTOX® Cosmetic and aminoglycosides or other agents interfering with neuromuscular transmission (eg, curare-like compounds) should only be performed with caution as the effect of the toxin may be potentiated. Use of anticholinergic drugs after administration of BOTOX® Cosmetic may potentiate systemic anticholinergic effects.

The effect of administering different botulinum neurotoxin products at the same time or within several months of each other is unknown.

Excessive neuromuscular weakness may be exacerbated by administration of another botulinum toxin prior to the resolution of the effects of a previously administered botulinum toxin.

USE IN SPECIFIC POPULATIONS
There are no studies or adequate data from postmarketing surveillance on the developmental risk associated with use of BOTOX® Cosmetic in pregnant women. There are no data on the presence of BOTOX® Cosmetic in human or animal milk, the effects on the breastfed child, or the effects on milk production.

Please see BOTOX® Cosmetic Full Prescribing Information including Boxed Warning and Medication Guide.

References:
1. BOTOX® Cosmetic Prescribing Information, October 2017. 2. Solish N, Rivers JK, Humphrey S et al. Efficacy and Safety of OnabotulinumtoxinA Treatment of Forehead Lines: A Multicenter, Randomized, Dose-Ranging Controlled Trial. *Dermatol Surg*. 2016; 42(2):410–419. 3. Data on file, Allergan, Inc.: Clinical Study Report 191622-098 Amendment 5; April 4, 2012.

Patient name_____: I understand risks/ benefits of Botox. I read above Botox warning and precautions information from Botox website. I accept the risks and warning above and am willing to proceed with discussed Botox treatment. I know all my treatment options and elects to proceed with Botox treatment.

Patient signature:___ _____Date:___ _____

Page 2.

INFORMED CONSENT – NEUROLYTIC INJECTIONS Botox®, Dysport®, Myobloc®

INSTRUCTIONS This is an informed-consent document which has been prepared to help us inform you concerning our neurolytic agent injection, its risks, and alternative treatments. We require that you read this information carefully and completely before signing the consent for this procedure as proposed by our clinic.

GENERAL INFORMATION Clostridia botulina bacteria produce a class of chemical compounds known as "toxins". The Botulina Type A or B Toxin is processed and purified to produce a sterile product suitable for specific therapeutic uses. Once the diluted 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 to four months. Neurolytic agents have been approved to treat certain conditions involving crossed eyes (strabismus), eyelid spasm (blepharospasm), cervical dystonia (spastic muscle disorder with the neck) and motor disorders of the facial nerve (VII cranial nerve). As of April 2002, it has been FDA-approved for the cosmetic treatment of forehead wrinkles caused by specific muscle groups. Other areas of the face and body such as crows feet wrinkles and neck bands may be treated in an "off-label" fashion. Neurolytic agents have also been used to treat migraine headaches, colorectal disorders, excessive perspiration disorders of the armpit and hands, and musculoskeletal pain disorders. Neurolytic injections are customized for every patient, depending on his or her particular needs. These can be performed in areas involving the eyelid region, forehead, and neck. Neurolytic agents cannot stop the process of aging. It can however, temporarily diminish the look of wrinkles caused by muscle groups. neurolytic injections may be performed as a singular procedure or as an adjunct to a surgical procedure.

ALTERNATIVE TREATMENTS 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 skin peels, lasers, injection of filling material, or other skin treatments. Risks and potential complications are associated with alternative forms of medical or surgical treatment.

RISKS of Neurolytic Injections Every procedure involves a certain amount of risk and it is important that you understand these risks and the possible complications associated with them. In addition, every procedure has limitations. An individual's choice to undergo a surgical procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not experience these complications, you should discuss each of them with your plastic surgeon to make sure you understand risks, potential complications, limitations, and consequences of neurolytic injections. Additional information concerning neurolytic injection may be obtained from the package-insert sheets supplied by the corresponding companies.

Bleeding and Bruising- It is possible, though unusual, to have a bleeding episode from a neurolytic injection. Bruising in soft tissues may occur. Serious bleeding around the eyeball during deeper neurolytic injections for crossed eyes (strabismus) has occurred. Should you develop post-injection bleeding, it may require emergency treatment or surgery. Aspirin, anti-inflammatory medications, platelet inhibitors, anticoagulants, Vitamin E, ginkgo biloba, and other "herbs / homeopathic remedies" may contribute to a greater risk of a bleeding problem. Do not take these for ten days before or after neurolytic injections.

Damage to Deeper Structures- 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.

OTHER SIDE EFFECTS: Botox (onabotulinumtoxinA) is an injectable neuro-toxin used for the treatment of chronic migraines, limb spasticity, axillary hyperhidrosis, cervical dystonia, strabismus, spine pain, and blepharospasm. Side effects of Botox include allergic reactions, rash, itching, headache, neck or back pain, muscle stiffness, difficulty swallowing, shortness of breath, nausea, diarrhea, stomach pain, loss of appetite, weakness, injection site reactions (muscle weakness, bruising, bleeding, pain, redness, or swelling), fever, cough, sore throat, runny nose, flu symptoms, dizziness, drowsiness, dry mouth, ringing in your ears, and increased sweating in areas other than the underarms. Drooping of the eyelid (ptosis), inflammation of the cornea (keratitis), eye dryness, itchy eyes, double vision, tearing, and sensitivity to light, and eyelid swelling or bruising may occur when used for treating blepharospasm.

Botox is administered by injection and dosing depends on the condition that it is used for. Administration of botulinum toxin with other agents (for example, aminoglycosides, curare) that affect neuromuscular function may increase the effect of botulinum toxin. There are no adequate studies of Botox in pregnant women and it has not been evaluated in nursing mothers.

The botulinum toxin contained in Botox can spread to other body areas beyond where it was injected. This has caused serious life-threatening side effects in some people receiving botulism toxin injections, even for Migraine headache, spine pain, or cosmetic purposes.

Some of serious side effects can occur up to several weeks after an injection:

- trouble breathing, talking, or swallowing;
- hoarse voice, drooping eyelids;
- unusual or severe muscle weakness (especially in a body area that was not injected with the medication);
- loss of bladder control;
- problems with vision;
- crusting or drainage from your eyes;
- severe skin rash or itching;
- fast, slow, or uneven heartbeats; or
- chest pain or heavy feeling, pain spreading to the arm or shoulder, general ill feeling.

Less serious side effects may include:

- muscle weakness near where the medicine was injected;
- bruising, bleeding, pain, redness, or swelling where the injection was given;
- headache, muscle stiffness, neck or back pain;
- fever, cough, sore throat, runny nose, flu symptoms,
- dizziness, drowsiness, tired feeling;
- nausea, diarrhea, stomach pain, loss of appetite;
- dry mouth, dry eyes, ringing in your ears;
- increased sweating in areas other than the underarms;
- itchy or watery eyes, increased sensitivity to light; or
- eyelid swelling or bruising.

CREDIT AGREEMENT

Although your insurance may pay for this service, your insurance frequently only pays a portion of the charges. Therefore, each patient or responsible party must understand these credit terms. Proceeds from your insurance will be promptly credited to your account. Any remaining balance must be paid within 30 days.

Medicare Patient's Release of Information: I certify that the information given by me in applying for payment under Title XVIII of the Social Security Act is correct. I authorize release of any information needed to act on this request. I request that payment of authorized benefits be made in my behalf. I understand that I am responsible for any remaining balance not covered by my insurance(s).

Release of Information: I authorize the release of any medical information necessary to process this claim with my insurance carrier. I hereby certify that the information is true and correct. I understand that I am financially responsible for the unpaid balance of all accounts in the event that the authorization is insufficient to liquidate my account. In understand that the financial information herein supplied to me may be provided to a consumer credit bureau and/or to other health care providers involved in the performance of patient care. I understand that should by account be sent to collections or require litigation to liquidate, I will be responsible for any and all costs or fees incurred, including reasonable attorney fees. Assignment of Benefits: The undersigned assigns and hereby authorizes direct payment to the San Mateo Spine Center all insurance and plan benefits otherwise payable to or on behalf of the patient for services rendered. It is understood that I am financially responsible for charges not covered by this assignment.

XRAY services: Vista Imaging Services, Inc. will be providing XRAY services during the procedure. You may see separate charges or fees on your insurance statement related to your procedure from Vista Imaging Services, Inc. Please call 858/622-0792 for any XRAY-related billing questions. Address: 5288 Eastgate Mall, San Diego, CA 92121

California state law guarantees that you have both the right and obligation to make decisions concerning your health care. Your physician can provide you with the necessary information and advice, but you must enter into the decision making process. This form has been designed to acknowledge your acceptance of treatment recommended by Dr. Chen. I was given enough time to read the consent form and I was allowed to ask all questions about the risks of the proposed procedure. I understand side effects of steroid. I have read and understand all of the above. I agreed with the proposed injection procedure. By signing below, I agree to comply with all of the pre- and post-procedure requirements. Furthermore, I acknowledge that I have discuss with the doctor, sought other opinions, understand, and accept the risks from this procedure and accept the side effects of steroid. By signing below, I do not hesitate to relieve the doctor and his staff from exercising due care on my behalf.

Patient's Printed Name: _____ Patient's Signature: _____ Date: _____

Witness' Signature: _____ Physician's Signature: _____ Date: _____

Guardian/Translator Printed Name: _____ Guardian/Translator Signature: _____ Date: _____

Medication(s) Allergies: _____ Pharmacy: _____

SAN MATEO SPINE CENTER
-101 S. SAN MATEO DR. SUITE 301, SAN MATEO, CA 94401, TEL: 650-558-1802, FAX: 650-558-1808-

PRE-PROCEDURE INSTRUCTIONS

- **STOP** taking **Aspirin, Aspiring-containing products, Anti-Inflammatories, or Blood-thinners** for **5-7 days** prior to the procedure. These may include, but are not limited to: **Ibuprofen, Advil, Motrin, Aleve, Naprosyn, Daypro, Relafen, Voltaren, Coumadin, Warfarin, Plavix, Heparin, etc**. Call your pharmacist if you are in doubt of what your current medications may contain. Before stopping any blood-thinners, make sure to get your prescribing doctor's written clearance fax to our office, stating that you may be off your blood-thinners for the duration. If you neglect to follow these instructions, you will be required to do a Bleeding Time Test on the day prior to your procedure. You may be required to do PT/PTT/INR Tests.
- **DO NOT STOP** taking your **heart, blood pressure, or lung medications**. Bring your asthma inhalers with you. **You may take Tylenol for pain control.**
- If you are **diabetic or hypoglycemic**, your appointment should be scheduled **before 10:00AM**. Do not take your diabetes medications on the day of your appointment. However, do NOT forget to bring them with you. You will be asked to take your medications after your procedure is performed.
- **Inform Dr. Chen** if you are taking **antibiotics**, had **recent surgery**, have an **infection**, experiencing **chest pain**, or getting a **cold or flu**.
- You must **begin fasting and not consume alcoholic beverages at 12 midnight** the day of the procedure. Sips of water may be taken with medications.
- **Shower before procedure** using any skin cleansers. If undergoing a cervical procedure, men should be clean-shaven from chin to neck.
- **Dress casually. Wear socks. Please wear undergarments. Do not wear any jewelry.**
- You **MUST HAVE A DRIVER ALL THE TIME** accompanying you on the day of the injection except during the actual procedure. A cab driver is not considered a companion. Please park in the underground **parking at Mills Square Hillsborough Plaza**, entrance located on Ellsworth Street.
- Please **bring your most recent MRI, XRAY, and CT films** to the appointment. This is your responsibility.
- Please **read consent below and fill out the paperwork completely and bring it** with you to your appointment.

WHAT TO EXPECT ON THE DAY OF THE PROCEDURE

- Following check-in, you will be taken to a preparation room. Your designated driver may accompany you to this room. However, the driver will not be viewing the procedure.
- You will be asked to change, depending on the necessity and your procedure, to a pair of shorts and/or a half gown. You may choose to provide your own attire as appropriate.
- The staff member will then take your blood pressure and a brief history of your current region of concern. The staff member will mark the location that will be undergoing the procedure for verification purposes.
- You will have the opportunity to speak with Dr. Chen to review XRAY, MRI, CT, or other related lab results and voice any final concerns or questions before the procedure.
- The staff member will then escort you to the procedure room where you will be asked to lay flat on your stomach in most cases.
- The staff member will assist in the positioning and sterilization procedure before Dr. Chen performs the procedure.
- You will feel a cold spray as the region undergoing the procedure is locally anesthetized.
- Dr. Chen will guide the needle placement using live XRAY equipment.
- Dr. Chen will subsequently proceed with the procedure, which will be approximately 5 minutes in duration.
- Following the procedure, the staff member will assist in the cleansing and bandaging of the treated area.
- The staff member will escort you back to your preparation room, measure your blood pressure, and provide you with a light snack and beverage.
- You will be asked to stay and relax in the room with your designated driver, as Dr. Chen and the staff members wants to ensure your stability before discharge.
- A staff member will then review the post-procedure instructions with you and answer any questions or concerns you may have.
- You will be provided with a copy of the post-procedure instructions, an antibiotics prescription, and a follow-up appointment date in two weeks.
- We hope you will feel better soon!

POST-PROCEDURE INSTRUCTIONS

- **Do not drive** within the next 12 hours. Coordination may be impaired. **Avoid** twisting, bending, turning, pushing, pulling, lifting >5lbs, walking uphill, physical therapy, excessive exercise, chiropractic work, swimming, massages, or bath tubs for one week even if you feel great! Shower is OK anytime.
- If you are **diabetic**, inform your attending physician. **Steroids elevate blood sugar**.
- **Cortisone or Steroid** can have the following side effects: sweating, slight fever, flushing, palpitations, increased heart rate, insomnia, anxiety, mood swings, depression, hiccoughs, headaches, generalized swelling, upset stomach, menstrual changes, frequent urination, or flu-like symptoms. If they occur, they usually only last for one week. If any of these side effects becomes significant or persists longer than one week, contact your physician.
- **Icing** the injection area 20 minutes at a time, 3 times a day, for 2 days, will reduce local soreness. Use an ice bag covered with a thin cloth.
- **Increased pain** may be experienced 1-14 days after the injection. **Improvement** may be seen in 2-3 days but may not occur for 2-3 weeks.
- **Return to work**: Usually, patients return to work 1-7 days following the injection. The doctor will determine this.
- **Resume ALL medications**. Antibiotics prescribed are for your precautionary safety to prevent infection. Please contact San Mateo Spine Center for any further question(s).

INFORMED CONSENT

I was given enough time and plenty of the opportunity to ask Dr. Chen all questions about my spinal/musculoskeletal condition. Prognosis of my condition was discussed. I was presented with all treatment options, surgical vs. none surgical options about my condition. The proposed spinal procedure and its associated risks and benefits were discussed. I am aware that spinal injection is not a cure and may not eliminate all the pain I have. I am also aware that pain relief may be temporary and may not provide any long term pain relief. I am aware that I may require more than one injection for additional pain control. I was informed that the procedure will be performed as outpatient procedure in the office and only local anesthesia is utilized prior to procedure. I am aware I will not be put out and there is no general anesthesia involved. I was informed that with any injection procedure there are risks involved, such as vascular injury, vital organs injury, cardiac injury, lung injury, gastrointestinal injury, bleeding, infection, or neurological damage such as spinal cord injury, nerve injury, or brain injury. If bleeding complication does occur, a transfusion of blood products would be necessary. I was informed of the potential for spinal cord injury (paralysis) or nerve root injury, which can lead to permanent pain and/or weakness, and laceration of the spinal dura, which can lead to prolonged spinal headaches and will require blood patch in the hospital. The spinal injection occasionally causes infections which can occur in disc, vertebral body, epidural space, soft tissue, muscle, and/or meningitis (brain infection) after injection procedures. The infection could lead to epidural abscess with paralysis or even death. If an infection does occur it will require prolonged hospitalization with IV or central line antibiotics and potentially will require surgery, and I also understand that some patients may have a severe flare-up in their pain for 1-2 weeks or prolonged period of time after an injection procedure. Rarely, injection may cause skin scar and tissue atrophy. In some individuals the injection can cause increase in pain temporarily, or in rare cases even be long lasting and permanent. If injection is performed in the neck and mid back spine, vital organs may be punctured, such as neck vascular structures, heart and or lung which may lead to serious cardiovascular injury and lung collapsed, which may require hospitalization and emergency medical care. Additionally, I understand that Dr. Chen may be injecting a variety of substances into the spine for diagnostic and/or therapeutic purposes. These substances include, but are not limited to, local anesthetics, corticosteroids, contrast agents, and antibiotics. Although unusual, adverse reactions to these medications can occur, including allergic reactions and temporary seizures. If corticosteroids are used there is a risk of reducing immune system which can cause new infection, or exacerbate existing infection. Steroid can occasionally lower immune system and leads to Shingles, Herpes Zoster. Steroid can make my Tuberculosis worse. Steroid may also make your osteoporosis worse and occasionally cause bony fracture or compression vertebral fracture. Occasionally steroid can cause irregular bleeding, and menstruation. Steroid can also cause ulcer and make my stomach ulcer worse. Steroid may also cause skin rash. Steroid can make my cataract worse. Steroid can increase my blood pressure. Steroid can also increase my blood sugar (hyperglycemia) which can cause diabetes and make my diabetes worse. Steroid can also make my adrenal glands not working properly leading adrenal insufficiency syndrome. Steroid can also cause muscle, tendon damage and soft tissue atrophy. Psychologically, steroid can cause mood changes, such as increasing anxiety, depression, and insomnia. And occasionally it can cause psychosis and suicidal ideation. If I am on any anti depressant or any mood related medication, I understand I have to obtain psychiatric / psychological clearance and medical clearance for my spine steroid injection. Steroid can also make me gain weight and make me having moon face. If I am on blood thinner, such as NSAIDs/Aspirin/Plavix/Coumadin and others, I also need medical and or cardiac clearance to be off blood thinner for my spinal injection. In rare cases, the steroid may cause aseptic necrosis of the hip (severe arthritis of hip) which may require hip surgery.

If I am a woman, I am 100% certain that I am not pregnant now. I will take steps to be certain that I do not become pregnant over the period of time I am being treated. I understand that if I am pregnant now or become pregnant during the course of treatment, there is a risk that my unborn baby could be damaged by one or more of the medications used for treatment, sedation, or anesthesia. If during the course of treatment, I become uncertain whether or not I might be pregnant, I will immediately notify my treating physician and discontinue the treatment until I am again sure that I am not pregnant.