DALLAS
PLASTIC SURGERY
INSTITUTE

Patient Name: _____

Date: _____

KYBELLA® INFORMED CONSENT

This is an informed-consent document that has been prepared to help inform you concerning using deoxycholic acid injection injections with Kybella®. The use of aesthetic injections with Kybella has its risks and alternative treatments.

GENERAL INFORMATION

Kybella® is a cytolytic drug indicated for improvement in the appearance of moderate to severe convexity or fullness associated with submental (neck) fat in adults. The safe and effective use of Kybella® for the treatment of subcutaneous fat outside the submental region (neck) has not been established and is not recommended. Kybella® is injected into the fat under the chin (no more than 50 injections or 10mL under the skin). Kybella® injections will be given at least one month apart. Your healthcare provider will decide how many treatments and injections are needed. Any other cosmetic use is considered "off label."

ALTERNATIVE TREATMENTS

There are alternative forms to Kybella® that are non-surgical and surgical. The non-surgical alternatives consist of topical neck products, weight loss, and neck homeopathic treatments. The surgical alternatives of Kybella® are a neck lift, neck liposuction, and several others. Risks and potential complications are associated with alternative forms of treatment.

RISK OF KYBELLA

There are risks of using Kybella®. Every cosmetic procedure involves a certain amount of risk, and it is important that you understand the risks involved. An individual's choice to undergo a cosmetic procedure is based on the comparison of the risk to potential benefit. Although the majority of patients do not experience complications, you should discuss each risk with your provider or affiliated medical personnel.

Risks include bruising, skin irritations including but not limited to tingling, swelling, itching, skin tightness and headache. Additional risks, although unlikely include, nerve injury, damage to deeper structures, difficulty swallowing, skin ulceration, alopecia, bleeding, blindness, skin infection, unsatisfactory results, allergic reaction, medication reaction, herpes simplex virus eruption, and pregnancy or nursing complications.

Tell your provider about all past or planned surgeries and treatments of the face, neck, or chin as these could affect the effectiveness and safety of Kybella®

ADDITIONAL TREATMENTS MAY BE NECESSARY

In some situations, it may not be possible to achieve optimal results with a single aesthetic injectable treatment. Multiple sessions may be necessary. Should complications occur, additional injectables or other treatments may be necessary.

OFF-LABEL FDA USE

There are many devices, medications and injectable fillers and botulinum toxins that are approved for specific use by the FDA, but this proposed use is "Off-Label", that is not specifically approved by the FDA. It is important that you understand this proposed use is not experimental and your physician believes it to be safe and effective.

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Examples of commonly accepted "Off-Label" use of drugs or devices include the use of aspirin for prevention of heart disease, retinoids for skin care, and injection of botulinum toxin for wrinkles around the eyes. Botox® is approved for Glabellar frown lines, Blepharospasm, and would be Off-Label for all other uses.

_____ I acknowledge that I have been informed about the Off-Label FDA status of Kybella®, and I understand it is not experimental and accept its use.

DISCLAIMER

Informed consent documents are used to communicate information about the proposed injectable treatment along with disclosure of risks and alternative forms of treatments. The informed consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances.

This informed consent should not be considered all inclusive in defining other methods of care and risks encountered. Your provider or affiliated medical personnel may provide you with additional or different information, which is based on all the facts in your particular case and the state of medical knowledge. 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.

Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with Kybella®. Other complications and risks can occur but are even more uncommon. The practice of medicine and aesthetic injectables is not an exact science. Although good results are expected, there cannot be any guarantee or warranty expressed or implied on the results that may be obtained.

INFORMED CONSENT FOR NEUROTOXIN INJECTIONS

1. I hereby authorize Dr. Rohrich and such assistants as may be selected to perform the following procedure or treatment**: BOTOX INJECTION**
2. I recognize that during the course of the procedure and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or her 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 is begun.
3. I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.
4. I consent to be photographed or televised before, during, and after 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.
5. For purposes of advancing medical education, I consent to the admittance of observers to the treatment room.
6. IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:
    a. THE ABOVE TREATMENT OR PROCEDURE TO BE UNDERTAKEN
    b. THERE MAY BE ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT
    c. THERE ARE RISKS TO THE PROCEDURE OR TREATMENT PROPOSED

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

Treatment Date _____

Patient Name _____ Patient Signature _____

Witness Name _____ Witness Signature_____

_____

Treatment Date _____

Patient Name _____ Patient Signature _____

Witness Name _____ Witness Signature_____

_____

Treatment Date _____

Patient Name _____ Patient Signature _____

Witness Name _____ Witness Signature_____