Dr. James B. Lowe – Plastic Surgery FACIAL OR HEAD AND NECK NERVE SURGERY INFORMATION SHEET AND INFORMED CONSENT

INSTRUCTIONS

This is an informed-consent document that has been prepared to help inform you of peripheral facial nerve surgery, its risks, as well as alternative treatments.

It is important that you read this information carefully and completely. Please initial each page, indicating that you have read the page and sign the consent for surgery as proposed by your plastic surgeon and agreed upon by you.

GENERAL INFORMATION

Peripheral nerves are nerves that are located outside the brain and spinal cord. These nerves provide movement and sensation to the face, upper and lower extremity, and trunk. Peripheral nerve surgery involves the release of compressed nerves, and the repair or reconstruction of injured or diseased nerves. Peripheral nerves that are compressed for a long time can result in pain, discomfort, or loss of function. Head and Neck nerves that are injured should be repaired or reconstructed in a timely manner in most cases because recovery is often related to the level of injury and the time of repair. Injured nerves rarely will recover completely, but new techniques in reconstruction have significantly improved treatment options and outcomes. Sensory and motor (i.e. movement) peripheral nerve function recoveries at different paces, but motor function is often more difficult to obtain. Nerve injury or compression results in an injury at the site and nerve recovery distal to that site occurs at approximately 1 inch per month making recovery a slow process. Complete recovery should never be expected and complete failure in recovery is possible.

Facial nerve injury or disease results in asymmetry of the face, loss of motion, and possible loss of sensation. The facial nerve can be injured due to trauma or even removed during tumor or cancer removal of the head and neck. It is usually best to reconstruct the facial nerve within a reasonable time frame or at the time of the injury to increase the chance of partial recovery. Certain facial nerve injuries can not be reconstructed. Certain facial nerve injuries are reconstructed immediately or require a period of delay. Patients who undergo facial nerve reconstruction require close follow-up and may require secondary procedures within a certain time frame based on the recovery. Head and neck and facial nerves can be reconstructed with nerve transfers taken from other areas of the body or with nerve grafts harvested from the head and neck or extremities. If a nerve is harvested to reconstruct a head or neck nerve it will result in a deficit in the area of the body it is taken from. This will result in permanent weakness, numbness, scarring, and pain in some cases. Facial nerve reconstruction usually results in improvement of symptoms over time or prevention complete loss of function.

Nerve injury can be partial or complete. The impact of peripheral facial nerve injury depends not only on the nerve injured but the way and time it was injured. Crushed nerves can be quite serious and the extent of the injury unclear for some time. The area of injury is often easier to determine in sharp injuries. Some incomplete injuries will recovery over time, but the course of the injury may not be clear for several months. The options for treatment for peripheral facial nerve injuries depend on a variety of factors that should be discussed with your physician. Diagnostic studies such as EMGs or electro-diagnostic studies will often allow your surgeon the ability to determine the extent, position, and clinical course of a patient's peripheral nerve disease. These studies are often performed after a period of observation or conservative management. The studies often involve some discomfort particularly if the electric activity of muscles is examined. Nevertheless, such studies often allow your physician the ability to optimize your care and recovery before and after peripheral nerve surgery. On occasion patients will benefit from intermittent nerve stimulation during the recovery period.

Peripheral nerve surgery involves some risks and unknowns. Often these issues are not clear until after surgery. The surgery itself has risks and potential complications listed below. Restoration of maximal function after injury or compression of facial nerves often requires surgery, aftercare, and supervised hand rehabilitation. Injuries severe enough to cut peripheral facial nerves may damage other vital structures in the area important to normal function. These structures may require repair in addition to the nerve(s). Damage to these structures may be only discovered at the time of surgery.

ALTERNATIVE TREATMENTS

Alternative treatment consists of not undergoing peripheral facial nerve surgery. There is the possibility of loss of function if not repaired. Risks and potential complications are associated with alternative forms of surgical treatment.

RISKS OF PERIPHERAL NERVE SURGERY

Every surgical procedure involves a certain amount of risk and it is important that you understand the risks involved with peripheral nerve surgery 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 the risks, potential complications, and consequences of peripheral nerve surgery.

Bleeding- It is possible, though unusual, to experience a bleeding episode during or after surgery. Intraoperative blood transfusions may be required. Should post-operative bleeding occur, it may require an emergency treatment to drain the accumulated blood or blood transfusion. Do not take any aspirin or antiinflammatory medications for ten days before surgery, as this may increase the risk of bleeding. Nonprescription "herbs" and dietary supplements can increase the risk of surgical bleeding. If blood transfusions are needed to treat blood loss, there is a risk of blood related infections such as hepatitis and the HIV (AIDS). Heparin medications that are used to prevent blood clots in veins can produce bleeding and decreased blood platelets.

<u>Infection</u>- Infections after peripheral nerve surgery may occur. Additional treatment may be required. There is the possibility of nerve repair failure or scarring from an infection. Should an infection occur, additional treatment including antibiotics, hospitalization, or additional surgery may be necessary.

<u>Nerve Scarring</u>- Injuries to peripheral facial nerves also affect other structures necessary for proper function. Scarring can occur within the nerve repair itself or in nearby structures to prevent the return of maximal function. Additional surgery may not be successful in freeing the nerve from scar tissue or allowing the nerve to function properly. When nerve scarring occurs, function may be affected and pain may result from local scar build-up.

<u>Donor Nerve or Tissue Loss</u>- Patients with facial nerve injury who require donation of tissue or nerve for reconstruction will often experience a loss of function in the area of nerve or tissue loss. It may result in chronic pain, permanent loss of function or sensation. Sometimes the donor areas will require future surgery or revision depending on the location and extent of surgery.

<u>Change in Skin Sensation</u>- A diminished (or loss) of skin sensitivity in the area may occur and not totally resolve after peripheral nerve surgery.

Failure of Nerve Repair or Release- Sutures are used to hold the nerve repair together until it has healed and has enough strength for function. It is possible to break the sutures or tear apart the nerve repair. Sometime a nerve graft or movement of an existing nerve is required to decrease tension. Breakage of nerve repairs are a serious problem. If this occurs, additional surgery would be necessary to secondarily repair the nerve. It is important that you follow all post-operative instructions concerning protecting the nerve repair from damage.

<u>Failure of Nerve Release</u>- The area compression may be incompletely released during nerve surgery. It may be fully released but then a scar forms that may result in another compression point that could be worse than before surgery. Often areas of re-compression can be identified and treated with another operation that will improve symptoms. On occasion further surgery may not be beneficial. It is important that you follow all post-operative instructions concerning protecting the nerve release from re-forming.

<u>Skin Contour Irregularities</u>- Contour irregularities and depressions may occur after peripheral nerve surgery. Visible and palpable wrinkling of skin can occur. Residual skin irregularities at the ends of the incisions or "dog ears" are always a possibility and may require additional surgery. This may improve with time, or it can be surgically corrected.

Skin Discoloration / Swelling- Some bruising and swelling normally occurs following surgery. The skin in or near the surgical site can appear either lighter or darker than surrounding skin. Although uncommon, swelling and skin discoloration may persist for long periods of time and, in rare situations, may be permanent.

<u>Scarring</u>- All surgery leaves scars, some more visible than others. Although good wound healing after a surgical procedure is expected, abnormal scars may occur both within the skin and deeper tissues. Scars may be unattractive and of different color than the surrounding skin tone. Scar appearance may also vary within the same scar. There is the possibility of visible marks in the skin from sutures. Scars may limit motion and function. In some cases scars may require surgical revision or treatment.

<u>Inability to Restore Function</u>- Facial nerve injuries and compressions never recover completely from the insult. Not all damaged structures can be surgically repaired. Injuries to other soft tissues and bone may prevent adequate nerve function despite a successful repair or release. Loss of soft tissues in the area may require other reconstructive surgical operations. Some injuries may be so severe that there is no reasonable expectation of return of function. Complications involving other parts of the body may occur after peripheral nerve surgery. When a nerve is harvested to repair another nerve this will result in some permanent loss of sensation in the area of the nerve harvest.

<u>Surgical Anesthesia</u>- Both local and general anesthesia involves risk. There is the possibility of complications, injury, and even death from all forms of surgical anesthesia or sedation.

<u>Delayed Healing</u>- Wound disruption or delayed wound healing is possible. Depending on the type of surgery performed, complete healing may be prolonged. Areas of skin may die. This may require frequent dressing changes or further surgery to remove the non-healed tissue. **Smokers have a greater risk of skin loss and wound healing complications.**

<u>Damage to Associated Structures</u>- Structures such as nerves, blood vessels, bones and soft tissues may be damaged during surgery. The potential for this to occur varies with the type of surgical technique utilized. Additional surgery may be necessary should this problem occur. Injury to associated structures may be temporary or permanent.

<u>Additional Incisions Necessary</u>- Cut nerves may retract. It may be necessary to extend the original wound where the nerve was cut or make new incisions to retrieve the retracted nerves(s). Further incisions will be required if nerve grafts are harvested. In patients with nerve compression, the compression point may require a longer incision than anticipated to fully release the area of compression.

<u>Allergic Reactions-</u> In rare cases, local allergies to tape, suture materials and glues, blood products, topical preparations or injected agents have been reported. Serious systemic reactions including shock (anaphylaxis) may occur to drugs used during surgery and prescription medications. Allergic reactions may require additional treatment.

<u>Pain-</u> You will experience pain after your facial nerve surgery. Pain of varying intensity and duration may occur and persist after peripheral nerve surgery. Chronic pain may occur very infrequently from nerves becoming trapped in scar tissue. A more serious chronic pain (i.e. RSD) can occur when performing surgery on extremities and trunks particularly around nerves that may be permanent or require other interventions.

<u>Radiation</u>- In certain circumstances, patients with undergoing reconstruction of the facial nerves following tumor resection may require radiation treatment. Radiation will result in an increased risk of nerve scarring and increased chance of incomplete nerve recovery. Although complete failure of the procedure is unlikely, radiation or other post operative complications such as infection can result in soft tissue compromise, scarring, and decreased long term recovery.

<u>Recurrent Disease</u>- In certain circumstances, in patients undergoing tumor excision will experience a failure to cure the tumor or recurrent disease. If the tumor recurs or is in-completely removed this will have a negative impact on recovery and may require revision or re-operation. If the tumor recurs or is not completely removed, hospitalization and additional treatment including another reconstruction would be necessary.

<u>Shock</u>- In rare circumstances, your surgical procedure can cause severe trauma, particularly when multiple or extensive procedures are performed. Although serious complications are infrequent, infections or excessive fluid loss can lead to severe illness and even death. If surgical shock occurs, hospitalization and additional treatment would be necessary.

Cardiac and Pulmonary Complicationsthe formation of, or increase in, blood clots in the venous system. Pulmonary complications may occur
secondarily to both blood clots (pulmonary emboli), fat deposits (fat emboli) or partial collapse of the lungs
after general anesthesia. Pulmonary and fat emboli can be life-threatening or fatal in some circumstances.
Inactivity and other conditions may increase the incidence of blood clots traveling to the lungs causing a
major blood clot that may result in death. It is important to discuss with your physician any past history of
blood clots or swollen legs that may contribute to this condition. Cardiac complications are a risk with any
surgery and anesthesia, even in patients without symptoms. If you experience shortness of breath, chest
pains, or unusual heart beats, seek medical attention immediately. Should any of these complications occur,
you may require hospitalization and additional treatment.

ADDITIONAL ADVISORIES

<u>Unsatisfactory Result-</u> Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained. There is the possibility of an unsatisfactory result from the peripheral nerve surgery. This would include risks such as skin and soft tissue loss, wound disruption, chronic pain, loss of hand function, visible deformities, poor healing, and loss of sensation. There is the possibility that hand function after tendon repair surgery may not be adequate for return to your regular occupation. It may be necessary to perform additional surgery to attempt to improve your results.

<u>Female Patient Information</u>- It is important to inform your plastic surgeon if you use birth control pills, estrogen replacement, or if you believe you may be pregnant. Many medications including antibiotics may neutralize the preventive effect of birth control pills, allowing for conception and pregnancy.

<u>Medications-</u> There are many adverse reactions that occur as the result of taking over the counter, herbal, and/or prescription medications. Be sure to check with your physician about any drug interactions that may exist with medications which you are already taking. If you have an adverse reaction, stop the drugs immediately and call your plastic surgeon for further instructions. If the reaction is severe, go immediately to the nearest emergency room. When taking the prescribed pain medications after surgery, realize that they can affect your thought process. Do not drive, do not operate complex equipment, do not make any important decisions, and do not drink any alcohol while taking these medications. Be sure to take your prescribed medication only as directed.

Smoking, Second-Hand Smoke Exposure, Nicotine Products (Patch, Gum, Nasal Spray)-

Patients who are currently smoking, use tobacco products, or nicotine products (patch, gum, or nasal spray) are at a greater risk for significant surgical complications of skin dying, delayed healing, and additional scarring. Individuals exposed to second-hand smoke are also at potential risk for similar complications attributable to nicotine exposure. Additionally, smokers may have a significant negative effect on anesthesia and recovery from anesthesia, with coughing and possibly increased bleeding. Individuals who are not exposed to tobacco smoke or nicotine-containing products have a significantly lower risk of this type of complication. Please indicate your current status regarding these items below:

I am a non-smoker and do not use nicotine products. I understand the risk of second-hand
smoke exposure causing surgical complications.
I am a smoker or use tobacco / nicotine products. I understand the risk of surgical complications
due to smoking or use of nicotine products.

It is important to refrain from smoking at least 6 weeks before surgery and until your physician states it is safe to return, if desired.

ADDITIONAL SURGERY NECESSARY

Should complications occur, additional surgery or other treatments may be necessary. Secondary surgery may be necessary to obtain optimal results. Even though risks and complications occur infrequently, the risks

cited are particularly associated with peripheral nerve surgery. Other complications and risks can occur but are even more uncommon. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied on the results that may be obtained. In some situations, it may not be possible to achieve optimal results with a single surgical procedure.

PATIENT COMPLIANCE

Peripheral facial nerve structures after surgery are vulnerable to breakage until healing has occurred. Follow all physician instructions carefully; this is essential for the success of your outcome. It is important that the surgical incisions are <u>not</u> subjected to excessive force, swelling, abrasion, or motion during the time of healing. Personal and vocational activity needs to be restricted. Protective dressings and splints should <u>not</u> be removed unless instructed by your plastic surgeon. Successful restoration of function depends on both surgery and subsequent hand rehabilitation. Physical activity that increases your pulse or heart rate may cause bruising, swelling, fluid accumulation and the need for return to surgery. It is wise to refrain from intimate physical activities after surgery until your physician states it is safe. It is important that you participate in follow-up care and hand rehabilitation, return for aftercare, and promote your recovery after surgery.

HEALTH INSURANCE

Depending on your particular health insurance plan, peripheral nerve surgery may be considered a covered benefit. Please review your health insurance subscriber-information pamphlet, call your insurance company, and discuss this further with your plastic surgeon. **Many insurance plans exclude coverage for secondary or revision surgery**.

FINANCIAL RESPONSIBILITIES

The cost of surgery involves several charges for the services provided. The total includes fees charged by your doctor, the cost of surgical supplies, anesthesia, laboratory tests, and outpatient hospital charges, depending on where the surgery is performed. Additional charges may include hand rehabilitation therapy after surgery. Depending on whether the cost of surgery is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges not covered. The fees charged for this procedure do not include any potential future costs for additional procedures that you elect to have or require in order to revise, optimize, or complete your outcome. Additional costs may occur should complications develop from the injury or surgery. Secondary surgery or hospital day-surgery charges involved with revision surgery would also be your responsibility. Health insurance may not completely cover the costs of surgery and rehabilitation. You may require more hand rehabilitation services than your insurance plan covers. In signing the consent for this surgery/procedure, you acknowledge that your have been informed about its risk and consequences and accept responsibility for the clinical decisions that were made along with the financial costs of all future treatments.

DISCLAIMER

Informed-consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s), including no surgery. 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 risks encountered. Your plastic surgeon may provide you with additional or different information which is based on all the facts in your particular case and the current state of medical knowledge.

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 change 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 on the next page.

CONSENT FOR SURGERY / DROCEDURE or TREATMENT

	CONSENT FOR SURGERT / FROM	EDUNE OF TREATMENT	
1.	I hereby authorize DrLowe to perform the following procedure or treatment:	and such assistants as may be selected	
	PERIPERAL FACIAL NERVE SURGERY		
	I have received the following information sheet:		
	INFORMED CONSENT – PERIPHERAL FACIAL NERVE SURGERY		
2.	I recognize that during the course of the operation 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 consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risk and the possibility of complications, injury, and sometimes death.		
4.	I acknowledge that no guarantee or representation has been given by anyone as to the results that may be obtained.		
5.	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.		
6.	For purposes of advancing medical education, I consent to the admittance of observers to the operating room.		
7.	I consent to the disposal of any tissue, medical devices or	body parts which may be removed.	
8.	I consent to the utilization of blood products should they be deemed necessary by my surgeon and/or his/her appointees, and I am aware that there are potential significant risks to my health with their utilization.		
9.	I authorize the release of my Social Security number to medical-device registration, if applicable.	appropriate agencies for legal reporting and	
10.	I understand that the surgeons' fees are separate from the fees are agreeable to me. If a secondary procedure is ne required.		
11.	I realize that not having the operation is an option.		
12.	IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UN a. THE ABOVE TREATMENT OR PROCEDURE TO BE b. THERE MAY BE ALTERNATIVE PROCEDURES OR c. THERE ARE RISKS TO THE PROCEDURE OR TRE	E UNDERTAKEN METHODS OF TREATMENT	
	I CONSENT TO THE TREATMENT OR PROCEDURE AI AM SATISFIED WITH THE EXPLANATION.	ND THE ABOVE LISTED ITEMS (1-12). I	
	Patient or Person Authorized to Sign for Patient		

Witness

Date