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Atlas Neurosurgery & Spine

INFORMED CONSENT

I, _____, (patient or guardian) authorize Doctor _____, his associates and assistants of his or her choosing to perform the following operations or procedure(s).

_____
_____
_____

I have been strongly advised to carefully read and consider this operative consent. I realize that it is important that I understand this material. I also understand that if certain sections are not clear to me, I have the opportunity to ask for clarifications. My doctors have discussed and fully informed me of the nature of my problem, the proposed operation, all known alternative treatments and the possible complications of both operative and non-operative care of my problem. Reasonable alternative treatments and their risks, consequences and probable effectiveness have been discussed with me including doing nothing, conservative therapy with drugs and/or exercise and/or nerve blocks or injections. I do not wish to engage in the alternative treatments. I have had ample opportunity to discuss my condition, treatment and surgery with my doctor(s), his/her associates, and with my family. All of my questions have been answered to my satisfaction. I believe that I have adequate knowledge upon which to base my decision regarding the proposed operation and to sign this consent.

- I understand that this document will discuss craniotomy and spinal surgery in a general fashion including cranial, cervical, thoracic, lumbar or sacral disk removal or decompression including foraminotomy, laminectomy and/or facetectomy, anterior or posterior fusion utilizing metal or other non-metallic implants or substances anteriorly or posteriorly to assist in fusion, deformity correction or stability success. Also, the use of instrumentation may not be approved by the Food and Drug Administration (FDA) such as posterior occipital, cervical and thoracic screws or various bio-implants. This may also include use of instrumentation or other spinal implants in other areas of the spine, which to date have not been approved by federal government, but which the surgeon believes is in my best interests as a patient.
- I understand that my doctors may be able to more comprehensively evaluate the problems within my spine at the time of surgery. During the operation, they may deem it necessary to vary the exact nature of the procedure in order to best treat my problem and to obtain the best chance for a good outcome with the smallest possible operative risk. I, therefore, consent to the performance of surgical procedures in addition to, or different than, those now contemplated. If presently unforeseen conditions arise during my surgery, I authorize and fully consent to, my doctors and his associates performing the necessary procedures.
- I understand that medical or non-medical personnel may be present to observe and assist with surgery. I also understand that pictures or videotapes of my surgery or x-rays may be used for educational or marketing purposes. I give my consent to such efforts and realize that they, in no way, will affect my care. My identity will not be disclosed if my images, pictures or videotapes are used at any time.
- I understand that I am free to seek other opinions about the proposed surgery and that my doctors encourage me to do this if I wish.
- I understand that, in general, the goal of surgery is to help relieve pain and to improve function, but I am also aware that after surgery there may be unresolved symptoms or worsening of symptoms as well as other neurological signs or symptoms which may have not been present before surgery. I understand that less common problems may occur as a result of surgery such as muscle weakness or paralysis, airway difficulties, hematoma, prolonged intubation, numbness, hoarseness (i.e. superior or recurrent laryngeal nerve palsy), lack of improvement or worsening myelopathy or neurogenic claudication, esophageal, great vessel or nerve injury or difficulty swallowing with anterior cervical procedures, spinal fluid leakage, loss of bowel or bladder control, arachnoiditis (i.e. scarring of the nerves in the dural sac) and in men, erectile dysfunction, impotence and retrograde ejaculation. I also understand that other problems may require additional treatment or operation. I

am aware that it may not be possible to cure or totally correct my problem and depending on the pathology i.e. tumor or infection, there may be recurrence of spread.

- In procedures requiring bone grafting, I understand that healing of my bone graft into a bone fusion is largely a biological function of my body. Failure of the bone graft to heal may result in persistent symptoms necessitating additional surgery.
- I understand that other general problems may occur with any surgery such as death, deep venous thrombosis (blood clots), stroke, phlebitis, embolism, infection (wound, diskitis, osteomyelitis, epidural abscess), pneumonia, stroke, cardiac arrest, anesthesia problems, worsening vision or blindness, blood loss, allergic reaction to medications or materials and diseases transmitted by blood transfusions or other means.
- It has been determined that, to best treat my spinal problem, a fusion may be necessary. A fusion is an operation designed to eliminate movement between two or more adjacent vertebrae. My doctor may take bone from my body or use bone from a cadaver and place this around vertebrae that are meant to be fused. Therefore, my body must complete the healing process. Unfortunately, not all fusions heal. Excessive motion, smoking, steroid use, use of non-steroidal anti-inflammatory medications and certain medical conditions such as diabetes and renal disease may cause the fusion to not heal. In an effort to provide the highest probability that my fusion will heal, my doctor has determined that the use of a fixation device, bio-implant or fusion enhancer may be appropriate. These devices or substances may consist of screws, hooks, rods, plates, wires, various polymers, cement, bio-implants (absorbable or non-absorbable) or various bone graft alternatives, enhancers or extenders. These devices may be anchored by screws or other attachments inserted into the bony pedicles, vertebral bodies, the cranium or lateral masses of the vertebral bodies. Rods, plates or wires may then be connected to these implanted screws or anchors, thus constructing a rigid framework to hold the bones immobile until the fusion heals. It is my doctor's conviction that the use of the fixation devices will significantly increase the probability that my fusion will heal. My doctor has completed a residency in Neurosurgery with a concentration in spine surgery. His primary practice deals with the evaluation and treatment of Neurological and spinal disorders. By virtue of his special training and practice experience, he has developed the knowledge and ability to safely use these internal fixation devices and bio-substances. Any fixation device may fail or break. If my fusion does not heal, the graft, screws, wires, rods, cages, intervertebral devices or plates may break or disengage and they may be loss of spinal fixation and/or correction. This may cause injury to the surrounding soft tissue structures. When my doctor implants these devices, there exists the possibility of injury to the bones, nerves or adjacent tissues such as blood vessels, tendons or ligaments. There is a possibility that these devices may need to be removed at a later date. Alternatives to the use of fixation devices include the use of no internal fixation at all or the use of brace or cast. I do not wish to engage in these alternatives exclusively.
- The FDA has not approved screws for use in certain pedicles of the spine or several spine disorders. The use of methyl methacrylate or bone cement is also not approved by the FDA for use in the spine. These devices and substances are considered investigational by the FDA. Pedicle screws are approved for use in the sacrum and various lumbar disorders. It is quite common, and legally and medically appropriate, to use FDA approved devices, substances of medications for uses other than those for which they are specifically approved. My doctor believes that use of a pedicle fixation device, occipital screw attachment, lateral mass screws, or other devices or substances within my spine will significantly improve the chances that my fusion will heal or my condition will improve. In spite of the risk inherent in their use and in spite of the investigational nature of the devices. I am aware that my physician strongly believes that he can safely use them to increase the probability that my fusion will heal.
- I understand that during fusion procedures, bone morphogenetic protein (BMP) might be utilized as a growth factor to aid in bony fusion. I understand that BMP use may not be FDA approved in my clinical condition; however, I consent to its use. I also understand that growth factors such as BMP have been associated with adverse outcomes including but not limited to retrograde ejaculation, antibody formation, postoperative radiculitis, postoperative nerve root injury, ectopic bone formation, vertebral osteolysis/edema, dysphagia and

neck swelling, hematoma formation, wound healing, interbody graft lucency and oncogenic potential. I thoroughly and unequivocally understand those risks and consent to BMP use to allow for bony healing and operative success.

- Pre-operative and post-operative bracing may be prescribed for any spinal disorder. I have been instructed on the use of immobilization device, when I must wear it, and various activities that are contraindicated during the bracing period. I consent to such bracing.
- Donor site complications may result from harvesting my bone which includes numbness and tingling, pain, infection, nerve damage, damage to the vessels and muscles and pelvic or bony instability due to bone loss.
- I understand that my surgeon maybe participating as a paid consultant or have a financial interest in the development of products that may be used in my planned surgical procedure.
- I understand that FDA has specific indications for spinal cord stimulation; however, my condition may or not be included in those strict guidelines. I have had ample time to consider my options and have decided to proceed further with a trial and a permanent implant, if successful. I recognize the variety of risks, benefits and alternatives to surgical implantation and have decided to proceed. I recognize obvious risks of coma, death, paralysis, paresis, spinal cord injury, hardware failure or complications, lead migration, potential limitations with obtaining MRI pending device clearance or lack thereof, initial improvement with delayed worsening, re-operation, bleeding, infection, cerebrospinal fluid leak, meningitis and/or encephalitis.
- During my surgery, neurological monitoring may be necessary to protect my spinal cord, brain or nerves from injury. I understand that, although neurological monitoring is useful to provide information on the status of my spinal cord, brain or nerves during surgery, there are risks to its uses including infection, tongue or oral laceration, seizures or failure of the monitoring to effectively determine the status of my spinal cord or nerve roots. For certain technical reasons including the severity of my spinal disease, monitoring may not be able to provide useful information or may fail to provide reliable signals during the course of my surgery. In this event, my surgeon would be blinded as to the status of my brain, spine cord or nerves. I understand that this may increase the risk of a permanent neurological deficit from surgery. I have had the opportunity to discuss my wishes with regard to halting surgery or continuing with the planned procedure in the event that the signals are not available or are lost during the procedure. The mother of neuromonitoring may not be FDA approved and may require specific anesthetic protocols necessary for optimal neurological assessment.
- I understand smoke and nicotine exposure from cigarette, cigars, nicotine patches, chewing tobacco and other forms of smoke/nicotine may significantly worsen the outcomes of my surgery. It is my responsibility to avoid these and other sources of smoke and nicotine exposure. If I choose not to avoid these sources of nicotine or smoke, I understand that my actions may increase my risk of infection, poor healing, scarring, persistent pain, bony non-healing and failure of surgery.
- I understand the necessity for my compliance with post-operative, post-discharge directions that have been explained to me, including among others, possible immobilization, and/or physical therapy, and/or required medications. I am aware that it is medically important that to achieve the best possible recovery, I must continue on the regimen prescribed for me.

_____ _____

Patient Signature Date

_____ _____

Physician Signature Date