CALIFORNIA ORTHOPEDICS & SPINE

# Consent for Spinal Surgery

☐ Dr. Robert H. Byers
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PATIENT: _____ DATE: _____

Please read carefully and initial each numerical space. Not all sections may be related to your particular surgery. Those items can be left blank. For example, if you are not having a fusion, items related to hardware placement would not be relevant. If you are unsure if an item pertains to your surgery, please ask your doctor.

1. _____ I have been strongly advised to carefully read and consider this operative permit. 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 clarification. As I read each section, I will place my initials in the space provided to indicate that I understand what I have read.

2. _____ I am fully aware of the condition of my spine, and after careful consideration, I have decided to undergo surgery to try to improve my condition. I hereby authorize my doctors and their assistants to perform my surgery.

3. _____ I understand that this permit will discuss spinal surgery in a general way including cervical, thoracic, lumbar or sacral disc removal; occipital, cervical, thoracic, lumbar or sacral decompression including laminectomy, foraminotomy, and/or facetectomy; anterior or posterior occipital, cervical, thoracic, lumbar or sacral fusion with extension to the occiput or sacrum/the use of metal or other non-metallic implants or substances anteriorly or posteriorly to assist in fusion, deformity correction or stability success; the use of instrumentation that may not be approved by the Food and Drug Administration such as posterior occipital, cervical and thoracic screws (e.g. occipital screws, cervical lateral mass screws, pedicle screws in the cervical and thoracic spine) as well as various bio-implants, posterior spinal instrumentation with use of screws. This may also include the use of instrumentation or other spinal implants in other areas of the spine which to date have not been approved by the federal government but which the surgeon believes is in my best interests as a patient.

4. _____ 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.

5. _____ I understand that medical or non-medical personnel may be present to observe surgery. I also understand that pictures or videotapes of my surgery or x-rays may be used for educational purposes. I give my consent to these educational efforts and realize that they in no way affect my care. My identity will not be disclosed if my x-rays, pictures or videotapes are used at any time.

6. _____ 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.

7. _____ My doctors have discussed and fully informed me about 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.

8. _____ 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. At this time, I do not wish to engage in these alternative treatments.

9. _____ I understand that, in general, the surgery is to help relieve pain and to improve function, but I also am aware that after surgery there may be unresolved symptoms or worsening of symptoms as well as other sensations which may not have been present before surgery. I understand less common problems may occur as a result of surgery such as paralysis, airway difficulties, hematoma, prolonged intubation, numbness, hoarseness (i.e., recurrent laryngeal nerve palsy), muscle weakness, nonimprovement 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, impotence, loss of sexual function and retrograde ejaculation. I also understand that other problems might develop within my spine which may require additional treatment or even another operation. I am aware that it is not possible to cure or totally correct my spinal problem and depending on the type of pathology, i.e. tumor or infection, there may be recurrence or spread.

10. _____ 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.

11. _____ I understand that other general problems may occur with any surgery such as death, deep venous thrombosis (blood clots), stroke, phlebitis, embolism, infection (wound, discitic, osteomyelitis, epidural abscess), pneumonia, stroke, blindness, cardiac arrest, anesthesia problems, blood loss, allergic reaction to medications or materials and diseases transmitted by blood transfusions or other means.

12. _____ I have had ample opportunity to discuss my condition, treatment and surgery with my doctor(s), his/their 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 permit.

13. _____ 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 will take bone from my body or use bone from a cadaver and place this around vertebrae that are meant to be fused. Thereafter, my body must complete the healing process. Unfortunately, not all fusions heal. Excessive motion, smoking, steroid use and the use of non-steroidal anti-inflammatory medications within six to ten weeks of surgery and certain medical conditions such as diabetes and renal disease may act to 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 spinal fixation device, bio-implant or fusion enhancer is appropriate. These devices, or substances, may consist of screws, hooks, connecting 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, intervertebral bodies, the cranium or the 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 these fixation devices will significantly increase the probability that my fusion will heal. My doctor has completed a fellowship in spinal surgery. His elected practice is primarily the evaluation and treatment of spinal disorders. By virtue of his special training and extensive 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 there may be loss of spinal correction. This rarely 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 also is the possibility that these devices may need to be removed at a later date. Alternatives to use of these fixation devices include the use of no internal fixation at all or the use of a brace or cast. I do not wish to engage in these alternatives.

14. _____ The Food and Drug Administration has not approved screws for use in certain pedicles of the spine or in several spinal 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 or 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 screw, or other devices or substances within my spine will significantly improve the chances that my fusion will heal or my condition will approve. In spite of the risks inherent in their use and in spite of the investigational nature of these devices, I am aware that my physician strongly believes that he can safely use them to increase the probability that my fusion will heal.

15. _____ Pre-operative and post operative bracing may be prescribed for any spinal disorder. I have been instructed on the use of this immobilization device, when I must wear it, and various activities that are contraindicated during the bracing period. I consent to such bracing.

16. _____ Donor site complications may result from harvesting my bone should it be necessary which include numbness and tingling, pain, nerve damage, infection, damage to the vessels and muscles and pelvic or bony instability due to bone loss.

17. _____ Drs. Byers and Su, due to their experience and expertise in spinal research may ask me to participate in research protocols sponsored by various spinal research societies, industry or of his own design. If I decide to participate in such research, I understand I will be asked to read and sign a separate consent form that has been approved by the Marin General Hospital Institutional Review Board, a committee that approves and monitors research in which humans are involved.

18. _____ During my surgery, neurologic monitoring may be necessary to protect my spinal cord or nerves from injury. I understand that although neurologic monitoring is useful to provide information on the status of my spinal cord or nerves during surgery, there are risks 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 spinal cord or nerves. I understand that this may increase the risk of a permanent neurologic deficit from surgery. I have had the opportunity to discuss my wishes with regards to halting surgery or continuing with the planned procedure in the event that spinal cord signals are not available or become lost during the planned procedure. The method of neuromonitoring may not be FDA approved and may require specific anesthetic protocols necessary for optimal neurologic assessment.

19. _____ I understand the necessity for my compliance with the post-operative and postdischarge 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 my best possible recovery after discharge from the hospital I must continue on the regimen prescribed for me.

I _____have read and fully understand the information presented above.
(Print Name)

_____ _____
Patient Signature Date