

It is very important to Dr. Himmelwright that you understand and consent to the treatment he is rendering or may perform. You should be involved in any and all decisions concerning surgical procedures that may be needed. Sign this form only after you understand the procedure, the risks, the alternatives, the risks associated with the alternatives, and all of your questions have been answered. Please initial and date directly below this paragraph indicating that you understand this paragraph.

Initials of Patient or Authorized Individual: _____ Date: _____

INFORMED CONSENT TO INSTRUMENTED SPINAL FUSION PROCEDURE

I, _____, hereby authorize Dr. Himmelwright
(Name of Patient or Authorized Individual)
to perform instrumented spinal fusion surgery upon _____.
(Name of Patient)

I am fully aware of the condition of my / the patient's spine, and, after careful consideration, I have decided to undergo / have the patient undergo instrumental spinal fusion surgery.

The following assistant may be selected by my surgeon to assist in the procedure. _____

I understand that spinal fusion surgery involves internal fixation and bone grafting. The internal fixation system will use bone screws and either plates or rods. The bone screw is a device that is regarded by the Food and Drug Administration as being safe and effective in many areas on the body, including the base of the spine (sacrum). However, we may also insert the screws through the pedicle of the lumbar and / or the thoracic spine. Either the patient's own (autograft) or banked bone taken from storage (allograft) may be used for bone grafting. The bone graft may be placed along the side of the spine or in the disc space. Fusion may also be done by placement of metal cages in the disc space (the front of the spine) with bone grafting.

In the cervical spine, fusion is done with plates and screws placed through the vertebral bodies (the bones in the front of the spine). Fusion can also be done with plates, rods and screws in the back of the spine. The doctor has discussed with me the details of the planned surgery.

Patient Name: _____ Med Rec #: _____

I understand that while this operation is performed on the spine, the doctor may evaluate the nerves and remove any structures that are impinging on the nerve, including disc material and bone. I understand that the doctor will be best able to evaluate the exact condition of the spine at the time of the surgery. During the operation, the exact nature of the procedure may vary to optimize the outcome and risk. I understand that unforeseen conditions may be revealed that may necessitate change or extension of the original procedure or a different procedure than those already explained to me. I therefore authorize and request that Dr. Himmelwright, his assistants, or his designees perform such procedure(s) as necessary and desirable in the exercise of his professional judgment. I authorized the administration of sedation and / or anesthesia as may be deemed advisable or necessary for comfort, well being and safety.

The doctor has explained to me that there are risks and possible undesirable consequences associated with any surgical procedure, including instrumented spinal fusion surgery. Those risks include, but are not limited to:

I. General Problems (may occur with any surgery)

- a.) Death;
- b.) Blood clots (deep vein thrombosis, embolis, phlebitis);
- c.) Infection;
- d.) Pain or discomfort;
- f.) Potential skin breakdown and / or wound complications;
- g.) Non-union or delayed union of wound;
- h.) Pneumonia;
- i.) Stroke;
- j.) Anesthesia problems;
- k.) Blood loss;
- l.) Transfusion reactions;
- m.) Disease transmitted by transfusion of blood products, including HIV / AIDS, hepatitis or other diseases;
- n.) Heart complications including heart attack / myocardial infarction;
- o.) Vascular or visceral injury;
- p.) Pulmonary embolism (blood clot in lung);
- q.) Loss or future loss of body parts; and
- r.) Adverse reaction to medication(s).

II. Problems Specific to Spinal Surgery

- a.) Failure of the instrumentation, such as loosening, bending, or breakage of the screws, nuts, rods, or plates. Also there may be problems related to malposition of the instrumentation;
- b.) Unresolved or worsened symptoms;
- c.) Recurrence of symptoms;
- d.) Change of normal spinal curvature;
- e.) Bursitis;
- f.) Pain, discomfort, tissue sensitivity or other sensations which might be related to the spinal instrumentation or its placement;
- g.) Decrease in bone or density due to stress shielding;
- h.) Loss of bone or fracture of bone above or below the level of surgery;
- i.) Fracture of vertebrae;
- j.) The bone graft placed at surgery might not grow together resulting in lack of fusion; and
- k.) Loss of fixation

III. Less Common Problems Specific to Spinal Surgery:

- a.) Paralysis;
- b.) Numbness;
- c.) Nerve damage;
- d.) Loss of neurological function;
- e.) Dural tears;
- f.) Paresthesia;
- g.) Spinal fluid leakage;
- h.) Gastrointestinal complications;
- i.) Loss of bowel or bladder control;
- j.) Allergic reaction to metals;
- k.) Scarring of the nerve and / or arachnoiditis;
- l.) Impotence, loss of sexual function, retrograde ejaculation;
- m.) Pressure sores on chest, facial area, pelvis, knees, legs, or foot and ankle areas;
- n.) Visual difficulty or blindness;
- o.) Rib fractures; and
- p.) Onset of symptoms where there are none presently.

Patient Name: _____

Med Rec #: _____

I understand that the healing of a bone graft into a bone fusion is largely a biologic function of the body, and the failure of a bone graft to incorporate is not related to the operative technique. I understand that until a fusion has occurred, I may be required to wear a rigid external support brace and observe restrictions on normal activities of daily living.

I am aware that following spinal surgery large amounts of narcotic medication to suppress pain may be required as well. While the doctor will provide medications to suppress the pain associated with surgery, after an appropriate period the doctor will limit the use of these medications. The goal will be to avoid all of those types of medications.

I am aware that it is not possible to totally "cure" or correct a spinal condition. I understand that there is a high likelihood of ongoing discomfort in the spine that may require reevaluation and possibly additional surgery. I understand that sufficient time must be allowed for healing following the surgery, repeat or revision surgery is more difficult, has a higher incidence of complications, and has a generally less favorable outcome.

The instrumentation that will be used in this spinal surgery is intended to maintain immobilization in the segment of the spine undergoing the fusion. The instrumentation is not intended to replace normal body structures or bear the weight of the body forever in the presence of incomplete bone fusion. If the bone graft does not fuse, it is likely that the screws and plates will become loose and / or break due to excessive and repeated stresses transmitted from the body to the instrumentation. In this case, additional surgery may be necessary.

The doctor has explained the benefits of the surgery to me. However, I understand there is no certainty that these benefits will be achieved, and no guarantee has been made to me regarding the outcome of the surgery. I understand that spinal care is not an exact science, and there are differences in opinion among doctors as to the best methods of treatment and when or if they should be employed. I understand that this also is the case for the different types of spinal operations, and that it is not known with absolute certainty which procedures provide the best outcomes for a given spinal problem.

Patient Name: _____

Med Rec #: _____

Reasonable alternative treatment to the procedure, their risks, consequences, and probable effectiveness have been attempted or have been explained to me. These alternatives include, but are not limited to:

- a.) No Specific treatment;
- b.) Non-operative management (medication, bracing, exercise therapy, anesthetic blocks);
- c.) Spinal Stimulation;
- d.) Percutaneous disc surgery;
- e.) Decompression and / or discectomy without fusion;
- f.) Anterior disc surgery and fusion;
- g.) Decompression and / or discectomy with fusion; and
- h.) Fusion with instrumentation

I understand that spinal surgery is elective in nature. I understand the nature and purpose of the proposed spinal surgery is to help relieve pain and improve function. I understand that I am free to seek other opinions about the proposed surgery, and that Dr. Himmelwright has encouraged me to do this if I wish.

I hereby authorize Dr. Himmelwright to utilize or dispose of removed tissue, bone or organs resulting from the surgery.

I consent to any photographing or videotaping of the procedure that may be performed, provided that the patient's identity is not revealed by the pictures or by descriptive texts accompanying them. I also consent to the admittance of students or authorized equipment representatives to the procedure room for purposes of advancing medical education or obtaining important product information.

I have ample opportunity to discuss my / the patient's condition, treatment options, and planned spinal surgery with Dr. Himmelwright. All of my questions have been answered to my satisfaction and I believe that I have adequate knowledge upon which to base my decisions regarding the proposed operation. I have discussed all the issues that were unclear to me with the doctor. I am under no pressure or duress from anyone to proceed with surgery. I understand that the use of spinal instrumentation is perceived by the doctor as an essential tool to best surgically treat my / the patient's spinal disorder.

Patient Name: _____ Med Rec #: _____

Signature of Patient or Authorized Individual _____
Date: _____ Time: _____

Relationship of Authorized Individual to Patient _____

- The Patient / Authorized Individual has read this form or had it read to him / her.
- The Patient / Authorized Individual states that he / she understands this information.
- The Patient / Authorized Individual has no further questions.

Signature of Witness _____
Date: _____ Time: _____

CERTIFICATION OF PHYSICIAN:

I hereby certify that I have discussed and explained the facts, risks, and the alternatives (and the risks associated with the alternatives) to the procedure described in this consent form with the individual granting consent.

Signature of Physician _____
Date: _____ Time: _____

USE OF INTERPRETER OR SPECIAL ASSISTANCE:

An interpreter or special assistance was used to assist the patient in completing this form as follows:

- Foreign language (specify) _____
- Sign language
- Patient is blind, form read to patient
- Other (specify) _____

Interpretation _____
(Fill in name of Interpreter and Title or Relationship to Patient)

Signature of Physician _____
Date: _____ Time: _____