I, _____, have been asked to carefully read
(Name of patient or substitute decision-maker)
all the information contained in this consent form and to consent to the procedure described below on behalf of _____. I have been told that I should ask
(Name of patient)
questions about anything that I do not understand. (If the decision-maker signing this form is not the patient, references to "I," "my" or "me" should be read as if referring to "the patient," when applicable.)

I understand that the information about the procedure described in this consent form, in addition to discussions with my physicians and any other written materials they may provide, is intended to help me make an informed decision whether to voluntarily undergo the treatment.

I understand that after being examined and having my radiological studies reviewed, I have been diagnosed as having probable stenosis (narrowing) of the spinal canal and foramina in the lumbar area (lower back) at the following level(s) _____. The spinal canal is a tunnel inside the bony
(Levels of suspected involvement)
segments of the spine (vertebrae) that contains the spinal cord and nerves to the legs, bowel and bladder. The foramina are openings through which nerves leave the spine and travel to the muscles of the legs and pelvis. My symptoms are most likely caused by bone thickening, bone spur (osteophyte) formation, slippage of the vertebrae (spondylolisthesis), thickening of ligaments and/or disc bulges that narrow the spinal canal and cause pressure on a nerve or nerves. (Discs are the "cushions" that sit between the vertebrae.) The most common symptoms include back pain, leg pain and numbness and weakness in the legs that may worsen with activity.

I acknowledge that my physician(s) has/have recommended that I undergo the below recommended procedure:

_____

_____.

The side/site/location is: □ Upper back □ Lower back □ Side (lateral) □ Front abdominal

A lumbar decompression is the removal of the bone, ligaments, spurs, or portions of disc material that are narrowing the spinal canal causing my symptoms. If there is also instability, slippage of vertebrae and/or other degenerative processes involving my spine, the recommended procedure may also include a bone fusion. A bone fusion is the placement of real or artificial bony material between the vertebrae (interbody fusion); along the side of the spine (posterior fusion); or in both places to help stabilize the existing bony structures. The bony material used may be my own bone (autograft) taken from my vertebrae during the decompression, from my pelvic bone or from another place in my body; bone from another person or dead body (allograft); or artificial (synthetic) bone. My physician(s) may also recommend use of "instrumentation." Instrumentation involves the attachment of metallic fixation devices (rods, cages, screws and/or plates) to the bone for stabilization.

I understand that my physician(s) are currently recommending the following procedure(s) to try to eliminate some or all my symptoms:

□ Lumbar decompression □ Thoracic decompression **without** bone fusion or instrumentation

□ Lumbar decompression □ Thoracic decompression **with**: (more than one box may be checked):

□ anterior fusion using: □ oblique fusion using: □ lateral fusion using:

□ posterior fusion using: □ interbody fusion using:

□ autograft □ allograft □ artificial bone

□ use of instrumentation

Although, my physician(s) have indicated above what they believe the recommended surgery will involve, I understand that my physician(s) may later determine in their reasonable judgment, to modify the recommended procedure before or during the surgery. For example, instability of my spine may require unanticipated fusion or instrumentation to alleviate my symptoms and/or stabilize my spine; poor quality of bone may prevent the physician(s) from performing a planned fusion; or a planned autograft using bone from my pelvic bone may have to be converted to a fusion using bone from a cadaver or other person (allograft) or artificial bone. Bone graft substitutes may be used in addition to autografts and allografts. These bone graft materials include demineralized bone matrix (DBM) which is a manufactured product that includes pieces of bone with the calcium and phosphate removed so that proteins that promote bone growth (bone morphogenetic proteins or BMP) are exposed. Bone Morphogenic Proteins are also available in various mediums for use with instrumentation and allografts or autografts to improve bone growth and fusion. This is especially valuable in patients who are at risk for poor bone healing such as diabetics, smokers, patients with thinning bones and patients who are receiving steroids or immunosuppressant drugs. The FDA (United States Food and Drug Administration) has approved various BMPs for use in specific types of spinal fusions. Physicians can prescribe, administer and/or recommend off-label uses of drugs and devices based on scientifically sound standards of clinical practice. My fusion may include the off-label use of BMPs.
Use of BMPs in anterior cervical fusions may be associated with additional risks as addressed below.

Description of Procedure: I will be put to sleep under general anesthesia. (The type of anesthesia and the risks of anesthesia will be explained to me by a representative of the Anesthesia Department.) I will then be positioned on the operating room table and my designated surgical site will be cleaned and covered. An incision (cut) will be made as designated by the side/site/location previously defined and the spine will be exposed. The surgeon(s) will remove as much material (bone, bone spurs, ligament, disc) as they reasonably believe should be removed in order to relieve my symptoms and will perform bone fusion and/or instrumentation as deemed necessary. I understand and consent to the surgeon(s) removing material at the level(s) of the spine identified above as well as at other level(s) that they believe in their judgment should be removed in order to relieve my symptoms or improve my health or well-being. In 1-7% of the population a transitional or extra vertebra exists between the lumbar and sacral area. If a transitional vertebra exists, the chance of surgery at an additional level may be increased. If the physicians decide to take the bone from my iliac crest (pelvic bone), an incision will be made at the site of the iliac crest and bone will be removed from the iliac crest to be used for the fusion.

The wound(s) will then be closed.

Post-Surgical Care and Recovery. After the surgery, I will be given pain medications. I may need to take other drugs such as muscle relaxants and antibiotics, depending on my condition. I understand that it is important for my physician(s) to know all drugs that I am currently taking in order to avoid any unwanted and harmful drug interactions. I agree that prior to the surgery I will inform my physicians about all drugs and medications I am taking.

It is anticipated that I will be discharged within 3 days of my surgery. In many cases, patients who have undergone lumbar decompression without fusion are discharged the morning following the surgery. My physician(s) will determine when I can be discharged from the hospital.

I understand that I may have significant post-operative restrictions and limitations that have been thoroughly discussed with me.

Risks of Surgery. I understand that there are inherent risks in the performance of the recommended procedure. These include:

1. Post-operative pain. In most cases the pre-operative pain diminishes there is less pain after the surgery than before. Most patients obtain good to excellent pain relief with this surgery. However, there is the risk that the pain could remain the same after surgery or increase. Pain related to the incision(s), including the bone harvest site near the hip (if used), can be significant but usually improves within weeks.
2. Muscle weakness. In most cases, any preoperative muscle weakness and/or numbness will diminish and be less than before surgery. Full resolution may take weeks or months. However, there is the risk that the muscle weakness, numbness, or other deficit could remain the same after surgery or increase or new muscle weakness or numbness could develop.
3. Scar tissue at site(s) of incision(s).
4. Recurrence of the stenosis. This may occur over a period of years following decompression surgery. Also, stenosis may develop in areas that were not decompressed previously. Further surgery may be necessary.
5. Hematomas (blood poolings) can form at the sites of the surgeries (back, pelvis or another site).
6. Blood clots (thromboemboli) can form in different parts of the body, most often in the legs. These clots can break free and move through the heart to the lungs. In the lungs, they can cause serious interference with breathing, which can lead to death. Blood clots are treated with blood-thinning drugs that may need to be taken for an extended period.
7. Other bleeding either during surgery or after surgery. In approximately 30% of fusion surgeries, the bleeding may require blood transfusions or blood products. These risks include, but are not limited to bleeding, which may require the use of blood or blood products, infection, stroke, heart attack or death. If needed, blood and/or blood products have the following general risks: reactions resulting in itching, rash, fever, headache or shock; respiratory distress (shortness of breath); kidney damage; systemic infection; exposure to blood borne viruses including hepatitis (an inflammatory disease affecting the liver) and Human Immunodeficiency Virus (HIV, the virus that causes AIDS); and death. Alternatives to transfusion include the use of devices that filter and return blood lost in surgery to me or by providing medications that boost my blood count prior to an elective procedure. Bleeding and/or severe anemia could put my life in danger or cause permanent brain damage. I understand that substitutes for blood or plasma might not work well enough. Blood and/or blood products might offer the only chance to preserve my life and I will be asked to sign an additional Blood or Blood Product consent form.

   ☐ I refuse the transfusion of blood and/or blood products and understand that I will be asked to sign a separate form entitled, Release from Liability for Refusal of Blood Transfusion.

8. Nerve damage at or near the site(s) of the surgery(ies) that can cause neurological dysfunction such as numbness or loss of use of lower extremities, decrease or loss of bowel or bladder control and sexual dysfunction.
9. Damage to nerves from pressure or positioning of the arms, legs or back during the surgery. Nerve damage can cause numbness, weakness, paralysis and/or pain. In most cases these symptoms are temporary, but in rare cases they can last for extended periods or even become permanent.
10. Damage to the eye from pressure or positioning of the face during the surgery. Corneal or optic nerve damage can cause visual field disturbances that are usually temporary. In rare cases, retinal artery occlusion or cortical blindness can occur and are usually irreversible.
11. Tears in the dura (covering of the spine) resulting in spinal fluid leak. Spinal fluid leak can cause headaches and spinal fluid infection (meningitis). In rare cases, surgery may be required to repair the leak.
12. Injury to adjacent organs.
13. Pressure sores on the skin due to positioning.
14. Burns caused by use of electrical equipment that may be needed to stop bleeding or by other equipment.
15. Infection at the site of the surgical incision(s), in the disc space between the vertebrae, in the blood, in the bladder, in the spinal fluid or other areas of the body.
16. Injury to other organs near the surgical site including, rectum or intestine.
17. As with all surgeries conducted under general anesthesia, a very small risk of heart attack, stroke and death, even in healthy patients.
18. Other risks, if any:_____

Additional Risks related to Lateral Lumbar Interbody Fusion/Oblique Lateral Lumbar Interbody Fusion

1. Risks of Surgery: I understand that there are inherent risks in the performance of the recommended procedure. These include:

2. Post-operative pain as a result of positioning and/or at the incision site. Thigh pain as a result of neural retraction/nerve injury. In most cases, pain improves over weeks to months. Most patients obtain good to excellent pain relief with this surgery. However, there is the risk that the pain could remain the same after surgery or increase.

3. Scar tissue at site(s) of incision(s)

4. Muscle weakness/Hip flexion weakness. In most cases, any preoperative muscle weakness and/or numbness will diminish and end up being less than before surgery. Full resolution may take weeks or months. However, there is the risk that the muscle weakness, numbness, or other deficit could remain the same after surgery or increase or new muscle weakness or numbness could develop.

5. Graft failure/subsidence can occur resulting in a failed fusion surgery and/or vertebral body fracture. Additional surgery is sometimes needed to address these problems.

6. Hernia formation can occur as a result of weakness in the fascial closure. Pseudohernia formation can occur as a result of injury to the nerves which innervate the abdominal wall musculature.

7. Less likely injury to surrounding organs or major vascular structures can occur which can result in organ failure, limb loss, and the need for additional surgery.

8. Some of these risks can be minimized and/or eliminated with posterior only approaches to the spine.

If a fusion (bone graft) is undertaken, the following additional risks apply:

1. Bone graft (fusion) failure. Occasionally, the bone fails to form a complete or stable union (bond). Without a fixation device (plate, etc.), there is a slight possibility that the bone graft will displace (pop out). In cases of non-union or displacement, further surgery may be required to fuse the bone.
2. If bone is removed from the hip (autograft), blood clots or infection could develop at the site where the pelvic bone is taken. Other risks include fracture of the bone surrounding the site and up to a 30% chance of damage to a lateral femoral cutoneous nerve (a sensory nerve on the skin), causing numbness and/or pain.
3. Ectopic (extra) bone growth can occur resulting in pressure on nerves and return of or development of new symptoms of muscle weakness, numbness and pain.
4. An immune response associated with the bone morphogenetic protein can occur resulting in antibodies. It is unknown what the effects of these antibodies may be on unborn children. Fetal death or birth defects may theoretically occur. I understand that if I am a woman of child-bearing age I should use effective birth control for 18 months following the use of BMP. I should notify my doctor immediately if I become pregnant.

If instrumentation is undertaken (use of fixation device), the following additional risks apply:

1. Breakage, failure or loosening of device (possibly causing chronic pain)
2. Misalignment or poor positioning of device (possibly causing pain)
3. Infection at the site of the device
4. Need for surgery to remove device
5. Occasionally, small pieces of instruments used during surgery may break off and be left in the surgical area. Usually these are small pieces or shavings from a drill bit (used to get through bone) or the tip of an electrocautery instrument (used to stop bleeding). Generally, this material causes no harm. However, there may be limitations to the use of MRI in the future. Also, other material used during surgery can be left behind unintentionally (cotton pledgets, plastic drains, needle tips). Sometimes additional surgery is required to remove this material.
6. Every effort is made to operate on the part of the spine that pre-operative examination and images (x-ray, CT myelogram or MRI) have indicated is the cause of your problem. However, several factors (congenital spine abnormalities, normal anatomical variations, obesity) can result in a procedure performed at a different anatomic level than originally planned. If recognized during the exposure of the

spine, the procedure will be redirected to the appropriate spinal elements. If not recognized until after surgery, a second procedure may be necessary to accomplish the goal of the original surgery.

Alternatives: I understand that I have the choice NOT to undergo the recommended procedure or any procedure. On occasion, conservative therapy or non-surgical treatment, such as medication, rest, physical therapy, manipulation, traction, injection and/or massage, may relieve the symptoms associated with a herniated disc. I acknowledge that my physician(s) or physician representative has described the alternative treatments, the risks and benefits of the alternative treatments, the likelihood of me achieving my goals; any potential problems that might occur during recuperation and the likely medical results should I decide not to undergo the recommended procedure.

Teaching Facility: I understand that the facility is a teaching facility. The health care team may include residents, fellows, students, and skilled healthcare professionals. Credentialed team members may perform all or parts of my procedure under the supervision and guidance of my physician(s). My attending physician may also be caring for one other patient during my surgery but remains responsible to me and will perform or be present for the key portions of the procedure. If unanticipated circumstances require my surgeon to be unavailable during my surgery, another qualified surgeon will promptly come to the operating room. Representatives of medical device companies may be present to provide devices and observe and advise on their use. Who will participate and in what manner will be decided at the time of the procedure and will depend on the availability of individuals with the necessary expertise and on my medical condition. If an accidental exposure to my blood or body fluids occurs to staff during the surgery or procedure, I agree to blood tests for hepatitis B, hepatitis C and HIV.

I understand that the physician(s) or others may choose to photograph, televise, film, or otherwise record all or any portion of my procedure for medical, scientific, or educational purposes. I consent to the photographing, televising, filming, or other forms of recording the procedure(s) to be performed, including appropriate portions of my body, body functions or sounds, provided my identity is not revealed. I understand and agree that 1) any photographs, films, or other audio or visual recordings created will be the sole property of the facility: and 2) the facility or any appropriate staff member may edit, preserve, or destroy all or any part of the photographs, films, or other audio or visual recordings.

I authorize the disposal or retention, preservation, testing, or use for scientific, educational, or other purposes for all or any portion of specimens, tissues, body parts, or other things, including prostheses and medical/surgical appliances, that may be removed from my body.

I understand that if any medical device defined by federal regulations is implanted in a patient's body, the facility is required by law to report to the manufacturer the name, address and social security number of the patient and the description and identity of the device

If my procedure is to be performed in an Ambulatory Surgical Facility (ASF), the comparative risks, benefits and alternatives associated with performing the procedure in the ASF instead of a hospital have been fully explained to me.

I understand the hospital may require that all jewelry and/or body piercing hardware be removed prior to surgery.

MY SIGNATURE ACKNOWLEDGES THAT:

1. **I have read (or had read to me), understand and agree to the statements set forth in this consent form.**
2. **A physician or physician's representative has explained to me all information referred to in this consent form. I have had an opportunity to ask questions and my questions have been answered to my satisfaction.**
3. **All blanks or statements requiring completion were filled in before I signed.**
4. **No guarantees or assurances concerning the results of the surgery have been made.**
5. **I am signing this consent voluntarily. I am not signing due to any coercion or other influence.**
6. **I understand that I can withdraw my consent at any time prior to the procedure.**
7. **I herby consent and authorize Dr._____ ("my physician(s)") and/or those associates, assistants and other health care providers designated by my physician(s) to perform a lumbar decompression with or without fusion and/or instrumentation. I authorize them to remove bone, disc and other material; perform a bone fusion (with autograft, allograft or artificial bone); and/or use instrumentation as may be deemed necessary in their judgment. I understand that during the course of the surgery, conditions may become apparent that require my physicians or their designees to take steps or perform additional procedures that they believe are medically necessary for my well-being or to achieve the desired benefits, including but not limited to, the administration of blood and/or blood products, the performance of unanticipated bone fusion with autograft, allograft or artificial bone; the use of instrumentation (fixation devices) and/or the extension of the procedure(s) to levels of the spine above or below the levels originally identified. I authorize and request my physician(s) or their designees to perform whatever medical acts or additional procedures they, in the exercise of their sole professional judgment, deem reasonable and necessary, and I waive any obligation on their part to stop or delay the continuation of my surgery to obtain additional consent.**

_____ _____

Witness Signature of patient or authorized representative

_____ _____ _____

Date Time Relationship to patient if signer is not patient

I have explained to the patient signing above all the information contained in this consent form. I have given no guarantee or assurance as to the results that may be obtained.

_____ _____ _____

Date Time Signature of Physician or Representative

UPMC LIFE CHANGING MEDICINE

PATIENT IDENTIFICATION

LUMBAR DECOMPRESSION WITH OR WITHOUT STABILIZATION CONSENT

INTERPRETER'S STATEMENT

Execute if an interpreter is provided to assist the individual in understanding this informed consent form:

I have translated the information and advice presented orally to the individual to be treated by the person obtaining this consent.

In addition, I have sight translated the consent form (read it aloud in his/her language). To the best of my knowledge and belief he/she understood this explanation.

_____
Cyracom ID (if applicable)

_____
Print Name

_____
Signature (Not required if a Cyracom Interpreter Was Used)