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, treated, and having my radiological studies reviewed, I have been diagnosed as having a probable bulging or herniated disc(s) in the cervical portion of my spine (neck) surgery will be at the following level(s) _____. Discs are shock-absorbing cushions between the bony segments of the spinal column (vertebrae). My symptoms are probably caused by disc material pressing on a nerve or nerves. The most common symptoms include pain, numbness and weakness.

I acknowledge that my physician(s) has/have recommended that I undergo a cervical discectomy (the "recommended procedure"). A cervical discectomy is the surgical removal of the portion of the disc material that is causing my symptoms. I understand that other material may also have to be removed to reduce the likelihood that my symptoms could recur. 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) to help stabilize the existing bony structures. The bony material used may be my own bone (autograft) taken from my pelvic bone or from another place in my body or bone from another person (allograft). 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 physicians are currently recommending the following procedure(s) to try to eliminate some or all my symptoms:

- ☐ Anterior cervical discectomy **without** bone fusion or instrumentation
- ☐ Anterior cervical discectomy with:
  - ☐ interbody fusion using:
  - ☐ autograft
  - ☐ allograft
  - ☐ 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; or poor quality of bone may prevent the physician(s) from performing a planned fusion. . 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 Morphogenetic 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 be positioned on the operating room table and my neck will be cleaned and covered. An incision (cut) will be made at the front of the neck (anterior position) a few inches above the collarbone and to the side of the windpipe. An x-ray will be taken to try to determine where the involved disc material is located. Neck muscles and tissue will be held aside (retracted) so the physician(s) can view the front of the spinal column and the disc material(s). The surgeon(s) will then remove as much disc and other material(s) as they reasonably believe should be removed 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 to relieve my symptoms or improve my health or well-being. If the recommended procedure involves fusion (autograft or allograft), bone will be inserted into the space in my neck where the disc material was removed and fused (connected) to the adjacent bony portions of my spine. If the fusion involves an autograft (my own bone), the surgeon(s) will also make an incision at the site of my iliac crest (pelvic bone) and remove bone from my iliac crest. If for some reason bone cannot be used from my pelvic bone, the surgeon(s) may have to convert to an allograft.

The wound(s) will then be closed. The surgery should take approximately 1 to 2 hours.

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 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 24 hours of my surgery. In most cases, patients are discharged the same day. 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. Postoperatively, I may be prescribed a neck brace.

1. **Risks of Surgery:** I understand that there are inherent risks in the performance of the recommended procedure. These include:
2. Post-operative pain. In most cases, the pain diminishes, and patients end up with 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.
3. Muscle 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.
4. Scar tissue at site(s) of incision(s).
5. Further bulging or herniation of the disc. (This happens very rarely.)
6. Diminished speech. Retraction of tissue during the procedure may inadvertently put pressure on the nerve that controls the vocal cords (recurrent laryngeal nerve) causing diminished ability to speak or hoarseness which usually lasts a few days but can last several weeks or months. In rare cases, vocal cord damage can be permanent.
7. Difficulty swallowing. This usually lasts 1 to 2 weeks.
8. Hematomas (blood pooling) can form at the sites of the surgeries (back, pelvis or another site).
9. 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, or by insertion of a filter in the inferior vena cava to prevent clots from reaching the lungs.
10. Other bleeding either during or after surgery. The chances of requiring a blood transfusion or use of blood products are extremely unlikely during this procedure. 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.

☐ 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.

11. Damage to nerves at or near the site(s) of the surgery(ies) that can cause neurological dysfunction, such as weakness, numbness or loss of use of arms and/or lower extremities, decrease or loss of bowel or bladder control and sexual dysfunction.
12. Damage to nerves from pressure or positioning of the arms, legs or back during the surgery. This type of 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.
13. 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.
14. Damage to adjacent organs.
15. Pressure sores on the skin due to positioning.
16. Burns caused by use of electrical equipment that may be needed to stop bleeding or by other equipment.
17. 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 portions of the body.
18. Sometimes a special device that keeps the head fixed during surgery (head holder or stereotactic frame) is used. If it is used, it can slip causing a laceration of the scalp. These lacerations are sewn up at the time of slippage. Rarely, other problems with the application of the device can occur, e.g., penetration of the skull, hematoma (blood clot) and air embolism (air in the blood stream). Sometimes additional surgery is required to properly manage these occurrences.
19. As with all surgeries conducted under general anesthesia there is a very small risk of heart attack, stroke and death, even in healthy patients.
20. Other risk(s), if any:_____

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

21. 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. (<5%)
22. 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 cutaneous nerve (a sensory nerve on the skin), causing numbness and/or pain. (<30%)
23. Use of bone graft substitutes like BMP may result in inflammation that can cause swelling that can compress the airway and may require additional emergency treatment to secure my airway, such as placement of an endotracheal tube or tracheotomy.

24. Ectopic (extra) bone growth can occur resulting in pressure on nerves and return of or new symptoms of muscle weakness, numbness and pain.

25. 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 12 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:

20. Breakage, failure or loosening of device (possibly causing chronic pain) (<2%)

21. Misalignment or poor positioning of device (possibly causing pain) (<5%)

22. Infection at the site of the device (<1%)

23. Need for surgery to remove device (<2%)

24. 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. (Estimated risk: <1%)

25. 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, a number of 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. (Estimated risk: <1%)

Alternatives: 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. On occasion, conservative therapy or non-surgical treatment, such as medication, rest, physical therapy, manipulation, traction, bracing, injection and/or massage, may relieve the symptoms associated with a herniated or bulging disc. Stronger pain medications (painkillers, or narcotics) and/or injections may also be tried if the pain is severe. Muscle relaxants or certain anti-depressants may help reduce any nerve-type pain (neuropathic pain) and help restore normal sleep patterns. I acknowledge that the alternative therapies that may be medically acceptable treatments for my condition, if any, have been thoroughly discussed with me.

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.

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 of 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. Such recordings are not part of the medical record and I understand I cannot obtain a copy.

I authorize the disposal or retention, preservation, testing, or use for scientific, educational or other purposes of 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, as 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.

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

MY SIGNATURE BELOW 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 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 insertion or 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 hereby consent and authorize Dr._____ ("my physician(s)") and/or those associates, assistants and other health care providers designated by my physician(s) to perform an anterior cervical discectomy and remove as much disc and other material as deemed necessary in their judgment, with or without bone fusion and/or instrumentation. 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

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.

UPMC LIFE CHANGING MEDICINE

PATIENT IDENTIFICATION

ANTERIOR CERVICAL DISCECTOMY WITH OR WITHOUT STABILIZATION 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)

UPMC LIFE CHANGING MEDICINE

PATIENT IDENTIFICATION

ANTERIOR CERVICAL DISCECTOMY WITH OR WITHOUT STABILIZATION CONSENT