Patient Name: _____
Identification Number: _____

UPMC LIFE CHANGING MEDICINE

LAPAROSCOPIC VENTRAL/INCISIONAL HERNIA REPAIR CONSENT FORM

I, _____ have been asked to read carefully all of the
(name of patient or substitute decision-maker)
information contained in this consent form and to consent to the procedure described below. I have been told that I should ask 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 undergo the proposed treatment voluntarily.

I understand that after evaluation including, but not necessarily limited to an interview, physical examination and a review of diagnostic studies, such as blood tests and x-rays, I have been diagnosed as having a **ventral/incisional hernia**. I understand that a hernia is a weakness or tear in the abdominal wall through which abdominal contents protrude and may cause a bulge or discomfort. I understand that a hernia may be congenital (from birth) or may result from obesity, previous surgery, chronic coughing, or heavy lifting. Ventral refers to a location on the front surface of the abdomen. An incisional hernia occurs within the scar from a previous surgery. I understand that my physician(s) have recommended that I undergo a laparoscopic ventral/incisional hernia repair.

Surgery. The type of anesthesia and the risks of anesthesia will be explained to me by a representative of the Anesthesia Department and I will sign a consent for anesthesia. Prior to surgery, I may be given an antibiotic through a tube placed in my vein(s) and I will wear compression stockings on my legs to help prevent blood clots. After I have been identified, I will be put to sleep under general anesthesia. I will be positioned lying on my back on the operating room table. After I am asleep under anesthesia, a catheter will be inserted into my bladder to empty the urine and my abdomen will be cleansed and may be shaved.

The surgery will be performed using several small cuts, or incisions. Long instruments and a telescope called a laparoscope will be inserted into my abdomen through these incisions. Carbon dioxide gas will be used to inflate my abdomen create a working space for surgery. The inside of my abdomen will be visualized using television screens. Any scar tissue that causes the internal organs and intestines to stick to the abdominal wall will be peeled away from my abdominal wall to uncover the hernia. The hernia will be measured and a piece of synthetic or biologic mesh will be inserted into my abdomen to patch the hernia, thereby preventing my internal organs from protruding into the hernia. Sutures will be passed through my abdominal wall to keep the mesh in place. Additionally, titanium tacks may be used to keep the mesh in place.

If the surgery cannot be accomplished safely using the laparoscope, I understand that my surgeon may have to make a larger incision to perform the hernia repair. In this case, one or more plastic tubes may need to be inserted under my skin to permit drainage and these may need to stay in place after I leave the hospital. The tubes may be able to be removed at my next office visit.

If my surgeon finds that the scar tissue inside my abdomen is too extensive to perform the operation, or if there is damage to internal organs that might make it unsafe to complete the surgery, I understand that my surgeon may abandon the operation and try to perform surgery to repair the hernia again at another date.

The surgery usually takes from one (1) to five (5) hours, depending on the complexity of the surgery. If this is a repeat surgery to repair a hernia, I understand that the surgery may take longer or be more difficult.

Post-Surgical Recovery, Care and Conditions. After the surgery, I will probably have pain. I may be given pain medications, antibiotics or other drugs as needed. I understand that it is important for my physician(s) to know all drugs

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that I am currently taking in order to avoid any unwanted and harmful drug interactions and I agree that prior to the surgery I will inform my physicians about all medications, drugs, herbs and supplements I am taking.
My physician(s) will determine when I can be discharged from the hospital. I understand that I may have some restrictions and limitations after the surgery. I acknowledge that these restrictions and limitations have been thoroughly discussed with me.

I understand that I will most likely develop scar tissue at the site of the incisions. I may experience bloating or gas, fatigue, and nausea.

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

1. Bleeding inside my abdomen or from my abdominal wall. I may have severe bruising of my abdominal wall. The need to use blood products is extremely unlikely. 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.

   ☐ 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.

2. Infection or allergy. This may occur at the surgical site or incision(s). Allergy to the mesh may result in similar redness and warmth as might occur with infection. If the mesh used to repair my hernia becomes infected or causes an allergic reaction, it may need to be removed in another surgical procedure. I understand that removing the mesh may leave a large open abdominal wound which could take months to heal and may require prolonged wound care.
3. Injury to nerves in my abdominal wall which might cause prolonged pain or numbness.
4. Injury to internal organs and structures, including, but not limited to my intestines, colon, bladder, abdominal wall, and abdominal muscles.
5. Pain. This should resolve within a few days but may be prolonged.
6. Fistula. When the intestine has been damaged, an abnormal connection between my intestine and my skin may develop which causes intestinal juices to leak chronically, requiring wound care and possibly surgery.
7. A collection of fluid (seroma) or blood (hematoma) may occur in the area of the hernia. This may cause discomfort. I understand that the skin bulging may not go away immediately after surgery but may shrink eventually.
8. Blood clots. These clots usually develop in the legs and 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 of time.
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 permanently.

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10. Burns caused by use of electrical equipment that may be needed to stop bleeding or by other equipment.
11. As with all surgeries, there is a risk of heart attack, stroke, multisystem organ failure, reactions to medications, and death, even in healthy patients.
12. Air or gas bubbles from the insertion of gas into the abdomen may enter the blood stream causing cardiac arrest, stroke, pulmonary embolus, or heart attack
13. Pneumonia, urinary tract infection, or catheter infection may occur.
14. Other unforeseen risks or complications could occur.

Alternatives. I understand that I have the choice NOT to undergo the recommended procedure or any procedure. If I do not undergo the procedure, the condition for which I am being treated may get worse and may cause an intestinal obstruction and gangrene of the intestine. I acknowledge that my physician(s) have discussed other alternative procedures or treatment(s) for my particular condition, if any. These alternatives may include open hernia repair through a large incision or observation without surgery. 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. These team members may perform all or parts of my procedure under the supervision and guidance of my physician(s). I understand my physician(s) will perform or be present for the key portions of the surgery. Who will participate and in what manner will be decided at the time of procedure and will depend on the availability of individuals with the necessary expertise and on my medical condition.

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. 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 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.

Teaching Facility: I understand that the facility is a teaching facility. The health care team may include residents, fellows, students, and skilled healthcare professionals. These team members may perform all or parts of my procedure under the supervision and guidance of my physician(s). I understand my physician(s) will perform or be present for the key portions of the surgery. 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.

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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.

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 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 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 procedure(s) 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 laparoscopic**

   ventral/incisional hernia repair, and remove or repair any organs/tissues as 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 to achieve the desired benefits or for my well-being, including but not limited to division of scar tissue ("adhesions") and the administration of blood and/or blood products. 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 in order to obtain additional consent.

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Witness	Signature of patient or person authorized to consent for patient
Date Time	Relationship to patient if signer is not patient

I have explained to the patient signing above all of 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 Physician's Representative

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