Consent for Uterine Artery Embolization

INTRODUCTION:

You have been diagnosed as having symptomatic uterine fibroids. Your doctors feel that the best treatment for you is to undergo uterine artery embolization. During this procedure, a material known as an embolic agent, is injected into the arteries supplying the uterus to reduce the blood flow to the fibroids. A variety of embolic agents are available and your doctor will choose the one that is best suited to your condition. We are asking you to read and sign this form so that we can be sure you understand the procedure and potential benefits, along with the associated potential risks, complications, alternatives, the likelihood of achieving the goals, and the recuperative process. Please ask questions about anything on this form that you do not understand.

PROCEDURE:

Uterine artery embolization involves the placement of a plastic tube (catheter) into the artery in your leg. Some numbing medicine will be injected in the skin over the artery that will be used before the catheter is inserted. Intravenous medications may also be given to you to make you more comfortable and relaxed. This is known as moderate sedation. Once the catheter has been placed into the artery, it will be advanced through the blood vessels. During this time, x-ray contrast material (x-ray dye) will be injected through the catheter and x-ray pictures taken. You may be asked to hold your breath for several seconds as these pictures are taken. During the injection of x-ray contrast material, you may experience a warm feeling or a strange taste in your mouth. Both of these sensations are temporary and will go away soon. Once the catheter is placed into the uterine arteries, the embolization agents will be injected until there is reduced flow through that vessel. At the completion of the procedure the catheter will be removed and pressure will be applied to the insertion site until the bleeding has stopped. It will be very important for you to lie flat in bed without moving your leg for up to six hours.

RISKS:

Risks associated with the procedure include, but are not limited to, pain or discomfort at the catheter insertion site, bleeding at the site, injury to a blood vessel, infection which may result in an infection of the blood stream or in an infection of your uterus which may require a hysterectomy, the development of a blood clot (embolization) in other areas of your body, and stroke. When a vessel is blocked to decrease blood flow, some of the tissue supplied by that vessel may not get enough blood. This may result in damage or death of the tissue (necrosis), which could require hysterectomy. Tissue breaking off the fibroid into the uterine cavity may be passed spontaneously through your vagina or might require a procedure to help remove it. There is a chance of menopause as a result of the procedure. In addition, the blood flow to other, non-targeted areas may become diminished which may result in injury to the organs or tissues in that area. Risks associated with the x-ray contrast material include an allergic reaction and reduced kidney function. The medications used for the moderate sedation are associated with the risks of aspiration (inhaling food or liquid into your lungs) or respiratory depression. In addition to these potential risks associated with the procedure, the x-ray contrast material, and the moderate sedation medications, there may be other unpredictable risks including death.

(Complete this paragraph if applicable or document “NA”)

Due to your additional medical history of

added risks for you include but are not limited to:

________________________

ALTERNATIVES:

There may be other methods to treat your condition, including hysterectomy, myomectomy, and medical management. If you are unsure about undergoing uterine artery embolization, please discuss these other alternatives with your physician.
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AGREEMENT:
The information on this form was explained to me by __________________________. I understand the information and I have had the opportunity to ask any other questions I might have about the procedure, the reasons it is being performed, the associated risks, and the alternatives to the procedure. I agree to undergo the procedure to be performed by an authorized member of the Division of Vascular and Interventional Radiology and his/her associates, assistants, and appropriate hospital personnel, and accept the risks. I also agree that fellows, residents and surgical assistants may participate in significant tasks that are part of the procedure. In addition, I agree to have any other appropriate personnel present for the procedure.

I assign to the University of Pennsylvania Health System ("Health System") all rights to any tissues, organs, cells, body parts, and/or body fluids that may be removed during this procedure and I authorize the Health System to use or dispose of such specimens according to its standard practices.

The University of Pennsylvania Health System routinely suspends all resuscitative aspects of living wills and Do Not Attempt Resuscitation orders during the pre-procedure, procedural and post-procedural period, unless you specifically tell us otherwise. This applies to all invasive and operative procedures.

Signature: __________________________ Date: _________ Time _______
Patient

Signature: __________________________ Date: _________ Time _______
Authorized Healthcare Professional obtaining and witnessing patient’s signature

Signature: __________________________ Date: _________ Time _______
Attending physician (if applicable)

To be used if the patient is a minor, unconscious, or otherwise lacking decision making capacity.

I, __________________________, the __________________________
Relationship to patient
of __________________________ hereby give consent.

Signature: __________________________ Date: _________ Time _______
Legally Authorized Representative

Signature: __________________________ Date: _________ Time _______
Authorized Healthcare Professional obtaining and witnessing representative’s signature

Signature: __________________________ Date: _________ Time _______
Attending physician (if applicable)

Signature: __________________________ Date: _________ Time _______
Witness to telephone consent

1/02, 4/05, 8/06, 10/07, 11/09