CONSENT FOR STEREOTACTIC RADIOSURGERY
Vascular Malformations

I, _____ have been asked to carefully read all of the
(name of patient or substitute decision-maker)
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 questions
(name of patient)
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 and/or audiovisual 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 evaluated by having imaging studies (CT scan, MRI or angiogram) reviewed, I have been determined to have one or more of the following lesions (diagnoses) affecting the brain or its coverings (dura).

- ❑ Arteriovenous malformation (AVM)
- ❑ Arteriovenous fistula (AV fistula)
- ❑ Cavernous malformation (CM) or cavernous angioma
- ❑ Other_____

An **arteriovenous malformation (AVM) or cavernous malformation** is a tangle of abnormal vessels. Arteries carry high-pressure blood and have thick walls that contain muscle to regulate the rate of blood flow. Veins carry low-pressure blood and have thin walls. An AVM carries blood with relatively high pressure but its walls are weaker and thin, similar to those of a vein. AVMs have a tendency to leak or rupture (average risk 2-4% each year). AVMs can occur anywhere in the body but most commonly occur in the brain. Symptoms arise from the effects of pressure on surrounding tissue, high rate of blood flow (shunting) or from bleeding. Symptoms may be quite variable depending on the location of the AVM. Patients with an AVM may experience headache, migraines and/or epilepsy (seizures or convulsions). Any leakage or rupture of blood into the brain or spinal fluid can cause symptoms that may range from a severe headache and stiff neck, double vision, dizziness and/or nausea to sudden stroke-like symptoms (trouble speaking, numbness and/or weakness in the arm(s) or leg(s) and trouble walking), coma or death.

A **cavernous malformation (CM)**, sometimes called a cavernous angioma or angiographically occult vascular malformation, has distinct imaging features on CT and MRI. However, the lesion does not show up on angiogram. These lesions sometimes leak or rupture. If the CM leaked only once in the past the risk of another leak is approximately 1% each year thereafter. If the CM leaked more than once in the past the risk of another leak may be as high as 30% each year thereafter. Symptoms may be absent or quite variable depending on location and may range from sensory changes (numbness and tingling) to seizures or major loss of neurologic function. Bleeding from a CM can cause symptoms similar to an AVM leak or rupture.

An **arteriovenous fistula (AV fistula)** is a direct communication between an artery and vein by way of a common, abnormal opening in the walls of both the artery and the vein, each of which is in contact with the other. This connection allows high-pressure blood from the artery to enter the normally low-pressure venous system. Symptoms arise from the effects of pressure on surrounding tissue, high rate of blood flow (shunting) or from bleeding. Symptoms may be quite variable depending on the location of the AV fistula. Patients with an AV fistula may experience headache, migraines and/or epilepsy (seizures or convulsions). Sometimes the high rate of blood flow through the fistula may create a noise in the head (bruit or tinnitus). Bleeding from an AV fistula involving the covering of the brain (dura) and vessels on the surface of the brain can cause symptoms similar to an AVM leak or rupture.

Stereotactic radiosurgery is a technology that focuses high-dose radiation upon a desired target with surgical precision utilizing three-dimensional targeting (stereotactic frame), imaging (CT, MRI and/or angiography) and complex computer-assisted planning. Gamma Knife® is a technology for brain radiosurgery.

I understand that my physician(s) are currently recommending that I have stereotactic radiosurgery using the Gamma Knife® to try to 1) remove or greatly reduce the risk of bleeding 2) improve some or all of my symptoms and/or 3) reduce the likelihood and risks of more invasive procedures.

Although my physician(s) have indicated what they believe the recommended procedure(s) will involve, I understand that my physician(s) may later determine in their reasonable judgment, to modify the procedure before or during the procedure. For example, the imaging study used in planning my treatment (angiogram, CT and/or MRI) may show additional lesions or features of the lesion(s) that may require the treatment plan to be altered or the procedure to be staged or stopped.

Description of Procedure:

Prior to stereotactic radiosurgery, I will be given medications to moderately sedate me (make me drowsy, decrease my consciousness and relax me) or, in the case of children, general anesthesia ("put me to sleep"). Sedating medications are given through an intravenous (IV) line. I have been told that the risks of moderate sedation include slow or inadequate breathing (hypoventilation), lack of breathing (respiratory arrest) and low blood pressure (hypotension). If I will be "put to sleep", a representative of the Department of Anesthesiology will explain the risks of general anesthesia to me.

After careful cleansing, my scalp will be numbed by injecting a local anesthetic. Once my scalp is numb, a metal stereotactic frame will be fixed onto the skull using pins. With the head frame in place an imaging study will be obtained (CT, MRI and/or angiogram). These images with the head frame in place will allow accurate targeting, radiation planning and radiosurgery. When ready for radiosurgery I will be placed on the movable bed of the Gamma Knife®. Treatment may require several changes of my position in the Gamma Knife®. At the end of the procedure, the frame will be removed and a pressure bandage will be applied around my head. On average, the entire procedure will take from 2 to 4 hours. If angiography is used for imaging, an additional consent will be obtained from me that will explain the risks of angiography.

My physician(s) will determine the best time for me to return home and to normal activity. Often patients will spend the night in the hospital for observation. On occasion, patients will return home on the day of treatment following a brief observation period (2-4 hours).

Post-Procedure Recovery, Care and Conditions. After the procedure, I may have some scalp pain or headache. If my imaging involved angiography, I may have some groin pain. I may be given pain medications as needed. I understand that it is important for my physician(s) to know of all drugs that I am currently taking in order to avoid any unwanted and harmful drug interactions. Prior to the procedure I agree to inform my physician(s) about all of the medications, drugs, herbs and supplements that I am taking. My physician(s) will determine when I can be released to return home. 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.

Risks of Procedure: I understand that there are inherent risks in the performance of the recommended procedure. These include but are not limited to:

1. Incomplete treatment. The effects of high-dose radiation occur over weeks to months or years. In some instances the impact of radiation may not completely treat my problem. In these cases the abnormality is considered incompletely treated and there is no reduction of the risks associated with the lesion (rupture, leakage, neurologic loss, coma death). Additional treatment(s) including further stereotactic radiosurgery, embolization and/or traditional surgery may be required. (Estimated risk: 5-30% depending on size of the vascular lesion)
2. Neurologic loss. Loss of neurologic function can be temporary or permanent and related to changes in blood flow, brain swelling and/or cell death. Symptoms may include seizures; weakness, numbness,

paralysis and/or spasticity (stiffness) of arm(s) and/or leg(s); facial weakness and/or numbness; hearing loss; visual loss; double vision; memory loss; speech and/or swallowing difficulty; sexual dysfunction; trouble controlling bowel and/or bladder; hormone imbalance (pituitary); personality changes; loss of appetite, energy and/or alertness; coma and death. (Estimated risk: 1-15% depending on location of the vascular lesion in the brain)

3. Stroke. The effect of radiation on blood vessels in the brain may result in narrowing or closure of the blood vessels. Inadequate blood flow to the brain may result in stroke. Symptoms may be absent or may result in varying degrees of neurologic loss including coma and death. (Estimated risk: <3%)

4. Epilepsy. Seizures (convulsions) may develop after radiosurgery due to swelling or scarring of the brain. Usually, medications control or reduce seizures. The disorder may be temporary or permanent and may require medication for an indefinite period of time. Symptoms may include loss of consciousness, uncontrolled movements, hallucinations or dream-like states, sensory and/or psychological disturbances. (Estimated risk: <5%)

5. Brain swelling (edema). The effects of radiation on brain cells and blood vessels in the brain (normal and abnormal) can cause localized or regional swelling of the brain. Symptoms may be absent or quite variable depending on the location and amount of brain affected. For example, brain swelling may cause seizures; weakness, numbness, paralysis and/or spasticity (stiffness) of arm(s) and/or leg(s); facial weakness and/or numbness; visual loss; double vision; memory loss; speech and/or swallowing difficulty; sexual dysfunction; trouble controlling bowel and/or bladder; hormone imbalance (pituitary); loss of appetite, energy and/or alertness; coma and death. (Estimated risk: <10%)

6. Post-procedure pain. Headache or scalp pain due to the procedure is usually temporary, mild to moderate and controlled with medication. (Estimated risk: <5%)

7. Infection. Rarely, a superficial infection can occur at the head frame pin sites. (Estimated risk: <1%)

8. Bleeding in the brain (hemorrhage). The risk of bleeding into the brain and/or spinal fluid remains until the effect of radiosurgery results in complete closure of a vascular abnormality (AVM, AV fistula). The consequences of an incompletely treated vascular abnormality include rupture, leakage, neurologic loss, coma and/or death. (Estimated risk: 1-10% per year until AVM closure occurs)

9. Blood clots (thromboemboli). These clots usually develop in the legs and/or pelvic veins. They 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. (Estimated risk: <1%)

10. Delayed development of cancer. It is known that radiation rarely can cause certain types of malignant tumors. Reports of tumors developing in patients after stereotactic radiosurgery using the Gamma Knife® have been reported rarely. (Estimated risk: 1 per 1,000 patients over the next 5-30 years).

11. Hair loss. Rarely, a small area of temporary or permanent hair loss may occur if the scalp receives a significant dose of radiation. Generally, this risk is limited to lesions that are on or near the surface of the brain. (Estimated risk: <1%)

12. Other risks, if any: _____

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 lead to serious neurological problems and sometimes death. However, some people have no problems if left untreated. I acknowledge that my physician(s) have discussed other alternative procedures or treatment(s) for my particular condition, if any. These alternatives may include medication, embolization and/or traditional surgical approaches including craniotomy for removal of all or part of a lesion.

Teaching Facility. Since my surgery will be performed at a facility associated with the UPMC or another teaching facility, I agree that for the purpose of advancing education, residents, fellows, students and others may assist with or perform all or parts of the recommended procedure or other acts as deemed appropriate by and

under the supervision of my physician(s); and that others not directly responsible for my care may observe the procedure.

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 insertion or 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 hereby consent and authorize Dr(s). _____ (my physician(s)) and/or those associates, assistants and other health care providers designated by my physician(s) to perform stereotactic radiosurgery using the Gamma Knife® as may be deemed necessary in their judgment. I understand that during the course of the procedure, 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. 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 procedure in order to obtain additional consent.**

_____	_____
Witness	Signature of patient or person authorized to consent for patient
_____	_____
Date	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	Signature of Physician or Physician's Representative