

# Consent for Radioembolization of the Liver

## INTRODUCTION:

You have been diagnosed as having a tumor (cancer) in your liver, either a cancer of the liver itself or a cancer that has spread to the liver from somewhere else in your body. Your doctors feel that the best treatment for you is to undergo radioembolization of your liver. During this procedure, radioactive microspheres (“beads”) are injected into the artery feeding the tumor. These tiny beads become lodged in the tumor and surrounding liver, and deliver continuous radiation therapy to the tumors over the next few weeks. 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:

On the day of the procedure, an intravenous line will be placed in your arm to give you fluids and medications. An arteriogram will then be performed. This involves the placement of a plastic tube (catheter) into an artery in either your leg or your forearm. 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. A series of X-ray pictures will then be taken of the arteries and veins to your liver. Once the catheter is placed into one artery supplying the tumor, the radioactive microspheres (“beads”) will be injected. If there is evidence of blood circulation from the liver to other organs outside the liver, side branches of the artery to the liver may be blocked with coils or small particles (“embolized”) in order to be able to deliver the microspheres (“beads”) safely. At the completion of the procedure, which takes about 1-2 hours, the catheter will be removed and pressure will be applied to the insertion site until the bleeding has stopped. To help prevent bleeding, it will be very important for you to lie flat in bed without moving your arm or leg for up to four hours. If needed, medications to control any pain, fever, nausea, or vomiting you may be experiencing after the procedure are available to you. Most patients go home the day of the procedure. You may be discharged from the hospital as soon as you no longer require injections to control your pain or nausea and you feel well enough to eat and drink.

You will be prescribed a few days of steroids and an acid-blocking medication to protect your stomach from effects of the radiation. Radioembolization causes some predictable symptoms that affect up to one-half of patients. The most common are fatigue and nausea. Less commonly patients may have various degrees of pain, fever, or vomiting. Three weeks after the radioembolization, you will have outpatient blood tests to check the effects of the procedure. Four weeks after the procedure, you will have another artery to your liver radioembolized. Generally, two procedures are necessary to completely treat the liver. Depending on the number of arteries you have supplying your liver, you may require more or less than two treatments. In order to assess how the treatments have affected your tumor, four weeks after your entire liver has been radioembolized you will have additional blood tests and another scan of your liver. If you have responded to the treatments, these studies will be repeated every three months. If your tumor starts to grow again, you can be treated with additional radioembolization procedures. If the studies indicate that you did not respond to the initial treatments, no more radioembolization procedures will be performed and other possible treatment methods will be discussed with you.

## 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, the development of a blood clot (embolization) in other areas of your body, stroke, the development of a liver abscess, acute or chronic liver failure, and radiation injury to other organs near the liver (such as the stomach). If a side branch is blocked, some of the tissue supplied by that vessel may not get enough blood, which may result in injury to the organ the vessel feeds. 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:

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### ALTERNATIVES:

There may be other methods to treat your tumor. If you are unsure about undergoing a radioembolization of the liver, please discuss these other alternatives with your physician.

### 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

