Consent for Percutaneous Transcisternal Catheterization of the Thoracic Duct for Diagnosis and Embolization

INTRODUCTION:

The purpose of this procedure is to find and close the tear in your thoracic duct (a long vein like tube in your chest) which is persistently leaking large amounts of protein and fat rich lymph fluid around your lungs. You are being offered this treatment because it may prevent you from having open chest surgery performed. 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:

In order for us to know whether this procedure is possible in your case, you must first be studied with a lymphangiogram, which will tell us whether your lymph ducts are wide enough for us to thread a small plastic catheter (tube) from your abdomen to your thoracic duct. In order to perform the lymphangiogram, after injecting numbing medicine, short incisions will be made on the tops of your feet, with or without injecting blue dye between your toes (to help find the lymph vessels). Intravenous medications may also be given to you to make you more comfortable and relaxed. This is known as moderate sedation. A needle will be placed into a tiny lymph duct and oily contrast (“x-ray dye”) will be injected into each lymph duct (usually one in each foot) over a period of an hour or more. If the cisterna chyli (a lymph fluid sac deep in the abdomen which connects to the thoracic duct) is found to be of adequate size, some numbing medicine will be injected in the skin just below your breast bone and the cisterna chyli will be punctured with a very fine needle under fluoroscopic (x-ray) guidance. Once the needle is in proper position, it will be possible to exchange it for a small flexible plastic tube which will be advanced into your thoracic duct. If the leak can be identified when we inject x-ray contrast material (x-ray dye) through the tube, we will insert a special metal coil and/or surgical glue into the thoracic duct which will plug up the leak.

PROCEDURE (cont’d):

After the leak in your thoracic duct is controlled, it may be possible to discharge you home within a few days, provided you do not have a fever and the fluid in your chest has been adequately drained.

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), and stroke. Risks associated with the x-ray contrast material include an allergic reaction. Although rare, the oily contrast material may result in shortness of breath, usually in people with existing lung disease. Puncture of the cisterna chyli could result in symptomatic leakage of lymph fluid into the abdomen. 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:

If you do not wish to have this procedure done, you may need to have the leak repaired with surgery. This can be more risky since it involves the administration of general anesthesia and requires that your chest be opened to localize and tie your thoracic duct. If you are unsure about having a thoracic duct embolization performed, 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.

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

I, __________________________, the __________________________

of __________________________ hereby give consent.

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