INTRODUCTION:

Your physician has requested that you undergo a percutaneous biliary drainage procedure to further treat the condition affecting your liver and/or bile ducts. Based on the findings of this study, additional interventions, such as a stricture dilation, stent placement, tissue sampling, or stone removal may be 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:

A percutaneous biliary drainage procedure involves the placement of a fine needle through your skin and into your liver. Some numbing medicine will be injected in the skin before the needle is inserted. Intravenous medications may also be given to you to make you more comfortable and relaxed. This is known as moderate sedation. Following insertion, the needle will be guided to the correct location by an x-ray camera or ultrasound machine. The position of the needle will then be confirmed by the injection of x-ray contrast material (x-ray dye) and/or removal of fluid. X-ray pictures of your liver will then be taken. It may be necessary to make more than one pass of the needle in order to enter the bile duct. Depending on your condition, a drainage tube may be placed, a tissue sample taken, a stone removed, or a blockage of the bile ducts opened with a balloon catheter or stent placement. If a drainage tube is placed it will be inserted through the skin and secured in place. It may need to stay in place for a long time to allow your bile fluid to drain. Tubes in the bile system often become plugged after time, which may result in the need to replace the tube at a future date. If not replaced, a plugged tube may result in a serious infection. If an area of blockage is discovered, an attempt to open the blockage may be performed with a balloon catheter. This involves the insertion of a special tube, which has a tiny deflated balloon. The balloon is positioned at the site of the blockage and is then inflated.

Following this procedure, if there still is not enough bile flow through the area of blockage, a metal mesh tube (stent) may be placed at the site. The stent will widen the duct and improve the bile flow. If a tissue sample is to be taken or a stone removed, either of these procedures can be performed through the needle access already created in your bile system.

RISKS:

Risks associated with the procedure include, but are not limited to, pain or discomfort at the needle insertion site, bleeding at the site, internal bleeding, injury to a blood vessel, organ puncture, and infection which may result in an infection of the blood stream. Because a needle is being placed into your bile system, there is the risk of developing a bile leak that may cause peritonitis (an infection of the lining of the abdomen). There is also the risk of causing cholangitis (an infection of the bile fluid). The development of any infection, including peritonitis or cholangitis, may result in the need for intravenous antibiotics. 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 procedures that can be performed to further evaluate or manage your liver and/or bile duct condition. If you are unsure about having a biliary tube check/change procedure, along with a possible stricture dilation, stent placement, tissue sampling, or stone removal, please discuss these other alternatives with your physician.
Consent for Percutaneous Biliary Drainage and Possible Stricture Dilation, Stent Placement, Tissue Sampling or Stone Removal

AGREEMENT:
The information on this form was explained to me by __________________________. I understand the information and 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