Informed Consent for Endoscopic Retrograde Cholangiopancreatography (ERCP)

Name: ___________________________ Procedure Date: ________________ Time: ___________

1. I, ______________________ (patient or guardian) give consent for Dr. Karthik Mohan or his/her associates to perform an endoscopic retrograde cholangiopancreatography or ERCP with possible biopsy, dilation, sphincterotomy (widening the sphincter), stone extraction, stent placement and/or injection therapy of blood vessels or tissue, and control of bleeding if necessary.

2. I understand this procedure involves the passage of a digital optic instrument through the mouth to allow the physician to visualize the interior of the esophagus, stomach, and duodenum (first several inches of the small intestines). Using a combination of endoscopic and x-ray techniques, visualization of the bile ducts is possible. Appropriate therapy can be performed as deemed necessary, including widening the opening of the bile ducts or pancreatic ducts (sphincterotomy), followed by removal of stones or placement of a stent or tube to allow bile or pancreatic enzymes to drain properly. Sedation and pain relieving medications may be given to minimize discomfort and relax me for the procedure. These medications may cause localized irritation and/or a drug reaction. I understand that with the anesthesia/sedation for this procedure I will not be able to drive the remainder of the day and I should not have plans after the procedure. I understand that I MUST HAVE A DRIVER take me home.

3. I understand the reasons for the procedure that have been adequately explained to me by my physician. I understand I may call the office where I regularly see my physician with any questions about the preparation or procedure. I have had many opportunities to ask questions before signing this consent.

4. RISKS: Possible complications of this procedure include, but are not limited to bleeding and tearing or perforation of the esophagus, stomach, small intestines, or bile ducts. These complications, should they occur, may require surgery, hospitalization, repeat ERCP, and/or a transfusion. Perforation of the bowels or bile ducts are known, but rare complications that can occur at a rate of 1 per 1,000 endoscopies. Bleeding, usually after a sphincterotomy, can continue up to two weeks after the procedure. There is also a risk of infection and pancreatitis, or inflammation of the pancreas, caused by the procedure. This occurs at a rate of 10 in 100 cases and can range from mild abdominal pain, managed with pain medications for a few days, to severe life-threatening cases that are very rare. Other extremely rare, but serious or possibly fatal risks include difficulty breathing, heart attack, and stroke. There is also a possibility that the procedure is unsuccessful due to anatomical limitations in finding the bile duct opening and cannulating, or passing a small wire inside. This is a well-known but acceptable risk and can occur at a rate of 5 in 100 cases.

5. I understand that there are no guarantees regarding the results of this procedure. Alternative options as deemed medically relevant have been discussed and may include radiological imaging and placement of a bile duct drain. I understand that these options have their own limitations and benefits.

6. I have read and fully understand this consent form, and understand that I should not sign if all of my questions have not been answered to my satisfaction or if I do not understand any of the words or terms used in this form.

IF YOU HAVE ANY QUESTIONS AS TO THE RISKS OR HAZARDS OF THE PROPOSED PROCEDURE OR TREATMENT, ASK YOUR PHYSICIAN NOW, BEFORE SIGNING THIS CONSENT FORM. DO NOT SIGN UNLESS YOU HAVE READ AND THOROUGHLY UNDERSTAND THIS FORM.

____________________  ______________________
Signature          Date

____________________  ______________________
Witness          Dare