

## PATIENT ID OR LABEL

DOB:

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CONSENT	FOR OPERATION OR PROCEDURE / SEDATION IF APPLICABLE				
Patient Nam	ne: Date of Birth:	-			
Procedure:	ERCP - Endoscopic Retrograde Cholangiopancreatography with Possible Sphincterotomy/ Possible Stent Placement/Biopsies				
Name of Pra	actitioner performing the procedure(s) or important aspects of the procedure:				
	ner practitioners who may perform significant surgical tasks: (include 1 <sup>st</sup> assists if they are perform of the procedure.)	forming a			
Name:					
Task:					

Patient Name:

I authorize my Physician/Practitioner and the other practitioners named above to perform the above procedure at Exeter Hospital.

An ERCP is a procedure performed by your gastroenterologist while you are sedated. It involves advancement of a thin flexible tube through your mouth, esophagus, stomach, and part of your small intestine. A catheter is then placed into either the bile duct and/or pancreatic duct. Contrast is injected and x-rays are obtained. Specific therapies are then performed based on these findings.

- 1. I understand that during the course of the procedure, my Physician/Practitioner or assistants may discover a condition that they did not or could not have anticipated which may necessitate the involvement of another practitioner. In that case, I authorize them to perform such additional or different surgical procedures as they think are important to be performed at this time and to involve other practitioners as appropriate for this purpose. I understand that the practice of medicine and surgery is not an exact science, and I agree that no guarantees have been made to me about the results of this procedure. I understand that surgery and procedures have certain risks, including, but not limited to infection, cardiac arrest, possible loss of blood and the need for further surgery.
- 2. All procedures entail certain risks; ERCP is no exception. Potential complications include:
  - Bleeding, this can typically be controlled with special instruments and medications, but may require surgery and/or transfusions.
  - Perforation of the esophagus, stomach or small intestine. The risk of esophageal perforation is increased by esophageal strictures. This may require hospitalization, antibiotics and urgent surgery.
  - Sedation risks, such as breathing problems or heart problems which are typically mild, but can be life threatening.
  - Although ERCP is a very sensitive test for most conditions affecting the upper GI tract, it is not a perfect test, and abnormalities can go undetected.
  - Pancreatitis occurs in about 1 in 20, or 5% of patients undergoing ERCP. Pancreatitis is typically mild, but may result in additional hospital days, abdominal pain, nausea and vomiting and in rare cases, death.
  - Cholangitis, or an infection of the bile ducts and liver can occur and can be life threatening. It is treated with antibiotics and may require additional procedures.
- 3. I agree to the administration of blood and/or blood products such as, but not limited to, packed red cells, platelets, frozen plasma or cryo, during or within 5 days of my procedure if it becomes necessary to prevent, stop bleeding or replace lost blood volumes. My physician/practitioner has explained the benefits to be expected as well as the risks. The principal risks are described below:
  - A. Transmission of an infectious disease.
  - B. Bacterial contamination of the blood products.





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- C. Non-infectious transfusion risks and adverse consequences include, but are not limited to, transfusion reactions, developing antibodies against the donor's antigens, some physical effects such as, cooling of my body, or too much fluid and/or chemical effects such as too little or too much calcium or iron in my blood.
- D. Immunologic Effects, such as, Transfusion-related acute lung injury (TRALI) and Transfusion-related Immune Modulation (TRIM):
  - <u>TRALI</u> is a rare but devastating complication of blood therapy. Clinically, symptoms are similar to that of adult respiratory distress syndrome, consisting of hypotension (low blood pressure), fever, dyspnea (difficulty breathing), and tachycardia (rapid heartbeat). The onset typically occurs within 6 hours of transfusion, but most cases present within 1 or 2 hours. Transfusions of all blood products have been associated with the disease.
  - <u>TRIM</u> causes relative immune suppression, thereby potentially increasing risk of infectious complications such as pneumonia, sepsis and surgical site infection. It has been associated with transfusion of cellular blood components such as red blood cells and platelets.
- 4. For procedures that do not require General Anesthesia, I agree to the use of certain types of sedation (drugs to make me more comfortable during the procedure) either intravenously or otherwise. I understand that there are certain risks of receiving sedation, including, but not limited to: awareness of the procedure and discomfort, injury to mouth or teeth, adverse reaction to medication, neurological complications, breathing problems, cardiovascular abnormalities, cardiac arrest or death. I have also been told about the option of not receiving sedation.
- 5. I authorize my Physician/Practitioner or Pathologist/designee, who are independent contractors, to examine any tissues, organs, other body parts, or foreign bodies that may be removed during the operation or biopsy performed on me. I further authorize my Physician/Practitioner, Pathologist/designee who are independent contractors, or such pathologists to retain, preserve, and use for scientific, educational, or research purposes any tissue or specimen, while keeping my identity confidential, or to dispose of these items in accordance with Hospital policies.
- 6. I understand that there may be Healthcare Industry Representatives or other people present if medically necessary for performance of the procedure or for purposes of medical education, training and equipment management.
- 7. I agree to have images taken during my treatment for medical documentation and medical education purposes. If images are used for medical education, my identity will be kept confidential.
- 8. If I am receiving an implantable medical device that is required to be tracked under the Safe Medical Devices Act, I authorize the hospital to release to the manufacturer, my name, address, social security number and my physician/practitioner's name and any other information required by law to be reported. I understand that this information will be used to help locate me if, in the future, the manufacturer needs to contact me with regard to the medical device.





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alternative therapies an	d the consequences of dec	lining the recommend	anticipated benefits, material risks, ed or alternative therapies based on and have had them answered to my
Date and Time			Power of Attorney for Healthcare or
If not signed by patient, st	ate reason:	incapacity  permaner	nt incapacity
Telephone / Verbal Conse	ent:   Yes Reason:		
signature:  I have explained to t procedure/sedation, income	(Signed when Physician / Pra che patient (or the persecutions the anticipated	on legally authorized benefits, material ris	Witness Signature t sign this document together.)  It to consent for the patient) the sks, alternative therapies and the d on available clinical evidence.
Date and Time		Signature of Physician	/ Practitioner
recover from the effects of		□ Yes □ No	ended during this procedure and until I   Yes No
Upon request, Palliative C	are consult is available		
opon request, ramative C	and consult is available.		
Date and Time	Signature of Patient	Date and Time	Signature of Physician/Practitioner

EXPIRATION: This consent is valid and effective as it pertains to this episode of care.