REQUEST AND AUTHORIZATION FOR
ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY
MIM #183

I request and authorize Dr. ___________________ and/or associates or assistants of his/her choice at The University of North Carolina Hospitals to perform an endoscopic retrograde cholangiopancreatography (ERCP) on ____________________________.

Authorization is also given for a biopsy, papillotomy, stone removal, and stent placement.

Description of the Procedure: The ERCP will involve the insertion of a long, flexible, video/fiberoptic instrument called a duodenoscope through my mouth and into my duodenum, the first part of my small intestine, into the area known as the papilla. The papilla is the mound of tissue through which the bile duct and pancreatic duct empty into the intestine. A small plastic tube will then be inserted through the duodenoscope into the papilla, dye will be injected to fill my pancreatic and/or bile ducts, and x-rays will be taken.

If any abnormalities are seen, a biopsy may be performed. A biopsy involves the removal through the duodenoscope of a small sample of tissue, which will be examined by a pathologist. Occasionally, a small brush is used to obtain cells from the digestive tract to look for evidence of infection or cancer, if these are suspected.

If the x-rays show that I have gallstones within my bile duct, an attempt will be made to remove them. If the x-rays show that I have a blockage in my pancreatic and/or bile ducts, an attempt will be made to alleviate the blockage. In such cases, a papillotomy may be performed, which involves making a small incision in the papilla using a wire loop and an electrocautery. An electrocautery is an instrument that directs a high frequency electrical current through an area of tissue. In some instances, a small catheter, called a stent, will be left in the duct to help relieve a blockage. Narrowed areas within my bile and/or pancreatic ducts may be enlarged using catheters and balloons.

I understand that sedatives such as midazolam, fentanyl, droperidol, or morphine will be given by intravenous line to cause relaxation and drowsiness. These medications also may cause a brief period of memory loss and result in my not having a recollection of the procedure.

Topical anesthetics will be applied to the back of my throat in order to minimize any discomfort from inserting the duodenoscope. I also may be given atrophine and glucangon to relax my intestine.

Many patients sleep through the procedure, which typically takes 30-90 minutes.
Risks: The following risks have been associated with ERCP:

1. **Slowing of breathing and abnormal heart rhythms:** Intravenous medications may cause a slowing of breathing, and in rare cases may cause breathing to stop. They also may cause abnormal heart rhythms. I will be carefully monitored for changes in my breathing and heart rhythms.

2. **Perforation of bowel wall:** A perforation or tear in the bowel wall occurs in less than 1 per 1000 procedures. If a papillotomy is performed, the risk of a bowel perforation is 1 per 100 procedures. Perforations are treated with antibiotics and/or surgery.

3. **Bleeding:** In fewer than 1 per 100 papillotomies, excessive bleeding may require a blood transfusion or surgery.

4. **Acute pancreatitis:** Acute pancreatitis is an inflammation of the pancreas which often requires hospitalization. It occurs in about 7 per 100 ERCPs and is usually mild and tends to heal by itself over time. However, more severe cases of acute pancreatitis may lead to life-threatening complications, prolonged hospitalization, surgery, or permanent disability.

5. **Infection:** Infections of the bile ducts and/or bloodstream may occur in up to 14 per 100 procedures, especially if stones or an obstruction is found. Antibiotics may be administered prior to the procedure if there is evidence of an obstruction. Patients with heart murmurs or artificial heart valves may be given antibiotics before an ERCP in order to reduce the risk of an infection of the heart valves.

6. **Aspiration of stomach contents:** Aspiration of stomach contents into the lungs occurs rarely in patients undergoing an ERCP procedure.

7. **Other complications:** Patients also may experience an unexpected, adverse drug reaction. Dental injuries may also occur. Other unforeseen severe complications can occur.

8. **Radiation Injury:** Exposure to X-rays may cause severe adverse effects, especially if a fetus is exposed early in pregnancy.

9. **Death:** Death is a rare complication of an ERCP.

Benefits: I understand that the purpose of my participation in an ERCP procedure is to provide information that may not be obtained by x-ray or other diagnostic means. The procedure is generally very safe and is well tolerated by most patients.

Alternative options: I understand that x-rays, MRI scan, and surgery are the alternatives to an ERCP, stone removal, papillotomy, and stent placement.

Statement of Voluntary Participation:
I have read the information contained in this form, and have had sufficient opportunity to discuss my medical condition and treatment with the undersigned physician. All of my questions have been answered to my satisfaction, and I believe that I have been given adequate information upon which to base an informed consent for an endoscopic retrograde cholangiopancreatography, bile stone removal, papillotomy, and stent replacement.

I am consenting to having an ERCP, biopsy, stone removal, papillotomy, and stent replacement. I understand that I can withdraw my consent at any point. My consent for this procedure is voluntary.

I understand that during the course of the ERCP, biopsy, stone removal, papillotomy and stent placement something may arise which may necessitate procedures in addition to or different from those described above. If such unexpected circumstances arise I further request and authorize the performance of additional operations or procedures which may be considered necessary or advisable by the undersigned physician and/or his/her associates or assistants.

I further request the administration of such anesthetics as may be considered necessary, desirable, or advisable by the physician responsible for this service.

I am aware that the practice of medicine is not an exact science, and I acknowledge that no guarantees have been made concerning the performance, results or interpretation of the ERCP.

For the purpose of advancing medical education I give my permission for observers to be admitted to the operating room or procedure room, and UNC Hospitals and the UNC School of Medicine staff to make and use any photographic or other illustrations of me for diagnostic, scientific, educational, or research purposes, provided that my identity is not revealed. I further authorize UNC Hospitals and the UNC School of Medicine staff to examine and dispose of any tissues or parts that may be removed and to use them for teaching, educational, or research purposes, provided that my identity is not revealed.

I confirm that I have read this form, or it was read to me, and that all blank spaces were filled in and all inapplicable paragraphs, if any, were stricken before I signed below.

Women of childbearing age: I certify that I have been advised of possible adverse effects of radiation upon an unborn fetus, and that if there is any chance that I could be pregnant, I will advise the staff of this and agree to undergo a pregnancy test.

_____________________________________________ Date: ___________________
Signature of Patient/Person Authorized to Sign for Patient

_________________________________  ________________________
Printed Name      Relationship to Patient

PHYSICIAN CERTIFICATION
I hereby certify that the patient has read, or had read to him/her, this form and I have explained the nature, purpose, usual and most frequent risks, benefits, and alternatives to the proposed endoscopic retrograde cholangiopancreatography, stone removal, papillotomy, and stent placement. I have offered to answer questions, and fully answered any questions by the patient about the procedure. I believe that the patient understands this form and what I have explained, and has consented to the proposed ERCP procedure, biopsy, stone removal, papillotomy, and stent placement.

______________________________    ______________________________
Physician Signature    Physician Name

Date: ____________________________

WITNESS CERTIFICATION

I hereby certify that the patient has acknowledged to me that he/she has requested an endoscopic retrograde cholangiopancreatography procedure, biopsy, stone removal, papillotomy and stent placement, and has received an explanation of the nature, purpose, benefits, usual and frequent risks and hazards of, and alternatives to the procedure, has had all of his/her questions answered, given his/her consent, and has signed the form above.

______________________________    ______________________________
Witness Signature     Witness Name

Date: ____________________________