NORTH MISSISSIPPI MEDICAL CENTER

TUPELO, MISSISSIPPI

Consent Form for
ERCP

STAMP WITH ADDRESSOGRAPH

1. I hereby authorize, Dr._____ ("my physician") and/or other physicians designated by him/her and the employees and staff of North Mississippi Medical Center, to perform an **ERCP (Endoscopic Retrograde Cholangiopancreatography)** upon me, referred to as the "procedure". I understand that my physician will be assisted by other physicians and health care professionals considered necessary in my care. I agree to their participation in my care.

2. My physician has discussed with me the items that are briefly summarized below:

   a. **Procedure**: ERCP refers to endoscopic retrograde cholangiopancreatography. Endoscopic refers to a procedure where a thin, lighted flexible tube (scope) with small video camera at the end is placed through the mouth and into the esophagus, stomach and first part of the small intestine, liver, pancreas and the gallbladder. The bile duct is a tube that drains fluid from the liver and gallbladder and empties into the small intestine. The pancreas is an organ that also has a tube, which drains fluid into the same area. These tubes connect to the small intestine at a nipple-like structure called the ampulla. These fluids help digest food after a meal.

   A cannula or small tube is then placed through the scope into the bile duct and pancreatic duct to inject a special liquid called contrast. This contrast then allows the ducts to be seen with X-ray. Retrograde refers to the direction the liquid is injected enabling X-rays to be taken to see the bile duct system (cholangio) and the pancreas (pancreat-). Sometimes the muscles or sphincter of the ampulla can be measured by a special technique called manometry. This requires the use of a special cannula. Some of the problems seen during the ERCP can be treated through the scope as stated in the following examples: If a stone is blocking the bile or pancreatic duct, it usually can be removed. Narrowing or blockages in the bile or pancreatic duct may be stretched or dilated and sometimes may require a plastic or metal tube (called a stent) to be placed across the blockage to provide drainage. The opening of the ampulla may also need to be enlarged and this can be cut open with a special cannula.

   The ERCP is usually done under "moderate sedation", or medication given intravenously to help you relax and fall asleep during the test. After the test is over, your doctor will discuss your findings and his recommendations with you and your family. You will feel the effects of the sedation for a number of hours, so you should not drive or make binding/legal contracts until the following day.

   b. **Nature and Purpose of Procedure**: Usually an ERCP may be recommended for several reasons. Listed are the various reasons. I have circled the reason(s) that you are having the test:
      i. Abnormal test of the liver and/or jaundice
      ii. Abnormal X-rays suggesting changes in the liver, bile duct system or the pancreas
      iii. Gallstones
      iv. Acute or chronic pancreatitis (inflammation of the pancreas)
      v. Suspected tumor of the ampulla, bile duct system or the pancreas
      vi. Abdominal pain
      vii. Other _____

   c. **Known Risks of the Procedure**:
      Risks common to any invasive procedure:
      i. Worsening of underlying medical condition which may require medical treatment
      ii. Aspiration of stomach content into the lung which may require further medical treatment
      iii. Neurological changes: coma, stroke which may require medical treatment
      iv. Complications associated with heart and lung disease
      v. Death

      Risks specifically associated with ERCP:
      i. Perforation-tearing a hole in the esophagus, stomach, bile duct, pancreatic duct or intestine which may require surgery
      ii. Bleeding which may require blood transfusions and surgery
      iii. Infection which may require medical treatment or surgical drainage
      iv. Drug reaction and/or trouble with sedation which may require medical treatment or termination of the procedure prior to completion
      v. Pancreatitis or inflammation and bruising of the pancreas. This may require hospital care or even surgery
      vi. Other unpredicted consequences that may occur

      Specific risks associated with my medical condition are as follows:

      _____

      _____

      _____

100867

d. **Alternatives to the Procedure**: The alternatives to the ERCP are as follows:
   i. X-ray: MRI and/or MRCP, CAT scans, abdominal ultrasound
   ii. Observation with no test being done
   iii. Consideration for trial medical therapy
   iv. Empiric treatment of the underlying condition or symptoms

e. **Predicted Outcome (Prognosis) with No Treatment**: The prognosis if the ERCP is not done may include the following:
   i. Incorrect diagnosis
   ii. Progression or worsening of your current illness
   iii. Missed diagnosis of a cancer
   iv. Curable cancer could spread due to lack of a diagnosis
   v. May not be able to treat the underlying problem effectively because the cause or extent of the problem is not known.

f. **Anesthesia**: I have been told that the use of anesthesia adds additional risk to the procedure including respiratory (breathing) problems, drug reactions, paralysis, brain damage and death. Other anesthesia risk include discomfort or injury to the vocal cords, teeth or eyes.

3. Should a complication arise, I therefore authorize my physician, and/or other physicians designated by my physician and the employees and staff of North Mississippi Medical Center, to provide such medical treatment including additional surgery or procedures as are necessary and desirable in the exercise of professional judgement.

4. I appreciate and understand that there are certain risks associated with this procedure and I freely assume these risks. I also understand that there are possible benefits associated with this procedure. However, I understand there is no certainty that I will achieve these benefits. I have been informed and I am aware that the practice of medicine and surgery is not an exact science, and I acknowledge that no guarantees have been made to me concerning the outcome and results of the proposed procedure. I have been told that this procedure carries risks and that some of these risks may be serious.

5. I have had the opportunity to ask questions of my physician and/or physician's associates concerning my condition, and about the procedure, the alternatives and risks to the procedure, and my physician and/or physician associates have answered all questions to my satisfaction.

6. I authorize my physician and/or physician's associates and staff of North Mississippi Medical Center to permit other persons, including but not limited to students, interns, residents and representatives of medical equipment manufacturers to observe the procedure with the understanding that such observation is for the purpose of advancing medical knowledge.

_____
Initial

7. I certify that all blanks requiring insertion of information were completed before I signed this consent form.

8. I have read the two (2) pages of information. I acknowledge that the information I have received, as summarized on this form, is sufficient information for me to understand the risks and benefits of the procedure and to consent to and authorize the procedure described above. This procedure has been explained to me to my satisfaction. Risks, benefits and alternative treatments have been explained to my satisfaction. I understand that the explanations which I have received may not be exhaustive and all inclusive and that more remote risks not discussed may exist. I am signing this form freely and voluntarily indicating my agreement consent and authorization for this procedure.

_____ / _____ _____ / _____
Patient's Signature/Date (Witness to Patient's Signature/Date)

_____/_____
If Patient is unable to consent, signature of Patient Representative signing and consenting on behalf of Patient. Date

I have explained the above procedure with the risks and benefits of the procedure to the above-named Patient or Patient's Representative. The Patient (Patient Representative) has acknowledged understanding the nature of the procedure with the risks and benefits and has consented to the procedure. I have answered all questions posed to me by the Patient (Patient Representative).

Physician _____ Date: _____