

Metairie Gastroenterology, A.P.M.C.

Consent for Medical Procedure and Acknowledgment of Receipt of Information

You have been told that you should consider endoscopy. Louisiana Medical Disclosure Panel Law requires us to tell you (1) the nature of your condition, (2) the general nature of the procedure/treatment, (3) the risks of the proposed procedure/treatment, (4) reasonable therapeutic alternatives and risks associated with such alternatives, and (5) risks of not submitting to the procedure/treatment.

You have the right as a patient to be informed about your condition and the recommended diagnostic or therapeutic procedure to be used so that you may make the decision whether or not to undergo the procedure after knowing the risks and hazards involved. In keeping with the Louisiana State Law of Informed Consent, you are being asked to sign a confirmation that we have discussed all of these matters. We wish to inform you as completely as possible. Please read this form carefully, ask about anything you do not understand, and we will be pleased to explain it.

Direct visualization of the digestive tract and abdominal cavity with lighted instruments is referred to as gastrointestinal endoscopy. Your physician has advised you of your need to have this type of examination. The following information is presented to help you understand reasons for and possible risks of these procedures. At the time of your examination, the inside lining of the digestive tract will be inspected thoroughly and possibly photographed. If any abnormality is seen or suspected, a small portion of tissue (biopsy) may be removed for microscopic study or the lining may be brushed and washed with a solution which will be sent for special study of abnormal cells (cytology). If bleeding is present or there is a potential for bleeding, a probe may be inserted through the fiberoptic instrument through which heat is applied to try to stop bleeding or prevent future bleeding (electro-cauterization). Occasionally, during the examination, a narrow portion of the intestine (stricture) will be stretched to a more normal size (dilatation).

The procedure(s) you are scheduled to receive today is checked below. In general terms, the nature and purpose of the procedure(s) you will receive is:

- Gastroscopy** - to pass a flexible lighted instrument through the mouth for examination of the esophagus, stomach pouch, and duodenum with possible biopsy, polypectomy or cauterization. There will be administration of intravenous conscious sedation as necessary. The choice of sedation to be used shall be made by the doctor.
- Flexible sigmoidoscopy** - to pass a flexible lighted instrument into the anus, rectum, and sigmoid colon up to a distance of 60 cm, for examination with possible biopsy or polypectomy or cauterization. There may be administration of intravenous conscious sedation as necessary. The choice of sedation to be used shall be made by the doctor.
- Esophageal dilatation** - to stretch the esophagus in persons who have an esophageal stricture. This involves passing gradually increasing sized tubes through the mouth into the esophagus. This includes the administration of intravenous conscious sedation as necessary. The choice of sedation to be used shall be made by the doctor.
- Colonoscopy** - to pass a flexible lighted instrument into the rectum to examine the colon, take biopsies, remove polyps or cauterization as indicated and perform additional procedures considered appropriate by the physician. This includes the administration of intravenous conscious sedation as necessary. The choice of sedation to be used shall be made by the doctor.

Patient Condition: Your diagnosis, description of the nature of the condition or ailment for which the medical treatment or procedure checked above is indicated and recommended: _____ .

The principal risks of these procedures are:

- 1) **Injury to the digestive tract** by the instruments which may result in perforation of organs of the intestinal tract with leakage of intestinal juices into body cavities. If this occurs, surgery to repair the perforation and/or drain the region is usually needed.
- 2) **Bleeding.** If this occurs, it is usually a complication of a biopsy or dilatation. Management of this complication may consist only in careful observation or may require transfusion or possibly a surgical operation.
- 3) **Medication Phlebitis.** Medications used for sedation may irritate the vein in which they are injected. This causes a red, painful swelling of the vein and surrounding tissue. The area may become infected. Discomfort in the area may persist for several weeks to several months.

Other risks include drug reactions and complications from other associated diseases which you may have, such as stroke or heart attack. You should inform your physician of all your allergic tendencies and medical problems. All of these complications are possible, but occur with very low frequency. If you wish, your physician will discuss this frequency with you with particular reference to your own indications for gastrointestinal endoscopy.

Some risks known to be associated with this procedure, including anesthesia, are listed below. They are not all-inclusive, but are merely a guideline derived from a general history of medical practice:

Death
Hemorrhage
Quadriplegia
Respiratory Arrest

Pain
Allergic Reaction
Paraplegia

Brain Damage
Disfiguring Scars
Infection

Loss of Function of Organ(s)
Loss of Function of Arm or Leg
Loss of Organ or Arm/Leg
Cardiac Arrhythmias (irregular heartbeats)

Additional risks (if any) particular to the patient because of a complicating medical condition are:

- Increased risk of bleeding due to cirrhosis or blood disorders or medications that affect clotting
- Increased risk of respiratory depression from sedation due to lung disease
- Increased risk of heart attack or stroke from changes in blood pressure due to heart disease, hypertension or artery disease
- Increased risk of valve infection due to valvular disease

Alternatives to Gastrointestinal Endoscopy

Although gastrointestinal endoscopy is a safe and effective means of examining the gastrointestinal tract, it is not 100% accurate in diagnosis. In a small percentage of cases identifying an abnormality may not be possible and a misdiagnosis may result. Other diagnostic or therapeutic procedures, such as medical treatment, x-ray and surgery are available. Another option is to choose no diagnostic studies and/or treatment. Your physician will be happy to discuss these options with you.

Some of the risks of no treatment are death, hemorrhage, pain, loss of organ, undiagnosed cancer, ulcer, bleeding and/or organ perforation.

ACKNOWLEDGMENT

I have had the opportunity to fully discuss my (the patient's) condition and treatment with the doctor including the risk of the procedure, the chances of occurrence, the prospect of success, the risk of failing to undergo the proposed treatment at all, the availability of alternative methods of treatment and their risks.

All of my questions have been answered to my satisfaction. All blanks of this form were filled in prior to my signature. I believe that I have adequate knowledge upon which to base an informed consent.

No Guarantees: All information given me and, in particular, all estimates made as to the likelihood of occurrence of risks of this or alternate procedures or as to the prospects of success, are made in the best professional judgment of my physician. The possibility and nature of complications cannot always be accurately anticipated. Therefore, there is no guarantee, either express or implied, as to the success or other results of the medical treatment or procedure.

Additional Information: Nothing has been said to me; no information has been given to me; and I have not relied upon any information that is inconsistent with the information set forth in this document.

Particular Concerns: I have had an opportunity to disclose to and discuss with the physician providing such information those risks or other potential consequences of the medical treatment or procedure that are of particular concern to me.

CONSENT

I consent to taking any photographs in the course of this operation for the purpose of treatment and medical education.

I certify that I understand the information regarding gastrointestinal endoscopy and that I have been fully informed of the risks and possible complications thereof. I hereby authorize and permit _____, M.D. to perform upon me the procedure as indicated above.

If any unforeseen condition arises during this procedure, requiring in his judgment additional procedures, operations, or medication (including anesthesia and blood transfusion), I further request and authorize him to do whatever he deems advisable.

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 results of the procedure. This consent form is valid until revoked by me in writing.

Patient Name: _____ Date: _____

Witness Signature: _____ Patient Signature: _____

Signature of other than Patient: _____ Relationship to patient: _____

I certify that the procedures, together with the known material risks and alternatives, if any, were explained to this patient or his representative and that all blanks were completed before requesting the patient or his representative to sign this form.

Physician's Signature: _____