

Informed Consent for Gastrointestinal Endoscopy

You will receive a copy of this document to sign on the day of your procedure.

Brief Description of Endoscopic Procedures

Gastrointestinal endoscopy is the direct visualization of the digestive tract with a flexible, lighted endoscope. It is usually done under sedation. During your procedure, the lining of the digestive tract will be thoroughly inspected and possibly photographed. Ultrasonography may also be used to study the internal organs that lie next to the gastrointestinal tract. If an abnormality is seen or suspected, a small portion of the tissue (biopsy) may be removed. Small growths (polyps), if seen, may also be removed. These specimens are sent to pathology to determine if abnormal cells are present.

- () **EGD (ESOPHAGOGASTRODUODENOSCOPY)** - Examination of the upper gastrointestinal tract, including esophagus, stomach, and duodenum to look for ulcers, tumors, infections, inflammation, and areas of bleeding. Biopsy, polyp removal, injection therapy, dilation/stretching of a stricture, and/or coagulation by heat may be necessary.
- () **FLEXIBLE SIGMOIDOSCOPY** - Examination of the anus, rectum and lower colon usually to a depth of less than 60 cm (25 inches). Biopsies may be taken. Sedation is normally not given. The exam is stopped if and when discomfort occurs.
- () **COLONOSCOPY** - Examination of the lower gastrointestinal tract, including all or a portion of the colon or large intestine to look for bleeding, inflammation, polyps, or tumors. Biopsy, polyp removal, and/or coagulation by heat may be necessary.
- () **EUS (Endoscopic Ultrasonography)** – Examination of the lining and walls of the upper or lower gastrointestinal tract as well as imaging organs that lie next to the gastrointestinal tract, e.g. bile ducts, lymph nodes and/or pancreas. Fine needle aspiration of fluids (cytology) inside or outside the wall of the gastrointestinal wall may be necessary.

Principal Risks and Complications of Gastrointestinal Endoscopy

Gastrointestinal endoscopy is a very low risk procedure. However, all the complications listed below are possible. Your doctor will discuss their frequency with you, if you desire. **YOU MUST TALK TO YOUR DOCTOR IF YOU HAVE ANY UNANSWERED QUESTIONS ABOUT YOUR PROCEDURE.**

1. **BLEEDING:** Bleeding, if it occurs, is usually a complication of biopsy, polyp removal, dilation, or fine needle aspiration. Management of this complication may consist only of careful observation. Blood transfusions and surgery are rarely needed.
2. **PERFORATION:** Passage of the endoscope may result in an injury or tear to the gastrointestinal tract wall, with possible leakage of gastrointestinal contents into the body cavity. Perforations can be small requiring a few days of hospitalization, but could be severe requiring prolonged hospitalization and/or surgery.
3. **INFECTION AND PHLEBITIS:** Infection or irritation resulting in inflammation (phlebitis) may occur at the intravenous site and may require treatment. Rarely, passage of the endoscope and manipulations may cause infection elsewhere in the body. Fine needle biopsy could possibly cause a serious infection.
4. **INACCURATE DIAGNOSIS:** Endoscopy is an extremely effective means of examining the gastrointestinal tract, but it is not 100% accurate in diagnosis. Rarely, a failure of diagnosis or mis-diagnosis may result, particularly with colonoscopy due to the numerous turns and folds in the colon. Although endoscopic ultrasonography is a valuable tool for the diagnosis of gastrointestinal, pancreatic and biliary conditions, a missed lesion such as cancer, can occur even in expert hands.
5. **OTHER RISKS:** These include drug reactions, and complications from other diseases you may already have. Instrument failure could occur rarely, requiring a repeat procedure. Aspiration or dental injury is a possible risk of upper endoscopy procedures. Pancreatitis may result from endoscopic ultrasonography procedures if needle biopsy of a lesion or tumor of the pancreas is performed. Serious or fatal complications from endoscopy are extremely rare. ***You must inform your physician of all your allergies and medical problems.***

Alternatives to Gastrointestinal Endoscopy

Other diagnostic or therapeutic procedures, such as medication treatment, x-ray, and surgery may be available. Another option is to choose no diagnostic exam and/or treatment.

Informed Consent

I hereby authorize: _____ (Print Physician Full Name)

And whoever designated as his/her assistant(s) to perform the following:

- () **EGD (ESOPHAGOGASTRODUODENOSCOPY), WITH POSSIBLE BIOPSY, POLYP REMOVAL, INJECTION THERAPY, DILATION AND/OR COAGULATION BY HEAT**
- () **ENDOSCOPIC ULTRASONOGRAPHY, UPPER GI, WITH POSSIBLE FINE NEEDLE ASPIRATION**
- () **FLEXIBLE SIGMOIDOSCOPY**
- () **COLONOSCOPY, WITH POSSIBLE BIOPSY, POLYP REMOVAL, INJECTION THERAPY, AND/OR COAGULATION BY HEAT**
- () **ENDOSCOPIC ULTRASONOGRAPHY, LOWER GI, WITH POSSIBLE FINE NEEDLE ASPIRATION**

To treat my condition which has been explained to me as:

If any unforeseen condition arises during this procedure calling for (in my doctor's judgment) additional procedures, treatments, or surgeries, I authorize whatever is deemed advisable. I acknowledge that the practice of medicine and surgery is not an exact science and that no guarantees have been made to me concerning the result of this procedure.

I am aware that in the event of a life-threatening emergency, PEC will perform any necessary emergency procedures and transfer me to an acute care facility.

I consent to the administration of moderate sedation or general anesthesia as may be considered appropriate by my doctor. If sedation or anesthesia is used, I agree not to drive, operate machinery, make critical decisions, sign legal documents, or consume alcohol for 24 hours following my procedure.

I consent to the taking and publishing of any photographs or videotapes made during my procedure for the purpose of treatment and medical education. Confidentiality will be maintained.

I consent to the disposal of any tissue that may be removed.

I certify that I have read (or have had read to me) this document and I fully understand the information regarding gastrointestinal endoscopy, with or without ultrasonography, its risks and possible complications.

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|--|------|------|-----------------------------|
| Patient/Legal Representative Signature | Date | Time | Relationship to the Patient |
| Witness | Date | Time | |

Translator/Interpreter's Statement

I have accurately reviewed this document with the Patient/Legal Representative in the Patient/Legal Representative's primary language _____ (identify language). He/she understood all of the terms and conditions and acknowledges his/her agreement by signing the document in my presence.

| | | |
|-----------------------|------|------|
| Interpreter Signature | Date | Time |
|-----------------------|------|------|

Physician's Certification

I acknowledge that I have explained the above to the Patient/Legal Representative. It is my opinion that said Patient/Legal representative understood and comprehended all of the matters discussed.

| | | |
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| Physician Signature | Date | Time |
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