

Digestive Disease and Endoscopy Center, LLC.

Informed Consent for Gastrointestinal Procedures

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Explanation of Procedure

Direct visualization of the digestive tract with lighted instruments is referred to as gastrointestinal endoscopy. Your physician has advised you to have this type of examination. The following information is presented to help you understand the reasons for and possible risks of these procedures.

At the time of your examination, the lining of the digestive tract will be inspected and photographs are often taken to document your condition. If an abnormality is seen or suspected, a small portion of tissue (biopsy) may be removed or the lining may be brushed. These samples are sent for laboratory study to determine if abnormal cells are present. Polyps (growths), if seen, may be removed.

Brief Description of Endoscopy Procedures

EGD (Esophagogastroduodenoscopy): Examination of the esophagus, stomach and duodenum. If active bleeding is seen, coagulation by heat may be performed. If polyps are found, they may be removed and mucosal abnormalities may be biopsied.

Gastrointestinal Dilation: Dilating tubes or balloons are used to stretch narrow areas of the gastrointestinal tract.

Flexible Sigmoidoscopy: Examination of the anus, rectum and left side of the colon, usually to a depth of approximately 60 cm (2 feet).

Colonoscopy: Examination of all or a portion of the colon. Older patients and those with extensive diverticulosis or previous pelvic surgery are more prone to complications. Polypectomy (removal of growths called polyps) is performed, if necessary by the use of a wire loop and electric current or by biopsy technique with or without coagulation.

Principal Risks and Complications of Gastrointestinal Endoscopy

Gastrointestinal endoscopy is generally a low risk procedure. However, all the complications listed below are possible. Your physician will discuss their frequency with you, if you desire, with particular reference to your own indications for gastrointestinal endoscopy.

YOU NEED TO TELL YOUR PHYSICIAN OR ANESTHESIA PROVIDER IF YOU HAVE ANY UNANSWERED QUESTIONS ABOUT YOUR TEST.

1. *Perforation:* Passage of the instrument may result in an injury to the gastrointestinal tract wall with possible leakage of gastrointestinal contents into the body cavity. If this occurs, hospitalization and surgery to close the leak and/or drain the region is usually required.

2. *Bleeding:* Bleeding, if it occurs, is usually a complication of biopsy, removal of polyps or dilation. Management of this complication may consist of careful observation, hospitalization, transfusions and/or a surgical operation.

3. *Trauma to Internal Organs or Intestines:* Passage of the instrument may result in trauma to an internal organ such as the intestines or the spleen. If this occurs, hospitalization, a surgical operation and/or medical treatment may be required.

4. *Moderate and Deep Sedation:* Moderate sedation is given to produce a state that helps you relax and minimizes unpleasant sensations while maintaining adequate heart and lung functions and the ability to respond to verbal stimulation and/or touch. Deep sedation is a deeper level of sedation in which you do not respond purposefully to repeated or painful stimuli. Potential complications of any administered sedation include: breathing problems (decreased respiration, aspiration leading to pneumonia, airway blockage), heart problems (low blood pressure or irregular rhythm), or potential allergic reaction to an administered medication. You will be monitored throughout the procedure and treated for any of these if necessary. Your physician and/or the anesthesiologist or CRNA (nurse anesthetist) can answer any of your sedation questions.

5. *Infection and Phlebitis:* Infection or irritation resulting in inflammation (phlebitis) may occur at the intravenous site and may require treatment. Passage of the endoscope and manipulation may, on rare occasions, cause infection elsewhere in the body.

6. *Missed Lesions/Misdiagnosis:* 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 a failure of diagnosis or a misdiagnosis may result. For example, polyps and/or cancerous lesions can be missed. Other diagnostic or therapeutic procedures, such as medical treatment, x-ray and surgery are available to examine the gastrointestinal tract. Your physician will be happy to discuss these options with you.

7. *Other Risks:* Include drug reactions and complications from other diseases you may already have. Teeth and/or dental work may be injured during the procedure. Instrument failure and death are rare, but remain remote possibilities.

YOU MUST INFORM YOUR PHYSICIAN AND ANESTHESIA PROVIDER OF ALL ALLERGIES (SUCH AS TO MEDICATIONS, ANESTHETICS AND LATEX) AND OF ALL YOUR MEDICAL CONDITIONS.

Consent and Authorization

I acknowledge that I have had the opportunity to review this consent form with my physician and discuss with him/her the proposed procedure and ask any questions I have, and that I have been fully informed of the risks and possible complications of the procedure.

I hereby authorize and permit ______, MD and any associates and/or assistants that he/she deems appropriate to perform upon me the following procedure:

- $\hfill\square$ Upper Endoscopy with possible biopsy, polypectomy and/or dilation
- □ Colonoscopy with possible biopsy, polypectomy and/or dilation
- Flexible Sigmoidoscopy with possible biopsy, polypectomy and/or dilation
- Other:

1. I further acknowledge, if any unforseen condition arises during this procedure, calling for (in the physician's judgement) additional treatments or operations, I hereby authorize the physician to do whatever he/she deems advisable. I am aware that the practice of medicine and surgery is not an exact science and I understand that no guarantees have been made to me concerning the results of the procedure.

2. I consent to the taking of any photographs and/or video made during my procedure for use in education, research or my clinical care. I certify that I understand the information regarding gastrointestinal endoscopy.

3. I understand that, as part of my endoscopy procedure, my physician or other person may obtain or remove blood, fluids and/or tissue ("samples"). I understand and agree that all such samples are the property of Washington Gastroenterology and Digestive Disease and Endoscopy Center, will be retained as part of my medical record and may be used for any lawful purpose, and I waive any further rights thereto.

Date Signed (by patient or legally authorized person)