

Endoscopy Center of North Carolina

Informed Consent for Endoscopy

Patient Label

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 reason for and the possible risks of these procedures.

At the time of your examination, the 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 or the lining may be brushed. These samples are sent for laboratory study to determine if abnormal cells are present. Tumors (polyps) will be removed if feasible. **I authorize my physician to take samples for diagnostic or research purposes.**

The Endoscopy Center of NC is dedicated to advancing medical knowledge and education through several training programs involving physicians, nurses, technicians, and other health care providers. Generally, your doctor, a nurse anesthetist (CRNA), a pre-procedure preparation nurse, and a recovery room nurse will be directly involved in your procedure at the Endoscopy Center of NC.

Asheville Gastroenterology (a division of Digestive Health Partners, PA) is committed to the education and training of the Mountain Area Health Education Center (MAHEC) family practice residents in flexible sigmoidoscopy. Periodically residents will observe and possibly participate in your procedure under the direct supervision of your doctor. If you do not wish for the residents to participate in your procedure, please tell the pre-procedure preparation nurse and she will notify your doctor.

Principal Risks and Complications of Gastrointestinal Endoscopy

Gastrointestinal endoscopy is generally a low risk procedure. However, all of the complications below are possible. **YOU MUST ASK YOUR PHYSICIAN IF YOU HAVE ANY UNANSWERED QUESTIONS ABOUT YOUR PROCEDURE.**

- 1. Perforation:** Passage of the instrument may result in any injury to the gastrointestinal tract wall with possible leakage of gastrointestinal contents into the body cavity. If this occurs, 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, polypectomy, or dilation. Management of this complication may consist only of careful observation, but may require a blood transfusion, or possibly a surgical operation.
- 3. Aspiration:** Food, drink or stomach contents/secretions can go into the respiratory system or lungs and cause pneumonia or difficulty breathing, and could require antibiotics, hospitalization, or in rare cases, a ventilator.
- 4. Medications:** 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 could become infected. Discomfort in the area may persist for several weeks to several months.

I UNDERSTAND THAT THERE WILL BE DIFFERENT TYPES AND LEVELS OF SEDATION. THE TYPE OF SEDATION THAT I WILL RECEIVE WILL BE BASED ON SEVERAL FACTORS WHICH INCLUDE, BUT ARE NOT LIMITED TO, MY MEDICAL HISTORY, PREVIOUS EXPERIENCE, PREFERENCE, AND WHAT IS DEEMED APPROPRIATE BY MY PROVIDER. I UNDERSTAND THAT RECEIVING SEDATION FOR ANY PROCEDURE INVOLVES RISK AS WELL AS BENEFITS, AND THAT NO GUARANTEES CAN BE MADE CONCERNING THE RESULTS OF SEDATION. RISKS AND COMPLICATIONS MAY INCLUDE, BUT ARE NOT LIMITED TO, ADVERSE DRUG REACTION, INJURY TO VEINS, HEADACHE, NAUSEA, AND VOMITING.

- 5. Organ Damage:** The endoscope passes by several internal organs including the liver and spleen. Rarely, tears, lacerations, or rupture could occur to these organs or other internal structures.
- 6. Other Risks:** Include pneumonia, phlebitis, and complications from other diseases you may already have. Instrument failure, and death are extremely rare, but remain remote possibilities. You must inform your physician of all your allergic tendencies and medical problems.

I have received a copy of the organization's Patient Rights and Responsibilities.

You **WILL RECEIVE** sedation for your procedure.

DO NOT drive or operate machinery today.

DO NOT consume any alcoholic beverages today.

AVOID making critical decisions or signing legal documents within 24 hours.

The above instructions have been explained to me. I understand them. I have signed this form prior to receiving sedation.

Patient Signature

Date

Time

Nurse Signature

Informed Consent Continues on the Back Side of This Form

I certify that I understand the information regarding gastrointestinal endoscopy. I have been fully informed of the risks and possible complications of my procedure. I hereby authorize and permit:

- | | | | |
|---|---|---|--|
| <input type="checkbox"/> James R. Alexander, MD | <input type="checkbox"/> Brian P. Garvin, MD | <input type="checkbox"/> Angela M. Meyer, MD | <input type="checkbox"/> Matthew W. Wood, MD |
| <input type="checkbox"/> Thomas M. Bond, MD | <input type="checkbox"/> William R. Harlan, III, MD | <input type="checkbox"/> Michael K. Newcomer, MD | <input type="checkbox"/> Adam S. Zivony, MD |
| <input type="checkbox"/> Craig J. Cender, MD | <input type="checkbox"/> Michael N. Heacock, MD | <input type="checkbox"/> Rodney A. Perez, MD | |
| <input type="checkbox"/> Andrew C. Dukowicz, MD | <input type="checkbox"/> Brentley D. Jeffries, MD | <input type="checkbox"/> Charles W. Shrode, MD | |
| <input type="checkbox"/> Jessica M. Fisher, MD | <input type="checkbox"/> David Thomas May, MD | <input type="checkbox"/> Tom L. Whitlock, MD, MPH | |

and his/her assistant as designated to perform upon me the following:

- Colonoscopy:** Refers to examination of all or a portion of the colon (large intestine). In some instances, the last portion of small intestine (terminal ileum) can be visualized. Older patients, women who have had pelvic surgery and those with extensive diverticulosis are more prone to complications. Tumors (polyps), if seen, will be removed if feasible. Biopsies may be taken and polyps may be removed.
- Esophagogastroduodenoscopy (EGD):** Examination of the esophagus, stomach, and duodenum. If active bleeding is found, treatment of the bleeding site may be performed. Biopsies may be taken and polyps may be removed.
- Dilation:** A dilating tube or balloon is used to stretch narrowed areas of the gastrointestinal tract.
- Treatment of Esophageal Varices:** A chemical is injected or a band applied onto abnormal blood vessels or veins to prevent bleeding.
- Flexible Sigmoidoscopy:** Refers to examination of the anus, rectum, sigmoid, and sometimes the left side of the colon, usually to a depth of approximately 60 cm. Biopsies may be taken and polyps may be removed.
- Gastrostomy Tube Placement:** Refers to the placement of a feeding tube through the abdominal wall and into the stomach (gastrostomy tube) for those patients who cannot take adequate nourishment by mouth. In some instances, a small tube will be placed through the gastrostomy tube and advanced out into the small intestine (jejunostomy tube).

Alternatives to Gastrointestinal Endoscopy

Although gastrointestinal endoscopy is a low risk and effective means of examining the gastrointestinal tract, it is not 100 percent accurate in diagnosis. In a small percentage of cases a failure of diagnosis or a mis-diagnosis may result. Other diagnostic or therapeutic procedures, such as a medical treatment, x-ray and surgeries are available. Another option is to choose no diagnostic studies and/or treatment.

Please note that your endoscopy can be performed at the Endoscopy Center of NC or Mission Health System. The place of service is your choice.

If any unforeseen condition arises during this procedure calling for (in the physician's judgment) additional procedures, treatments or operations, I authorize him to do whatever he deems advisable. I am aware that the practice of medicine is not an exact science, and I acknowledge that no guarantees have been made to me concerning the result of this procedure.

Physician Signature: _____ Date: _____ Time: _____

Patient Signature: _____ Date: _____ Time: _____

Witness Signature: _____ Date: _____ Time: _____

(Informed Consent Information Begins on the Front of this Form)

Patient Label

Consent for Anesthesia Services

To the patient and/or parent, guardian, designee: this form is designed to confirm the discussion of and consent for proposed anesthesia to be administered for surgical, medical or therapeutic procedure.

Anesthesia is a specialty medical service that administers anesthetic agents to patients and manages patients who are rendered unconscious or have diminished response to pain and stress during the course of a medical, or surgical procedure. I hereby authorize and direct DIGESTIVE HEALTH PARTNERS and the individual anesthesia provider to care for me, and to administer anesthesia for my medical or surgical procedure. Risks and complications associated with anesthesia may include: allergic reaction, aspiration/pneumonia, respiratory problems, changes in blood pressure, damage to dentition, brain damage, infection, muscle aches, nausea, ophthalmic (eye) injury, pain, positional nerve injury, and in very rare cases, death. If a topical local spray is used, there is a rare drug-induced complication called methemoglobinemia. With this condition, hemoglobin in the blood is converted to another chemical that cannot deliver oxygen to tissue.

My questions regarding the nature, purpose and risks of the anesthetic, as well as the possibility of complications, have been explained to me. I do understand that although favorable results can be expected, they cannot be and are not guaranteed.

I hereby authorize Digestive Health Partners to furnish information to insurance carriers and other physicians concerning my illness and treatments, and I hereby assign Digestive Health Partners to provide treatment to me. Necessary forms will be completed to expedite insurance carrier payments, but I hereby acknowledge that I am responsible for all fees regardless of insurance coverage.

I certify that information given by me as a patient, parent, or guardian regarding history, problems, medication, food and fluid intake is correct.

I understand that a responsible adult must accompany every patient home when discharged from the Recovery Room. I understand that disregarding such advice could place one at risk if problems develop and go unreported.

Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, providers are prepared to rescue a patient from a deeper level of sedation than intended providing an intervention by a practitioner proficient in airway management and advanced life support. The qualified practitioner corrects adverse physiologic consequences of the deeper-than-intended level of sedation (such as decreasing ventilation, oxygen saturation level and hypotension) and returns the patient to the intended level of sedation. At the Endoscopy Center of North Carolina, anesthesia types range from light sedation to deep anesthesia. The type of anesthesia chosen will be determined by the anesthesia provider and will depend on your medical condition and the nature of the procedure. For this reason, it may also be necessary to change the type of anesthesia on the day of your procedure. The initial plan calls for you to have deep sedation/Monitored Anesthesia Care.

The checked box below indicates the intended plan of anesthesia

<input type="checkbox"/> Minimal Sedation	Definition	Is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilatory and cardiovascular functions are unaffected.
	Expected Result	Reduced anxiety while maintaining a normal level of consciousness.
	Risks	Increased awareness, anxiety, and/or discomfort
<input type="checkbox"/> Moderate Sedation "Conscious Sedation"	Definition	Is a drug-induced depression of consciousness during which patients respond purposefully to verbal command. No interventions are required to maintain a patent airway and spontaneous ventilation is adequate.
	Expected Result	Comfort and tolerability
	Risks	May have some recall, awareness, anxiety, and/or discomfort
<input type="checkbox"/> Deep Sedation Monitored Anesthesia Care (with sedation)	Definition	Is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated stimulation. The ability to independently maintain ventilatory function may be impaired. Patient may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. Monitored Anesthesia Care does not describe the continuum of depth of sedation, rather it describes "a specific anesthesia service"
	Expect Result	Reduced anxiety and pain, partial or total amnesia
	Risks	An unconscious state, depressed breathing
<input type="checkbox"/> Monitored Anesthesia Care (with No Sedation)	Definition	does not describe the continuum of depth of sedation, rather it describes "a specific anesthesia service"
	Expect Result	Measurement of vital signs, availability of anesthesia provider for further intervention
	Risks	Awareness of surroundings

I voluntarily authorize and consent to the administration of anesthesia.

Date: _____ Time: _____ **X** _____

Signature

Please Circle One: Patient Guardian Designee

Anesthesia Provider Signature _____