INFORMED CONSENT FOR GASTROINTESTINAL ENDOSCOPY

It is very important to us that you understand and consent to the treatment your doctor is providing and any procedure your doctor may perform. You should be involved in any and all decisions concerning surgical procedures your doctor has recommended.

Sign this form only after you understand the procedure, the anticipated benefits, the risks, the alternatives, the risks associated with the alternatives and all of your questions have been answered. Please initial and date directly below this paragraph indicating your understanding of this paragraph.

_____ _____
Patient's Initials or Authorized Representative Date

I, _____, hereby authorize Dr. _____and any associates or assistants the doctor deems appropriate, to perform upon me the following:

❑ Upper Endoscopy (EGD) ❑ Flexible Sigmoidoscopy ❑ Esophageal Dilation ❑ Enteroscopy
❑ Colonoscopy ❑ Variceal Banding ❑ EIS (Injection Sclerotherapy) ❑Polypectomy
❑ Other_____

Brief Description of Endoscopic Procedures

EGD (Esophagogastroduodenoscopy): Examination of the esophagus, stomach, and duodenum. If active bleeding is found, coagulation by heat may be performed.

Esophageal Dilation: Dilating tubes or balloons are used to stretch narrow areas of the esophagus.

EIS (Endoscopic Injection Sclerotherapy): Injection of a chemical into varices (dilated varicose veins of the esophagus) to sclerose (harden) the veins to prevent further bleeding. Injection is done with a small needle probe through the endoscope.

Variceal Banding: The physician places a latex (rubber) bank around the varices to reduce the flow of blood to the vein, thereby preventing further bleeding.

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

Colonoscopy: Examination of all or a portion of the colon. The procedure may involve collection of a tissue specimen.

Enteroscopy: Small intestinal endoscopy beyond the second portion of the duodenum and not including the ileum. The procedure may involve collection of a tissue specimen.

Polypectomy: Using a wire loop and electric current, polyps (protruding growths) can be removed from the digestive tract; this is commonly done with colonoscopy and less commonly with EGD.

The doctor has explained to me the potential benefits of gastrointestinal endoscopy. However, I understand there is no certainty that I will achieve these benefits and no guarantee has been made to me regarding the outcome of the procedure. I also authorize the administration of sedation and/or anesthesia as may be deemed advisable or necessary for my comfort, well-being, and safety. In most cases of gastrointestinal endoscopy, conscious sedation is used, which is the administration of IV medications prior to the procedure to achieve a state of relaxation sufficient to improve tolerance for the procedure but not result in significant depression of breathing or total inability to respond.

Gastrointestinal endoscopy involves the direct visualization of the digestive tract with lighted instruments. My physician has advised me to have this type of examination. At the time of my examination, the lining of the digestive tract will be inspected thoroughly and possibly photographed. 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. Small growths (polyps), if seen, may also be removed.

I understand that although gastrointestinal endoscopy is a safe and effective means of examining the gastrointestinal tract, it is not a hundred percent accurate in diagnosis. In a small percentage of cases a failure of diagnosis or a misdiagnosis may result.

Principal Risks and Complications

The doctor has explained to me that there are risks and possible undesirable consequences associated with any procedure including, but not limited to:

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, surgery to close the leak and/or drain the region is usually required.

Bleeding: Bleeding, if it occurs, is usually a complication of biopsy, polypectomy or dilation. Management of this complication may consist only of careful observation, or may require transfusions or a surgical operation.

Conscious Sedation Medication and Pregnancy: I understand that to keep me comfortable during the procedure, either my doctor or a registered nurse directed by my doctor will administer medication defined as *conscious sedation*.

- I understand that there are risks involved with anesthesia, including conscious sedation, and to my knowledge, I am not pregnant._____
  initial
- If there is any question that I may be pregnant, then I will allow a urine pregnancy test to be performed prior to my procedure._____
  initial

Missed Lesions (Polyps and Cancer): During my colonoscopy the physician will attempt to identify all polyps and cancer, and remove all polyps if possible. Although colonoscopy is the best test to find and remove these lesions, there is a small chance that one or more may be missed.

Splenic Tear: As the scope passes through the splenic flexure in the colon, there is the rare possibility that an injury can occur to the spleen. A splenic tear is an abrasion on the spleen that could result in hospitalization, the need for blood transfusion, and may even require surgery to treat.

Other risks include, but are not limited to, blood loss, transfusion reactions, infection, heart complications, blood clots, loss of or loss of use of body part, other neurological injury, respiratory problems, decrease in blood pressure, allergic reaction, slurred speech, unaroused sleep, impaired cardiovascular function, aspiration and pneumonia, heart attack, damage to teeth or dental work (when instruments are inserted through the mouth), collapsed lung when visualizing the respiratory tract (a special tube may be placed into the chest to re-expand the lung when this occurs), nose and throat pain, clotting or infection in the vein where medication is given and/or death. Instrument failure is also extremely rare but remains a remote possibility. Drug reactions and complications from other diseases are possible. I understand that if I need blood or blood products these carry a risk of contracting HIV/AIDS, hepatitis, or other diseases.

I HAVE INFORMED MY PHYSICIAN OF ALL MY ALLERGIC TENDENCIES AND MEDICAL PROBLEMS.
I understand that older patients and those with extensive diverticulitis are more prone to complications and that all of the above complications are possible but occur with a very low frequency. Occasionally one or more of these complications could result in transfer to the hospital for hospitalization, blood transfusion, or the need for surgical intervention for correction. If I have any questions about the frequency of these complication related to my own case, I will discuss this with my physician.

In permitting my doctor to perform the procedure, I understand that unforeseen conditions may be revealed that may necessitate change or extension of the original procedure or a different procedure(s) than those already explained to me. I therefore authorize and request that the above-named physician, his/her assistants, or his/her designees perform such procedure(s) as necessary and desirable in the exercise of his/her professional judgment.

In the unlikely event that one or more of the above inherent complications may occur, my physician or covering physician will take appropriate and reasonable steps to help manage the clinical situation and be available to me and my family to address our concerns and questions.

The reasonable alternatives to gastrointestinal endoscopy, as well as the risks to the alternatives, have been explained to me. The alternatives include but are not limited to the other diagnostic or therapeutic procedures such as medical treatment, x-ray and surgery. Another option is to choose no diagnostic studies and/or treatment.

I hereby authorize the doctor and/or hospital or surgical facility to utilize or dispose of removed tissues, parts or organs resulting from the procedure authorized above.

I consent to any photographing or videotaping of the procedure that may be performed, provided my identity is not revealed by the pictures or by descriptive texts accompanying them.

I consent to the admittance of students or authorized equipment representatives to the procedure room for purposes of advancing medical education or obtaining important product information.

By signing below, I certify that I have had an opportunity to ask the doctor all my questions concerning anticipated benefits, material risks, alternative therapies, and risks of those alternatives, and all of my questions have been answered to my satisfaction.

_____ _____ _____/_____
Signature of Patient or Authorized Representative | Relationship | Date Time

❑ The Patient/Authorized Representative has read this form or had it read to him/her.

❑ The Patient/Authorized Representative states that he/she understands this information.

❑ The Patient/Authorized Representative has no further questions.

_____ _____/_____
Signature of Witness | Date Time

CERTIFICATION OF PHYSICIAN:

I hereby certify that I have discussed with the individual granting consent, the facts, anticipated benefits, material risks, alternative therapies and the risks associated with the alternatives of the procedure(s).

Physician:_____ Date/Time_____/_____

USE OF INTERPRETER OR SPECIAL ASSISTANCE

An interpreter or special assistance was used to assist patient in completing this form as follows:

_____Foreign language (specify)

_____Sign language

_____Patient is blind, form read to patient

_____Other (specify)_____

Interpretation provided by _____
(Fill in name of Interpreter and Title or Relationship to Patient)

_____ _____/_____
Signature (Individual Providing Assistance) | Date Time