

CONSENT FOR COLONOSCOPY

This document helps us inform you about this procedure. Please read it carefully and address any questions or concerns you may have personally with the doctor prior to signing it.

Dr. Patrick D. Gerstenberger, Dr. Steven R. Christensen, Dr. Stuart B. Saslow or Dr. Paula M. Dionisio, and his or her assistants are authorized to perform:

Colonoscopy - Examination of the large intestine, and often a portion of the lower small intestine, with a flexible tube passed through the anus.

Biopsy - Remove small pieces of tissue for analysis.

Polypectomy - Remove small growths with special instruments.

Treatment of hemorrhoids with infrared coagulation or band ligation - Treat internal hemorrhoids with an infrared light-heated probe or placement of small rubber bands internally.

Treatment of bleeding or abnormalities likely to cause bleeding - Use heat, metal clips, synthetic string-like loops, or rubber bands applied internally to stop or prevent bleeding.

Sedation and analgesia (moderate-deep procedural sedation with propofol) - Administer medication into a vein, under the doctor's direction, prior to and during the procedure, to make the procedure comfortable by relieving anxiety, discomfort, and pain.

Colonoscopy is frequently performed for the following reasons: screening and prevention of colon cancer, follow-up of prior polyps or cancer, evaluation of symptoms (such as bleeding/pain/diarrhea/constipation), evaluation of anemia, and evaluation or monitoring of inflammatory bowel disease.

ALTERNATIVES: Imaging tests (barium enema x-ray, CT, MRI or ultrasound) and a specialized form of CT scan (virtual colonoscopy) also provide information about the colon. Imaging tests are less likely to cause a procedural complication, but are less accurate for diagnosing some important conditions, and do not allow common treatments such as the removal of growths (polyps), which are removed in >1/3 colonoscopies performed by Digestive Health. No test at all is always an alternative, but no testing carries risks of failure to diagnose or prevent serious disease, such as colon cancer. In most cases we perform colonoscopy using moderate-deep propofol-based procedural sedation, under the endoscopy doctor's supervision. It is possible to perform this procedure in some cases without sedation. General anesthesia administered by an anesthesiologist is indicated in some cases, and is an alternative available at Mercy Regional Medical Center.

RISKS: These procedures involve some risks. To help you put these risks into perspective it is important to know that the average American has about a 1/17 risk for developing colon cancer, which is frequently fatal if detected in an advanced stage, but is usually preventable by colonoscopy. This risk is higher in individuals who have a family history of colon cancer or polyps. Major published reports of complications of colonoscopy include: **perforation** requiring surgery (up to 1/400), **bleeding** that potentially requires transfusion with its associated risks or surgery (up to 1/60 polyp removals), **diverticulitis** (1/3500), **heart or lung problems** (major problems are rare), infection (rare), damage to other internal organs or structures including injury to the spleen (rare), twisting of bowel causing blockage (rare), appendicitis (rare), allergic reactions (rare), nerve injury (rare), and death (rare). Minor complications (needle site irritation, internal burns or bruises, minor medication reactions, temporary bowel distention or prolonged sleepiness) occur infrequently. The treatment of hemorrhoids can lead to transient pain, bleeding, urinary symptoms and rare but potentially life-threatening problems with infections or blood clots.

At Digestive Health our perforation rate is <1/2000 and our rate of bleeding requiring hospital care is <1/450. Our endoscopic research consortium (www.cori.org) reported data describing the frequency of colonoscopy-related complications leading to hospitalization in May 2007. This study of over 18,000 colonoscopy procedures performed at multiple sites in the U.S. (over 1000 of these procedures were performed at the Southwest Endoscopy Center by Drs. Christensen, Gerstenberger and Saslow) reported admission for bleeding in 1/730 cases, perforation in 1/4600, diverticulitis in 1/3700, and postpolypectomy syndrome in 1/9,200. While perforations usually require surgery for repair, full recovery is typical. Colon cancers however, if not prevented, frequently present at an advanced state for which cure is not possible. These are highly accurate procedures, but with any medical test there is a small chance of missing something. **Not all cases of colon cancer are preventable with current techniques**, because not all colon cancers arise in growths that we are able to see with the colonoscope. Colonoscopy is the most effective available means for preventing colon cancer, and is estimated to prevent approximately 75% of cases if performed at recommended intervals by an experienced physician.

SEDATION: Sedation involves a risk of heart or lung problems (<1/200), which rarely (<1/160,000) can be fatal. Sedation (moderate-deep propofol procedural sedation) at this facility is administered and monitored by trained registered nurses under the continuous direction of the physician performing your procedure. While gastroenterology and endoscopy organizations in the U.S. support the use of propofol by gastroenterologists in the manner now employed at this facility for over 3 years, propofol sedation by gastroenterologists is not FDA approved. Anesthesia care provided by an anesthesiologist may be preferred to moderate-deep procedural sedation in some situations. Anesthesiologist services are not available at the Southwest Endoscopy Center but are available at Mercy Regional Medical Center and can be arranged at the request of either the patient or the physician performing your procedure, at an additional cost.

MEDICATIONS THAT AFFECT BLOOD CLOTTING: In most cases these drugs (such as Coumadin, Plavix, Effient, aspirin, nonsteroidal anti-inflammatory agents and others) are discontinued before colonoscopy to reduce possible bleeding risk related to polyp removal. Stopping and restarting these drugs carries some risk of blood clot related problems, including stroke and heart attack. In some cases we may advise you to continue these medications, in the belief that possible bleeding is less of a risk to your health than the risk of heart attack or stroke.

Complications may occur even when a procedure is properly performed. Treatment of major complications may require hospitalization, surgery (rarely including colostomy, a bag on the abdomen to collect waste), and blood transfusion.

RECUPERATION: Recuperation from colonoscopy is generally complete within a few hours following the procedure. Most individuals can return to typical activities and diet at that time. Because the effects of sedation on memory, coordination and judgment may linger however, activities such as driving, operation of machinery, vigorous physical exertion or activities requiring full mental attention, coordination or recall should not be resumed until the following day. **Increasing abdominal pain, bleeding, fever or other signs of illness could be signs of complication of colonoscopy or of your sedation, and should be reported promptly to the on call Digestive Health physician.** You will be provided with written instructions on discharge telling you how to contact us in the event of a problem after the procedure.

TRANSFUSION: Blood transfusions are not administered at the Southwest Endoscopy Center. Transfusions are occasionally necessary during the hospital management of colonoscopy-related bleeding.

SUCCESS: Complete examination of the colon (from the rectum to the cecum) is achieved in over 99% of Southwest Endoscopy patients. Most polyps we detect are removed at the time of the examination. Some large polyps or growths may require additional colonoscopy procedures or surgery to allow complete removal.

ASSISTANTS: Registered nurses and/or technicians who are employees of the facility providing your procedure will assist the physician. Students, industry representatives or other observers will not be permitted to be present without your written permission. Other physicians or assistants are rarely necessary during colonoscopy, though occasionally the physician may request an opinion regarding a finding or technique from another physician during a procedure.

PATIENT CONSENT

I have had sufficient opportunity to discuss my condition and treatment with my physicians and/or their associates, and all of my questions have been answered to my satisfaction. I believe that I have adequate knowledge upon which to base an informed consent to the proposed procedure.

I have read and fully understand this form and I voluntarily authorize and consent to this procedure. I understand that I should not sign this form until all my questions have been answered to my satisfaction and until I understand all the words or terms on this form.

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 results of the procedure. I have been advised that the proposed procedure may not improve my condition and may, in fact, worsen it.

X _____ Date: _____ Time: _____
Signature of Patient or Authorized Agent

_____ Date: _____ Time: _____
Signature of Witness to Above Signature

**Must be the physician, provider or an assistant who observed the patient or authorized agent sign above.*

PHYSICIAN/PROVIDER DECLARATION

I have explained the contents of this document to the patient and have answered all the patient's questions, and to the best of my knowledge, I feel the patient has been adequately informed and has consented.

_____ Date: _____ Time: _____
Physician Assistant (if applicable)

_____ Date: _____ Time: _____
Physician performing procedure