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, or Dr. Stuart B. Saslow and his nurses and assistants, including a certified nurse anesthetist (CRNA), 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
Injection – Inject fluid under the surface of the colon lining for marking (tattoo) or for facilitating tissue removal
Polypectomy - Remove small growths, which in some cases required advanced techniques (endoscopic mucosal resection)
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, injection of medication or application of internal devices (clips) to stop or prevent bleeding
Procedural sedation/anesthesia (with monitored anesthesia care) – Administration of medication into a vein, by a certified registered nurse anesthetist (CRNA), prior to and during the procedure, to make the procedure comfortable by relieving anxiety, discomfort, and pain. Most patients experience partial or total amnesia for their procedure with this form of sedation/anesthesia.

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 known as virtual colonoscopy) also allow examination of 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 is done in >1/3 colonoscopies. Testing of the stool for blood or DNA abnormalities are alternative screening tests. No test at all is 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/anesthesia, which is provided by a CRNA. It is possible to perform this procedure in some cases without sedation, or with moderate sedation, during which the patient remains conscious throughout the procedure. Anesthesia care provided by an anesthesiologist is a sedation alternative that is 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. Reported 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 routine polyp removals, up to 1/20 large polyp removals), **diverticulitis** (1/3500), **heart or lung problems** (such as **inhalation of fluid)** occur infrequently but major problems are rare, vasovagal symptoms (fainting, sweating, nausea and vomiting), infection (rare), damage to other internal organs or structures including **injury to the spleen** (1/6000), 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. **Complications may occur even when a procedure is properly performed.** Symptoms following a procedure may require evaluation in a hospital emergency department or other hospital care (1/50 Medicare cases nationally during the week after an endoscopic procedure). Treatment of major complications may require hospitalization, surgery, and blood transfusion. Hospital treatment may require endoscopy by another physician (rather than your established Digestive Health gastroenterologist) at Mercy Regional Medical Center or another hospital.

Our endoscopic research consortium (www.cori.org) published a study in February 2010 defining the frequency of colonoscopy-related complications leading to hospitalization in over 21,000 colonoscopy procedures performed at multiple sites in the U.S., including the Southwest Endoscopy Center. Serious complications directly or indirectly related to colonoscopy occurred in 1/315 cases. These included: hospital admission for bleeding in 1/630 cases, bleeding requiring transfusion in 1/1,265, perforation in 1/5265, diverticulitis requiring hospitalization in 1/4350, angina or heart attack in 1/1,785, stroke/TIA in 1/3,030 and postpolypectomy syndrome in 1/11,110. 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 70% of cases if performed at recommended intervals by an experienced physician.

SEDATION/ANESTHESIA: Sedation/anesthesia involves a risk of heart, lung, allergic or other drug reaction problems (<1/200), which rarely (<1/160,000) can be fatal. Sedation/anesthesia is administered and monitored by a CRNA.

MEDICATIONS THAT AFFECT BLOOD CLOTTING: Your doctor may recommend that these drugs, be discontinued before colonoscopy to reduce possible bleeding risk related to polyp removal. Stopping and restarting these drugs however carries some risk of blood clot related problems, including stroke and heart attack. In some cases we may advise you to undergo colonoscopy without stopping these medications, in the belief that possible bleeding is less of a risk to your long-term health than the risk of possible heart attack or stroke.

Complications may occur even when a procedure is properly performed. Treatment of major complications may require hospitalization, interventional radiology procedures, 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. A separate written consent prior to transfusion is obtained if transfusion is needed.

SUCCESS: Complete examination of the colon (from the rectum to the cecum) is achieved in 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 permission. CRNA services at this facility are provided by Animas Anesthesia Associates, LLC. 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

_____

Printed Patient Name

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 or Nurse Practitioner (if applicable)

_____ *Date:* _____ *Time:* _____

Physician performing procedure

_____ *Date:* _____ *Time:* _____

CRNA (declaration limited to matters pertinent to anesthesia consent)