

## CONSENT FOR BRAVO pH MONITORING

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 Saslow and his assistants are authorized to perform:

**Bravo pH monitoring** – monitor esophageal acid exposure using a wireless sensor capsule placed at endoscopy. Following endoscopic inspection (*see Consent for Upper Gastrointestinal Endoscopy*), and while you are under sedation, the Bravo pH radiotelemetry sensor capsule is attached to the wall of your lower esophagus. The Bravo sensor capsule will record pH (acidity) measurements in your lower esophagus and transmit data to a small external receiver worn on your waistband or belt for 48 hours. The disposable sensor capsule will detach and pass naturally through your intestines and out of your body naturally during a bowel movement.

**ALTERNATIVES:** Catheter-based pH monitoring provides similar information over a shorter period of time, typically 24 hour. The patient wears a pH probe catheter that is passed through a nostril and positioned in the esophagus where it is kept for the duration of the test.

**RISKS:** These procedures involve some risks. In addition to the risks of endoscopy, the most common risks of Bravo pH monitoring are premature detachment of the pH capsule; failure of the pH capsule to detach from the esophagus within several days after placement, or discomfort associated with the pH capsule, requiring endoscopic removal; tears in the lining of the esophagus, causing bleeding and requiring possible medical intervention; and, perforation. Reactions to chromium, nickel, copper, cobalt and iron have been reported in patients with sensitivities to these metals.

**Complications may occur even when a procedure is properly performed.** Treatment of major complications may require hospitalization, surgery, and blood transfusion.

**MEDICATIONS THAT AFFECT BLOOD CLOTTING:** Your doctor may recommend that these drugs (such as Coumadin, Pradaxa, Xarelto, Eliquis, Plavix, Effient, aspirin, nonsteroidal anti-inflammatory agents and others) 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 health than the risk of possible heart attack or stroke.

**RECUPERATION:** Recuperation from placement of a Bravo sensor capsule 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. Mild chest discomfort is not unusual. **Increasing throat, chest or abdominal pain, bleeding, fever, chills or other signs of illness could be signs of complication of endoscopy 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 administered at Mercy Medical Center during endoscopy if a patient has lost a large amount of blood prior to the procedure. A separate written consent prior to transfusion is obtained if transfusion is needed.

**SUCCESS:** Successful placement of the Bravo sensor capsule and acquisition and retrieval of the data of interest is achieved in over 95% of cases.

**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 endoscopy, 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.*

\_\_\_\_\_  
PA or NP (if applicable) Date: \_\_\_\_\_ Time: \_\_\_\_\_

\_\_\_\_\_  
Physician performing procedure Date: \_\_\_\_\_ Time: \_\_\_\_\_