



3112 Fairview Drive
Owensboro, KY 42303
Phone: 270-922-2500
Fax: 270-922-2505
info@Landmarkgi.com

Miguel Lalama, MD, MPH

Brittany Davidson, APRN

Simone McCormack, APRN

Informed Consent for Capsule Endoscopy

I, _____, consent to having a capsule endoscopy.

A capsule endoscopy is an endoscopic exam of the small intestine. It is not intended to examine the esophagus, stomach, or colon. It does not replace upper endoscopy or colonoscopy.

I understand that the procedure consists of swallowing a small, pill-shaped camera that will allow the doctor to visualize the interior of my intestine. During the procedure, I will carry around a recorder that will record the images transmitted by the camera.

I understand that, despite precautions, there are risks associated with any endoscopic examination including, but not limited to, capsule retention, bowel obstruction, or perforation of the small bowel wall and missed lesions. These complications, should they occur, may require surgery and/or a transfusion.

I understand that there are no guarantees regarding this procedure.

I am aware that I should avoid MRI machines during this procedure, which includes the entire time from after I ingest the camera until after the capsule passes.

I understand that due to variations in patients' intestinal motility, the capsule may only image part of the small intestine. It is also possible that due to interference, some images may be lost and this may result in the need to repeat the capsule procedure.

I understand that the images and data collected from my capsule endoscopy may be used, under complete confidentiality, for educational purposes in future medical studies or conference presentations.

Landmark Digestive Health Staff has explained the procedure and its risks to me, along with alternatives of diagnosis and treatment, and I have been allowed to ask questions concerning the planned examination.

I have read and fully understand this consent form. I understand I should not sign this form if all items, including all of my questions, have not been explained or answered to my satisfaction, or if I do not understand any of the terms or words contained in this consent form.

IF YOU HAVE ANY QUESTIONS AS TO THE RISKS OR HAZARDS OF THE PROPOSED PROCEDURE, OR ANY QUESTIONS CONCERNING THE PROPOSED PROCEDURE, PLEASE ASK YOUR PHYSICIAN NOW, BEFORE SIGNING THIS CONSENT FORM. DO NOT SIGN UNLESS YOU READ AND UNDERSTAND ALL THE INFORMATION.

I authorize Dr. Lalama and any additional assistants he deems appropriate to perform a Capsule Endoscopy on me.

PATIENT SIGNATURE _____ DATE _____ TIME _____

If patient is unable to sign, please indicate the reason here: _____

GUARDIAN/PARENT SIGNATURE _____ DATE _____ TIME _____

WITNESS (MA) SIGNATURE _____ DATE _____ TIME _____



3112 Fairview Drive
Owensboro, KY 42303
Phone: 270-922-2500
Fax: 270-922-2505
info@Landmarkgi.com

Miguel Lalama, MD, MPH

Brittany Davidson, APRN

Simone McCormack, APRN

PATIENT RESPONSIBILITY FOR PILLCAM RECORDER

Dearest Patient,

The recorder you are taking home with you is very sensitive. We try to maintain these recorders to the best of our ability so that you can have trouble-free usage. Please follow these guidelines to make sure the recorder stays in good condition:

- DO NOT let the recorder get wet
- DO NOT bend the wires or let them get pulled or kinked
- DO NOT bend the belt after removing it
- DO NOT let the monitor sit in the sun or other heat source
- DO NOT shower or bathe during this procedure
- KEEP this monitor positioned in a safe place so that it will not get bumped or smashed

I, _____, realize that I am solely responsible for this Pillcam recorder while it is checked out to me.

I will return the recorder to Landmark Digestive Health within 24 hours. (You may ask for an extension for up to 36 hours). The recorder should be returned in good working condition. Drop-off times are typically 8:00-12:00 and 1:00-5:00, Monday thru Friday. Sometimes the office closes for holidays, please check this ahead of time.

I understand that I will be charged for any damage in excess of normal wear and tear, up to the total value of the monitor (replacement cost of the recorder (as of November 2022) is \$4,630.

I also understand that I will be charged for all collection and legal fees required to recover the recorder and/or to collect charges for a damaged or non-returned recorder.

I also understand that if my actions prevent me from completing the study because I did not follow the Instructions for Pillcam Endoscopy, Landmark Digestive Health will charge me for the disposable pillcam that I ingested. Cost of the pillcam is \$525.30.

By signing below, I indicate that I understand and agree to the terms of this agreement:

PATIENT SIGNATURE _____ DATE _____ TIME _____

If patient is unable to sign, please indicate the reason here: _____

GUARDIAN/PARENT SIGNATURE _____ DATE _____ TIME _____

WITNESS (MA) SIGNATURE _____ DATE _____ TIME _____