

PHGI Associates, LTD.  
230 West Washington Square  
Philadelphia, Pennsylvania 19106

Patient Name: \_\_\_\_\_  
MRN: \_\_\_\_\_  
DOB: \_\_\_\_/\_\_\_\_/\_\_\_\_

**CONSENT FOR CAPSULE ENDOSCOPY**  
**DO NOT SIGN THIS FORM WITHOUT READING AND UNDERSTANDING ITS CONTENTS**

**INTRODUCTION:** Your doctor, \_\_\_\_\_, has scheduled you for an examination of your small intestine using the capsule endoscopy technique. The examination is being performed for the following reason(s): \_\_\_\_\_  
\_\_\_\_\_. We are asking you to read and sign this form to indicate that you understand the procedure and its benefits, and accept its risks. Please ask any questions about the procedure or this form that you do not understand.

**PROCEDURE:** Capsule endoscopy involves the examination of the small intestine by a miniature digital video camera that is the shape and size of a large vitamin tablet. You will swallow the capsule to permit the camera to obtain pictures of your small intestine. The capsule transmits images of your small bowel through radio communication to a special receiver that you will wear on a belt. The camera will transmit to the receiver through sensors that are attached with adhesive pads to the skin of your abdomen.

You will swallow the capsule early in the morning and return to the offices of PHGI Associates, Ltd. approximately 8 hours later, or the next morning as instructed, so that the nurse or physician may remove the receiver, belt and sensors. The capsule is disposable and you will excrete it naturally in your bowel movement. You should continue to avoid powerful electromagnetic fields (MRI machines) until you are sure that you have excreted the capsule. If four days have passed and you are not sure whether you have excreted the capsule, the physician can arrange for a plain x-ray of your abdomen. **You cannot have an MRI unless you are 100% sure that the capsule has passed.**

During the capsule endoscopy, you will need to avoid drinking or eating until instructed by the physician, avoid any strenuous physical activity and avoid any source of powerful electromagnetic field such as MRI machines, radio stations or other patients having capsule endoscopy. In addition, you will need to verify that the small light on top of the recorder is blinking. If the light stops blinking, then you should record the time and contact the physician. You also may need to record the time(s) that you drink, eat or experience any unusual sensations, and give all of these notes to the physician.

The physician will review the images of your small bowel taken by the camera, and will plan treatment based on the findings of the test.

**RISKS:** The risks associated with the procedure range from minor discomfort to significant medical problems. During the procedure many patients note: **1)** difficulty swallowing the capsule, **2)** temporary sore throat, **3)** skin reaction to the adhesive pads and **4)** mild nausea and indigestion. The significant medical risks include: **1)** bowel obstruction, **2)** perforation tear of the gastrointestinal lining, **3)** mucosal ulceration bleeding, and **4)** failure to excrete naturally the capsule. These complications may be serious and may necessitate hospital admission, antibiotics, transfusions or surgery. Capsule endoscopy does not replace upper endoscopy, colonoscopy, barium enema, UGI series, CT scan or MRI. In addition, there is approximately a 10-14% likelihood of missing a diagnostic finding.

In addition, due to variations in intestinal function, environmental (i.e. radio wave) interference, patient interference or computer glitches, images could be lost and the procedure may need to be repeated.

The effects of capsule endoscopy on a developing fetus or pregnant woman are unknown. Therefore, this procedure is **contraindicated during pregnancy**. You should notify the physician if there is a reasonable chance of pregnancy prior to this study. The physician or nurse can arrange for a pregnancy test if you have a concern.

**BENEFITS:** A successful capsule endoscopy may provide the following benefits: **1)** Checks for small bowel disease that might cause pain, low blood count, or blood in bowel movements when the obvious reason for bleeding cannot be found during other diagnostic tests such as endoscopy or barium studies; **2)** Improves the accuracy of diagnosis; and **3)** Detects causes of intestinal bleeding. The doctors cannot guarantee you will receive any of these benefits. Only you can decide if the benefits are worth the risks.

**ALTERNATIVES:** There may be other alternatives to capsule endoscopy that your physician could use to help diagnose your problem, including **1)** surgery with or without endoscopy during the surgery or **2)** watchful waiting with iron replacement therapy and/or blood transfusions to maintain a normal blood cell count. There are risks associated with a decision not to have the capsule endoscopy. If you are reluctant to have the capsule endoscopy procedure, please discuss this with your physician.

**AGREEMENT:** By signing this consent form, I acknowledge that I have read or had this consent form read and/or explained to me, and that I understand the information contained in this consent form. I also acknowledge that I have been given an opportunity to ask my physician any other questions I might have and that my questions have been answered satisfactorily. I agree to have the procedure performed and accept the risks.

Signature: \_\_\_\_\_  
PATIENT OR RELATIVE DATE \_\_\_\_\_

Signature: \_\_\_\_\_  
WITNESS DATE \_\_\_\_\_

**CERTIFICATION OF PHYSICIAN**

I certify that I have discussed and explained capsule endoscopy with the above-named patient and, in my opinion, he/she fully understands what I told him/her and the matters set forth in this consent form, which he/she has signed voluntarily in my presence.

\_\_\_\_\_  
Physician Signature Date \_\_\_\_\_