Harford Gastroenterology Associates

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Pathologist

SMALL BOWEL CAPSULE ENDOSCOPY CONSENT FORM

Patient Name: _____ DOB: _____ Acct #: _____

I agree and authorize Dr. _____ and/or associates or assistants of his/her choice at **Harford Gastroenterology Associates, P.A.** to perform a capsule endoscopy.

Reason for the Procedure: _____

Description of the Procedure: Capsule endoscopy involves swallowing a pill with a digital camera (called Endo Capsule) through my mouth and into my upper digestive tract. This will allow physicians to view and examine my small intestines. In most cases, the capsule is easily swallowed, travels painlessly through the digestive tract, and is naturally passed from the body with a bowel movement.

RISK: The following risks have been associated with a capsule endoscopy.

1. ***Capsule retention***. Retention of the capsule is estimated to occur in 1 to 2 studies per every 200 that are performed. Surgery is required to remove the capsule in those events where capsule retention occurs.
2. ***Delayed capsule passage***. Variations in intestinal anatomy or motility due to certain health conditions may cause a delay in the capsules' passage and affect the ability to complete the study. This may occur in up to 20 studies per 100 that are performed. This may affect the quality of the study and/or the ability to complete the test.
3. ***Image loss***. Malfunctions of the capsule or software may also affect the outcome of the study. This is estimated to occur in 1 to 2 patients per 100 studies. It may require repeating the capsule procedure.
4. ***Other rare complications are aspiration of the capsule or stomach contents, sore throat, and dental injury***. Infection, bleeding or perforation of the bowel is possible.

Benefits: I understand that a capsule endoscopy is a non-invasive diagnostic test that provides and improves levels of visual imaging for early detection and diagnosis of gastrointestinal tract diseases and may identify a cause for symptoms that may not be obtained by x-ray or other diagnostic means. The procedure is generally very safe and is well tolerated.

Alternative options: I understand that x-rays and surgery are the alternatives to a capsule endoscopy.

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STATEMENT OF VOLUNTARY PARTICIPATION:

I have had an opportunity to ask questions, and I have had those questions answered. Based on my discussion with my physician and the information that I have received, I am consenting to have a capsule endoscopy performed. I understand that I can withdraw my consent at any time. My consent for this procedure is voluntary. I understand that during this course of the capsule endoscopy something may arise which may necessitate procedures in addition to or different from those described above. If such unexpected circumstances arise, I further request and authorize the performance of additional surgery or procedures which may be considered necessary or advisable by the undersigned physician and/or his/her associates or assistants. **I understand that I cannot have a capsule endoscopy study if I have a defibrillator or a pacemaker.**

I confirm that I have read this form, or it was read to me and I understand this information.

_____ *Date*: _____
(Patient Signature)

_____
(Patient Name Printed)

Physician Certification

I hereby certify that the patient has read, or had read to him/her, this form and I have explained the nature, purpose, common and most frequent risks, and alternatives to the proposed capsule endoscopy procedure. I have offered to answer questions and have fully answered any questions by the patient about the procedure. I believe that the patient understands this form and what I have explained and has consented to proceed with the capsule endoscopy study.

_____ _____ _____
(Physicians Signature) *(Physicians Printed Name)* *(Date)*

Witness Certification

_____ _____ _____
(Witness Signature) *(Witness Printed Name)* *(Date)*