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CAPSULE ENDOSCOPY CONSENT FORM

Name: _____ DOB: _____

Capsule endoscopy involves swallowing a capsule camera called a capsule endoscope through my mouth and into my upper digestive tract. This will allow physicians to view and examine my small intestine. It will also allow possible partial visualization of my esophagus, stomach and colon. In most cases the capsule is easily swallowed, travels painlessly through the digestive tract and is naturally passed from the body.

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

1. Capsule retention. Retention of the capsule camera is estimated to occur in 1 to 2 studies per 200 evaluations performed. The performance of small intestinal x-rays (such as a small bowel follow through) prior to the capsule endoscopy study does not appear to decrease this risk. Surgery is required in the event of capsule retention. This surgery is typically elective, but emergency surgery may be necessary and could result in surgery related complications.
2. Delayed capsule passage. Variations in intestinal anatomy or motility may delay capsule passage or affect the ability to complete the study. This may occur in up to 20 studies of every 100 evaluations performed. This may require further evaluations, such as physician assessment or x-rays to localize or document capsule passage. In addition, it may affect the quality of the study and/or the ability to complete the evaluation.
3. Image loss. Malfunction of the capsule or system (hardware or software) may also affect the study quality or completeness. This is estimated to occur in 1 to 2 studies per 100 studies. It may require repeating the capsule endoscopy procedure.
4. Other complications may occur. Capsule endoscopy is a new technology to evaluate the small intestine. Rare complications may occur, including aspiration of the capsule or stomach contents, sore throat and dental injury. In addition, infection, bleeding or perforations of the digestive tract are possible.
5. I am aware that I should avoid MRI machines during the procedure and until the capsule passes following the exam.

Benefits: I understand that a capsule endoscopy is a non-invasive diagnostic exam that provides an improved level 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 by most patients.

Statement of Voluntary Participation

I have had an opportunity to ask questions, have had those questions answered and have received sufficient information so that I have a general understanding of my (the patient's) medical condition; the nature of capsule endoscopy; the benefits of capsule endoscopy; the usual and most frequent risks of capsule endoscopy; the risks without capsule endoscopy.

Based on my discussion with my (the patient's) physician or designated representative and the information that I have received, I am consenting to have the capsule endoscopy performed. My consent for this procedure is voluntary.

I understand that during the 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 operations or procedures which may be considered necessary or advisable by the undersigned physician and/or his/her associates or assistants.

I am aware that the practice of medicine is not an exact science and I acknowledge that no guarantees have been made concerning the performance, results or interpretation of the capsule endoscopy procedure.

I confirm that I have read this form, or it has been read to me.

Signature of patient/person authorized to sign for patient

Date_____

Printed Name

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, usual and most frequent risks, benefits and alternatives to the proposed capsule endoscopy procedure. I have offered to answer questions and fully understand 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 the proposed capsule endoscopy study.

Physician or representative signature

Date_____

Printed Name