

Patient MRN: _____ Patient DOB: _____

Capsule Endoscopy Procedure Consent Form

I CONSENT TO HAVING CAPSULE ENDOSCOPY.

- 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.
- Although rare, all capsule endoscopy procedures carry some risk. Possible complications include aspiration into the lungs or capsule retention due to small bowel obstruction. Endoscopic placement may present additional procedure risks. Medical, endoscopic or surgical intervention may be necessary to address those complications should they occur.
- I am aware that I should avoid MRI examinations until the capsule passes through the system and is excreted and retrieved.
- I am aware that I should not board an aircraft until after the capsule is excreted.
- I understand that due to variations in a body's intestinal motility, the capsule may only image part of the small intestine and this may result in the need to repeat the capsule procedure.
- I understand that images and data obtained from my capsule endoscopy may be used, under complete confidentiality, for educational purposes such as a reference library of images, in future medical studies, and in publications that may include pictures from capsule endoscopy tests without identifying me.
- I further understand my images, data, final report and any associated observations, findings and pathology may also be used by the manufacturer of the capsule, under complete confidentiality, for regulatory submissions, for improving the capsule images and analyzing images in better and faster ways in future designs and for finding new uses for and adding new capabilities to the capsule. (Example: creating a capsule that records images in other areas of the gastrointestinal tract or software that automatically analyzes capsule videos.) The images and data used by the manufacturer for these activities will have all identity removed and will be stored in a secure location. Only select members of the manufacturer's clinical and technical teams will have access to these images and data.
- My physician 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 certify that I have read the above consent form, understand the information regarding the capsule endoscopy procedure and do hereby consent to this procedure.

Patient Name (Print) _____ Date: _____

Patient Signature _____ Witness _____

Signed in Presence of: Medical Staff Other (relationship) _____