

**UNC HOSPITALS
CHAPEL HILL, NORTH CAROLINA 27514**

**REQUEST AND AUTHORIZATION FOR CAPSULE ENDOSCOPY
MIM #**

I request and authorize Dr. _____ and/or associates or assistants of his/her choice at The University of North Carolina Hospitals to perform a capsule endoscopy on _____.
Patient's Name

Description of the Procedure: 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 or Enteroclysis) prior to the capsule endoscopy study do 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.
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 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 perforation of the digestive tract are possible.
5. Death. Capsule endoscopy may rarely result in death related to the procedure itself or related interventions, such as surgery for capsule retention.

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.

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

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 and benefits of alternatives to capsule endoscopy; and the prognosis of my (the patient's) condition with and without capsule endoscopy.

Based on my discussion with my (the patient's) physician and the information that I have received, I am consenting to have capsule endoscopy performed. I understand that I can withdraw my consent at any point. 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 further request the administration of such anesthetics as may be considered necessary, desirable, or advisable by the physician responsible for this service.

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.

For the purpose of advancing medical education I give my permission for observers to be admitted to the operating room or procedure room, and UNC Hospitals and the UNC School of Medicine staff to make and use any photographic or other illustrations of me for diagnostic, scientific, educational, or research purposes, provided that my identity is not revealed. I further authorize UNC Hospitals and the UNC School of Medicine staff to examine and dispose of any tissues or parts which may be removed and to use them for teaching, educational, or research purposes, provided that my identity is not revealed.

I confirm that I have read this form, or it was read to me, and that all blank spaces were filled in and all inapplicable paragraphs, if any, were stricken before I signed below.

Signature of Patient/Person Authorized to Sign for Patient

Date: _____

Printed Name

Relationship to Patient

Hospital Number

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 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 the proposed capsule endoscopy study.

Physician Signature

Physician Name

Date: _____

WITNESS CERTIFICATION

I hereby certify that the patient has acknowledged to me that he/she has requested a capsule endoscopy, has received an explanation of the nature, purpose, benefits, usual and frequent risks and hazards of, and alternatives to the procedure, has had all of his/her questions answered, given his/her consent, and has signed the form above.

Witness Signature

Witness Name

Date: _____

