APPROVED
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WIRB®

Thomas Jefferson University
Informed Consent Document for Human Subjects Research

TITLE:	A Multicenter, Consecutive, Randomized Study to Optimize the Bowel Preparation Regimen for the PillCam COLON 2 Capsule Endoscopy Procedure
PROTOCOL NO.:	MA-205 / COVGIC20482 WIRB® Protocol #20150338 15C.273
SPONSOR:	GI Solutions, Covidien
INVESTIGATOR:	David M. Kastenberg, MD 132 South 10th Street Philadelphia, Pennsylvania 19107 United States
STUDY-RELATED PHONE NUMBER(S):	Dr. David Kastenberg 215-955-8108 215-955-8900 (24-Hours)

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

WHAT IS INFORMED CONSENT?
You are being asked to take part in a medical research study. As required by federal regulations, this research study has been reviewed and approved by an Institutional Review Board (IRB), a committee that reviews, approves and monitors research involving humans. Before a knowledgeable decision about whether to participate in a research study can be made, you should understand the possible risks and benefits related to the study. This process of learning and thinking about a study before deciding to participate is known as *informed consent* and includes:

- Receiving detailed information about this research study;
- Being asked to read, sign and date this consent form once the nature of the study is understood and a decision is made to participate. If there is anything about the study you don't understand or if there are questions, you should ask for explanations before signing this form;
- Receiving a copy of the signed and dated consent form to keep.

A patient who joins a research study has a relationship with the study doctor that is different than the relationship with a treating or personal doctor. A treating doctor treats a specific health condition with the goal of improving that condition. A study doctor treats all subjects according to a research plan to obtain information about the experimental drug, device or procedure being studied and with the understanding that there may or may not be benefit from being in the study. The study doctor and study staff can provide more information about research as opposed to treatment.

PURPOSE OF THE STUDY

The purpose of the study is to compare two bowel preparation regimens to see which gives the best outcome. The bowel preparation regimens used in this study are made up from materials that are approved for use by the Food and Drug Administration (FDA).
The bowel preparation regimen will be used with the PillCam® COLON 2 Capsule endoscopy procedure. The PillCam Colon 2 Capsule is an ingestible capsule that takes video images throughout the digestive system.

Up to 500 subjects will be tested in the study. This is a multi-center study with 5-10 testing sites participating.

PROCEDURES

Your participation in the study will last a total of 11 days. This includes two days of bowel preparation plus the day of capsule ingestion and 9 days of follow up. A phone call will occur 5 to 9 days after capsule ingestion to make sure it has left your body and to assess how you are doing. You might be asked to undergo an x-ray of your abdomen to make sure the capsule has exited your body.

You will be randomly assigned (like flipping a coin) to one of two bowel preparation regimens. You will have a 50% chance of receiving either regimen. Your study doctor will let you know which regimen to follow.

If you choose to participate in this research study and sign this consent form, you will need to be evaluated by your study doctor. Your study doctor will decide if you are eligible to participate. An appointment will be made with you for a baseline visit. At this visit, you will:

- Be asked about your medical and surgical history.
- Be asked about the medications you are taking.
- If you are a women of child bearing potential will be asked to undergo a urine pregnancy test.

The below table shows the procedures and assessments that will be performed.

	Screening / Baseline Visit	2 Days Prior to Capsule Ingestion	1 Day Prior to Capsule Ingestion	Capsule Ingestion (Procedure Day)	Telephone Follow-Up (5-9 Days Post-Capsule Ingestion)
Sign Informed Consent	X				
Surgical and medical history; collect demographic information	X				
Collect information about your medications	X				
Pregnancy test (if applicable)	X			X	
Senna tablets (bedtime)		X			
Drink at least 10 glasses of liquid		X			
2 Liters PEG-ELS, clear liquid diet only			X		
2 Liters PEG-ELS 45-75 min prior to capsule ingestion				X	
Boosts and suppository				X	
Verify Capsule Excretion				X	X
Collect information on how you are doing		X	X	X	X

You will be asked to keep a diary of your bowel preparation steps, your bowel activity, and capsule excretion. You will be provided with instructions on how to complete the diary.

During the study you will be asked to take colon-cleansing preparations.

- Two days before your visit at the clinic you will be asked to drink at least 10 glasses of fluids (preferably water) during the day, and take 4 Senna tablets at bed time. Senna is a laxative used to cause a bowel movement.

- One day before your visit at the clinic you will be asked to follow a clear liquid diet and drink two liters of Sulfate-free PEG (Polyethylene glycol) electrolyte lavage solution (ELS). PEG-ELS is a standard colon preparation typically used before a colonoscopy procedure.

- The morning of the capsule ingestion day you will be asked to drink an additional two liters of Sulfate-free PEG-ELS.

- One hour after you complete capsule ingestion, you may be provided a 10mg Metoclopramide tablet or 250 mg Erythromycin. Metoclopramide is used to relieve symptoms of slow stomach emptying. It helps treat symptoms such as nausea, vomiting and feeling full after a meal. Erythromycin is used to prevent infection.

- Both groups will drink SUPREP (3-ounces diluted in water) after capsule ingestion. SUPREP is a standard colon preparation typically used before a colonoscopy procedure. One group will also need to drink 60 ml (about 2 ounces) of Gastrografin. Gastrografin causes influx of fluid into the bowel. It is also used during a medical tests or imaging procedures to help body parts show up better.

- Three hours later, both groups will drink an additional dose of SUPREP (3-ounces diluted in water) and one group will also need to drink 30 ml of Gastrografin (about 1 ounce), ONLY if the capsule has not been excreted.

- Two hours later, you will insert a Dulcolax suppository (10mg Bisacodyl), ONLY if the capsule has not been excreted.

- Two hours after suppository insertion, you will be able to eat a standard full meal.

- Five to nine days after capsule ingestion, you will receive a follow-up phone call from the study staff to find out how you are doing.

- You might be asked to undergo an x-ray of your abdomen to make sure the capsule has exited your system.

You will be asked to inform the study staff if there is any change in your well-being any time during the course of your participation in the study.

The below table shows the bowel preparation procedures as they are described above.

Two Days Prior to the Capsule Ingestion	**Bowel Preparation A**	**Bowel Preparation B**
All Day	Drink at least 10 glasses of liquid	
Bedtime	Four Senna tablets	
The Day Before the Procedure Day		
Meals	Clear liquid diet all day	
7:00pm - 9:00pm	2 liters sulfate-free PEG-ELS; One 8-10 oz. cup every 10-15 minutes.	
Capsule Ingestion Day		
Meals	None until 2 hrs. after suppository	
45-75 min prior to capsule ingestion	2 liters sulfate-free PEG-ELS	
	Capsule Ingestion	
1 hour after capsule ingestion	Optional Prokinetics (only if capsule is in stomach more than1 hr.): 10 mg Metoclopramide (Reglan/Pramin) or 250 mg Erythromycin	
First Boost: After capsule entry into small bowel	3 oz. SUPREP*	3 oz. SUPREP* plus 60 ml (2 oz) Gastrografin
Second Boost: 3 hrs. after first boost, only if capsule not excreted	3 oz. SUPREP*	3 oz. SUPREP* plus 30 ml (1 oz) Gastrografin
Suppository: 2 hrs. after second boost, only if capsule not excreted	10 mg Bisacodyl	
2 hrs. after suppository	Standard full meal	

*Diluted in water per subject instructions form

WHAT ARE THE SIDE EFFECTS AND OTHER RISKS OR DISCOMFORTS INVOLVED?

Things you should know about side effects:

- Who will or will not have side effects is not predictable
- Some side effects are mild while others may be severe
- The study doctor/research staff will discuss the risks listed below in greater detail with you.

Bowel cleansing preparations may have the following risks:

- Dehydration (loss of body water) and/or imbalance in the levels of salts in the bloodstream. These risks may be avoided by strictly following the instructions given to you, such as carefully drinking the amounts of fluids required before and during the capsule preparation procedure.
- Nausea
- Vomiting
- Abdominal pain

The intended effect of the colon cleansing medications you will drink is that you will have many loose bowel movements and diarrhea. You may find this uncomfortable.

Potential risks of Gastrografin include:

- Dehydration
- Aspiration
- Severe allergic reaction. If you have had a previous reaction to contrast dye or if you have a known sensitivity to iodine, please let your study doctor know.

Common side effects associated with the use of Gastrografin are:

- Vomiting
- Nausea
- Diarrhea

The PillCam COLON 2 capsule may involve risks of capsule retention or delayed excretion. Although unlikely, surgical removal will be performed at the investigator's discretion.

The PillCam capsules have been used in more than 30,000 colon capsule endoscopy (CCE) procedures worldwide to date, in addition to approximately 2 million capsule procedures of all types (including small bowel).

If you have an X-ray to make sure the capsule has left your system, the amount of radiation you're exposed to during an X-ray is so small that the risk of any damage to cells in your body is very low. If you have had other procedures involving radiation exposure, you should be aware that the risk of effects from radiation is believed to increase with each exposure you receive (including procedures performed as part of your medical care).

WHAT ARE THE RISKS TO FETUSES AND PREGNANT WOMEN

Pregnant women or women who are breast feeding will not be enrolled in this study. To be in this study you and your partner must practice adequate birth control measures. The study doctor will discuss acceptable methods of birth control with you. If you are a woman of childbearing potential, you will have a pregnancy test before making a decision about being in this study. The results of this pregnancy test will be made available to you prior to the start of the study.

If you become pregnant during the course of this study, you should notify the study doctor as soon as possible.

If you are a man participating in this study, you also should practice adequate birth control because of potential adverse effects on sperm. If your partner becomes pregnant during the course of the study, the sponsor may want to follow her through the pregnancy and receive information on the pregnancy outcome. She will be asked to sign a separate consent form or a release of medical information form.

If you are a person in a same sex relationship, it is not necessary for you to practice birth control. However, if you are female, you will still have to have pregnancy tests according to the study protocol.

There may be side effects that are not known at this time.

Please tell your study doctor or a staff member if you have any side effects or any other problems in your health whether or not you think they are related to the study procedure.

NEW INFORMATION
You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

BENEFITS
The capsule procedure may give the study doctor important disease information about your colon and this may lead to medical treatment. However, this cannot be guaranteed.

You may not personally benefit from being a participant in this study. The results of this study may help us learn how to benefit patients in the future.

ARE THERE COSTS RELATED TO BEING IN THIS STUDY?
Study Procedures

All procedures done are study related and none are standard of care. Your insurance will not be billed for any procedures done as part of this study.

You will not need to pay for the device or any medication (including laxatives) used in this study.

Standard Testing Procedures
Standard of care procedures and doctor visits will be billed to your health insurance carrier. These are charges that would be billed to insurance whether in a research study or not. It is possible that insurance coverage may be denied. If that happens, you may be responsible for some or all of these charges. The study doctor will explain which procedures, tests and doctor visits are considered standard of care.

If you receive a bill that you think is wrong, please discuss it with the study doctor or research coordinator.

PAYMENT FOR PARTICIPATION
You will be paid up to a total of $500 if you complete the study. You will receive $100 upon completing a successful screening visit, $200 upon completion of the capsule ingestion, and an additional $200 upon completion of the telephone follow-up. If you do not complete the study, you will be paid for the visits you have completed. You will receive payment at the conclusion of your study participation. Payment is to reimburse you for your time and traveling expense for participating.

ALTERNATIVE TREATMENT
Your alternatives include the PillCam procedure outside of this study or other imaging of your colon, such as a standard colonoscopy, computed tomography colonoscopy, or double contrast barium enema study.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

How will privacy and confidentiality (identity) be protected?

Federal regulations require that certain information about individuals be kept confidential. This information is called "protected health information" (PHI). PHI includes information that identifies an individual personally such as name, address and social security number, or any medical or mental health record, or test result, that may have this sort of information on it. The laws state that people may see and review their medical records at any time. However, in a research study, people may not see the study results or other data about the study until after the research is completed unless the study doctor decides otherwise.

- The study doctor will use and disclose your PHI to do the research, for regulatory purposes, to study the results, and to make sure the research is done correctly.
- The following individuals or entities may have access to your PHI and by law must protect it. These include investigators listed on this consent form and other personnel of Thomas Jefferson University, Jefferson University Physicians, and Thomas Jefferson University Hospitals, Inc. involved in this specific study, the University's Division of Human Subjects Protection and the Institutional Review Board (IRB), and your health insurance company (if necessary for billing for standard medical care).

PHI collected during this study may also be shared with the following entities that, while not obligated by law to protect PHI, will protect it to the best of their ability:

- Covidian which is providing funds to Thomas Jefferson University to conduct this research
- The Food and Drug Administration (FDA)
- A Data and Safety Monitoring Committee (DSMC),
- Research Monitors hired by the sponsor to oversee the study and review medical records to ensure study-related information is correct,
- Western Institutional Review Board,
- With any person or agency required by law.
- Once your information has been disclosed it may no longer be protected and may be disclosed without your permission.
- The following information will be provided to the study sponsor and other entities noted above:

Study data for analysis: Lab results: blood chemistry, complete blood count, pregnancy test results, past medical history, medications, colonoscopy reports, vital signs.

Demographic data: Race, ethnicity

If you develop an illness or injury during the course of participation in this study, other PHI about treating and following the condition may be generated and disclosed as it relates to this study.

PHI collected as part of this research may be used/disclosed indefinitely.

You may quit the study and revoke permission to use and share PHI at any time by contacting the principal investigator, in writing, at:

David Kastenberg, MD
132 South 10th Street, Suite 585 Main Building
Philadelphia, PA 19107

Further collection of PHI will be stopped on those who quit the study, but PHI that has already been collected may still be used.

The results of clinical tests and procedures performed as part of this research may be included in your medical records. The information from this study may be published in scientific journals or presented at scientific meetings but no individuals will be personally identified in these publications and presentations.

You do not need to sign this form, but if you do not you cannot be in this study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, this Web site will include a summary of the results. You can search this Web site at any time.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission.

Confidentiality
The sponsor of the study, Given Imaging, Inc., is creating a confidential database for healthcare professionals for academic and research purposes and Given Imaging for educational and promotional purposes. The database may contain medical information about you such as age, gender, diagnosis and treatment. The personal and medical data collected will be maintained in confidence and will be used anonymously without any information that can lead to the revelation of your identity to any third party, other than to the study team and the sponsor's personnel. By signing this informed consent, you hereby agree to the use of your medical information in any media (i) for academic and research purposes including in

scientific publications, (ii) for the purposes of educating healthcare professionals, and (iii) for promotional purposes of Given Imaging in order to explain and demonstrate the use of Given imaging's products to healthcare professionals and patients.

The company responsible for the processing of data is the study sponsor, Given Imaging, Inc. If the results of this study are made public, information that identifies you will not be used. If you decide not to give permission for the use and distribution of this information you will not be able to be in this research study.

Absolute confidentiality cannot be guaranteed because of the need to give information to these parties. The results of this research study may be presented at meetings or in publications. Your identity will not be disclosed in those presentations.

WHAT HAPPENS IN CASE OF INJURY AS A RESULT OF BEING IN THIS STUDY?

In the event of a research-related injury, necessary and available medical care (including hospitalization) will be provided. A research-related injury is a physical injury or illness that is directly caused by any procedure or treatment used in this study that is different from the treatment you would receive if not participating in a research study. If physical injury occurs due to any drug/substance or procedure properly given under the plan for this study, medical expenses for treating the injury will be billed to your insurance carrier. Costs not covered by your insurance, a government program or by another 3rd party will be paid for by the sponsor of this study. There is no plan to provide compensation for loss of wages, lost time from work, personal discomfort, or for injuries or problems related to your underlying medical condition(s).

If you have questions about the sponsor’s agreement regarding payment for a research-related injury please discuss with the study doctor.

If you receive a bill related to a research-related injury that seems wrong, please discuss it with the study doctor or research coordinator.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent for any reason, including:

- if it is in your best interest;
- if you become pregnant;
- if you do not follow your doctor's instructions;
- if your study doctor end his/her participation;

- if you do not consent to continue in the study after being told of changes in the research that may affect you;
- or, if the sponsor decides to terminate the study.

SOURCE OF FUNDING FOR THE STUDY
The sponsor, Given Imaging, will pay for this research study

DISCLOSURE OF FINANCIAL INTEREST

The sponsor of this clinical study, Given Imaging, is paying Thomas Jefferson University to conduct this study.

QUESTIONS
Contact Dr. David Kastenberg at 215-955-8108 or 215-955-8900 (24-Hours) for any of the following reasons:

- if you have any questions about your participation in this study,
- if you feel you have had a research-related injury , or
- if you have questions, concerns or complaints about the research

If you have questions about your rights as a research subject or if you have questions, concerns, or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com.

WIRB is a group of people who independently review research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

OR

The Jefferson Institutional Review Board
215-503-8966

If you want more information about the Jefferson Institutional Review Board or Jefferson's Human Research Protection Program, please visit our website at: http://www.jefferson.edu/human_research/irb/index.cfm.

Subject Communications

Do you wish to communicate with the study staff by e-mail? YES _____ NO _____

If you checked yes, please print your e-mail address on the line below.

RISKS: E-mail correspondence is not always secure and there is a risk of loss of confidentiality. To help protect against loss of confidentiality, all e-mail that originates from Jefferson University or Jefferson Hospital employees using Jefferson University or Jefferson Hospital e-mail addresses is encrypted. That means, unless you have allowed others to have access to your e-mail, only you will see the e-mail.

YOU SHOULD **NEVER** USE E-MAIL TO REPORT A SUSPECTED ADVERSE EVENT OR ANY OTHER MEDICAL PROBLEM. THESE SHOULD BE REPORTED BY TELEPHONE.

Non-Waiver of Legal Rights Statement

- ✓ **By your agreement to participate in this study, and by signing this consent form, you are not waiving any of your legal rights.**
- ✓ **In order to be in this research study, you must sign this consent form.**
- ✓ **You affirm that you have read this consent form. You have been told that you will receive a copy.**

Do not sign this consent form unless you have had a chance to ask questions and have gotten satisfactory answers.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results.

You can search this Web site at any time (21 CFR 50.25 (c)).

CONSENT
I have read this consent form (or it has been read to me). All my questions about the study and my part in it have been answered. I freely consent to be in this research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

SIGNATURES

_____

Your Name

_____

Your Signature **Date**

_____

Name of Person Conducting Consent Interview

_____

Signature of Person Conducting Consent Interview **Date**

_____ _____

Witness Signature Date

[Include only if subject understands and speaks English but cannot read English or if subject is blind or cannot physically sign the consent form.]

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_____

Copy of Signed and Dated Consent given to Subject by (Signature above) **Date**