MEDICAL FACULTY ASSOCIATES
THE GEORGE WASHINGTON UNIVERSITY

RESEARCH CONSENT FORM

TITLE:	CAPSULE ENDOSCOPY FOR HEMMORHAGE IN THE ER **(CHEER)**
PROTOCOL NO.:	
MANUFACTURER OF PILL-CAMERA:	Medtronic United States
INVESTIGATOR:	Andrew Meltzer, MD 202-741-2952
STUDY-RELATED PHONE NUMBER(S):	Andrew Meltzer, MD 202-445-7044 (24 hours)
STUDY COORDINATOR:	Nataly Montano 202-741-2917

Introduction

This consent form may contain words you do not understand. Before you decide to participate, please ask the study doctor or staff to explain anything that you do not clearly understand and take the time to discuss the study with family, friends or personal physician.

This study will test the ability of a miniature pill-camera (called "PillCam UGI") to detect bleeding in your esophagus, stomach, and the beginning of your small intestine (these parts of your body are called the "upper GI tract"). We are asking you to participate in this research study because the doctors in the Emergency Room (ER) think that you might have some bleeding in your upper GI tract.

Summary

- You are being asked to be in a research study.
- Being in this study is voluntary.
- If you join the study, you can leave at any time.
- This study will test the ability of a miniature pill-camera to detect bleeding in your upper GI tract.

- The pill-camera is FDA approved for inspection of the upper gut but has not been studied in this setting.

Please tell the Principal Investigator or study staff if you are participating in another research study.

Why is this study being done?

Our primary goal is to determine whether using the PillCam UGI in the Emergency Department will be able to accurately tell the difference between patients who are at high risk and those who are at low risk for serious bleeding in their esophagus or stomach.

This device has been approved by the U.S. Food and Drug Administration (FDA).

This study will look at how well the "pill camera" can detect bleeding in your upper GI tract compared to an endoscopy, which is a flexible tube with a light and camera attached to it that goes down your esophagus. It will also look at how well ER doctors are at interpreting these images compared to specialists.

If you decide not to participate in this study it will not affect your ability to receive standard medical care for your condition.

Will this affect my usual medical care?

Being involved in this study will possibly affect your usual medical care. While you are in this study you will assigned to one of two different groups. Only study participants in the experimental group will receive the PillCam UGI. The other group, however, will receive standard care, which involves admission to the hospital for most people. Most of the people in the other group will not be admitted to the hospital. They will be discharged to home if there are no evident complications or active bleeding based on the reading of the pill camera.

What is involved in this study?

Once you have agreed to participate in our study you will be randomized to one of two groups. This means that the group you are in will be determined by chance, kind of like flipping a coin.

- Group One receives standard of care. All patients in this group will be admitted for next day endoscopy in the hospital. An endoscopy is when a specialist puts a camera down your esophagus while you are sedated in order to look for signs of bleeding. This is standard of care.

- Group Two receives the PillCam UGI. If the PillCam UGI result appears normal or shows a low-risk problem and you are stable medically, you will be discharged home. We expect about 80% of the people in this group to be discharged home. If you are discharged, we will call you and plan for you to get an endoscopy as an outpatient within 3 days.

The research team will gather the following information from you or from your health care record:

- Chief complaint
- History of present illness,
- Past medical history,
- Medications,
- Vital signs,
- Physical exam findings.

Group 1 patients will undergo an Endoscopic examination of the upper GI tract after hospital admission.

Group 2 patients will swallow the PillCam UGI.

Before we have you swallow the PillCam UGI you will receive a single dose of intravenous metoclopramide 10 mg, which help the capsule move through your stomach easier.

We will also place a set of 3 sensors on your body. This allows the pictures that the PillCam UGI takes to be sent to the GI Specialist, who will be reviewing your images. They will be removed after the procedure is completed.

You will then be given the PillCam UGI to swallow. It will record images for about 20-60 minutes. You will be monitored for a minimum of 4 hours. The PillCam UGI results will be read by a GI specialist and site PI. If you show no sign of active bleeding, show no serious findings on capsule, and have stable blood cell count, blood pressure and heart rate for at least 4 hours, you will be discharged home.

The research staff will schedule you to have an outpatient endoscopy within 3 days after discharge prior to leaving the hospital.

If the PillCam UGI does detect any bleeding, a drop in your red blood cells or abnormal vital signs, you will be admitted to the hospital like the other group for standard treatment.

For either group, if you are admitted, we expect that you will undergo an endoscopy within 24 hours but if you are discharged to home it may take up to 3 days for some patients or at certain times like weekends or holidays.

You will also be called on Day 7 and Day 30, to see how you are doing and if you had any complications.

You will be asked to sign a release/obtain of information to keep on file, in the event that you are seen in another hospital facility. This will allow us to easily obtain your records for review. As part of that review, we may be reviewing date and length of hospital stay, recurrent bleeding and if you had a repeat endoscopy.

What is the capsule endoscopy procedure?
In order to perform the video capsule endoscopy, you will swallow the PillCam UGI capsule, which is about the size of a multivitamin.

It uses 2 cameras at either end that flash 18 times per second, each time capturing images of the inner lining of the gastrointestinal (GI) tract. There are no wires and you will not feel the capsule once you have swallowed it.

Images are passed wirelessly to a data recorder belt over a total of 30 to 60 minutes. Video images are then moved to a computer from which the physician can view and assess the results.

You do not return the capsule – it is disposable and used only once per person. In most people it passes in a bowel movement.

How many people are being enrolled in the study?
Approximately 100 subjects will be in this study.

How long will I be in the study?

The total amount of time you will spend in connection with this study is one month.

You always can choose to stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

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What are the risks of the PillCam UGI?

The PillCam UGI is manufactured by Medtronic and has been FDA approved with a published safety profile since approval in 2004.

This is a randomized trial. This means you will be randomized to either Group1 or Group 2. One group will be admitted to the hospital for standard care. The other group will be discharged home if the experimental PillCam UGI does not find any serius problems. People in this group will be asked to return for the endoscopy.The research staff will assist with making this appointment.. This is different between the two groups.

If you decide to not take part in this study, you will probably be admitted to the hospital for a next day endoscopy, and will not receive the PillCam UGI.

The main risk associated with this study is that you may be discharged home instead of admitted to the hospital for endoscopy. You will only be discharged home if the PillCam UGI does not find evidence of serious bleeding, but we cannot be completely sure that the PillCam UGI will always be right.

The physical risks associated with the PillCam UGI are:

- difficulty swallowing the PillCam UGI and
- the capsule could become stuck in the stomach or bowel.
- not being able to pass it naturally through a bowel movement.
  The PillCam UGI may have to be surgically removed if this happens.
- aspiration
- possible skin irratation from the sensors

If you do not pass the PillCam UGI naturally through the upper GI tract, an endoscopy will probably be sufficient to retrieve the capsule. Given that most patients will receive an endoscopy as part of their standard work-up for the disease, this risk is very small.

The device is made of biocompatible material and its internal parts are non-toxic. The incidence of capsule retention has been reported to be less than 1% but this figure may be higher in Crohn's disease or other conditions.

There is a low risk that you may be bothered by the knowledge that the PillCam UGI device will pass naturally and may take several days to be pass through a normal bowel movement.

There is a low risk that information that we collect about you in this study may be seen by people who are not on the study team. To prevent loss of confidentiality, all data will be encrypted and no identifiable information about you will be stored with data. All study documents both electronic and hardcopy will be either locked in file drawers in the study coordinator’s office or on password-protected computers.

Patients are advised NOT to have an MRI for 30 days and to consult with their doctor prior to receiving an MRI in the future. For patients who are unsure whether they excreted the PillCam UGI, an abdominal X-Ray may be required as an outpatient to confirm that it has passed.

If any new information or significant findings develop during the research that may affect your willingness to be in the study, you will be informed.

Can I participate if I am pregnant?
Women who are pregnant can NOT participate in this study. A pregnancy test is standard of care in the Emergency Department for all woman of child bearing age. If you are pregnant you cannot participate in this study.

What are the benefits of participating?
Participation in this study has no direct benefit to you. The information from this research study may lead to a better test in the future for people with bleeding in their gut.

Will I be billed for participation?
There are no charges for your participation. Neither you nor your insurance will be billed. Standard of care procedures will be billed in the usual manner.

Will I be paid for participating?
You will receive a $60 gift card through the mail once the 30 day follow up call has been completed.

Are the researchers being paid for the study?
Medtronic is funding the George Washington University Department of Emergency Medicine to do this study.

What are my alternatives to participating?
You do not have to be in this study to be treated for bleeding in your stomach or gut. Your alternative is to not be in this study. As part of normal standard of care, diagnostic tests may include:

- Nasogastric lavage (a thin tube that is inserted down your nose into the stomach.)
- EGD – endoscopy
- Observation
- Serial Blood tests

The study doctor will discuss these options with you.

Will my privacy be protected?
If you are in this study, your medical records may become part of this research. They may be seen by a number of other people or groups associated with the study. We will be collecting information about medical procedures performed and discharge information.

Access to your study records will be limited to those who need the information for purposes of this study, as well as your health care providers if they need access to the information. All records will be kept in a secure location and access will be limited to research study personnel.

Except as required by law, name, social security number, address, telephone number, or any other direct personal identifier will not identify you. The results of this research study may be presented at a scientific or medical meeting or published in scientific journals. However, your identity will not be disclosed.

Federal law requires that hospitals, researchers and other healthcare providers (like physicians and labs) protect the privacy of your health information. This section tells you about your rights regarding your health information. By signing this form and agreeing to be in this study, you are agreeing to the following uses of your health information. You are free to not allow these uses. If you do that though, you cannot participate in the study.

Protected health information (PHI) that may be used and released (disclosed) in this study includes information such as:

- This consent form
- Demographic information (age, sex)
- Info about your medical history from your medical records (medications, past medical history, social history, vital signs)
- Results of physical examination
- Medical images – specifically from the pill camera and from an endoscopy.
- Admission and discharge information
- Health care expenses (the cost of standard work-up)
- Questionnaire's that you complete
- Laboratory blood results (blood count)
- Results of procedures

By signing this form, you allow the use, sharing, copying and release of your PHI carry out the study by your healthcare providers and by the study doctor and his research team.

You also allow the study doctor and the research team to release your health information to:

- GWU Institutional Review Board (the "IRB") to ensure protection of the rights of research subjects
- Office of Human Research at GWU to ensure safety in research
- U.S. Food and Drug Administration FDA to review safety and effectiveness of the pill camera.
- Accrediting agencies and GWU legal counsel
- Clinical staff who are not involved in the study who may become involved in your care, if it might be relevant to your care
- Medtronic. Any data that is released to Medtronic will be de-identified, i.e. name and contact info will be removed.

You may request to review or have a copy of your PHI collected during this study. This right to review and copy your PHI only extends to information that is placed in your medical record; it does not extend to information that is placed in your research record.

Your PHI will be treated confidentially to the extent permitted by applicable laws and regulations. Once your health information from this study is used or released as explained in this section, it is no longer protected by the Privacy Rule.

By signing this form you authorize the Study Doctor and members of the research team to use and share with others (disclose) your PHI for the purpose of this study. If you do not wish to authorize the use or disclosure of your PHI, you cannot participate in this study because your PHI is necessary to conduct this study.

Do I have to give you permission to use my information? Can I change my mind?
Not signing this form or later canceling your permission will not affect your health care treatment outside the study, payment for health care from a health plan, or ability to get health plan benefits. However, if you do not give permission to use your PHI, you may not take part in this study because your PHI is needed in order to conduct this study.

However, you may cancel this authorization at any time. Even if you cancel this authorization, the researchers may still use the protected health information they already have collected about you. However, no new PHI will be collected from you after you cancel your permission.

This authorization does not expire unless you cancel it.

To cancel your permission, you will need to send a letter to Dr. Andrew Meltzer stating that you are canceling your authorization. This letter must be signed and dated and sent to this address:

Andrew Meltzer, MD
Department of Emergency Medicine
2120 L Street NW, Suite 450
Washington DC 20037

Who pays for my medical care if I become ill or injured because of the study?
If you believed that you have been injured or have become ill from taking part in this study, you should seek medical treatment right away. This can be done through:

- GWU Hospital and/or GWU Medical Faculty Associates (MFA)
- Your Physician
- The Treatment center of your choice

You or your insurance company will be billed for this care. Your insurance company may not pay for such care because you are participating in a research study. Neither you nor your insurance will be billed if the pill camera gets stuck and will need to be removed. Medtronic, LTD has agreed to provide payment to cover the costs of reasonable efforts to remove the pill camera. You should contact the study doctor as soon as possible about any related illness or injury.

There are no plans for GWU, GWU Hospital and/or GWU MFA to pay for any injuries or illnesses. By signing this form, you will not give up any legal rights.

Can I withdraw from the study?
Taking part in this study is voluntary. You may decide NOT to join the study. Your decision will not cause any penalty or loss of benefits to which you are entitled. If you join the study, you may decide to leave the study at any time. Again, your decision to leave will not cause any penalty or loss of benefits to which you are entitled.

Your part in this study can be stopped at any time and without your consent by the study doctor. The study doctor may stop the study at any time. This would be done for the following reasons:

- the study doctor thinks it is necessary for your health or safety;
- you do not follow study protocol
- you are unable to swallow the video capsule;
- Medtronic has stopped payments to support the study; or
- Administrative reasons require your withdrawal.

This study is registered with clinicaltrials.gov. ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by law. This website will not include information that can identify you. At most the website will include a summary of the result. You can search this website at any time.

Who do I call if I have questions or problems?

Contact Dr. Andrew Meltzer at 202-741-2952 or 202-445-7044 or the study coordinator, Nataly Montano at 202-741-2917 for any of the following reasons:

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

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: GWU – Office of Human Research Telephone: 202-994-2715or email: ohrirb@gwu.edu

DOCUMENTATION OF CONSENT:

- **You will receive a signed and dated copy of this consent form for your records**
- **If you agree to be in this study, please sign below.**

_____
Subject Name (Printed)

CONSENT SIGNATURE:

_____ _____
Signature of Subject Date

_____ _____
Print Name of Person Conducting Informed Consent Date

_____ _____
Signature of Person Conducting Informed Consent Date

_____ _____
Principal Investigator's Signature Date