CONSENT FOR INVESTIGATIONAL STUDIES
CONSENT FOR RESEARCH
(v. 11.2012)

Project Title: Office Based Screening Test for Barrett's Esophagus

University Hospitals Case Medical Center Principal Investigator: Dr. Amitabh Chak, MD
Cleveland Clinic Co-Investigator: Dr. Prashanthi Thota, MD
Ahuja Medical Center Co-Investigator: Dr. John Dumot, DO

Introduction/Purpose

You are being asked to participate in this research study because you are at least 18 years old and you are scheduled to undergo standard of care upper endoscopy (EGD) at the endoscopy unit at University Hospitals Case Medical Center in Cleveland Ohio. The purpose of this research study to develop a new screening and surveillance method for Barrett's esophagus (BE). BE is a condition where the lining of the esophagus (the swallowing tube) changes and may lead to cancer. The screening method will test a device that is a capsule balloon that will brush against the walls of the esophagus to collect a sample. A capsule balloon is a capsule tethered to a thin tube, with a balloon inside the capsule. Unlike standard of care methods, this screening method is inexpensive and does not require sedation.

The device being studied, an inflatable balloon brush, is considered investigational, which means that the U.S. Food and Drug Administration (FDA) has not approved it for use.

About 120 people will take part in this research study at the endoscopy suites of the University Hospitals Case Medical Center (UHCMC), Ahuja Medical Center (AMC) and the Cleveland Clinic Foundation (CCF).

Study Procedures

Your participation in this study will last for one visit and will add 30-60 minutes in addition to your standard of care EGD. You will be one of 120 participants enrolled in this research, which includes three sites across Cleveland. Approximately 40 participants from each facility will participate in this study. The study will be performed at the endoscopy suites of the University Hospitals Case Medical Center, Ahuja Medical Center and the Cleveland Clinic Foundation**.**

If you are undergoing an endoscopy scheduled by your doctor for your routine care, you will be asked to undergo an additional capsule balloon test before the endoscopy. If you agree, you will have screening without sedation using the capsule balloon test, just before your sedated upper endoscopy (EGD); the capsule balloon test is a new method that examines the esophagus without using sedative medications.

The capsule balloon test will be performed by a qualified physician. While you are awake, the back of your throat may or may not be sprayed with a numbing agent. This should take about 5-10 min. You will then be asked to swallow the balloon, which will be deflated (no air in the balloon). After the balloon is swallowed, it will then be inflated (filled with air) fully with 15 cc of air.

The balloon will be withdrawn until a tug is felt at the gastroesophageal junction (base of the chest) (GEJ). Once the GEJ is located, 10 cc of air will be removed and the 5 cc balloon will be

pulled back 5 cm to sample the bottom of the esophagus. The balloon will then be completely deflated and then withdrawn (taken out) of your throat.

After you have the capsule balloon test, you will also be asked to complete a questionnaire. It will ask questions about your heartburn symptoms and inquire about how well you tolerated the procedure, and whether you would be willing to repeat the procedure. The questionnaire should take about five minutes to complete. If you do not wish to answer a question, you may skip it and go to the next question.

Upon finishing the questionnaire, you will have your endoscopy performed. After you have your endoscopy, the researchers will review your endoscopy records, the biopsy report if a biopsy was done, and your medical records to determine if you do or do not have Barrett's esophagus. They will then compare the results of the new capsule balloon test with your standard endoscopy test to determine how well the new method is able to detect Barrett's esophagus.

Consequences of Withdrawing or being Discontinued from the Research

If the procedure becomes too uncomfortable, you may ask the procedure be stopped and withdraw from the research study.

If an investigator chooses to withdraw you from participation in the research protocol to protect your overall wellbeing in the event that you are no longer fulfilling the basic study requirements/follow-up, study information collected prior to your removal will be retained.

Risks

Your participation in this study may involve the following risks. The Principal Investigator and his research team have taken steps to minimize the expected risks but your participation in this study involves only slight risks. We cannot predict all risks or potential side effects in all subjects. It is important that you tell the researchers about any injuries, side effects, or other problems that you experience during this study.

There may be mild discomfort while swallowing the capsule. Passage of the capsule through the throat and the attached tubing may stimulate gagging in some patients. You may experience a transient chest pressure or pain sensation when the balloon is inflated and pulled into the esophagus.

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If the capsule is not withdrawn after you swallow it, there is an additional risk of the capsule getting stuck in your intestine. There may be a very small risk of bleeding or perforation with a device in your esophagus.

Another risk is the breach of confidentiality of the questionnaire. A concerted effort will be made to ensure that any information about you is kept strictly confidential.

Benefits

This study may have potential benefits to you as a participant in this study. You may or may not directly benefit from participating in this study. Your participation may aid in medical research determining if screening for Barrett's esophagus is feasible by the new capsule balloon test.

Alternatives to Study Participation

Because of the nature of this research, the only alternative is to not participate in this study. In this case, the patients will still receive standard of care treatment outside of the research study. Their data will not be collected for this research study.

Financial Information

There is no cost to you or to your insurance company for participation in the research component of this protocol.

You will be paid a total of $50.00 for completing this one time study visit. In addition you will receive a parking voucher. To receive payment you must agree to complete a W-9 form which requires you to provide an address and social security number to the accounting department. This payment may be considered taxable income by the IRS. You will be issued a 1099-Misc form only if payment exceeds $600 from all studies in which they are participating, in a fiscal year.

Research-Related Injury

If injury occurs as a result of your involvement in this research, medical treatment is available from University Hospitals or another medical facility but you/your medical insurance will be responsible for the cost of this treatment. A research injury is an injury that happens as a result of taking part in this research study. If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not considered a "research injury". There are no plans for payment of medical expenses or other payments, including lost wages, for any research related injury. To help avoid injury, it is very important to follow all study directions. Medical treatment is available from University Hospitals and/or Cleveland Clinic or another medical facility, but you/your medical insurance will be responsible for the cost of this treatment.

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Confidentiality

Results of the research testing will be treated as confidential information and the results will not be included in your medical record. Similarly, your medical history will also be treated as confidential with no identifiable information released or shared with individuals outside the study team. If the study results are published, your name will not be used. Once all your results are collected, any identifiers will be removed and the information assigned a code. The date will be identified by a study number and not by your name or identifying information. The code assignment key will be maintained by the principal investigator and clinical research coordinator, on a password secured computer kept in a locked office. Assess to the code key will be limited to the principal investigator and the study personnel on a need only basis.
U.S. NATIONAL INSTITUTES OF HEALTH (NIH) CLINICAL TRIAL DATABASE: A description of this clinical trial will be available on http:///www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time to find out information about the trial and basic results.

Information About Genetic Testing

A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:
 Health insurance companies and group health plans may not request your genetic information to get from this research.
 Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
 Employers with 15 or more employees may not use your genetic information that we get from your research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009. Be aware that this new Federal law does **not** protect you against genetic discrimination by companies that sell health insurance, disability insurance, or long-term insurance.

Termination of Participation

Your participation in this study may be discontinued by the sponsor or investigator without your consent for the following reason:

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1) You no longer wish to participate in the research protocol
2) Any other situation that the principal investigator/research team deem necessary to remove your inclusion from the research trial

Privacy of Protected Health Information

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of University Hospitals. This Authorization form is specifically for a research study entitled "Office Based Screening Test for Barrett's Esophagus" and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigators, Dr. Amitabh Chak at UHCMC or Dr. John Dumot at the Ahuja Medical Center, and Dr. Prashanthi Thota at the Cleveland Clinic and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally the Principal Investigator and study staff at University Hospitals and Case Western Reserve University who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the following PHI about you: name, age, medical record number. This PHI will be used to screen you to see if you qualify for our study and on which date you will undergo a clinically-indicated EGD. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: Dr. Amitabh Chak, Dr. John Dumot, Dr. Sanford D. Markowitz, Dr. Joseph E. Willis, Dr. William Grady, Jenna Stump, and Samantha Long,; other staff from the Principal Investigator's medical practice group; University Hospitals, including the Center for Clinical Research and the Law Department; Dr. Prashanthi Thota and the Cleveland Clinic; Government representatives or Federal agencies, when required by law.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be

able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to Dr. Chak, MD, 11100 Euclid Avenue Cleveland OH 44106; If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

Summary of your rights as a participant in a research study

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Case Medical Center (UHCMC), Ahuja Medical Center (AMC) and the Cleveland Clinic Foundation (CCF) or elsewhere; however, UHCMC and AMC has no plans to provide free care or compensation for lost wages.

Disclosure of your study records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Case Medical Center Institutional Review Board and the Cleveland Clinic Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly foreign regulatory agencies may also review your records. If your records are reviewed your identity could become known.

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Contact information

UHCMC Patients Only

_____ has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator, Dr. Amitabh Chak, can also be contacted at UHCMC at (216) 844-3217 or Dr. John Dumot, DO can be contacted at AMC at (216) 593-1305 If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research- related injury; or other human subject issues, please call the University Hospitals Case Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Chief Medical Officer, The Center for Clinical Research, University Hospitals Case Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

Cleveland Clinic Patients Only

If you are a Cleveland Clinic patient, you should contact the page operator at (216) 444-2200 or toll free at (800) 223-2273, and ask for the Gastroenterologist on call.

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Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

X	
Signature of Participant	Date
X	
Printed Name of Participant	

X	
Signature of Witness	Date
X	
Printed Name of Witness	

Study personnel(only individuals designated on the checklist may obtain consent)

X	
Signature of person obtaining informed consent	Date
X	
Printed name of person obtaining informed consent	