19-002629

Minimally Invasive Molecular Approaches for the Diagnosis of Barrett's Esophagus and Esophageal Adenocarcinoma

NCT03961945

Document Date: 03/19/2025

MAYO CLINIC

Name and Clinic Number

Approval Date: **March 19, 2025**
Not to be used after: **March 18, 2026**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Minimally Invasive Molecular Approaches for the Diagnosis of Barrett's Esophagus and Esophageal Adenocarcinoma **Aim 2**

IRB#: 19-002629

Principal Investigator: Prasad Iyer, M.D. and Colleagues

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.	
It's Your Choice	This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part.
Research Purpose	The purpose of this research is to test the use of a minimally invasive screening tool (a sponge on a string device) to detect Barrett's Esophagus and esophageal adenocarcinoma. You have been asked to take part in this research because you are scheduled for a clinically-indicated endoscopy to examine your esophagus at Mayo Clinic Rochester, Mayo Clinic Arizona, Mayo Clinic Florida, or Mayo Clinic Health Systems.
What's Involved	Study participation involves a sponge capsule procedure, two questionnaires, height/weight, and hip/waist measurements. Research brushings and biopsies will be obtained during your endoscopy. Video and pictures of your esophagus will also be obtained during your endoscopy. There may be the possibility of a Visit 2. This would include a repeat sponge capsule procedure, an upper endoscopy with advanced

	imaging (volumetric laser endomicroscopy, if applicable), height/weight and hip/waist measurements as well as esophageal biopsies/brushings, video/pictures of esophagus during endoscopy, and a questionnaire.
Key Information	Costs: Costs for the research procedures will be covered by the research study. Risks: The risks for the research study include a mild sore throat, gagging, esophageal irritation/abrasions, and sponge detachment with the sponge capsule procedure. Risks of the upper endoscopy are the same as any clinically scheduled upper endoscopy and are described later in this consent form.
Learn More	If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep. A copy of this form will be put in your medical record.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

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Contact Information

If you have questions about …	You can contact …
▪ Study tests and procedures ▪ Materials you receive ▪ Research-related appointments ▪ Research-related concern or complaint ▪ Research-related injuries or emergencies Withdrawing from the research study	**Principal Investigators:** **Rochester:** Prasad Iyer, MD **Phone:** (507) 266-4338 Dr. John Kisiel, MD **Phone:** (507) 284-0959 **Florida:** Dr. Herbert Wolfsen, MD **Phone:** (907) 953-6319 **Arizona:** Dr. Francisco Ramirez, MD Dr. Allon Kahn, MD **Phone:** (480) 301-6990 **Mayo Clinic Health System in Austin:** Dr. Eduardo Antpack, MD **Phone:** (507) 434-1984 **Mayo Clinic Health System in Mankato:** Dr. Grace Dosanjh, MD **Phone:** (507) 594-4700 **Study Team Contacts:** **Rochester/Austin/Mankato:** [redacted] **Phone:** [redacted] **Phone:** [redacted] **Phone:** [redacted]

If you have questions about …	You can contact …
	Mayo Clinic Rochester 200 First Street SW Rochester, MN 55905 **Mayo Clinic Health System - Austin** 1000 1st Dr NW, Austin, MN 55912 **Florida:** [redacted] **Phone:** [redacted] **Mayo Clinic Florida** 4500 San Pablo Rd Jacksonville, FL 32224 **Arizona:** [redacted] **Phone:** [redacted] [redacted] **Phone:** [redacted] **Mayo Clinic Arizona** 13400 East Shea Blvd. Scottsdale, AZ 85259 **Mayo Clinic Health System – Mankato** 1025 Marsh Street Mankato, MN 56001
▪ Rights of a research participant	**Mayo Clinic Institutional Review Board (IRB)** **Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681

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If you have questions about …	You can contact …
▪ Rights of a research participant ▪ Any research-related concern or complaint ▪ Use of your Protected Health Information ▪ Privacy concerns related to data collected in the European Economic Area. ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study	**Research Participant Advocate (RPA)** **(The RPA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchparticipantadvocate@mayo.edu
▪ Billing or insurance related to this research study	**Patient Account Services** Toll Free (844) 217-9591

Other Information:
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.

A description of this research study will also be available on *mayoclinic.org*. This website will not include information that can identify you. You can search this website at any time.

Why are you being asked to take part in this research study?

You are being asked to take part in this research study because you are scheduled for a clinically-indicated endoscopy to examine your esophagus.

Why is this research study being done?

This research study is being done to evaluate the use of a sponge on a string device as a minimally invasive screening tool to detect Barrett's Esophagus and esophageal adenocarcinoma.

The device used in this study is an FDA 510(k) cleared device.

This study is being done in 3 phases. You are being asked to participate in Phase 3.

Information you should know

Who is Funding the Study?
This study is being funded by the National Cancer Institute.

Information Regarding Conflict of Interest:

- This research has been reviewed by the Mayo Clinic Conflict of Interest Review Board and is being conducted in compliance with Mayo Clinic Conflict of Interest policies.
- Both the Mayo Clinic Conflict of Interest Review Board and the Institutional Review Board have reviewed the Financial Conflict of Interest for one or more of the investigators and/or Mayo Clinic related to this research and they have determined that this Financial Conflict of Interest poses no additional significant risk to the welfare of participants in this research project or to the integrity of the research.
- Additional information is available to any interested study participant regarding the details of this Financial Conflict of Interest and how it is being managed by contacting the study coordinator or the Office of Conflict of Interest Review at (507) 284-0075.
- One or more of the investigators associated with this project and Mayo Clinic have a Financial Conflict of Interest in technology used in the research and that the investigator(s) and Mayo Clinic may stand to gain financially from the successful outcome of the research.

How long will you be in this research study?

You will be in the study until after a follow up phone call from the Study Coordinator seven days (+ or - 3 days) following your research procedure. You may be asked to have one additional visit several months after the initial sponge capsule procedure.

What will happen to you while you are in this research study?

If you agree to be in the study, you will be asked to participate in the following:

Visit 1:

- You will have nothing to eat at least 6 hours prior to your research appointment. You may drink clear liquids up to 2 hours prior to your research appointment.
- If you are a woman of child-bearing-potential, you may be asked to have a urine pregnancy test. You will be told the results of the pregnancy test. If the pregnancy test is positive, you will not be able to take part in the study.
- You will complete a short questionnaire regarding reflux symptoms.
- Measurements of your height, weight, hips, and waist will be taken.
- If needed, the back of your throat will then be sprayed with a numbing agent (Benzocaine 20%)
- You will be asked to swallow a capsule with a string attached that contains the sponge. You will be given water to help you swallow the capsule.
- The string is held without any tension to allow the capsule to move into the stomach. The string will be held for5-10 minutes to allow the capsule to dissolve in the stomach; a round mesh sponge about the size of a quarter is released and the expanded sponge will be withdrawn by gently pulling on the string.
- You will fill out a short questionnaire regarding your tolerability of the procedure.
- Within 24 hours of these procedures, your clinically indicated endoscopy will be performed with which you may have clinically indicated biopsies of your esophagus.
- Video and pictures of your esophagus will be obtained during your endoscopy.
- Research biopsy samples will be collected of your esophagus which involves a biopsy forceps being passed through the channel of the endoscope.
- Research brushings of your esophagus will be collected which involves a brush being passed through the channel of the endoscope.
- Rochester site only: if you have Barrett's Esophagus and are participating in the esophageal brushings/biopsies only portion of the study, a sponge will not be collected from you.
- Research brushings, research biopsies, and the sponge will be processed and analyzed by Mayo Laboratories and Exact Sciences.
- You will receive a follow-up phone call from the Study Coordinator 7 days (+ or - 3 days) following the research procedure.

- If you have Barrett's Esophagus you may be asked to return in several months for a sedated upper endoscopy to be done at which time esophageal biopsies will be taken along with an esophageal brushing for research. A repeat sponge on a string procedure will also be done.

Visit 2 (if applicable):

- You will be scheduled for a research upper endoscopy.
- You will have nothing to eat at least 8 hours prior to your appointment. You may drink clear liquids up to 2 hours prior to your research appointment.
- If you are a woman of child-bearing-potential, you may be asked to have a urine pregnancy test. You will be told the results of the pregnancy test. If the pregnancy test is positive, you will not be able to take part in the study.
- Measurements of your height, weight, hips, and waist will be taken.
- A sponge capsule procedure will be done as in Visit 1.
- You will fill out a short questionnaire regarding your tolerability of the procedure.
- You will have an upper endoscopy with esophageal brushings and biopsies as in visit 1.
- Video and pictures of your esophagus will be obtained during your endoscopy as in visit 1.
- Advanced imaging may also be done (volumetric laser endomicroscopy).
- The procedure will take 10-20 minutes to complete.
- You will then be watched for another 60 minutes and discharged. For this study, you will need to bring a person who can accompany you as you will not be able to drive for the next 24 hours due to the sedation. You should not operate power equipment or make any legal decisions for 24 hours following the procedure.

You will receive a follow-up phone call from the Study Coordinator 7 days (+ or - 3 days) following the research procedure.

Tests done only for research purposes are not meant to provide clinical information or help care for you. The results are only important for research. Therefore, the results of tests done with your information and samples will not be provided to you. In the rare event that a finding might affect the health of you or your family, we will contact you and you can choose whether to receive or refuse the information. If you decide to follow up and further medical testing or care is needed, the costs will be billed to you or your insurance.

What are the possible risks or discomforts from being in this research study?

Having the sponge on a string test is not painful. It would be like swallowing a pill or a capsule.

Risks of withdrawing the sponge are a mild sore throat, gagging and irritation/abrasions of the lining of the esophagus. There is chance that the sponge could become detached from the string. In this case the sponge would be retrieved during endoscopy.

Risks which may occur from the use of the Benzocaine 20% spray are: mild nausea, stinging, burning, dizziness, and drowsiness. As with any medication, allergic reactions are possible.

During your endoscopy, when the biopsy/brushing specimens are obtained, the tube may cause a cramping sensation in the stomach and you may feel bloated because air is introduced into the stomach during the procedure. The procedure is very safe, but bleeding from biopsies/brushings or a tear in the esophagus or stomach may occur in rare cases. Should bleeding occur and continue, an endoscopy will be performed to treat the bleeding. A tear in the stomach or esophagus usually requires surgery. The risk of such a tear is very low.

You may have pain, bruising or rarely infection at your IV site. You may experience a mild sore throat for a day after the endoscopy.

Risks from sedation during an endoscopy are rare, but include a decrease in your heart rate, breathing rate, and your blood pressure. Your heart rate, breathing rate, and blood pressure will be monitored throughout the entire endoscopic procedure and in the recovery area. There are medications in the endoscopy suite and the recovery area that can reverse the effects of the anesthesia, and they can be given immediately through your IV if the physician performing your endoscopy decides that your heart rate, breathing rate, or blood pressure require such treatment. As with any medication, allergic reactions are a possibility.

This study involves testing your DNA, which is the genetic information you inherited from your parents (also known as genetic testing). If a researcher finds that results from the genetic testing performed on your samples may be useful for your health care, you may be contacted and given the choice to learn the test results. At this time, you will be given general information on the potential risks, benefits, and costs of choosing to learn the test results. The risks of learning genetic test results may include emotional upset, insurance or job discrimination, and/or changes in family relationships because test results may affect other blood relatives. No genetic test results will be put into your medical record unless you choose to learn the results of the testing. Sometimes results should be released only through a genetic counselor who can help explain the possible risks and benefits of learning this information, as well as what these results could mean for you and your family.

As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

Are there reasons you might leave this research study early?

Taking part in this research study is voluntary. You may decide to stop at any time. You should tell the researcher if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the researchers or Mayo may stop you from taking part in this study at any time:

- if it is in your best clinical interest,
- if you do not follow the study procedures,
- if the study is stopped.

What if you are injured from your participation in this research study?

Where to get help:
If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries?
Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. Treatment costs for research-related injuries not covered by your insurance will be paid by Mayo Clinic.

What are the possible benefits from being in this research study?

This study will not make your health better. It is for the benefit of research.

What alternative do you have if you choose not to participate in this research study?

This study is only being done to gather information. You may choose not to take part in this study.

What tests or procedures will you need to pay for if you take part in this research study?

You will not need to pay for tests and procedures which are done just for this research study.

These tests and procedures are:

- Visit 1 sponge capsule procedure
- Visit 1 research brushing
- Visit 1 research biopsies
- Visit 1 questionnaires
- Visit 1 urine pregnancy test (if applicable)
- Visit 2 sedated endoscopy (unless clinically indicated), sponge capsule procedure, questionnaire, urine pregnancy test (if applicable), research brushing/biopsies

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care, including co-payments and deductibles.

- Visit 1 sedated clinically indicated endoscopy with or without clinical biopsy
- Visit 1 sedation/anesthesia medications used during clinically indicated endoscopy
- Visit 1 clinical interpretation of biopsy samples from clinically indicated endoscopy

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.

Will you be paid for taking part in this research study?

There is a very small chance that some commercial value may result from the use of your sample. This could include new products like a drug or a test to diagnose a disease. If that happens, you will not be offered a share in any profits.

You will receive $100 for Visit 1. An additional $200 will be paid for Visit 2. If you are unable to complete a visit after starting it you will receive a portion of this amount. If you are participating in the esophageal brushings/biopsies only portion of the study at the Rochester site, you will be offered a parking voucher.

Payment for participation in research is considered taxable income and reportable to the Internal Revenue Service (IRS). Accounts Payable at Mayo Clinic will be given your name, address, and Social Security number in order to issue a check for your study participation. If you receive research payments totaling $600 or more in a calendar year, a tax Form 1099 will be sent to you. For Mayo Clinic employees, research payments are included in your paycheck with applicable taxes withheld and reported on your Form W2 after calendar year-end.

Will your information or samples be used for future research?

Your samples will be used as described above for this research study. Some of your sample will be sent to Exact Sciences, Madison, WI for testing to confirm the study results. Samples will be sent to Exact Sciences in a coded format, which protects your identity.

Unless you give your permission below, your information or samples collected for this study will not be used or shared for future research, even if the identifiable information such as your name, Mayo Clinic number or date of birth is removed.

We would like to keep your information and samples for future research. You can still take part in this current study even if you don't want your information or samples used for future research.

Researchers at Mayo Clinic who aren't involved with this study may ask to use your information and/or samples for future research. Researchers at other institutions may also ask for a part of your information and/or samples for future studies. Unless you indicate otherwise, the future research may be on any topic. No direct benefits to you are expected from the future research.

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Your information and/or samples will only be shared consistent with your consent, and with all applicable laws and regulations.

If you approve release of your information and/or samples by checking 'yes' below, Mayo may send the information and/or samples to researchers who request them, but Mayo will not send your name, address, phone number, social security number, or any other identifying information with the information and/or samples. Your information and/or samples may be sent with a code, and only the researchers for this study at Mayo Clinic would be able to link the code to you.

Some future studies may examine your DNA, the genetic information you inherited from your parents (genetic testing). If there are findings which may be useful for your health care, the researchers may contact Mayo Clinic, so Mayo Clinic can give you the option of learning the results. You would be given general information on the potential risks, benefits, and costs of choosing to learn about the findings.

Please read the following statements and mark your choices:

1. I permit my information and samples to be stored and used in future research of Barrett's Esophagus/esophageal adenocarcinoma at Mayo Clinic:

☐ Yes ☐ No Please initial here: _____Date: _____

2. I permit my information and samples to be stored and used in future research at Mayo Clinic to learn about, prevent, or treat any other health problems:

☐ Yes ☐ No Please initial here: _____Date: _____

3. I permit Mayo Clinic to give my information and samples to researchers at other institutions:

☐ Yes ☐ No Please initial here: _____Date: _____

You may withdraw your consent for future use of your information and/or samples at any time, by writing to the Principal Investigator at the address provided in the "Contact Information" section of this consent form.

Your information and/or samples would be removed from any repository where they are stored, if possible. Information and/or samples already distributed for research use will not be retrieved.

How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study.

Methods used to safeguard the confidentiality of your data include:

- You will be given a unique study ID number-no other identifying information will be linked to your study data.
- All research materials are stored in a locked cabinet accessible only by the study team.
- Data stored on a computer is password-protected.

We have obtained a **Certificate of Confidentiality** from the Department of Health and Human Services (DHSS). The Certificate is designed to prevent us from being forced to disclose identifying information for use in any federal, state, or local civil, criminal, administrative, legislative, or other court proceeding, even if faced with a court subpoena. You should understand, however, that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. We may not withhold information if you give your insurer or employer or a law enforcement agency permission to receive information about your participation in this research. This means that you and your family must also actively protect your own privacy.

The Certificate does not prevent us from taking steps, including reporting to authorities, to prevent serious harm to yourself or others. Such disclosures will be made as described below.

The research team may share your information with:

- DHHS, to complete federal responsibilities for audit or evaluation of this research.
- Public health agencies, to complete public health reporting requirements.
- Mayo Clinic representatives, to complete responsibilities for oversight of this study.
- Your primary care physician if a medical condition that needs urgent attention is discovered.
- Appropriate authorities to the extent necessary to prevent serious harm to yourself or others.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so.

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Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

Health information may be collected about you from:

- Past, present, and future medical records.
- Research procedures, including research office visits, tests, interviews, and questionnaires.

Why will this information be used and/or given to others?

- To do the research.
- To report the results.
- To see if the research was done correctly.

If the results of this study are made public, information that identifies you will not be used.

Who may use or share your health information?

- Mayo Clinic research staff involved in this study.

With whom may your health information be shared?

- The Mayo Clinic Institutional Review Board that oversees the research.
- Other Mayo Clinic physicians involved in your clinical care. Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other United States agencies) or government agencies in other countries that oversee or review research.
- The sponsor(s) of this study and the people or groups it hires to help perform this research.
- A group that oversees the data (study information) and safety of this research.

In addition, individuals involved in study oversight and <u>not</u> employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, copy (using paper, digital, photographic, or other methods), or remove your identifying information from Mayo Clinic.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

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Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
200 1st Street SW
Plummer Building, PL 3-02
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Participant Advocate at: researchparticipantadvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts forever, unless you cancel it.

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Enrollment and Permission Signatures

Your signature documents your permission to take part in this research.

Printed Name | Date (mm/dd/yyyy) | Time (hh:mm am/pm)

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

Printed Name | Date (mm/dd/yyyy) | Time (hh:mm am/pm)

Signature