



Name and Clinic Number

Approval Date: March 12, 2021
Not to be used after: March 11, 2022

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Staging of Superficial Esophageal Adenocarcinoma using Volumetric Laser Endomicroscopy (VLE)

IRB#: 17-002723

Principal Investigator: Dr. Cadman Leggett, M.D., and Colleagues

Please read this information carefully. It tells you important things about this research study. A member of our research team will talk to you about taking part in this research study. If you have questions at any time, please ask us.

Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision.

To help you decide if you want to take part in this study, you should know:

- Taking part in this study is completely voluntary.
- You can choose not to participate.
- You are free to change your mind at any time if you choose to participate.
- Your decision won't cause any penalties or loss of benefits to which you're otherwise entitled.
- Your decision won't change the access to medical care you get at Mayo Clinic now or in the future if you choose not to participate or discontinue your participation.

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.

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 a copy of this form to keep. A copy of this form will be put in your medical record.



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CONTACT INFORMATION

You can contact ...	At ...	If you have questions about ...
<p>Principal Investigator: Cadman Leggett, M.D.</p> <p>Study Team Contact: Medy Clemens Lori Lutzke James Allen</p>	<p>Phone: (507) 284-4824</p> <p>Phone: (507) 255-4631 (507) 255-7495 (507) 284-7817</p> <p>Institution Name and Address: Mayo Clinic 200 First Street SW Rochester MN 55905</p>	<ul style="list-style-type: none"> ▪ Study tests and procedures ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints ▪ Withdrawing from the research study ▪ Materials you receive ▪ Research-related appointments
<p>Mayo Clinic Institutional Review Board (IRB)</p>	<p>Phone: (507) 266-4000</p> <p>Toll-Free: (866) 273-4681</p>	<ul style="list-style-type: none"> ▪ Rights of a research participant
<p>Research Subject Advocate (The RSA is independent of the Study Team)</p>	<p>Phone: (507) 266-9372</p> <p>Toll-Free: (866) 273-4681</p> <p>E-mail: researchsubjectadvocate@mayo.edu</p>	<ul style="list-style-type: none"> ▪ Rights of a research participant ▪ Any research-related concerns or complaints ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study
<p>Patient Account Services</p>	<p>Toll-Free: (844) 217-9591</p>	<ul style="list-style-type: none"> ▪ Billing or insurance related to this research study



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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.

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

You are being asked to participate in this research study because you have Barrett's esophagus with dysplasia and possibly esophageal adenocarcinoma. Biopsies will be taken as part of your standard medical care.

2. Why is this research study being done?

This study is being done to see if the Nvision® Imaging System (VLE) can accurately determine the diagnostic performance of staging of T1 esophageal adenocarcinoma.

The study has a target goal of enrolling 60 patients at Mayo Clinic Rochester.

3. Information you should know

Who is Funding the Study?

Mayo Clinic will be providing the funding for this research study.

4. How long will you be in this research study?

You will be in this study for the time of your scheduled endoscopy with resections, which is about 1 hour.



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

If you agree to be in this study, during the endoscopy being done for your regular clinical care, the physician will use the Nvision® Imaging System to locate and mark areas of dysplasia in your esophagus. After the areas of dysplasia are marked, biopsies will be taken from your esophagus as per standard care. Your physician may decide to perform resections as per standard of care. We will collect information from your medical record, including information about your procedure such as length of Barrett’s esophagus segment, therapy performed and pathology results. This information is recorded without using any personal identifiers; you will be assigned a unique study identification number.

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

Your physician will discuss the risks of endoscopic treatment including biopsies and resections with you as these procedures are part of your standard clinical care. The additional time needed for imaging is less than 5 minutes which does not increase or change the risk of the procedure you are undergoing for your clinical care.

7. Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator 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 at Mayo may stop you from taking part in this study at any time:

- If it is in your best interest,
- If you do not follow the study rules,
- If the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.



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We will tell you about any new information that may affect your willingness to stay in the research study.

8. 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.

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

This study may not make your health better. However, it may help us better identify areas of Barrett's esophagus with dysplasia and/or esophageal adenocarcinoma.

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

This study is experimental and only being done to gather information. You may choose not to take part in this study. If you choose not to take part in this research study, your care at Mayo Clinic will not be compromised.



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

You won't need to pay for tests and procedures which are done just for this research study. These tests and procedures are:

- The VLE imaging
- The imaging balloon

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.

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

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

You won't be paid for taking part in this study.

13. 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.

All study data will be entered into the password-protected database. Your identifying information will not be associated with the study research data. You will be assigned a Study ID number. Measures will be taken to safeguard that your privacy will be maintained and that the information you offer will be held in confidence.

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.
- Researchers involved in this study at other institutions.
- 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 not 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, or 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 Privacy Rights

You do not have to sign this form, but if you do not, you cannot take part in this research study.

If you cancel your permission 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.

If you choose not to take part or if you withdraw from this study, it will not harm your relationship with your own doctors or with Mayo Clinic.

You can cancel your permission 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
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Subject Advocate at: researchsubjectadvocate@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 lasts until the end of this study, unless you cancel it. Because research is an ongoing process, we cannot give you an exact date when the study will end.



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ENROLLMENT AND PERMISSION SIGNATURES

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

Printed Name Date Time 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 Time AM/PM

Signature