MAYO CLINIC

Name and Clinic Number

Approval Date: **September 27, 2023**
Not to be used after: **September 26, 2024**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Electronic Nose Identification of Fasting and Non-fasting Breath Profiles

IRB#: 14-009226

Principal Investigator: Dr. Cadman Leggett 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.

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CONTACT INFORMATION

You can contact …	At …	If you have questions about …
Principal Investigator: Cadman Leggett, M.D. **Study Team Contact:** Kevin Buller	**Phone:** (507) 255-7495 **Phone:** (507) 255-4803 **Address:** Mayo Clinic 200 1st Street SW, Rochester, MN 55905	▪ 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
Mayo Clinic Institutional Review Board (IRB)	**Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681	▪ Rights of a research participant
Research Participant Advocate **(The RPA is independent of the Study Team)**	**Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchparticipantadvocate@mayo.edu	▪ 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
Patient Account Services	**Toll-Free:** (844) 217-9591	▪ Billing or insurance related to this research study

1. 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 have been identified as someone who is fasting and undergoing an outpatient elective procedure requiring moderate sedation or anesthesia for an endoscopic procedure, or because you are a healthy adult who is accompanying a person scheduled for surveillance of Barrett's Esophagus. The plan is to have 1000 people take part in this portion of the study at Mayo Clinic.

2. Why is this research study being done?

The purpose of this study is to electronically characterize what the human breath smells like during a fasting state and in a non-fasting state. We are doing this research study to find out if we can easily screen individuals with a breath test before procedures that require fasting to improve patient safety. If you are scheduled for endoscopic surveillance of Barrett's Esophagus, we will also see if the electronic characterization is changed with presence of Barrett's Esophagus with or without dysplasia.

3. Information you should know

Who is Funding the Study?
The eNose Company (Zupten, Netherlands) is providing electronic nose equipment necessary to perform this study. The Principal Investigator or the institution will otherwise independently cover costs related to running the study. No direct monetary funding is being provided by the eNose Company to investigators or to the institution.

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

You will be in the study until your breath samples have been obtained.

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

If you agree to be in the study you will undergo 1 breath test.

For the breath test, you wear an external nose plug and breath in and out of a hand-held sensor through a sterile disposable mouthpiece with sterile disposable air filters for approximately 5 minutes.

You grant us permission to use the data generated by electronic nose analysis of your breath for further research studies. This will not impact or influence the results of your scheduled procedure.

We will also review your medical record for information to correspond to your breath profile including but not limited to age, gender, medications, medical conditions, smoking history, and other laboratory results.

Optional Storage of Data Results
We would like to keep your data results for future research. You can still take part in this current study even if you don't want your data results used for future research. If you agree to give your data results, it will be the property of Mayo Clinic. Your data will be identified in a coded format which protects your identity.

There is a very small chance that some commercial value may result from the use of your data result. If that happens, you won't be offered a share in any profits.

Please read the following statements and mark your choices:

1. I permit my data results to be stored and used in future research to learn about, prevent or treat other health problems

   ☐ Yes ☐ No Please initial here: _____Date: _____

2. I permit Mayo Clinic to give my deidentified data results to researchers at other institutions:

   ☐ Yes ☐ No Please initial here: _____Date: _____

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

We anticipate no significant risk to you for participating in this study.

For the breath test you will need to be able to sit still and breathe in and out of your mouth during the test. Some individuals may feel uncomfortable and if you have a history of *claustrophobia*, *anxiety*, or a *significant lung disease such as COPD, asthma, lung cancer, lung surgery, or even active smoking* it would be important to let us know as it may cause discomfort to you or exclude you from the study.

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

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

You may decide to stop at any time. If you cannot tolerate breathing into the device you can inform us that you will not like to participate and your participation will be terminated.

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

- if it is in your best interest,
- if you don't follow the study procedures,
- 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.

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:
We do not anticipate any possibility for injury during the participation of this study; however, 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?

Others undergoing procedures that require fasting and sedation may benefit in the future from what we learn in this research study to improve our safety protocols to prevent non-fasting complications.

10. 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.

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.

The tests and procedure are:

- Breath Test

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.

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

You won't be paid for taking part in this study, but will receive a 2-hour parking voucher. There is a chance that some commercial value may result from the use of your breath sample. This could include new products like a test to diagnose a condition or disease, or a new drug. If that happens, you will not be offered a share in any profits.

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. We will safeguard the confidentiality of your health information by coding data and samples with de-identified numbers. Access and stored electronic data is password protected and encrypted. If the results of the research are made public, information that identifies you will not be used.

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. 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.

Health information may be collected about you from:

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

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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.
- 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.

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.

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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 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 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.

	/ /	: AM/PM
Printed Name	Date	Time

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.

	/ /	: AM/PM
Printed Name	Date	Time

Signature