The Cleveland Clinic Foundation
Consent to Participate in a Research Study

Study title: **Ventilation During Endoscopy**

Sponsor: **Linshom**

PI: **John J. Vargo, MD (phone 216-445-5012)**

You are being invited to participate in a research study. A research study is designed to answer specific questions about new ways to prevent, detect, and treat disease. Being in a research study is different from being a patient. The purpose of this document is to provide a written summary of the discussion and exchange of research information you had with the research team. It is also for use as a reference during the study.

Please note:

- **You are being asked to participate in a research study**
- **Ask as many questions as needed so you can make an informed decision.**
- **Carefully consider the risks, benefits, and alternatives of the research**
- **Your decision to participate is completely voluntary and will have no effect on the quality of your medical care if you choose not to participate. You can also withdraw from the study at any time.**

This research study has been approved by the Institutional Review Board (IRB). The IRB is a committee that reviews human research studies to ensure the safety and welfare of research volunteers are protected in accordance with federal human subject regulations and ethical principles.

1. INFORMATION ON THE RESEARCH

Why is this study being done?

The purpose of this study is to evaluate to monitor the movement of air in and out of the lungs during endoscopy. This monitoring device called “Linshom” is considered investigational because it has not been approved by the US Food and Drug Administration (FDA). This device uses temperature to measure air movement, and we are evaluating how accurately it measures breathing. We will use a standard device in addition to the research device in order to compare them.

This research will take place only at the Cleveland Clinic and will include 50 patients. You are being asked to participate in this study because you are scheduled for an endoscopic procedure and will be receiving monitored anesthesia care. Such procedures include upper endoscopy, ERCP (endoscopic retrograde cholangio-pancreatography), EUS (endoscopic ultrasonography), balloon enteroscopy, and colonoscopy.

If you agree, your participation in the research study will last approximately 30-60 minutes, and will be conducted during your standard endoscopy procedure and in the in the recovery room. You will remain in your stretcher or bed throughout. Your study participation will end when you are fully recovered from the procedure. There is no study medication involved, and no blood or tissue samples will be taken.

What is involved if you decide to take part in this research study?
A member of the study staff will review the study with you and answer any questions you may have. If you agree to participate, we will ask you to sign this consent form before having any study-related tests performed. The following will occur:

During your scheduled standard of care endoscopy procedure, a small device (with two sensors) will be attached to a standard oxygen mask to measure temperature and CO_2 (carbon dioxide). You will breathe through the mask for 10 minutes and will be observed during this time by the study investigators. We will measure your breathing during and after your endoscopy procedure.

- If you agree to participate in this research study, you will wear the oxygen mask for an additional 10 minutes before your procedure starts. Some patients find wearing an oxygen mask uncomfortable. If you cannot tolerate wearing the mask for 10 minutes, you will be withdrawn from the study.
- To collect the data being measured, the device (sensors) will be connected to a laptop computer provided by Linshom. Your personal information will not be included. You will be identified using a unique study subject number.

The Linshom device does not replace a standard monitor but will be used in addition to our normal monitors. As you breathe in and out of the oxygen mask, the monitor will carefully watch your breathing and is designed to alert medical attention should you require it.

The study staff will collect and record the following data from your medical record: gender, age, BMI (height and weight), type of procedure, doses of medication; and at 5 minute intervals we will record blood pressure, pulse oximetry (measure of oxygen in your blood) and exhaled CO_2. Only the study staff will have access to your information.

2. ALTERNATIVES

What are the alternatives to participation in the research study?
You can choose not to participate in this research study. If you choose not to participate, this will not impact your current or future care at the Cleveland Clinic.

3. RISKS

What are the risks of participating in the research study?
Since the device is only measuring your inhaled and exhaled air, there are no conceivable risks to you. No part of the device should come into contact with your skin or face. You will only be wearing the plastic oxygen mask to which it is attached.

Confidentiality of data
Any time that information is collected, there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

4. BENEFITS

What are possible benefits of participating in the research?
There will be no benefit to you for taking part in this research; however, information gained from this research may help patients in the future.

5. COSTS

Are there any costs to you if you participate in this study?
There is no cost to you to participate in this study. No additional costs will be billed to your insurance. Your procedure is standard of care. The cost for routine tests and services that would normally be performed even if you don't participate in the study will be billed to you or your insurance provider.

6. COMPENSATION

Are there any payments to you if you participate in this study?
You will not be paid for your participation in this research.

7. PRIVACY AND CONFIDENTIALITY

What will happen to your information that is collected for this research?
Cleveland Clinic has rules and procedures to protect information about you. Federal and State laws also protect your privacy.

The research team working on the study will collect information about you. This includes your health information, data collected for this research study and personal identifying information including your name, address, date of birth and other identifying information. Generally, only people on the research team will know your identity and that you are in the research study. However, sometimes other people at Cleveland Clinic may see or give out your information. These include people who review research studies including the Institutional Review Board and Research Compliance, their staff, lawyers, or other Cleveland Clinic staff.

People outside Cleveland Clinic may need to see your information for this study. Examples include government groups (such as the Food and Drug Administration), safety monitors, other hospitals in the study and the sponsor of the research and their agents. Cleveland Clinic will do our best to ensure your information is kept confidential and that only the health information which is minimally required to conduct the study is

used or disclosed to people outside Cleveland Clinic; however, people outside Cleveland Clinic who receive your information may not be covered by this promise.

You do not have to give this permission to use and give out your information; however you will not be able to participate in this research study without providing this permission by signing this consent form. The use and disclosure of your information has no expiration date.

You may cancel your permission to use and disclose your information at any time by notifying the Principal Investigator in writing, John J. Vargo, MD. 9500 Euclid Avenue, A30, Cleveland, Ohio 44195. If you do cancel your permission to use and disclose your information, your participation in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in the study.

9. CONFLICT OF INTEREST

Do the researchers or institution have any conflicts of interest relating to this study?
The researchers and institution have no financial conflicts of interest related to this study.

10. QUESTIONS

Who do you call if you have any questions or problems?
If you have any questions about the research or develop a research related problem, you should contact Dr John Vargo at 216-445-5012 during normal business hours. If you need assistance after 5pm, on holiday or weekend, call the Cleveland Clinic main hospital number at 216-444-2200 and ask for the GI Fellow on Call. If you have questions about your rights as a research subject, you should contact the Institutional Review Board at (216) 444-2924.

11. VOLUNTARY PARTICIPATION

What are your rights as a research participant?
Taking part in this study is voluntary. You will be told of any new, relevant information from the research that may affect your health, welfare, or willingness to continue in this study. You may choose not to take part or may leave the study at any time. Withdrawing from the study will not result in any penalty or loss of benefits to which you are entitled.

12. SIGNATURES

Statement of Participant
I have read and have had verbally explained to me the above information and have had all my questions answered to my satisfaction. I understand that my participation is voluntary and that I may stop my participation in the study at any time. Signing this form

does not waive any of my legal rights. I understand that a copy of this consent will be provided to me. By signing below, I agree to take part in this research study.

_____
Printed name of Participant

_____ _____
Participant Signature Date

Statement of Person Conducting Informed Consent Discussion
I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

_____
Printed name of person obtaining consent

_____ _____
Signature of person obtaining consent Date