CONSENT FORM

Impulse Oscillometry and the Bronchoprotective Effects of Deep Inspiration

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This consent form describes a research study, what you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully and ask questions about anything that is not clear before you agree to participate. You may take this consent form home to think about and discuss with family or friends.

Key Information

- Being in this research study is voluntary – it is your choice.
- You are being asked to take part in this study because you are healthy and are vaccinated against COVID-19.
- The purpose of this study is to use a device called an impulse oscillometer to measure your lung function before and after you take a few deep breaths
- Your participation in this study will last for about 30 minutes.
- Procedures will include asking some questions about your health and medical history, as well as relaxed breathing through a oscillometry device for a few minutes before and after taking several deep breaths.
- There are risks from participating.
- The most common risk is discomfort from wearing a nose clip or breathing into the device. See the "Risks of Participation" section in this consent form for more information. You will not benefit from being in this study.

Purpose of Study

The purpose of this study is to understand if taking a few deep breaths changes lung function, measured with a device called an Impulse Oscillometer.

Description of Study Procedures

If you decide to take part in this study, you will be asked to sign this informed consent form after reviewing it with a study team member. You will be asked some questions about your health and medical history. You will be asked to avoid sighing or taking any deep breaths for 10 minutes before testing. Then you will perform the oscillometry breathing test.

Questionnaires: We will also ask you to take 4 questionnaires related to symptoms of breathing or vocal cord problems. This should take 5-10 minutes.

Neck circumference and Mallampati score: We will measure the thickness (circumference) of your neck with a disposable measuring tape. We will also ask you to open your mouth and look the back of your throat with a flashlight. This will allow us to calculate the Mallampati score, which estimates how open the airway is in the back of your throat. No instruments are involved. These two procedures should take less than one minute.

Oscillometry Breathing Test
Impulse Ocillometry is a kind of breathing test where airway pressure is measured at your mouth while a device applies small pressure waves at the mouthpiece. You will be asked to place a clip over your nose and to place your hands over your cheeks in preparation for the breathing test. Then you will make tight seal with your mouth on a disposable mouthpiece, and breathe in and out in a relaxed manner for a few minutes. During the test, the machine will apply pressure waveforms that you might feel as a slight vibration. You will then remove your mouth from the mouthpiece and rest for a few minutes. During this rest period, we will ask you to perform five deep breaths in and out. After the deep breaths, you will be asked to repeat the breathing test into the Impulse Oscillometer as described above.

Number of Subjects

Up to 50 subjects will take part in this study.

Risks of Participation

Collection of Private Identifiable Medical Information
We will be collecting private identifiable information about you during this study including but not limited to your medical history, diagnoses, medications and allergies to medication, laboratory values, and provider notes. Loss of privacy is a potential risk to collecting this information, if the information were to be released. We minimize this risk by removing information that identifies you (like your name or medical record number); keeping your information in a safe, secure server; and by restricting access to this information to the study team.

Breathing Test
Wearing the nose clip and breathing into the mouthpiece might make you feel uncomfortable. If you feel too uncomfortable wearing the nose clip and breathing into

the mouthpiece then we will stop the procedure. There is a small theoretical risk of acquiring an infection while breathing into the oscillometer. This risk is minimized through the use of a disposable high efficiency viral and bacterial filter and a disposable mouthpiece, that are both exchanged in between tests. The device will also be cleaned with a disinfectant in between tests.

Benefits of Participation

You will not benefit from being in this research study.

Costs

There will be no cost to you to participate in this study.

Payments

You will not receive any money or other reimbursements for your participation in the study.

Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes

The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we will code all data collected with unique identifiers; allow access to study records to only those involved in the study; retain all study related documents in a secure, locked location, giving access to only those who are involved in the study. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor.

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one.

What information may be used and given to others?

The study doctor will get your personal and medical information. For example:

- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Results of medical tests

Who may use and give out information about you?

- The study doctor and the study staff

- URMC and Affiliates

Your information may be given to:
- The Department of Health and Human Services
- The University of Rochester

Why will this information be used and/or given to others?
- To do the research
- To study 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.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

How long will this permission be valid?
This permission will last indefinitely.

May I cancel my permission to use and disclose information?
Yes. You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written notice, the study team will no longer use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

May I withdraw from the study?
Yes. If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
No. There is a risk that your information will be given to others without your permission.

Future Use of Information/Samples
Your oscillometry data collected as part of this research will not be distributed or used for future research studies without additional informed consent.

Return of Research Results
Because this is an exploratory study, we will not give you any individual results from your participation in the study. The clinical importance or meaning of the results are still uncertain and we may not know for sure what the results will mean for your health.

Contact Persons
For more information concerning this research or if you feel that your participation has resulted in any research related injury, emotional or physical discomfort, please contact**:** **Patrick Donohue, MD** at **XXX-XXX-XXXX** about any questions, complaints or concerns you have about this study.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

Voluntary Participation
Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.
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Use of E-mail in Research
You have the option to receive communications about this study via email. Email communications between you and the study team may be filed in your research record.

Email messages will be limited to scheduling and appointment reminders.

Email communications may be sent or received in an unencrypted (unprotected) manner. Therefore, there is a risk that the content of the communication, including your personal information, could be shared beyond you and the study team. Your consent below indicates that you understand this risk. The University of Rochester is not responsible for any interception of messages sent through email/text.

Signatures/Dates

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

Subject Consent

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

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Subject Name (Printed by Subject)

_____ _____

Signature of Subject Date

Person Obtaining Consent

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the

information. I have given the subject adequate opportunity to read the consent before signing.

_____

Name and Title (Print)

_____ _____

Signature of Person Obtaining Consent Date