RUSH

CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH STUDY

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Protocol Title: A Physiologic Study to Assess the Effect of an Inline Filter during Cardiopulmonary Exercise Testing (CPET): A Healthy Volunteer Study

Sponsor: Department fund

Name of Participant: _____

Key Information:

You are being invited to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Taking part in this research study is voluntary. You do not have to participate in this study and may choose to leave the study at any time. If you decide not to participate in this study or leave the study at a later time, your health care, benefits, or relationship with Rush University Medical Center will not change or be affected.

The purpose of this study is to investigate the effects of placing a filter on the breathing resistance as well as the amount of particles generated by the study participants during CardioPulmonary Exercise Testing (CPET).

If you agree to participate in this study, your participation may last up to two visits. Each visit will only last less than one hour each time.

During these visits, you will perform an exercise test twice, separated by approximately 45 minutes in two different days. One exercise test will be with an in line filter, the other without. Both tests will be done under close monitor by a pulmonary function lab technician and an attending physician with specialty of pulmonary and critical care medicine.

There are risks to you for participating in this study. In this study, you will perform high-intensity exercise (pedaling at times will be hard) that may lead to physical discomfort (for example, fatigue, shortness of breath, muscle fatigue or discomfort). The risks associated with taking part in this testing may include muscle cramps, muscle strain and/or joint injury, light-headedness, and fatigue (feeling tired). You may feel delayed muscle soreness for 24-48 hours after the exercise testing. There is a rare chance (less than 1 in 10,000) of experiencing a heart attack, irregular heartbeat, or other serious complication. This risk is the same if you are exercising outside of the laboratory.

You will not receive any direct benefit from being in this study. However, the information we get from this study may be useful scientifically and allow future exercise testing to be safer during pandemics. On your request, we will make the results of the exercise tests available to you and your primary physician.

You have the option to not participate in this study.

Detailed Information: Please review the rest of this document for details about the above topics and additional information you should know before making a decision about whether or not you will participate in this study.

Why are you being invited to participate in this study?
You are being asked to participate in this study because you are a healthy adult, with no serious heart, lung, metabolic, or muscle diseases.

Why is this study important?
This research has become necessary to make the exercise laboratory safe for subjects and study personnel during the COVID-19/SARS-2 pandemic. COVID-19/SARS-2 can be spread by coughing, sneezing, and breathing within a 3-6 feet area.

Usually we screen patients for symptoms and if they have any infectious symptoms (cough, fever, muscle aches, shortness of breath, fatigue, malaise, etc), we don't perform any testing until they feel better and are symptom free. However, with COVID-19/SARS2, you can be without symptoms and still be spreading the virus.

As such, procedures like exercise testing may increase the risk that study personnel may become infected with COVID-19/SARS-2 during testing of an asymptomatic subject.

Our study will determine if placing a filter can block the aerosol particles generated by subjects during exercise, we also aim to evaluate if adding the filter increase the resistance of breathing.

How many participants will take part in this study?
About 10 participants are expected to take part in the study at Rush University Medical Center.

What are the activities you will be doing if you participate in this study?

If you agree to be in this study, you will be asked to come to our pulmonary function test lab twice (approximately one hour every time) in two separate days to perform the exercise tests. During the test, we will fit you for a mouthpiece and nose clip, to monitor your breathing during exercise. We will place sticky patches on your chest and attach them to an electrocardiogram (ECG) machine (an electrocardiogram is a test to monitor your heart). We also will place a device on one of your fingers to measure your blood oxygen levels and measure your blood pressure from a cuff placed on your upper arm several times during the testing and recovery. During exercise you will begin cycling against no resistance, and we will slowly increase the work (the pedaling will become more difficult) until you can no longer pedal. At the point that you can no longer continue, we will remove the cycling resistance (pedaling will become easy) and monitor your recovery. The entire exercise test will take about 30 minutes.

One test will be done with filter connected to the mask while the other will be done without filter. The sequence to perform the test with or without filter will be randomly assigned.

What are the risks and discomforts of participating in this study?

You may have symptoms while on the study. We will you closely while taking part in the study for any new symptoms or side effects of the inline filter. However, doctors don't know all the side effects that may happen. Side effects may be anything from mild to very serious.

- **Electrocardiogram (ECG):** There may be some irritation when removing the sticky patches from your skin at the end of the recording.

- **Exercise tests:** You will perform high-intensity exercise (pedaling at times will be hard) that may lead to physical discomfort (for example, fatigue, shortness of breath, muscle fatigue or discomfort). The risks associated with taking part in this testing may include muscle cramps, muscle strain and/or joint injury, light-headedness, and fatigue (feeling tired). You may feel delayed muscle soreness for 24-48 hours after the exercise testing. There is a rare chance (less than 1 in 10,000) of experiencing a heart attack, irregular heartbeat, or other serious complication. This risk is the same if you are exercising outside the laboratory. To manage the risks, an exercise physiologist will be present during your exercise test. If at any time during the test you want to stop, you can signal or tell us to stop the test. You will feel very tired at the end of the test, but should recover within a few minutes. We recommend that when you leave the lab that you do no strenuous exercise for the rest of the day.

- **Unknown and unforeseeable risks:** In addition to the risks listed above, there may be some unknown risks related to the study procedures.

What if there is new information that may affect your decision to participate in this study?

During this study, you will be told about important findings (either good or bad), such as changes in the risks or benefits of participation in the study or new choices to participation that might cause you to change your mind about being in the study. If new information is shared with you, you may be asked to sign a revised consent form in order to continue participating in this study.

Will you receive your individual results from the study?
Yes, we will make the results of the exercise tests available to you and your primary physician if you want.

Can you leave or be removed from this study?
You have the right to leave a study at any time without penalty.

The researchers and Sponsor also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interests;
- You do not follow the instructions;
- The study is cancelled for any reason.

What about confidentiality of your medical information?
This authorization is voluntary. Rush University Medical Center and its affiliates ("Rush") will not withhold or refuse your treatment, payment, enrollment, or eligibility for benefits if you do not sign this authorization. You do not have to sign this authorization, but that means that you cannot be in the study or receive study-related treatment.

By signing this document, you voluntarily authorize (give permission to) Dr. Li, her study team, and other Rush personnel involved with the conduct and review of this study (which may include off-site personnel) to use or disclose (release) health information that identifies you for the study described in this document.

During the study, Dr. Li and her study team will collect Protected Health Information (PHI) about you for the purposes of this research. PHI is your health information that includes your medical history and new information obtained as a result of this study. Some of this information will come from your medical record. The health information that Rush may use or disclose for this research includes:

- Your demographic information, including age, gender;
- The two CPET results.

Dr. Li and her study team may share your health information and the results of your study-related procedures and tests with people outside of Rush who assist with the conduct and review of this study. The persons who receive your health information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, but only if permitted by the laws governing them. Your health information described above may be used or disclosed to:

- Monitoring agencies such as the Food and Drug Administration (FDA), the National Institutes of Health and the Rush Institutional Review Board (IRB).

While you participate in the study you will have access to your medical record, but Dr. Li is not required to release to you study information that is not part of your medical record. Rush is required by law to protect your health information, and study records that identify you will be kept confidential. The results of study tests/procedures performed as part of this study may become part of your medical record. Any study information in your medical record will be kept

indefinitely. Your identity will not be revealed on any report, publication, or at scientific meetings.

You have a right to inspect and copy the information to be disclosed with this authorization and you may obtain a copy of the information by contacting the office listed below.

If you no longer want to be in the study and do not want your future health information to be used, you may change your mind and revoke (take back) this authorization at any time by writing to Dr. Li at 1620 W Harrison St, Tower LL1202, Chicago, IL. 60612. If the authorization is revoked, you will no longer be allowed to participate in the study and previously authorized individuals/entities may still use or disclose health information that they have already obtained about you as necessary to maintain the integrity or reliability of the current study.

This authorization is valid for the entirety of this research study. It will expire upon completion of the study or if you revoke (take back) the authorization.

If you withdraw from this study, the data already collected from you may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Records of participation in this study will be maintained and kept confidential as required by law. We will use coded names or identification numbers, removal of all identifying information.

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human participants.

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.

What are the costs to participate in this study?

There are no costs to you for participating in this research. All costs for the required study will be paid for by the study sponsor.

Will you be paid for your participation in this study?

You will not be paid for being in this study.

SIGNATURE BY THE PARTICIPANT:

By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent/authorization form. You will be given a signed copy of this document.

Name of Participant	Signature of Participant	Date of Signature

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:
I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the participant. I further attest that all questions asked by the participant were answered to the best of my knowledge.

Signature of Individual Obtaining Consent	Date of Signature