RUSH

CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH STUDY

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Protocol Title: Aerosol particle concentrations among different oxygen devices for spontaneous breathing patients with tracheostomy: a randomized cross-over trial

Sponsor: **Fisher and Paykel Healthcare Ltd**
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 concentrations of the small invisible particles in your exhaled gas during the use of different oxygen devices.

If you agree to participate in this study, your participation may last up to 1.5 hours.

During the study, the oxygen devices will be rotated for use in a random sequence, each one of them would be used for five minutes.

There are little risks to you for participating in this study. You may feel discomfort with some devices, but the clinician will stay with you all the time. If you don't like it and want to switch, we will change it for you immediately. During the change of the device, you might cough. If you need suctioning, we will suction for you.

You may benefit from taking part in this study. You may find the oxygen device you like and feel comfortable to breathe with, and then we might notify your clinician to set up for you.

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 adult and have tracheostomy and can breathe without ventilator support.

How many participants will take part in this study?
Twelve participants are expected to take part in this 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 breathe normally with five different oxygen devices that the clinician would place for you. These oxygen devices are all commonly used devices to provide oxygen and humidification for tracheostomy patients like you, including cool aerosol with trach collar, cool aerosol with T-piece and filter, heat-moisture exchanger, heated humidified high-flow device, and heated humidified high-flow device with a mask/scavenger. We will rotate the five devices for you to use, each one will be used for 5 mins, and you can tell us your comfort with each device. Simultaneously, we will use with two hand size machines named particle sizers to measure the concentrations of small invisible particles in your exhaled gas, and the two machines will be placed at 1 and 3 feet away from your face and would not contact with you.

What are the risks and discomforts of participating in this study?
Side effects, risks, and/or discomforts from participation in this study may include:

- In this study, there is little risk of making you cough or feel discomfort with some device, due to the cool or hot humidified oxygen. If there is any discomfort and you want to switch, we will change it for you immediately.

What if there is new information that may affect your decision to participate in this study?
During this study, you will be asked about your comfort with different devices. 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?
Generally, activities performed for research purposes are not meant to provide clinical information. We may learn things about you from this study which could be important to your health or treatment. If this happens, this information will be shared with you. You will know which oxygen device works best for you.

Can you leave or be removed from this study?
You have the right to leave a study at any time without penalty. You will receive the standard care if you decide to withdraw from the research.

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, medical history, diagnosis, tracheostomy placement duration;
- Tracheostomy tube size, cuff inflation, secretion amount and color.
- Aerosol particle concentrations and your comfort with different oxygen devices.

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 600 S Paulina St, Suite 765, 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. This research study can be found by searching for the following Clinical Trial Registry Number (NCT#): 04654754.

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 devices will be paid by the sponsor.

Will you be paid for your participation in this study?

You will not be paid for being in this study.

Investigator Financial Disclosure

Dr. Li discloses research support from Fisher & Paykel Healthcare and Rice Foundation outside the submitted work. Dr. Vines provides consulting to Ohio medical and has research support from Teleflex Medical, INC. Dr. Fink is Chief Science Officer for Aerogen Pharma Corp, San Mateo, CA, USA. The institutions had no role in the study design, data collection, analysis,

preparation of the paper, or the decision to publish the findings. Other authors have no conflicts to disclose.

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