Outcome Comparisons of Two Vibratory Positive Expiratory Pressure Devices in Patients Unable to Clear Airway Secretions

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RUSH

CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH STUDY

Site Principal Investigator: David Vines, PhD, RRT, FAARC, FCCP
Department: Department of Cardiopulmonary Sciences
Address and Contact Information: 600 S Paulina St Suite 749, Chicago, IL 60612, Phone #: 312-942-4408, david_vines@rush.edu

Protocol Title: Outcome Comparisons of Two Vibratory Positive Expiratory Pressure Devices in Patients Unable to Clear Airway Secretions
Sponsor(s): Medica Holdings, LLC

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 (permission) 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 evaluate the clinical effectiveness of two secretion clearance devices.

If you agree to participate in this study, your participation may last up to until you are discharged from the intensive care unit.

The use of secretion clearance devices is a routine clinical practice for patients who are having difficulty clearing their own airway secretions; however, we would like your permission to participate in this clinical study. In this study, you will be randomly assigned to using one of two secretion clearance devices. To use the device, you will be instructed to blow into it. The frequency of use will be determined by your clinician. Data will be collected from your medical record to help us determine the effectiveness of these secretion clearance devices.

There is minimal risk to you for participating in this study. Repeated use of this device can cause dizziness in some patients, but you will be closely monitored by clinician during the process. In this study, there is also a risk that your study information or identity may be seen or used by someone other than the investigators working on this study, but we will do our best to prevent this from happening.

You may not directly benefit from taking part in this study, but we hope that knowledge gained from this study may benefit others in the future. You should not expect your condition to improve as a result of participating in this study. This study is not being done to improve your condition or health.

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 over the age of 18 and are now having difficulty clearing airway secretions on your own.

How many participants will take part in this study?
About 64 participants are expected to take part in this study.

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?
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. However, we will not share these results with you because there is a further need to evaluate this data to reach a conclusion.

Can you leave or be removed from this study?
You have the right to leave a study at any time without penalty. There are no consequences of your decision to withdraw from the study. 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 (keep back) 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. David Vines and his 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 (the personal information we collect about you) that identifies you for the study described in this document.

During the study, Dr. Vines and his 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:

- Medical record number
- Date of hospital admission and discharge
- Date of intubation and extubation

Dr. Vines and his 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 people 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:

- The study Sponsor, Medica Holdings, LLC
- Monitoring agencies such as the Rush Institutional Review Board (IRB).

While you participate in the study you will have access to your medical record, but Dr. Vines is not required to release study information to you 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. Vines at 600 S Paulina St, Suite 749, 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 (the entire time) of this research study. It will expire when the study is completed 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 and remove 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.

What are the costs to participate in this study?
There are no costs required to participate in this study.

Will you be paid for your participation in this study?
You will not be paid for being in this study.

Who can you contact for more information about this study?
Questions are encouraged. If you have further questions about this study, you may call Dr. David Vines, Principal Investigator at 312-942-4408 or email him at david_vines@rush.edu.

Who can you contact if you have concerns about your rights as a study participant?
Questions about the rights of research participants may be addressed to the Rush University Medical Center Office of Research Affairs at 1-800-876-0772.

What are your rights as a study participant?
Taking part in this study is voluntary. If you choose not to participate in this study or to leave the study at any time, your health care, benefits or relationship at Rush University Medical Center will not change or be affected.

If you choose to leave this study and you do not want any of your information to be used, you must inform Dr. David Vines in writing at the address on the first page. Dr. Vines may still use your information that was collected prior to your written notice.

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.

Name of Individual Obtaining Consent

Signature of Individual Obtaining Consent	Date of Signature

SIGNATURE OF THE PRINCIPAL INVESTIGATOR:
I attest that I am aware of the enrollment of this subject in the study discussed in this consent document.

Name of the Principal Investigator

Signature of the Principal Investigator	Date of Signature