Study Volunteer Initials

Lifespan Affiliate Site where research will be conducted

☒ Rhode Island Hospital	☐ The Miriam Hospital
☐ Bradley Hospital	☐ Newport Hospital
	☐ Gateway Healthcare

Agreement to Participate in a Research Study And Authorization for Use and Disclosure of Information

Committee # Name of Study Volunteer

Evaluating the Utilization and Effectiveness of Breath-Actuated Nebulizers in Acute COPD Exacerbations

You are being asked to take part in a research study. All research studies at Lifespan hospitals follow the rules of the state of Rhode Island, the United States government and Lifespan. Before you decide whether to be in the study, you and the researcher will engage in the "informed consent" process. During this process, the researcher will explain the purpose of the study, how it will be carried out, and what you will be expected to do if you participate. The researcher will also explain the possible risks and benefits of being in the study, and will provide other information. You should feel free to ask any questions you might have. The purpose of these discussions is for you to decide whether participating in the study is the best decision for you.

If you decide to be in the study, you will be asked to sign and date this form in front of the person who explained the study to you. This form summarizes the information you discussed. You will be given a copy of this form to keep.

1. Nature and Purpose of the Study

You are being asked to take part in a research project because you have been admitted to the hospital with an acute exacerbation of chronic obstructive pulmonary disease (AE-COPD). Chronic obstructive pulmonary disease (COPD) refers to two long-term lung diseases - chronic bronchitis and emphysema - that often occur together. COPD makes it hard for you to breathe. Tubes called airways carry air into and out of your lungs. If you have COPD, these airways may become partly blocked from swelling or mucus. AE-COPD is a flare-up of your COPD during which you may feel more short of breath, develop wheezing and a cough or worsened cough. AE-COPD can be brought on by an infection in your lungs or from exposure to something that irritates the lungs like cigarette smoke, smog and other air pollution, strong fumes from scented products, cold air or hot, humid air, or pollens that trigger allergies. Treatment for AE-COPD usually includes nebulizer breathing treatments, steroids and, if an infection caused the flare-up, antibiotics.

Nebulizer treatments are a type of treatment that delivers medication to your lungs – you breathe the medication in. The medication is usually a bronchodilator (medication that helps open the airways). Typically, a nebulizer treatment is given with either a hand-held device or through a mask. Liquid medication is placed in a small cup in the device and then oxygen is blown into it to make a mist you can breathe in. In standard nebulizers (SN) the flow of medication mist is constant. This means the medication is being blown around even when you are not inhaling it.

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The purpose of this study is to compare the use of a standard nebulizer (SN) with what is called a breath actuated nebulizer or BAN. The BAN device is designed so that the medication mist is only released when you take a breath on the device. This may result in delivering more of the medication to your lungs than with a standard nebulizer. We are conducting this study to determine if the BAN device will reduce the number of nebulizer treatments needed during hospitalization in patients with AE-COPD as compared to a standard nebulizer. Both SN and BAN are FDA approved for the delivery of nebulizer treatments. However, Rhode Island Hospital currently does not use BAN devices to treat AE-COPD.

We expect to enroll 150 subjects into this study at Rhode Island Hospital. The study is sponsored by Monaghan Medical Corporation.

2. Explanation of Procedures:

If you agree to take part in this study, you will first sign this consent form. The study staff will then verify you are eligible to take part in the study. You will not be able to take part in this study if you use a BAN as an outpatient at home. Once your eligibility is confirmed you will be randomly assigned "randomized" to receive nebulizer treatments with either SN or BAN. Randomization means you are put into a group by chance. It is like flipping a coin. You have an equal chance (50/50) of being placed in either group. Neither you, the study staff nor your doctor can pick which group you will be assigned.

Once you are randomized you will begin to receive your nebulizer treatments only using the device you were assigned to. If you are assigned to SN you will continue to use the SN device (handheld or mask) as you were before enrolling in the study. If you are randomized to BAN, a nurse or respiratory therapist will show you how to use the BAN device.

After signing the consent form patients in both groups willbe asked to complete the St. George's Respiratory Questionnaire for COPD patients. This is a 14-question survey that should take 5-10 minutes to complete. You will also be asked to complete a daily, one question survey rating how you feel about your shortness of breath while you are on nebulizer treatments for up to 7 days. If you are in the BAN group at some point during your hospital stay (likely within 3-4 days) a member of the study staff will ask you to complete a short (less than 5 minutes) survey about how easy or difficult you feel the BAN was to use.

Study staff will collect information from your medical record (for up to 6 months after you are discharged from the hospital) like the number of nebulizer treatments you receive, oxygen use, the need for breathing support, how long you stay in the hospital, pulmonary function test results performed after discharge and readmissions to the hospital. A member of the study team may call you after discharge during that 6 months to see how you are doing. They may also contact your primary care doctor or lung doctor. Your care will not be changed or influenced in any way by being in this study. You will receive nebulizer treatments as per your doctor's orders as frequently and for as long as your doctor feels you need them. There is nothing else you need to do as part of your participation in the study.

Costs for participating in this study

Some of the services you will receive are being performed only because you are participating in this research study. Examples of these 'research only' services include the BAN device (if so randomized) and the surveys. The BAN device is being supplied by the sponsor to Rhode Island Hospital at no cost. The survey will be paid for by the study and will not be billed to you or your

health insurance company. Other services you will receive during this research study are considered "routine clinical services" that you would have received even if you were not in the research study. Examples are the nebulizer medication(s), your hospital stay and all other medications, treatments, tests and procedures your doctor orders to treat your condition(s). Nebulizer treatments are billed as a bundle that includes the nebulizer device and the respiratory therapist time to administer the treatment together. Whether you are randomized to BAN or SN the charge for the treatment will be the same. These services will be billed to your health insurance company, but you will be responsible for paying any deductibles, co-payments, or co-insurance that are a normal part of your health insurance plan. If you do not have health insurance, you will be responsible for those costs.

Contact Information:
If you have any questions or concerns about this research study you may contact:

- **Dr. Jason Aliotta at 401-444-0008; or**
- **Pulmonary Research Office at 401-444-2733**

3. Discomforts and Risks

The BAN device is an FDA approved device to deliver nebulizer treatments. It is not being used in any way differently than what the BAN is approved for by the FDA. Being in this study will not change or influence any treatment you receive, what nebulizer medication is given to you through the nebulizer device or how often you receive nebulizer treatments.
The only possible risk to you by participating in this study would be breach of confidentiality. The likelihood of this happening is very small. Data collection methods and practices are in place to protect your identity. Your name will be replaced with a non-identifying subject number so that your name is not kept with the medical record data we collected. This consent form will be kept separate from your study data as well under double lock according to Lifespan policy.

4. Benefits
You may or may not benefit from taking part in this study. However, in general, your information will add to the body of knowledge of what doctors and researchers know about COPD. This knowledge may help patients with COPD in the future.

5. Alternative Therapies
You do not have to take part in this study to be treated for your condition. You can opt not to take part in which case you will receive your nebulizer treatments by standard nebulizer.

6. Refusal/Withdrawal
It is up to you whether you want to be in the study. You are not required to enroll or participate. If you decide to participate, you can always change your mind and quit at any time. If you decide not to be in the study, or if you quit later, you will still be able to get the health care services you normally get. If you join, but later on the researcher or your doctor feels being in the study is no longer good for you, they may choose to take you out of the study before it is over. If new information becomes available that might change your mind about whether you want to stay in the study the researcher will share this information with you as soon as possible.

Follow-up after Withdrawal of Consent
If you leave the study, it would still be useful for us to know how you do over the next 6 months. We would appreciate if you would permit us to get follow-up information about your health from your doctor or your medical record.

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____ If I withdraw from the study, you have my permission to collect information about my health from my doctor or medical record.

_____ I do not give my permission for you to continue to collect information about me if I stop participating in the study.

Signature of study volunteer Date

You have the right to change your mind at any time regarding follow-up after withdrawal. If you decide to quit the study please tell the head researcher Dr. Jason Aliotta at 401-444-0008.

7. Medical Treatment/Payment in Case of Injury

A research injury is any physical or mental injury or illness caused by being in the study. If you are injured by a medical treatment or procedure you would have received even if you were not in the study that is not a research injury. To help avoid research injury and added medical expenses, it is very important to follow all study directions carefully. If you do experience a research injury, Lifespan or the study doctor can arrange medical treatment for you. Such treatment will be paid for as described below.

If you have insurance and have a research injury that is not covered by the study, it is possible that some or all of the cost of treating you could be billed to your insurer. If your health insurance will not cover such costs, it is possible you would have to pay out of pocket. In some cases, Lifespan might be able to help you pay if you qualify for free care under Lifespan policy. However, Lifespan has no policy to cover payment for such things as lost wages, expenses other than medical care, or pain and suffering.

8. Rights and Complaints

Signing this form does not take away any of your lawful rights. If you have any complaints about this study, or would like more facts about the rules for research studies, or the rights of people who take part in research studies you may contact Janice Muratori in the Lifespan Office of Research Administration, at (401) 444-6246

9. Confidentiality and Research Authorization for Use and Disclosure of Your Health Care Information.

Your research records will be treated as private health care records and will be protected according to Lifespan privacy practices and policies that are based on state and federal law. In particular, federal law requires us to get your permission to use or disclose (release your information to someone outside of Lifespan) your health information for research purposes. If you sign this form you agree to be in this research study and you permit the use and disclosure of your health information for the purpose of conducting the research, providing treatment, collecting payment and running the business of the hospital. This permission has no expiration date. You may withdraw from the study at any time. However, if you do not want the researchers to use or disclose any further information in this study you must cancel permission in writing and may do so at any time. If you cancel your permission, you will stop taking part in the study and no new information will be collected about you. However, if you cancel your permission, it will not apply to actions already taken or information already collected about you by the hospital or the researchers before you canceled your permission.

Generally, the entire research record and any medical records held by the hospital may be used and released for research purposes. The following people or businesses/companies/ might use, release, or receive such information:

- The researcher and their support staff;
- The study sponsor: Monaghan Medical Corporation
- Doctors, nurses, laboratories and others who provide services to you or the sponsor in connection with this study;
- The company or section of the U.S. government that is paying for the study and others they hire to oversee, administer, or conduct the research;
- The United States Food and Drug Administration, the Department of Health and Human Services, the Office of Inspector General, and the Office of Civil Rights; European Medicines Agency
- People who volunteer to be patient advocates or research volunteer protectors;
- Members of the hospital's administrative staff responsible for reviewing, approving and administering clinical trials and other healthcare or research activities.
- Accrediting Organizations

There are times when the law might require or permit Lifespan to release your health information without your permission. For example, Rhode Island law requires researchers and health care workers to report abuse or neglect of children to the Department of Children, Youth and Families (DCYF) and to report abuse or neglect of people age 60 and older to the Department of Elderly Affairs.

All researchers and health care providers are required to protect the privacy of your health care information. Other people and businesses/organizations that are not health care providers are not required by law to do that so it is possible they might re-release your information.

You have the right to refuse to sign this form and not participate in the research. Your refusal would have no affect on your treatment, charges billed to you, or benefits at any Lifespan health care site. If you do not sign, you will not be able to enroll in the research study and will not receive treatment as a study participant.

If you decide to quit the study after signing this form (as described in Section 6) no new information will be collected about you unless you gave us permission to do so. However, the hospital or the researchers may continue to use information that was collected before you quit the study to complete analysis and reports of this research.

Additionally, 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.

For more detail about your privacy rights see the Lifespan Joint Privacy Notice which has or will be given to you.

SIGNATURE

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I have read this informed consent and authorization form. ALL OF MY QUESTIONS HAVE BEEN ANSWERED, AND I WANT TO TAKE PART IN THIS RESEARCH STUDY.

By signing below, I give my permission to participate in this research study and for the described uses and releases of information. *I also confirm that I have been now or previously given a copy of the Lifespan Privacy Notice*

This informed consent document expires on _____.
DO NOT sign this document after this expiration date

The Researcher is required to provide a copy of this consent to you.

_____ _____ _____
Signature of study volunteer/authorized representative* Date and Time when signed

I WAS PRESENT DURING THE CONSENT PROCESS AND SIGNING OF THIS AGREEMENT BY THE STUDY VOLUNTEER OR AUTHORIZED REPRESENTATIVE

_____ _____
Signature of witness (required if consent is presented orally or at the request of the IRB) Date

_____ _____
Signature of Translator Date

_____ _____ _____
Signature of researcher or designate Date and Time when signed

* If signed by agent other than study volunteer, please explain below.

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