Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Use of novel Sinusonic device for prevention of community acquired upper respiratory infection (URI)

Summary

You are being asked to participate in a research study. It is important that you understand that this is completely voluntary and it is your choice whether or not you participate.

This form describes the purpose, procedures, benefits, risks, discomforts and precautions of the study. It also describes the alternative procedures that may be available to you and your right to withdraw from the study at any time, for any reason. A member of the study staff will be available to discuss all information with you and be available for any questions you might have. When you think you understand the study, you will then be asked if you agree to take part. If you agree, you will be asked to sign this form. Once you sign it, we will give you a signed and dated copy to keep.

The entire study is expected to last for 9 weeks and will include 3 visits. Each visit will be conducted remotely and will consist of questionnaires meant to assess your condition. You will be provided with your SinuSonic device and instructed on how to use the device. Additional study details can be found in the procedures section (section B) of this document.

You may show this form to family, other doctors, and friends before you sign it. You may want to discuss it with them to help you decide if you want to be part of the study. If you do not know another doctor, but want a second opinion about this study, please ask. The study doctor will give you the name of another doctor that you can talk to. This study is being conducted remotely and no in-person visits are required. Visits will be conducted over the phone and over the internet and will take place over the course of two months. During these remote visits, you will be instructed on how to use the SinuSonic device and be given directions on how and when to complete your daily assessments. A detailed description of the study procedures can be found in the procedures section (section B) of this document.

The potential benefit of participating in this study is that use of the SinuSonic device may be successful in the prevention of vital upper respiratory infection, also known as the common cold, but this cannot be guaranteed.

There are a few potential risks associated with your participation in this study. These risks include the risk of having your condition going untreated because of being placed in the sham group or mild discomfort as a result of SinuSonic device usage. Further details on study risks can be found in the risks and discomforts section (section D) of this document.

Your alternative to taking part in this study is to receive standard medical care as prescribed by your doctor. There are various treatments available for Chronic Sinusitis. Your options may include:

• Regular care from your doctor

• Use of other types of medication

You are being asked to participate in this study because you have a history of URI. URI is a contagious infection of your upper respiratory tract. Your upper respiratory tract includes the nose, throat, pharynx, larynx,

and bronchi. The purpose of this study is to determine if SinuSonic decreases risk of acquiring viral upper respiratory tract infections, also known as the common cold.

If you are interested in learning more about this study, please continue to read below.

A. PURPOSE OF THE RESEARCH

Sinusonic is a simple handheld device that delivers acoustic vibrations and positive expiratory pressure, pressure that is experienced as you breathe out, as participants exhale through their nose. It is a legally marketed device used in accordance with its labeling. Beneficial effects have been shown in a clinical trial that showed improvements in nasal blockage/congestion, nasal drainage, nasal/sinus pressure and sense of smell. Acoustic vibrations, sound waves similar to humming, are known to increase nasal nitric oxide (NO) which has antiviral properties, properties that help kill viruses, and stimulates mucociliary clearance. Mucociliary clearance is the body's ability to get rid of mucus from your nasal passages. The SinuSonic device is compliant with all applicable FDA regulations. A small unpublished pilot study demonstrated a greater than 70% increases in peak nasal NO, the amount of NO released when you breathe out, after one use of Sinusonic. The purpose of this study is to determine if Sinusonic decreases risk of acquiring viral upper respiratory tract infections.

Healthy Humming, LLC is paying MUSC and the principal investigator to conduct this research. The investigator in charge of this study is Dr. Ted Meyer. Approximately 300 people will take part in this research study at MUSC, the only site conducting this research.

B. PROCEDURES

Before any study activities occur, the informed consent form must be signed.

If you agree to be in this study, the following will happen:

Visit 1 (Baseline Assessment/Initial Treatment):
If you decide that you want to be in the study, you will have the following procedures performed to find out if you qualify to be in this study:

- The study staff will review your medical history with you over the phone to ensure that you meet inclusion criteria. It is important that you inform the research staff of all prescription and nonprescription medications, dietary supplements and vitamins that you are presently taking or have taken in the past 1 month.
- The study staff will go over any potential risks that are associated with the study.
- The baseline assessment will last for approximately 15 minutes. If you are deemed ineligible following the baseline assessment, you will not be allowed to complete the treatment component of the visit.
- Once that is signed and returned to the study team, you will be randomized (assigned to your treatment group by chance) by the study team. 2/3 of subjects will receive an active device and 1/3 of subjects will receive a sham device, a SinuSonic device with no actual treatment. You will not be told which type of device you received until the end of the study.

- You will receive instructions on how to use the SinuSonic device properly from the study team. Instructions will be made available to you and included with the SinuSonic device that will be sent to you.
- Each use of the SinuSonic device will last for 1 minute.
- We will ask you to use the SinuSonic device 3 times per day each morning, noon and evening.
- You will be asked to gauge your upper respiratory tract-related symptoms each day. This process will take 1 minute.
- You will gauge the safety of the Sinusonic device through questionnaires administered electronically and any adverse side effects. An adverse event is any undesirable experience associated with the use of a medical product.

Daily assessments

- You will be asked to complete a daily checklist to record the date and time of each SinuSonic use.
- You will be asked to complete an online assessment to assess URI symptoms, safety concerns, and adverse events.
- This daily assessment should take 1 minute.

Participants should not modify the use of any sinonasal medication (Flonase, Nasonex,..) during the study duration. To ensure that the SinuSonic device stays cleans, the Nose Mask can be removed and cleaned using any sanitizing items (soap and water, alcohol wipes, etc.) Additional instructions for keeping the device clean will be provided to you with your SinuSonic Device.

It is possible that the PI will terminate your participation in the study at his discretion. The reasons for this could be due to study non-compliance or if you no longer meet eligibility requirements. A member of the study team will notify you if you will no longer be participating in the study.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled. If you wish to withdraw, please contact the study team at 843-876-1166.

C. DURATION

Participation in this study will consist of a baseline evaluation for inclusion or exclusion done over the phone that will last approximately 30 minutes. Daily assessments will take no longer approximately 10-15 minutes. The study will last 8 weeks. Weekly phone calls to ensure study compliance will occur until the end of the study and will take no more than 5 minutes. No in person visits are required.

D. RISKS AND DISCOMFORTS

DEVICE RISKS

Prior studies have reported: Mild discomfort in 2.5-5% of participants; Bleeding in 0% of participants; Crusting in 0% of participants (Soler ZM etal).

UNKNOWN RISKS

The experimental treatments may have unknown side effects. The researchers will let you know if they learn anything during the course of the study that might make you change your mind about participating in the study.

RISK OF INFECTION

There is an unknown risk of bacterial growth on the nose piece which could result in potential infection if not kept clean.

UNKNOWN RISKS TO PREGNANT WOMEN, EMBRYO, FETUS OR NURSING INFANT

Use of SinuSonic may involve unknown risks to a pregnant woman, an embryo, fetus (unborn baby), or nursing infant. Therefore, if you are pregnant, planning to become pregnant during the course of this study or are lactating (producing breast milk), (including breastfeeding a child), you cannot participate in this study.

RISK OF RANDOMIZATION
The treatment received may prove to be less effective or to have more side effects than the other study treatment(s) or other available treatments.

RISK OF PLACEBO
Participants in the placebo/sham group will have their condition go without treatment for the duration of the study.

CONFIDENTIALITY

There is a risk of a loss of confidentiality of your personal information as a result of participation in this study.

E. MEDICAL RECORDS

Information about your study participation will not be in your medical record. This means that neither your research participation nor any of your research results will be included in any MUSC medical record.

F. BENEFITS

This study is for research purposes only. There may be benefit if Sinusonic decreases your risk of contracting URIs (colds), but we do not know if this is the case and is the reason for doing the study. Information learned from the study may help other people in the future.

G. COSTS

There will be no additional costs to you as a result of being in this study.

H. PAYMENT TO PARTICIPANTS

You will not receive any payment for participating in this study.

You will receive a Sinusonic device free of charge.

I. ALTERNATIVES

Your alternative to taking part in this study is to receive standard medical care as prescribed by your doctor.

J. DATA SHARING

Information about you (including your identifiable private information) may have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you.

Records of your participation in this study will be held confidential except as disclosure is required by law or as described in this form. If the results of this study are published or presented at meetings, you will not be identified.

K. DISCLOSURE OF RESULTS

Clinically relevant research results and individual research results will not be disclosed to you.

L. AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, your research team will keep records of your participation in this study.

The health information we may use or disclose (release) for this research study includes certain health information indicating or relating to your condition.

Your research team will use and disclose (release) your health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
- Health insurer or payer in order to secure payment for covered treatment;

- Federal and state agencies and IRB committees having authority over the study such as:

    - The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.

Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You do not have to sign this consent form. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.

You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study or, if you are participating in a study designed for the development of a drug or device, your authorization will remain in effect until the drug or device is approved by the FDA or until the company's application to study the drug/device is withdrawn. You have the right to withdraw your agreement at any time. You can do this by giving written notice to study personnel. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.

If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at (843) 792-8740.

Regulations require that you be given a copy of the MUSC Notice of Privacy Practices (NPP) describing the practices of MUSC regarding your health information. One can be found at the end of this form.

M. SIGNIFICANT NEW FINDINGS

If there are significant new findings during the course of the study, you will be notified.

N. STUDENT PARTICIPATION

Your participation or discontinuance will not constitute an element of your academic performance, nor will it be a part of your academic record at any Institution.

O. EMPLOYEE PARTICIPATION

Your participation or discontinuance will not constitute an element of your job performance or evaluation, nor will it be a part of your personnel record at any Institution.

P. CLINICAL TRIALS.GOV

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.

Q. SPONSOR COMMITMENT

In the event you require medical treatment for a physical illness or injury, the Sponsor shall reimburse MUSC or other emergency care provider for the reasonable and necessary costs associated with the immediate treatment of the physical illness or injury sustained as a direct result of undergoing a procedure required by the Protocol, provided that those costs are not covered by your insurance, **excluding** government entitlement programs such as Medicare or Medicaid. For government entitlement programs such as Medicare or Medicaid, the Sponsor will provide reimbursement for all costs related to your illness or injury.

R. FUTURE CONTACT

The researcher in charge of this study might like to contact you in the future about other research opportunities. Please initial by your choice below:

____Yes, I agree to be contacted

____No, I do not agree to be contacted

T. VOLUNTARY PARTICIPATION/WITHDRAWAL

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The sponsor and the Food and Drug Administration (FDA) will receive copies of the research records. The investigators associated with this study, employees of the sponsor, the FDA, and the Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event of a study related injury, you should immediately go to your local emergency room, or in case of an emergency go to the nearest hospital and tell the physician on call that you are in a research study. They can call your study coordinator for further details regarding your care and the study. If your insurance company denies

coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. The data collected on you to this point remains part of the study database and may not be removed. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact Dr. Ted Meyer at 843-792-7165. I may contact the MUSC Patient and Family Care Liaison 843-792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the MUSC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at 843-792-4148 . This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.

Signature of Person Obtaining Consent Date	*Name of Participant

Signature of Participant Date

MUSC
Medical University of South Carolina

NOTICE OF PRIVACY PRACTICES

MUSC Organized Health Care Arrangement (OHCA)

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESSS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

UNDERSTANDING YOUR PROTECTED HEALTH INFORMATION (PHI)
The Medical University of South Carolina and its affiliates (including but not limited to the Medical University Hospital Authority, MUSC Physicians, MUSC Physicians Primary Care, MUSC Health Partners, MUSC Health Alliance, MUSC Strategic Ventures, LLC, and MUSC Strategic Ventures (MSV) Health, Inc.) participate in a clinically integrated health care setting. As a result of this clinical integration, these organizations function as an Organized Health Care Arrangement (OHCA) as defined by the Health Insurance Portability and Accountability Act (HIPAA). For purposes of this notice, the members of the MUSC OHCA are collectively referred to in this document as "MUSC." **We collect, receive, or share this information about your past, present or future health condition to provide health care to you, to receive payment for this health care, or to operate the hospital and/or clinics.**

OUR PLEDGE REGARDING YOUR HEALTH INFORMATION
MUSC is committed to protecting the privacy of health information we create and obtain about you. This Notice tells you about the ways in which we may use and disclose health information about you. It also describes your rights and certain obligations we have regarding the use and disclosure of your health information. We are required by law to: (i) make sure your health information is protected; (ii) give you this Notice describing our legal duties and privacy practices with respect to your health information; and (iii) follow the terms of the Notice that is currently in effect.

HOW WE MAY USE AND RELEASE YOUR PROTECTED HEALTH INFORMATION (PHI) –

A. The following uses do NOT require your authorization, except where required by SC law:
1. For treatment. Your PHI may be discussed by caregivers to determine your plan of care. For example, the physicians, nurses, medical students and other health care personnel may share PHI in order to coordinate the services you may need.
2. To obtain payment. We may use and disclose PHI to obtain payment for our services from you, an insurance company or a third party. For example, we may use the information to send a claim to your insurance company.
3. For health care operations. We may use and disclose PHI for hospital and/or clinic operations. For example, we may use the information to review our treatment and services and to evaluate the performance of our staff in caring for you.
4. Business Associates. Your medical information could be disclosed to people or companies outside our Health System who provide services. These companies typically are required to sign special confidentiality agreements before accessing your information. They are also subject to fines by the federal government if they use/disclosure your information in a way that is not allowed by law.
5. For public health activities. We report to public health authorities, as required by law, information regarding births, deaths, various diseases, reactions to medications and medical products.
6. Victims of abuse, neglect, domestic violence. Your PHI may be released, as required by law, to the South Carolina Department of Social Services when cases of abuse and neglect are suspected.
7. Health oversight activities. We will release information for federal or state audits, civil, administrative or criminal investigations, inspections, licensure or disciplinary actions, as required by law.
8. Judicial and administrative proceedings. Your PHI may be released in response to a subpoena or court order.
9. Law enforcement or national security purposes. Your PHI may be released as part of an investigation by law enforcement or for continuum of care when in the custody of law enforcement.
10. Military and Veterans. If you are a member of the U.S. or foreign armed forces, we may release your medical information as required by military command authorities.
11. Uses and disclosures about patients who have died. We may provide medical information to coroners, medical examiners and funeral directors so they may carry out their duties.
12. For purposes of organ donation. As required by law, we will notify organ procurement organizations to assist them in organ, eye or tissue donation and transplants.
13. Research. We may use and disclosure your medical information for research purposes. Most research projects are subject to Institutional Review Board (IRB) approval. The law allows some research to be done using your medical information without requiring your written approval.
14. To avoid harm. In order to avoid a serious threat to the health or safety of a person or the public, we may release limited information to law enforcement personnel or persons able to prevent or lessen such harm.
15. For workers compensation purposes. We may release your PHI to comply with workers compensation laws.
16. Marketing. We may send you information on the latest treatment, support groups, reunions, and other resources affecting your health.
17. Fundraising activities. We may use your PHI to communicate with you to raise funds to support health care services and educational programs we provide to the community. You have the right to opt out of receiving fundraising communications with each solicitation.
18. Appointment reminders and health-related benefits and services. We may contact you with a reminder that you have an appointment.
19. Disaster Relief Efforts. We may disclose your medical information to an entity assisting in disaster relief efforts so that your family can be notified about your condition.
Note: incidental uses and disclosures of PHI sometimes occur and are not considered to be a violation of your rights. Incidental uses or disclosures are by-products of otherwise permitted uses or disclosures which are limited in nature and cannot be reasonably prevented.

B. You may object to the following uses of PHI:
1. Inpatient hospital directories. Unless you tell us not to, we may include your name, location, general condition and religious affiliation in our patient directory so your family, friends and clergy can visit you and know how you are doing.

2. Information shared with family, friends or others. Unless you tell us not to, we may release your PHI to a family member, friend, or other person involved with your care or the payment for your care.
3. Health plan. You have the right to request that we not disclose certain PHI to your health plan for health services or items when you pay for those services or items in full.

C. Your prior written authorization is required (to release your PHI) in the following situations:
You may revoke your authorization by submitting a written notice to the privacy contact identified below. If we have a written authorization to release your PHI, it may occur before we receive your revocation.
1. Any uses or disclosures beyond treatment, payment or healthcare operations and not specified in parts A & B above.
2. Mental Health Records unless permitted under an exception in section A.
3. Substance Use Disorder Treatment records unless permitted under an exception in section A.
4. Any circumstance where we seek to sell your information.

WHAT RIGHTS YOU HAVE REGARDING YOUR PHI

Although your health record is the physical property of MUSC, the information belongs to you, and you have the following rights with respect to your PHI:
A. The Right to Request Limits on How We Use and Release Your PHI. You have the right to ask that we limit how we use and release your PHI. We will consider your request, but we are not always legally required to accept it. If we accept your request, we will put any limits in writing and abide by them except in emergency situations. Your request must be in writing and state (1) the information you want to limit; (2) whether you want to limit our use, disclosure or both; (3) to whom you want the limits to apply, for example, disclosures to your spouse; and (4) an expiration date**.**
B. The Right to Choose How We Communicate PHI with You. You have the right to request that we communicate with you about PHI and/or appointment reminders in a certain way or at a certain location (for example, sending information to your work address rather than your home address). You must make your request in writing and specify how and where you wish to be contacted. We will accommodate reasonable requests.
C. The Right to See and Get Copies of Your PHI. You have the right to inspect and/or receive a copy (an electronic or paper copy) of your medical and billing records or any other of our records used to make decisions about your care. You must submit your request in writing. If you request a copy of this information, we may charge a cost-based fee. MUSC will act on a request for access or provide a copy usually within 30 days of receipt of the request. We may deny your request in limited circumstances. If you are denied access to your records, you may request that the denial be reviewed by a licensed health care professional. Additionally, we may use and disclose information through our secure patient portal which may allow you to view and communicate with certain health care providers in a secure manner. For more information see our https://mychart.musc.edu/mychart/
D. The Right to Get a List of Instances of When and to Whom We Have Disclosed Your PHI. This list may not include uses such as those made for treatment, payment, or health care operations, directly to you, to your family, or in our facility directory as described above in this Notice of Privacy Practices. This list also may not include uses for which a signed authorization has been received or disclosures made more than six years prior to the date of your request.
E. The Right to Amend Your PHI. If you believe there is a mistake in your PHI or that a piece of important information is missing, you have the right to request that we amend the existing information or add the missing information. You must provide the request and your reason for the request in writing. We may deny your request in writing if the PHI is correct and complete or if it originated in another facility's record. Notification will be provided within 60 days.
F. The Right to Receive a Paper or Electronic Copy of This Notice: You may ask us to give you a copy of this Notice at any time. For the above requests (and to receive forms) please contact: Health Information Services (Medical Records), Attention: Release of Information / 169 Ashley Avenue / MSC 349 / Charleston, SC 29425. The phone number is (843) 792-3881.
G. The Right to Revoke an Authorization. If you choose to sign an authorization to release your PHI, you can later revoke that authorization in writing. This revocation will stop any future release of your health information except as allowed or required by law.
H. The Right to be Notified of a Breach. If there is a breach of your unsecured PHI, we will notify you of the breach in writing.

HEALTH INFORMATION EXCHANGES

MUSC, along with other health care providers, belongs to health information exchanges. These information exchanges are used in the diagnosis and treatment of patients. As a member of these exchanges, MUSC shares certain patient health information with other health care providers. Should you require treatment at another location that is a part of one of these exchanges, that provider may gather historical health information to assist with your treatment. You have the option of saying that this cannot be done. If you choose not to take part in these alliances, please contact the MUSC Privacy Office at 792-4037.

HOW TO COMPLAIN ABOUT OUR PRIVACY PRACTICES

If you think your privacy rights may have been violated, or you disagree with a decision we made about access to your PHI, you may file a complaint with the office listed in the next section of this Notice. **Please be assured that you will not be penalized and there will be no retaliation for voicing a concern or filing a complaint. We are committed to the delivery of quality health care in a confidential and private environment.**

PERSON TO CONTACT FOR INFORMATION ABOUT THIS NOTICE OR TO COMPLAIN ABOUT OUR PRIVACY PRACTICES

If you have any questions about this Notice or any complaints about our privacy practices please call the Privacy Officer (843) 792-4037, the Privacy Hotline (800) 296-0269, or contact in writing: HIPAA Privacy Officer / 169 Ashley Avenue / MSC 332 / Charleston SC 29425. You also may send a written complaint to the U.S. Dept. of Health and Human Services, Office for Civil Rights. The address will be provided at your request or by visiting www.hhs.gov/ocr/privacy/hipaa/complaints/.

CHANGES TO THIS NOTICE

We reserve the right to change the terms of this Notice at any time. The changes will apply to all existing PHI we have about you.. This Notice will always contain the effective date and may be reviewed at http://academicdepartments.musc.edu/musc/about/compliance/privacy.html

EFFECTIVE DATE OF THIS NOTICE

This Notice went into effect on April 14, 2003 and was last revised on August 2018.