Consent of an Adult to Be in a Research Study

In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study.

Participant's Name_____ **Medical Record Number**_____

Principal Investigator:	Bradley Kesser, MD University of Virginia Department of Otolaryngology – Head and Neck Surgery PO Box 800713 Charlottesville, VA 22908 Telephone: 434.924.5700

What is the purpose of this form?

This form will provide you with information about this research study. You do not have to be in the study if you do not want to. You should have all your questions answered before you agree to be in this study.

Please read this form carefully. If you want to be in the study, you will need to sign this form. You will be given a signed copy of this form.

Who is funding this study?

This study is funded by a contract with the Lions' Club of Virginia
ResMed, a medical supply company, is providing the CPAP machine and individual use masks without any financial agreement.

Why is this research being done?

The purpose of this study is to find out how much pressure needs to be delivered by a CPAP machine to "pop" your ears – which means air is being forced from the nose into the middle ear space. **CPAP, or continuous positive airway pressure**, is a treatment that uses mild air pressure to keep the airways open. CPAP typically is used by people who have breathing problems, such as sleep apnea.

Many people suffer from a condition **Eustachian Tube Dysfunction (ETD).** People with ETD may feel their ears are plugged or full, sounds are muffled, pain, ringing or trouble keeping their balance. ETD means that the Eustachian tube is blocked or does not open properly. Air cannot then get into the middle ear. Therefore, the air pressure on the outer side of the eardrum becomes greater than the air pressure in the middle ear. A few studies have provided data that suggest that CPAP can be safely used as a therapy for this dysfunction.

CPAP is used by millions of Americans every night to treat sleep apnea within the range of settings that we will use in this study.

You are being asked to be in this study because you are a patient at the UVA otolaryngology clinic (with or without Eustachian tube dysfunction) and are otherwise healthy. We are including participants regardless of any pre-existing ear disease.

Up to 31 people will be in this study at UVA.

How long will this study take?

Your participation in this study will require 1 study visit. This visit will last about 60 minutes.

What will happen if you are in the study?

NOTE: All procedures performed are purely for research purposes and do not provide any expected benefit to participants.

This will all occur at the Fontaine Research Park in the otolaryngology clinic.

SCREENING (will take about 5 minutes/hours to complete):

If you agree to participate, you will sign this consent form before any study related procedures take place. A member of the study team will review your medical history to make sure you are eligible and it is safe for you to participate.

If you are eligible and you agree to proceed we will perform the study on the same day. Otherwise, an additional time for you to return to resume study procedures will be discussed.

STUDY PROCEDURE

- **Symptom survey:** We will ask you to fill out an ETDQ-7. . This survey will aks you about any symptoms of pain, ringing, pressure that you feel in your ears. This should take less than 5 minutes to complete.
- **Tympanometry:** We will obtain a pressure reading of your middle ear pressure at the time we start and then at every CPAP pressure change. This involves placing a soft probe similar to an ear plug or headphone earbud into your ear canal. You may feel a small amount of pressure change in your ear drum. This is a safe procedure with no reported problems.
- **Otoscopy:** We will examine your ear drum multiple times, at the beginning of the evaluation and when middle ear pressure changes are noted. This is just like would be done in the office of your primary care physician or ENT. Just like an ear exam, a speculum will be inserted into the ear canal to view the ear drum.
  We will use a modification of an iPhone that allows us to capture this image, which will be attached to your participant ID. These images will be stored securely using a password-protected and encrypted device and deleted at the completion of the study.

- **CPAP delivery:** We will use an appropriately sized mask that covers your mouth and nose. You will be sitting up at the time. We will start this at a relatively low pressure similar to ambient pressure. At each pressure we will have you take a few breaths, and then we will have you swallow. At that point we will take a measurement of the pressure.
  We want you to notify us if you feel your ears "pop" like you would going over a mountain or flying in a plane.
  If you feel discomfort during this portion we can discontinue use and withdraw you from the study.

At the conclusion of the CPAP portion of the study, your participation in the study is complete.

What are your responsibilities in the study?

You have certain responsibilities to help ensure your safety. These responsibilities are listed below:

- You must be completely truthful about your health history.
- Follow all instructions given.
- Answer all of the study-related questions completely.

If you want to know about the results before the study is done:

During the study you are having an investigational procedure done using the CPAP machine. The purpose of the procedure is NOT to diagnose any disease or abnormality you may have. Because the procedure is investigational there is no way for the study leader to understand if the results are "normal" or "abnormal". However, if any results are concerning, your study leader will let you know.

In addition, as the research moves forward, your study leader will keep you informed of any new findings about the research itself that may be important for your health or may help you decide if you want to continue in the study. The final results of the research will not be known until all the information from everyone is combined and reviewed. At that time you can ask for more information about the study results.

What are the risks of being in this study?

Risks and side effects related to the CPAP:

Less Likely (mild)

- Facial skin irritation
- Nose bleeds or nasal irritation
- Upper airway dryness
- Ear pain
- Nasal congestion
- Runny nose
- Swallowing air
- Stomach upset

Rare:

- Dizziness
- Trouble breathing

There are no known risks associated with Tympanometry.

There are no known risks associated with the otoscopic examination

Other unexpected risks:
You may have side effects that we do not expect or know to watch for now. Call the study leader if you have any symptoms or problems.

Could you be helped by being in this study?

You will not benefit from being in this study. However the information researchers get from this study may help others in the future.

What are your other choices if you do not join this study?

You do not have to be in this study to be treated for your illness or condition. You can get the usual treatment even if you choose not to be in this study. The usual treatment would include:

- Regular follow up with an ENT doctor if indicated
- Regular audiograms if indicated
- Any other treatment by an ENT if indicated

If you are an employee of UVa your job will not be affected if you decide not to participate in this study.
If you are a student at UVa, your grades will not be affected if you decide not to participate in this study.

Will you be paid for being in this study?

You will not get any money for being in this study.

Will being in this study cost you any money?

The following procedures/tests, which are being done for research purposes, will be provided at no cost to you or your health insurance:

- Tympanometry
- Otoscopy
- CPAP

You will be responsible for the cost of travel to come to any study visit and for any parking costs.

What if you are hurt in this study?

If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your

insurance. You will be responsible for any amount your insurance does not cover. You do not give up a legal rights, such as seeking compensation for injury, by signing this form.

What happens if you leave the study early?

You can change your mind about being in the study any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study t get services you can normally get at the University of Virginia.

Even if you do not change your mind, the study can take you out of the study. Some of the reasons for doin so may include

a) Your study physician is concerned about your health
b) Your disease gets worse
c) The side effects of the treatment are too dangerous for you
d) The study sponsor closes the study for safety, administrative or other reasons

If you decide to stop being in the study, we will ask you to: notify the study coordinator or study administra in person at the time you present for the study.

How will your personal information be shared?

The UVa researchers are asking for your permission to gather, use and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receiv regular medical care at UVA.

If you sign this form, we may collect any or all of the following information about you:

- Personal information such as name, address and date of birth
- Your health information if required for this study. This may include a review of your medical records an test results from before, during and after the study from any of your doctors or health care providers. may include mental health care records, substance abuse records, and/or HIV/AIDS records.

Who will see your private information?

- The researchers to make sure they can conduct the study the right way, observe the effects of the stud and understand its results
- People or groups that oversee the study to make sure it is done correctly
- People who evaluate study results, which can include sponsors and other companies that make the dru device being studied, researchers at other sites conducting the same study, and government agencies t provide oversight such as the Food and Drug Administration (FDA) if the study is regulated by the FDA.
- If you tell us that someone is hurting you, or that you might hurt yourself or someone else, the law may require us to let people in authority know so they can protect you and others.

Some of the people outside of UVa who will see your information may not have to follow the same privacy laws that we follow. They may release your information to others, and it may no longer be protected by th laws.

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

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 if you sign the form but then decide you don't want your private information shared?

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation.

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator:
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PO Box 800713
Charlottesville, VA 22908 Telephone: (434)924-2040

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research
PO Box 800483
Charlottesville, Virginia 22908 Telephone: 434-924-9634

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the IRB-HSR Number (at the top of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

Signatures

What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form it means that you agree to join the study. You will receive a copy of this signed document.

Consent From Adult

PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

Person Obtaining Consent

By signing below you confirm that you have fully explained this study to the potential subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE

Consent from Impartial Witness

If this consent form is read to the subject because the subject is blind or illiterate, an impartial witness not affiliated with the research or study doctor must be present for the consenting process and sign the following statement. The subject may place an X on the Participant Signature line above.

I agree the information in this informed consent form was presented orally in my presence to the **identified individual(s)** who has had the opportunity to ask any questions he/she had about the study. I also agree that the **identified individual(s)** freely gave their informed consent to participate in this trial.

Please indicate with check box the identified individual(s):

☐ Subject

IMPARTIAL WITNESS (SIGNATURE)	IMPARTIAL WITNESS (PRINT)	DATE