VA Portland Health Care System (VAPORHCS) Informed Consent Form

Subject Name: _____ Date: _____

Title of Study: Feasibility and Acceptability of Using Low-Gain Hearing Aids for Bothersome Tinnitus

IRB Number: 4340

Principal Investigator: [redacted] ICF Version Date: 11/23/2020

WHO SHOULD I CONTACT IF I HAVE QUESTIONS OR CONCERNS OR WISH TO OFFER INPUT?
About the research, call [redacted], extension [redacted] or the National Center for Rehabilitative Auditory Research (NCRAR) front desk at extension [redacted].

If you become sick or injured or if you feel your privacy or confidentiality may have been violated (e.g., someone without authorization has received personal information about you), call [redacted] 2[redacted].

To speak with someone not connected with this research study about your rights, discuss problems, concerns and questions, obtain information and/or offer input, please call the VA Portland Health Care System Research Office at [redacted], or the VA Regional Counsel at [redacted].

SUMMARY OF KEY INFORMATION ABOUT THIS STUDY

WHAT AM I BEING ASKED TO DO?
We are asking you to take part in a research study that is being funded by the Department of Veterans Affairs Office of Rehabilitation Research & Development (RR&D), using hearing aids provided by Widex. We conduct research studies to try to answer questions about how to prevent, diagnose, and treat diseases.

We are asking you to take part in this research study because you have normal hearing and you have tinnitus that bothers you.

TAKING PART IN THIS STUDY IS YOUR CHOICE
You can choose to take part or not to take part in this study. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

The VA Authorization for Use and Release of Individually Identifiable Health Information (Collected) for VHA Research to use your protected health information is also your choice. You may refuse to sign this consent form and the authorization. However, to participate in this study, you must sign this consent form and the authorization.

This document has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It's important that you have as much information as you need and that all your questions are answered.

Do NOT Change Anything below this line, including bottom margin.

Subject's Identification (I.D. Plate or complete below)

_____, _____ __ __ __ __
LAST FIRST SSN (last 4 digits)

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WHY IS THIS STUDY BEING DONE?

This study is being done to answer the following question: Is it feasible for people with normal hearing and bothersome tinnitus to wear hearing aids, and does this have any impact on how much their tinnitus bothers them? We are doing this study because we want to find out if hearing aids may help people with normal hearing and tinnitus as they have been shown to help those with hearing loss and tinnitus.

WHAT IS THE USUAL APPROACH TO MY TINNITUS?

The usual approach for patients with normal hearing and bothersome tinnitus who are not in a study is to see an audiologist, who may recommend a behavioral therapy such as Cognitive Behavioral Therapy (CBT) or other techniques using sound.

WHAT ARE MY CHOICES IF I DECIDE NOT TO TAKE PART IN THIS STUDY?

- You may choose to have the usual approach described above.
- You may choose to take part in a different research study, if one is available.
- You may choose not to be treated for tinnitus.

WHAT WILL HAPPEN IF I DECIDE TO TAKE PART IN THIS STUDY?

If you decide to take part in this study, your participation will consist of 3 visits over 3 months. You will be fit with hearing aids that will provide a low level of amplification, and you will use them for about 3 months. You will be asked to perform some hearing and tinnitus evaluations at your study visits:

- Standard hearing test
- Speech in noise test
- Tinnitus questionnaires

A detailed description of all procedures, tests, and questionnaires that will be done as part of this study is located below in the “What will happen during this study?” section.

WHAT ARE THE RISKS AND BENEFITS OF TAKING PART IN THIS STUDY?

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

RISKS

We want to make sure you know about a few key risks right now, however we provide more below information in the “What risks can I expect from taking part in this study?” section.

This study involves wearing devices in your ears that you are not used to. As a result, the devices may cause some discomfort at first.

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BENEFITS
You may or may not directly benefit from taking part in this research. You will be allowed to keep the hearing aids at the end of the study.

IF I DECIDE TO TAKE PART IN THIS STUDY, CAN I STOP LATER?
Yes, you can decide to stop taking part in the study at any time.

The study team will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

If you decide to stop using the hearing aids, let the study team know as soon as possible. If you stop using the hearing aids, you can decide if you want to keep doing tests and questionnaires with the study team.

ARE THERE OTHER REASONS WHY I MIGHT STOP BEING IN THE STUDY?
The principal investigator may take you off the study if new information becomes available and the study is no longer in your best interest.

It is important that you understand the information in the informed consent before making your decision. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask the principal investigator or a member of the study team.

WHAT IS THE PURPOSE OF THIS STUDY?
The purpose of this study is to learn about fitting hearing aids on people with normal hearing and bothersome tinnitus that may help make their tinnitus less bothersome. Hearing aids are not normally fit on people with normal hearing, so we would like to find out if people with normal hearing feel ok wearing hearing aids, if they experience any problems, and if they think it might be helpful for their tinnitus.

HOW MANY PEOPLE WILL PARTICIPATE?
Approximately 20 people will participate in this research study at the VA Portland Health Care System.

WHAT WILL HAPPEN DURING THIS STUDY?
The following procedures will be done for research purposes and will not be completed if you decide not to take part in the study.

1. Number and Length of Appointments
   Your baseline visit will require approximately 3 hours, and the 2-3 week visit will take approximately an hour and a half, and 3 month follow-up visit will require approximately 2 hours.
2. Basic Hearing Test
   At your first visit, prior receiving hearing aids, you will undergo routine hearing tests using standard clinical procedures. First, the audiologist will use an "ear light" to inspect your ear canal and ear drum. Next, your

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hearing will be tested. The hearing test will find the softest tones you can hear at different pitches. After the hearing test, the audiologist may put a soft rubber tip into your ear that will cause some slight pressure changes in your ear while you sit still (called "tympanometry"). This test will determine whether you qualify for the study. This hearing test will also be repeated at the final study visit. The Basic Hearing Test will take about 15-30 minutes.

3. Case History Interview
   At your first visit, the audiologist will ask you some questions about your health history and any medications you may be taking. Some health conditions and medications may impact the results of the study, so it is important for us to collect this information from you. The brief interview will last 5-10 minutes.
4. Questionnaires
   At each visit, you will complete written questionnaires. These questionnaires ask questions about you (date of birth, gender, employment, etc.), your hearing (how well do you hear, have you been exposed to loud noise, etc.), and your tinnitus (how much does it bother you, etc.). Questionnaires will require up to about 20 minutes. At your return visits, you will fill out most of the same questionnaires that you complete at the first visit.
5. Inner Ear Testing (Otoacoustic Emissions).
   In this test you will hear different tones will be played through earphones and sometimes you will also hear noise played. You will hear the sounds through a small earphone inserted in your ear canal and a small microphone in the earphone will record sounds that return from your inner ear in response. This test lasts about 10 minutes.
6. Hearing aid Assessment and Fitting
   You will receive hearing aids. The hearing aids will be adjusted according to standard procedures to best fit your hearing ability. The audiologist will put a small tube in your ear to measure whether the hearing aid is working correctly (this is called real-ear testing). The audiologist may adjust the hearing aids louder or softer as needed, according to your feedback. You will also be able to adjust the volume of the hearing aids yourself, using volume buttons on the hearing aids, within a range set by the audiologist. You will be asked to wear your devices daily for 3 months. The device may also automatically keep track of when you wear the hearing aids, and if you change the volume. The hearing aid fitting will take about 30-45 minutes.
7. Speech in Noise Test
   At the first visit, you will hear speech with noise in the background through headphones during the hearing test. You will be asked to repeat the words you hear. This test is called the Quick Speech-in-Noise (QuickSIN). This test lasts about 10-20 minutes.
8. Auditory Processing Test (SCAN-3)
   You will be asked to listen to different types of speech, noises and tones, and respond to what you have heard. The stimuli may become difficult to understand, and that is intentional. We ask that you just try your best. This test takes about 20 minutes.

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9. Tinnitus Counseling
   At your initial visit, the study audiologist will talk to you about some things you can do to help you feel less bothered by your tinnitus. Some things they suggest may involve listening to sounds, finding ways to de-stress or relax, and finding ways to distract yourself from your tinnitus. This counseling may last about 20-30 minutes.

10. Exit Interview
    At your last visit, a member of the study team will ask you for your feedback on wearing the hearing aids. Another study team member may be present to take notes. This interview will last about 10 minutes.

Measure	Screen	Baseline	2-3 weeks	3 months
Tinnitus and Hearing Survey (THS)	X			
Inspect ear canal and ear drum		X	X	X
Tympanometry		X		X
Hearing test		X		X
Case History Interview		X		
Hearing aid assessment and fitting		X		
Inner Ear testing		X		X
Real Ear testing		X		X
Speech in Noise test (QuickSIN)		X		X
Auditory Processing test (SCAN-3)		X		X
Tinnitus Baseline Questionnaire		X		
Tinnitus Screener (TS)		X		
Tinnitus Functional Index (TFI)		X	X	X
Hearing Handicap Inventory (HHI)		X	X	X
International Outcome Inventory for Hearing Aids (IOI-HA)			X	X
Tinnitus Counseling		X	X	
Follow-up Questions				X
Exit Interview				X
Total Time	15 min	3.5 hrs	1.5 hrs	2.5 hrs

WHAT ARE THE RISKS and POSSIBLE DISCOMFORTS of PARTICIPATION?

In addition to the risks described above in the Summary of Key Information About This Study, "What are the risks and benefits of taking part in this study?" section, the following risks could occur if you choose to take part in this study.

1. Physical discomfort when wearing hearing aids.

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2. There is a remote risk of hearing damage if the devices were to malfunction and emit a loud sound. Although this has never happened to our knowledge, it is a potential risk.
3. Discomfort at being left alone in a sound booth to perform the testing.
4. Filling out the study questionnaires may cause you to become upset. Some of the questions may seem personal or embarrassing. You may refuse to answer any of the questions you do not wish to answer. If the questions make you very upset, we will help you find a counselor.
5. For some people with tinnitus, certain sounds make their tinnitus louder. It is possible that some of the sounds used during testing could cause your tinnitus to sound louder to you. This is not common, but has occurred in the past to people doing similar testing. In these rare cases, the effects typically subsided within the same day. However, the risk of this occurring and how long it could last are unknown.
6. The study requires you to use hearing aids daily for approximately three months. This may cause inconveniences or disruptions to daily life.

You may have some side effects we do not expect because we are still learning about fitting hearing aids on people with normal hearing.

Information that identifies you will be used in this study and shared with Widex (the company that manufactures the hearing aids being used for this study). The research team will make every effort to protect your information. However, a breach in confidentiality and a resulting loss of privacy could result in monetary loss due to identity theft. It also could carry other risks, such as embarrassment or affecting ability to get insurance, current or future job status, plans to have a family, relations with your family, immigration status, parental rights or responsibilities, credit history or status in the community.

If you should ever express thoughts of wishing to harm yourself or considering suicide, we may call the National Suicide Prevention Hotline and/or the Veterans Crisis Line and transfer you to that call.

HOW WILL MY CONFIDENTIALITY BE PROTECTED?

Your information used for this study will be kept confidential as required by law. The results of your participation in this study may be used for publication or for scientific purposes, but the results will not include any information that could identify you. Your identity will not be disclosed unless you give specific, separate consent or if required by law. All VA research records will be held in accordance with the VA records control schedule.

In the future, identifiers may be removed, and de-identified information about you may be used for future research studies (not part of this study) without additional informed consent obtained from you. This means the people working on future research studies will not be able to identify who you are.

Identifiers related to you (i.e. information that can identify you) will be used in this research study and will include: name, date of birth, visit dates, address, phone number(s), email address, social security number, and device numbers. These identifiers may be used to obtain information about you and/or your health from VA records.

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All other parties, including employers, insurance companies, personal physicians and relatives, will be refused access to the information, unless you provide written permission or unless otherwise required by law.

By signing this informed consent, you give permission for the transfer of a copy of the following data: name and device ID, to the hearing aid manufacturer (Widex). Widex will be responsible for maintaining the security and confidentiality of the transferred data. VAPORHCS will continue to have ownership of your research data for this research study. All original research records, both hard copy and electronic, will be maintained at the VAPORHCS in accordance with current records retention requirements. Any information shared with Widex may no longer be protected under federal law.

Mandatory reporting of suspected child or elder abuse. Under Oregon Law, suspected child or elder abuse must be reported to appropriate authorities.

This study involves a device regulated by the US Food and Drug Administration (FDA), the FDA may choose to inspect research records that include identifiable medical records, identifying you as a subject of this study.

Possibility of Disclosure and Notice of Privacy Practices.
The VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its privacy regulations and all other applicable laws that protect your privacy. We will protect your information according to these laws. Despite these protections, there is a possibility that your information could be used or disclosed in a way that it may no longer be protected. Our Notice of Privacy Practices provides more information on how we protect your information. If you do not have a copy of the notice, the research team will provide one to you. (Notice of Privacy Practices available online at http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=3048).

If you are a non-Veteran, we will provide you with the VA Notice of Privacy Practices and ask you to sign the acknowledgment (VA Form 10-0483) you received the document. This acknowledgement may be scanned into your medical record.

WILL I BE TOLD ABOUT ANY STUDY RESULTS?
You may request a copy of your hearing test at any time during the study. We may ask you to sign another form in order to give you this information. During this research study, you will not be able to see the research data collected about you. After the study is complete and the study results are determined or published, you may request the research data collected about you.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

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Participants. A VA participant will not be required to pay for care and services received as a subject in a VA research project.

None of the participants will pay for any of the following because they are only for research study purposes: hearing test, hearing aid fitting, tinnitus counseling, all testing procedures described above.

Some Veterans are also required to pay co-payments for medical care and services provided by VA ***that are not part of this study*** (e.g., normal hospital and prescription expenses that are not part of the research study, any treatment that is standard clinical treatment for your condition).

WILL I BE PAID FOR PARTICIPATING?

You will be paid $20 for each study visit that you complete. You will receive the cash, check or electronic payment at the end of each visit. If you drop out of the study before completing all the study visits, you will be paid for the number of visits that you completed. If you complete all of the scheduled study visits, you will have received a total of $60.

An Internal Revenue Service (IRS) Form 1099 may be generated, which will use your Social Security Number. This payment is considered taxable income. If you owe money to the government, this payment may be garnished to satisfy the debt.

WHAT WILL HAPPEN IF I AM HURT?

Every reasonable effort to prevent any possible injury from this study will be taken. In the event the study results in any physical, mental or emotional injuries to you, the VA will provide necessary medical treatment (not just emergency care) at no cost to you. This does not apply to treatment for injuries that result from if you do not follow the study procedures. Additional compensation, beyond paying for treatment, has not been set aside. The VA will also provide all necessary assistance in the event of any violation of confidentiality or privacy (for example, identity theft resulting from the loss of a social security number by anyone associated with this study). For eligible Veterans, compensation damages may be payable under 38 United States Code 1151. For all study participants, compensation damages resulting from the negligence of federal government employees may be available in accordance with the provisions of the Federal Tort Claims Act. For additional information concerning claims for damages, you may contact VA Regional Counsel at (503) 412-4580. You have not waived any legal rights or released the hospital or its agents from liability for negligence by signing this form.

WHAT DO I NEED TO DO TO DROP OUT (WITHDRAW) AFTER I SIGN THIS CONSENT FORM?

To withdraw, you must write to [redacted], or ask a member of the research team to give you a form to withdraw your consent and authorization. If you withdraw your consent and authorization, you may not be able to continue to participate in the study.

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Signature

[redacted] or a member of the study team has explained the study to me and answered all of my questions. I have been told of the risks and/or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me.

I have been told I do not have to take part in this study and refusal will involve no penalty or loss of VHA or other benefits to which I am entitled.

In case there are medical problems or questions, I have been told I can call [redacted], extension [redacted] from 7:30am – 5:00pm, Monday, Tuesday, Thursday or Friday. If any medical problems occur in connection with this study, the VA will provide emergency care.

If you wish to provide consent to allow your information to be used in research for future studies, you will be asked to sign the banking addendum portion of this consent form.

My signature below indicates that I have read, or had read to me, all of the above information about the study, and that my rights as a research subject have been explained to me. I authorize the use of my information as described in this form. In the future, if I decide that I no longer wish to participate in this research study, I agree that my information, which was already collected, may continue to be used only for this research by removing all identifying information. However, identifiers may be stored separately and held in accordance with the VA records control schedule.

I voluntarily consent to participate in this study. I have been told that I will receive a copy of this consent form.

_____
Printed Name of Subject

_____ _____ _____
Signature of Subject Date Time

_____
Printed Name of Person Obtaining Consent

_____ _____ _____
Signature of Person Obtaining Consent Date Time

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Addendum: Banking your Contact Information and Data for Future Research

WHAT IS THE PURPOSE AND WHAT WILL HAPPEN?

We are asking you to allow all data and identifiable information, including contact information (first and last name, address, phone number, and email, if applicable) collected from you to be stored ("banked") in a repository located at VA Portland Health Care System (VAPORHCS). The repository may then release your data and/or contact information for use in future research for use in future research, which may include research about tinnitus, hearing loss and any other research related to the information collected during the study " Feasibility and Acceptability of Using Low-Gain Hearing Aids for Bothersome Tinnitus." By signing this form below, you are also agreeing to allow your contact information and study information to be made available to researchers at the VAPORHCS for the purpose of contacting you about future research studies.

WHAT ARE THE RISKS?

Information that directly identifies you will be banked for the purpose of use in future research and will include: contact information (names, address, phone number, email address), all elements of dates, SSN (if applicable), and tracking/subject ID numbers. The repository team will make every effort to protect your information. However, a breach in confidentiality and a resulting loss of privacy could result in monetary loss due to identity theft. It could also carry other risks, such as embarrassment, monetary loss due to identity theft, or carry other risks affecting ability to get insurance, current or future job status, plans to have a family, relations with your family, immigration status, parental rights or responsibilities, credit history or status in the community.

HOW LONG WILL YOU KEEP MY INFORMATION?

Your study information will be stored in the repository indefinitely.

WILL I BE TOLD ABOUT ANY FUTURE RESEARCH RESULTS?

If you give your permission for your study data and contact information to be used in future studies, the results of those studies involving the use of your data may not be made available to you because repository personnel are not available to contact all past study participants with the results of future studies and analyses. Additionally, some analyses may be done on data sets that are de-identified. These results cannot be made available as they cannot be linked back to you.

CAN I WITHDRAW MY PERMISSION TO USE MY INFORMATION AND DATA?

If your research data are still identifiable, you may withdraw consent to use them at any time. To withdraw your consent for such use, you must write to the study principal investigator, [redacted], or you may ask a member of the research team to give you a form to withdraw your consent and authorization. You will still receive all the medical care and benefits for which you are otherwise eligible. This will not affect your rights as a VHA patient.

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HOW WILL MY CONTACT INFORMATION AND DATA BE USED FOR FUTURE RESEARCH?

If you agree, your first and last name, all elements of dates, address, phone number, last 4 of social security number, and screening data (i.e. hearing test, tinnitus characteristics) may be used by VAPORHCS researchers to contact you regarding future research studies.

I agree to the following future uses of my contact information:

- Contacting me in person when I come to the VA, by letter, by phone, or by email (if applicable)
- Research about any type of health care issue, disease or disorder
- By any VA researchers

If you agree, your contact information (name, address, phone number, email address), all elements of dates, SSN, and tracking/subject ID's, and study data may be used in future research as described below. The information in the repository will be linkable to identifiers - e.g. your name, SSN, and/or study ID number. This is necessary for us to be able to link your information from this study with any future data or information collected about you under another study protocol and stored in this repository.

Other researchers who receive your information from the repository for future research may be able to link the information to you. Your information will not be given to product manufacturers, such as drug companies.

I agree to the following regarding future uses of my identifiable data:

- Research about tinnitus, hearing loss or any type of health care issue, disease or disorder related to the data collected during this study
- By any VA researchers
- Without contacting me in the future for additional consent

Signature

[redacted] or a member of the study team has explained the banking of my contact information and data for future research to me and answered all of my questions. I have been told of the risks and/or discomforts and possible benefits of the banking.

I have been told that I may refuse permission for banking of my contact information and data for future research and that refusal will involve no penalty or loss of VHA or other benefits to which I am entitled.

In case there are problems or questions, I have been told I can call [redacted] extension [redacted], or the NCRAR front desk at extension [redacted] from 8am to 5pm, Monday through Friday.

My signature below indicates that I have read, or had read to me, all of the above information about the banking of my research data and contact information, and that my rights as a research subject have been explained to me.

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I voluntarily consent to allow the research data and contact information from this study to be stored in a repository and used for future research, as described in this form. I have been told that I will receive a copy of this consent form.

_____
Printed Name of Subject

_____ _____ _____
Signature of Subject Date Time

_____
Printed Name of Person Obtaining Consent

_____ _____ _____
Signature of Person Obtaining Consent Date Time

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