Subject Name: _____ Date: _____

Title of Study: Comprehensive Wide Bandwidth Test Battery of Auditory Function in Veterans (#3222)

Principal Investigator: M. Patrick Feeney, Ph.D. VAMC: 648 – Portland, OR

WHO SHOULD I CONTACT IF I HAVE QUESTIONS OR CONCERNS OR WISH TO OFFER INPUT?

1. About the research, call Dan Putterman, Au.D. at 503-220-8262 ext.57094.
2. 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 Dan Putterman, Au.D. at 503-220-8262 ext.57094, or M. Patrick Feeney, Ph.D. at 503-220-8262 ext.55306.
3. 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 Portland VA Medical Center Research Office at (503) 273-5125, or the VA Regional Counsel at (503) 412-4580.

WHAT IS THE PURPOSE OF THIS STUDY?

1. The purpose of the study is to improve the diagnosis of hearing disorders in adults. Tests with a wide frequency range will be used to test inner ear and middle-ear function. We will compare the newer experimental test results with standard clinical hearing tests.

2. You have been invited to be in this research study because you are a Veteran or a non-Veteran between 20 and 89 years old.

WHO IS PAYING FOR THIS STUDY?

Funding for this study is provided by VA Research and Development.

HOW MANY PEOPLE WILL PARTICIPATE?

We will be testing approximately 420 participants for the study at the Portland VA Medical Center.

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

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

Template Version Date: 06/3/2013

VA FORM APR 1991 **10-1086**

VA Portland Health Care System
INSTITUTIONAL REVIEW BOARD
PHONE NUMBER (503) 273-5122
CONSENT/AUTHORIZATION FORM APPROVAL DATE

September 9, 2019

Do not sign this form after the Expiration date of: September 8, 2020
Study ID: 3222

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Additionally, about 320 people will participate at the James H. Quillen VA Medical Center for a total enrollment of 740 people at all sites.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to join and do not withdraw from the study before all procedures are complete, your participation in this study will last for one study visit. Participants may withdraw from the study at any time.

WHAT WILL HAPPEN DURING THIS STUDY?

Informed consent will be provided by participants prior to their participation in this study. They will then undergo tests of hearing sensitivity and function. All of the tests will be performed by trained laboratory personnel. Each study session will take up to 2 hours. The procedures which will involve you may include:

Chart review: After you have agreed to participate, your previous audiologic evaluations and information about your ear health (e.g., from primary care doctor; emergency room doctor; ear, nose and throat doctor) will be gathered from your VA medical record. If you are a non-Veteran subject recruited from the community you will be asked to provide a copy of your medical record for your hearing or ear disorder.

Otoscopy: The researcher will look in both of your ear canals using an otoscope. This is a standard clinical procedure. Otoscopy will take approximately two minutes, and all you have to do is sit quietly. There are no known risks with the exception of discomfort of the speculum in your ear canal. If your ear canals are clogged with ear wax (cerumen), you may be asked to have them cleaned before participating in the study. If there is evidence of drainage or something else that may be associated with a medical condition, you will be referred to your primary care doctor or an ear, nose, and throat doctor. You may be asked to return to continue participation after you see the doctor and after any physician-recommended intervention.

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Pure tone hearing test: You will receive a standard clinical pure tone hearing threshold test. You will be asked to sit in a quiet booth with insert earphones in your ears or while wearing headphones. You will raise your hand or say 'yes' when you hear soft tones. This test will take approximately 20 to 30 minutes. There are no known risks for taking this test. You will not be excluded from the study based on your hearing test results unless you were specifically recruited for a normal hearing group, the results indicate you have a hearing loss, and we do not currently need subjects for our groups with hearing loss. If we identify a previously unknown hearing loss, you will be referred to an audiologist.

Speech perception tests: You will receive standard clinical speech audiometry tests. You will be asked to repeat words at soft levels and at a comfortable volume. You will be asked to indicate at what volume the words are uncomfortably loud. You will hear the words in the same location and with the same equipment as for the pure tone hearing test. This set of tests will take approximately 15 minutes. There are no known risks for taking these tests. You will not be excluded from the study based on the results from these tests.

Standard clinical immittance test battery: You will receive a standard clinical test battery that tells us how well your middle ears (tympanometry test) and middle ear muscles (acoustic reflex threshold test) are working. You will be tested in a quiet room. You will have a small plastic probe tip in each ear canal, you will hear several different beeps, but you do not have to do anything except quietly sit. This test battery will take approximately 10 minutes. Some people do not like the feeling of pressure in their ear canals that is associated with the tests. If you feel uncomfortable during this test, please tell the researcher and s/he will stop the test. You will not be excluded from the study based on the results of this test.

Experimental immittance test battery: This test is similar to the standard clinical immittance test battery with the exception that the sounds are different and it is completed using experimental equipment. The test environment, expectations for you, and risks are the same as for the standard test. You will not be excluded from the study based on the results of this test.

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Otoacoustic emissions (OAE): You will receive an OAE test that tells us how well your inner ears are working and it is completed using the same system as the experimental immittance test battery. You will be seated in a quiet room with a foam probe tip in your ear canal. You will hear some sounds but all you have to do is quietly sit. This test will take approximately 10 minutes. There are no known risks from taking this test. You will not be excluded from the study based on the results of this test.

WHAT ARE THE RISKS and POSSIBLE DISCOMFORTS of PARTICIPATION?

The tests in this study are standard clinical tests of hearing or tests that are similar to standard tests. The rubber tips that will be used in your ear canals for some tests may produce a plugged-up feeling, but they should not be painful. You may also experience slight discomfort from air pressure changes in the ear canal. The test uses loud sounds to evoke the middle-ear reflex which is detected in the ear response. The tests maintain safe levels of sound. However, you may find the sounds too loud which may cause discomfort. If so, please tell the researcher and the test will be stopped to prevent further discomfort. You can take a break anytime.

WILL I BENEFIT BY PARTICIPATING?

You may or may not personally benefit from being in this study. However, by serving as a subject, you may help us learn how to benefit patients in the future.

DO I HAVE TO PARTICIPATE IN THIS STUDY?

No, you may choose not to be in this study.

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. Current VA regulations require us to keep study records indefinitely.

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A code number will be assigned to you and your experimental hearing tests. Only the investigators named on this consent form will be authorized to link the code number to you. Other investigators who may receive samples of your experimental hearing tests for research will be given only the code number, which will not identify you.

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.

Ownership of a copy of the following information will be transferred to Boys Town National Research Hospital and James H. Quillen VA Medical Center and will be the responsibility of Doug Keefe, PhD at Boys Town National Research Hospital and Kim Schairer, PhD at James H. Quillen VA Medical Center: Hearing test data (e.g., pure-tone hearing, speech perception, and standard clinical immittance tests previously described) that do not contain information that could identify you. Electronic experimental hearing test data files that are the experimental immittance and OAE tests described previously, which contain a creation date that is the same as the date of your study visit.

By signing this informed consent, you give permission for the transfer of a copy of these hearing test data to a network drive location at Oregon Health and Science University that only the PVAMC personnel on this study and the above collaborators have permissions to access. The PVAMC study personnel, Doug Keefe, PhD at Boys Town National Research Hospital, and Kim Schairer, PhD at James H. Quillen VA Medical Center will be responsible for maintaining the security and confidentiality of the transferred data. PVAMC 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 PVAMC in accordance with current records retention requirements. Any information shared with Doug Keefe, PhD at Boys Town National Research Hospital and Kim Schairer, PhD at James H. Quillen VA Medical Center may no longer be protected under federal law. Research records may be reviewed and/or copied by the sponsor.

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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.

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 ABLE TO SEE MY RESEARCH DATA?

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 your health information.

WILL I BE TOLD ABOUT THE STUDY RESULTS?

You will receive results of your clinical hearing tests during the day of your visit. We will not contact you with results of the experimental hearing tests after this study is completed.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

There will be no cost to you or your insurance company to participate in this study.

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WILL I BE PAID FOR PARTICIPATING?

You will be paid $25.00 for the study session. You must arrive within 15 minutes of the scheduled session in order to receive payment for the session. If you drop out of the study before completing all the study sessions you will be paid for the sessions that you completed.

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. 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.

WHO SHOULD I CONTACT IF I AM INJURED DUE TO THE RESEARCH?

If you believe you have been injured or harmed while participating in this research and require immediate treatment, contact Dan Putterman, Au.D. at 503-220-8262 ext.57094, or M. Patrick Feeney, Ph.D. at 503-220-8262 ext.55306.

In the event of a life-threatening emergency, call 911 or go to the Emergency Department (ED).

WHAT ARE MY RIGHTS?

You may ask questions about research or about your rights as a subject. Dan Putterman, Au.D. at 503-220-8262 ext.57094, or M. Patrick Feeney, Ph.D. at 503-220-8262 ext.55306, will answer any questions you may have about this research study. If you have any questions regarding your rights as

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a research subject, you may contact the Portland VA Medical Center Research Office at (503) 273-5125, or VA Regional Counsel at (503) 412-4580.

Participation is voluntary. Your participation in this research study is voluntary. The Portland VA Medical Center Authorization for the Use and Disclosure of Protected Health Information for Research Purposes - Health Insurance Portability and Accountability Act (HIPAA) to use your protected health information is also voluntary. You may refuse to sign this Informed Consent Form and the HIPAA authorization. However, in order to participate in this study you must sign the Informed Consent Form and the HIPAA authorization.

What if I decide not to participate? You do not have to join this or any other research study. If you do join, and later change your mind, you may quit at any time. If you refuse to join or if you drop out of the study at any time, there will be no penalty or loss of any benefits to which you are otherwise entitled. This will not affect your relationship with or treatment by the Veterans Health Administration (VHA) or your rights as a VHA patient. You will still receive all the medical care and benefits for which you are otherwise eligible. If at any time you wish to drop out of the study, please call Dan Putterman, Au.D. at 503-220-8262 ext.57094, or M. Patrick Feeney, Ph.D. at 503-220-8262 ext.55306. If you choose to do so, there are no additional visits or procedures requested of you.

Can someone else stop me from being in the study?
You may be removed from the study if the investigator stops the study and/or you do not follow instructions.

Can I drop out after I sign this consent form?
You may drop out of this study at any time without prejudice to yourself or to any future medical care with this institution or with the Veterans Health Administration (VHA).

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WILL I BE TOLD IF THERE IS NEW INFORMATION THAT MIGHT CAUSE ME TO WANT TO QUIT THIS STUDY?

During this research project, new information may become available from the research that may affect whether or not you want to remain in the study. If this new information becomes available, you will be notified. You may decide if you still wish to stay in this study.

Signature

Patrick Feeney Ph.D. or a member of the research 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 Dr. M. Patrick Feeney, Ph.D. at 503-220-8262 ext.55306 from 8:00 AM to 5:00 PM Monday through Friday. If any medical problems occur in connection with this study, the VA will provide emergency care.

My signature below indicates that I have read, or had read to me, all of the above information about the study, and my rights as a research subject have been explained to me. I authorize the use of my identifiable information as described in this form. I voluntarily consent to participate in this study.

_____

Printed Name of Subject

_____ _____ _____

Signature of Subject Date Time

Subject Name: _____ Date: _____

Title of Study: Comprehensive Wide Bandwidth Test Battery of Auditory Function in Veterans (#3222)

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_____

Printed Name of Person Obtaining Consent

_____ _____ _____

Signature of Person Obtaining Consent Date Time

"I have received a copy of this informed consent document."
*Initials of Subject: _____

Addendum: Banking your Contact Information for Future Research

WHAT IS THE PURPOSE AND WHAT WILL HAPPEN?

This study will contribute your contact information to a repository for banking. The study will contribute your name, contact information and audiometric results to the NCRAR subject data repository located at VA Portland Health Care System (VAPORHCS). By signing this form below, you agree to allow your contact information to be made available to investigators at the VAPORHCS for the purpose of contacting you about future research studies.

WHAT ARE THE RISKS?

Contact information that identifies you will be banked. The repository team will make every effort to protect your information. A breach in confidentiality and a resulting loss of privacy could result in monetary loss due to identity theft, and could carry other risks affecting your 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, status in the

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community, or could result in embarrassment. However, the research team will make every effort to protect your private health information and guard against any loss of privacy.

HOW LONG WILL YOU KEEP MY INFORMATION?

Your research data will be stored indefinitely.

CAN I WITHDRAW MY PERMISSION TO USE MY INFORMATION?

To withdraw, you must write to the study PI, M. Patrick Feeney, Ph.D. at NCRAR, 3710 SW US Veterans Hospital Road, Portland, OR 97239, 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.

Use of personal health information if you withdraw your consent for future research on your data samples. If you do send a letter to the Principal Investigator to withdraw consent, the use and disclosure of your protected health information will stop as of the date she receives your request. However, the Principal Investigator is allowed to use information collected before the date of the letter or collected in good faith before your letter arrives.

Questions about revoking authorization. If you have any questions concerning your withdrawal of consent to use your protected health information, you may contact the Principal Investigator, M. Patrick Feeney at 503-273-5306.

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

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Practices available online at
http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=1089)

My contact information may be banked for future research
YES:___ NO:_____ Initials:_____(if no, skip to the end)

HOW WILL MY CONTACT INFORMATION AND DATA BE USED FOR FUTURE RESEARCH?
If you agree, your contact information and hearing test results 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, or by phone
- Research about any type of health care issue, disease or disorder
- Any VA NCRAR researchers

Signature

M. Patrick Feeney (study PI) or a member of the research team has explained the banking of my contact information 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 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 M. Patrick Feeney at 503-273-5306 from 8-4:30, Monday through Friday, and Dan Putterman at 503-220-8262 ext 57094 from 8-4:30, 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 contact information, and my rights as a research subject have been

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explained to me. I voluntarily authorize the use of my contact information as described in this form.

_____
Printed Name of Subject

_____ _____ _____
Signature of Subject Date Time

_____
Printed Name of Person Obtaining Consent

_____ _____ _____
Signature of Person Obtaining Consent Date Time

"I have received a copy of this informed consent document."
Initials of Subject: _____