Subject Name: _____ **Date:** _____ MONTH / DAY / YEAR

Title of Study: Comprehensive Wide Bandwidth Test Battery of Auditory Function in Veterans

Principal Investigator: Kim S. Schairer, Ph.D. **VAMC:** James H. Quillen VAMC

This Informed Consent will explain about being a research subject in this experiment. It is important that you read this material carefully and then decide if you wish to be a volunteer.

PURPOSE

The purpose of this research project is as follows: The purpose of the study is to compare results from an investigational device that tests inner ear, middle ear, and auditory brainstem function with results from the currently-used clinical equipment. This new device will allow us to measure how sound is transmitted across a wider range of sounds than the range used with current clinical equipment. Our goal is to determine whether the current and new devices are the same, or if one device is better at identifying hearing loss and middle ear dysfunction in Veterans.

DURATION

The expected duration of study participation is up to three hours.

PROCEDURES

The procedures which will involve you as a research subject include:

Chart Review: If you agree to participate, your previous audiological evaluations and information about your ear health (e.g., from primary care, emergency room, or ear, nose, and throat doctors) will be gathered from your medical record. If your medical record is not available (i.e., you are not a Veteran enrolled at the Mountain Home VA), then only information that is provided to the study staff will be included in the study.

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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 for this procedure, except possible discomfort with placement of the speculum (otoscope tip) in your ear canal. If your ear canals are blocked with cerumen (earwax), you may be asked to have them cleaned before participating in the study. You will be referred to your primary care doctor or an ear, nose, and throat doctor if there is evidence of drainage or another sign that may be associated with a medical condition. You may be asked to return and continue your participation after you see the doctor and complete any recommended treatment.

Pure Tone Hearing Test: You will receive a standard pure tone hearing threshold test, like those performed in the Audiology clinic. You will be asked to sit in a quiet room with insert earphones in your ears and respond 'yes' when you hear soft tones. The 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 in the groups with hearing loss. If a new hearing loss that was previously unknown is identified, you will be referred to an audiologist.

Speech Perception Tests: You will receive standard clinical speech audiometry tests. For these tests, you will be asked to repeat words at soft levels, repeat words at a comfortable volume, and indicate at which volume the words become uncomfortably loud. These tests will take approximately 15 minutes. They will be in the same location and use the same equipment as the pure tone hearing test. There are no known risks for taking these tests. You will not be excluded from the study based on these test results.

Standard Clinical Immittance Test Battery: You will receive a standard clinical test battery. These tests give us information about well your middle ears (tympanometry test) and middle ear muscles (acoustic reflex threshold test) are working. This set of tests will be completed in a quiet room and take approximately 10 minutes. During the tests, all you will be asked to do is sit quietly. You will have a small plastic probe tip in each ear, feel some pressure in your ear canals, and hear several different beeps. If you do not like the feeling of pressure in your ear canals or feel uncomfortable during this test, please tell the researcher and he or she will stop testing. You will not be excluded from the study based on the results of this test.

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Experimental Immittance Test Battery: This test is similar to the Standard clinical immittance test battery, but it is completed using experimental equipment and the sounds will be different. The test environment, expectations for you, and risks are the same as those stated for the Standard test. You will not be excluded from the study based on the results of this test.

Otoacoustic Emissions (OAE): You will receive an OAE test that is completed using the same system as the Experimental immittance test battery. The OAE test tells us how well your inner ears are working. You will be asked to sit quietly for approximately 10 minutes while the test is completed. The test will be completed in a quiet room, and you will hear some sounds through a foam probe tip in your ear canal. There are no known risks from taking this test. You will not be excluded from the study based on these test results.

ALTERNATIVE PROCEDURES/TREATMENTS

The alternative procedures/treatments available to you if you elect not to participate in this study are: The alternative to the experimental test is the clinical test, which is part of both this research protocol as well as a typical hearing test in the Audiology clinic.

POSSIBLE RISKS/DISCOMFORTS

The possible risks and/or discomforts of your involvement include: Discomfort with the insertion of the otoscope speculum, discomfort from the probes used for the clinical and experimental middle and inner ear tests, discomfort with pressure in the ear canals during these tests, and loudness discomfort from the sounds used in the middle ear and speech tests. If you are uncomfortable and/or want to stop during any of the tests, please tell the researcher and he or she will stop the test. There are no other known or expected risks from the tests included in this study.

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POSSIBLE BENEFITS

The possible benefits of your participation are: Benefits to you include the knowledge that you are making valuable contributions toward the application of new tests of inner ear and middle ear function in clinical practice. If a previously unidentified hearing loss is found, you will receive counseling and an audiologist and/or an ear, nose, and throat doctor will be recommended. If you have a previously diagnosed hearing loss, your participation in the study may provide you with additional information about your hearing. The proposed research may lead to better measurement procedures and clinical devices that could be used to improve the quality of screening and diagnostic procedures to detect inner and middle ear problems and related hearing loss in Veterans.

INJURY/COMPLICATIONS

For studies being conducted at the James H. Quillen VA Medical Center:

According to VA Regulations [38CFR17.85 (a)] the medical facility shall provide necessary medical treatment to a research subject injured as a result of participation in a research project (unless the injury is a result of not following study procedures). However, no additional compensation has been set aside. You have not waived any legal rights or released the VA or its agents from liability for negligence by signing this form.

FINANCIAL COSTS

Some veterans are required to pay copayments for medical care and services provided by VA. These copayment requirements will continue to apply to medical care and service provided by VA that are not part of this study.

There are no financial costs to you for participating in this study.

COMPENSATION IN THE FORM OF PAYMENTS TO RESEARCH SUBJECTS

You will be compensated $25 for your involvement in this study.

Subject Name: _____ **Date:** _____ (MONTH / DAY / YEAR)

Title of Study: Comprehensive Wide Bandwidth Test Battery of Auditory Function in Veterans

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VOLUNTARY PARTICIPATION

Participation in this research experiment is voluntary. You may refuse to participate and may quit at any time. If you quit or refuse to participate, the benefits or treatment to which you are entitled will not be affected. You may quit during any of the tests, or by calling Dr. Kim Schairer at 423-926-1171 ext. 7138. If any of the research results may lead you to change your mind about staying in the study, you will be informed right away. The Principal Investigator may take you out of the study at any time without your consent if he or she decides that it is not in your best interest to continue (i.e., not following study-related directions, adverse event). You may also be taken off the study if it ends early.

If there may be any adverse consequences (physical/social/economic, legal, or psychological), of a participant's decision to withdraw from the research, the consent process must disclose the consequences and procedures for orderly termination of participation.

If there are significant new findings are likely during the course of the research which may impact the subject's willingness to continue his or her participation, the consent process must disclose that these new findings will be provided to them.

CONTACT FOR QUESTIONS

If you have any questions, problems, research-related medical problems, or if you would like to verify the validity of a study, you may contact Dr. Kim S. Schairer at 423-926-1171 ext. 7138 or Mrs. Jeanne Lilly at 423-926-1171 ext. 7555. You may also contact the Chairman of the Institutional Review Board (IRB) at 423- 439-6054 for any questions you have about your rights as a research subject. If you have any questions or concerns about the research and want to talk to someone independent of the research team, or if you are unable to reach the study staff, you may call an IRB Coordinator at 423-439-6055 or 423-439-6002.

Version Date: 01/16/2019

Subject's Initials _____

Subject Name: _____ **Date:** _____ MONTH / DAY / YEAR

Title of Study: Comprehensive Wide Bandwidth Test Battery of Auditory Function in Veterans

Principal Investigator: Kim S. Schairer, Ph.D. **VAMC:** James H. Quillen VAMC

CONFIDENTIALITY

Every attempt will be made to see that study results/data remains confidential. A copy of the records from this experiment will be stored in the Applied Hearing Science Lab in building 77, room GB115 in accordance with the record control schedule. The results of this study may be published and/or presented at meetings, shared with clinicaltrials.gov, and with data collection software developers without identifying you as a subject. The study records are accessible to the study personnel, East Tennessee State University (ETSU)/VA IRB, VA Research & Development Committee, Office of Research Oversight (ORO), General Accountability Office (GAO), Food & Drug Administration (FDA), and Office of Human Research Protection (OHRP). Medical records will be kept completely confidential according to current legal requirements, and will not be revealed unless required by law, or as noted above.

Our collaborators, Doug Keefe, Ph.D. at Boys Town National Research Hospital and M. Patrick Feeney, Ph.D. at the Portland VA Medical Center, as well as their study staff, will receive your experimental hearing test data from a protected computer network drive located at Oregon Health & Science University (OHSU). These data will not contain personally identifiable information (e.g., full name, social security number, date of birth, street address, or telephone number). However, these data will contain the date on which you are seen for the study. The date on the experimental system has been manipulated to prevent any association with the research appointment schedule.

By signing this informed consent, you give permission to transfer of a copy of your de-identified research data to a network drive at OHSU. The James H. Quillen VAMC study personnel, Doug Keefe, Ph.D. at Boys Town National Research Hospital, and M. Patrick Feeney, Ph.D. at the Portland VAMC and their study staff will be responsible for maintaining the security and confidentiality of this transferred data. All original research records, both paper and electronic, will be maintained at the James H. Quillen VAMC in accordance with current records retention requirements. Any information shared with Doug Keefe, Ph.D. at Boys Town National Research Hospital and M. Patrick Feeney, Ph.D. at the Portland VA Medical Center, and their study staff, may no longer be protected under federal law. However, this information will not be identifiable to you.

For Veteran Research Subjects Only: If you are a Veteran taking part in a study at the James H. Quillen VA Medical Center, a copy of your signed and dated Consent Form will be placed in your medical record. Additionally, the results of your hearing test will be entered into your medical record.

Version Date: 01/16/2019

Subject's Initials _____

Approved by ETSU/VA Medical IRB / Approval Date: October 17, 2019 / Expiration Date: October 16, 2020

Subject Name: _____ **Date:** _____
MONTH / DAY / YEAR

Title of Study: Comprehensive Wide Bandwidth Test Battery of Auditory Function in Veterans

Principal Investigator: Kim S. Schairer, Ph.D. **VAMC:** James H. Quillen VAMC

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by United States law. The website may provide a summary of the results, but will not include information that may identify you. You may search this website at any time.

CONSENT

By signing below, I certify that I have read or have had this document read to me and I have been given a copy. I have also been given the opportunity to ask questions and to discuss my participation with the Investigator. I understand the consent process and I freely and voluntarily choose to participate in this research experiment.

Signature of Subject Date (MONTH / DAY / YEAR) Last 4 of SSN

Signature of Person Obtaining Consent Date (MONTH / DAY / YEAR)

Version Date: 01/16/2019

Subject's Initials _____

Subject Name: _____ **Date:**_____

Study Title: Comprehensive Wide Bandwidth Test Battery of Auditory Function in Veterans

VAMC: James H. Quillen VAMC

AUTHORIZATION TO USE AND DISCLOSE
PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES

The privacy law, Health Insurance Portability & Accountability Act (HIPAA), protects my individually identifiable health information (protected health information). The privacy law requires me to sign an authorization (or agreement) in order for researchers to be able to use or disclose my protected health information for research purposes in the study entitled *Comprehensive Wide Bandwidth Test Battery of Auditory Function in Veterans.*

I authorize Kim S. Schairer, Ph.D. and her research staff to use and disclose my protected health information for the purposes described below. I also permit the research staff to disclose my protected health information for the purposes described below. My protected health information that may be used and disclosed includes:

√ Names
√ All geographic subdivisions smaller than a state, except for the initial three digits of the zip code if the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people
√ All elements of dates except year for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
√ Telephone numbers
☐ Fax numbers
√ E-mail addresses
√ Social security numbers
√ Medical record numbers
☐ Health plan beneficiary numbers
☐ Account numbers
☐ Certificate or license numbers
☐ Vehicle identifiers and license plate numbers
☐ Device identifiers and serial numbers
☐ URLs
☐ Internet Protocol (IP) addresses
☐ Biometric identifiers including fingerprints and voiceprints
☐ Full-face photographs and any comparable images
☐ Any other unique, identifying characteristic or code, except as permitted for re-identification in the Privacy Rule

Health Information that will be collected from the following sources (please check all that apply):

Subject's Initials

_____

Subject Name: _____ **Date:**_____
Study Title: **Comprehensive Wide Bandwidth Test Battery of Auditory Function in Veterans**
VAMC: James H. Quillen VAMC

√ Review of the electronic Medical Record (CPRS):
√ History and Physical Exam:
√ Consultation Reports:
√ X-ray Reports:
☐ Laboratory tests:
√ Operative tests:
√ Discharge Summary:
√ Progress Notes:
√ Questionnaires, interview results, focus group survey, psychology survey, psychological performance tests:
☐ Photographs, videotapes, audiotapes, or digital or other images:
☐ Tissue and/or blood specimens:
√ Other:

In accordance with *38 USC 7332* (Applicable to Drug Abuse, Alcohol Abuse, HIV Infection, and Sickle Cell Anemia Records). The PI provides assurance in writing that the purpose of the data is to conduct scientific research and that no personnel involved in the study may identify, directly or indirectly, any individual patient or subject in any report of such research or otherwise disclose patient or subject identities in any manner. Please check all that apply:

☐ Acquired immunodeficiency syndrome (AIDS) or human immunodeficiency virus (HIV) infection.
☐ Treatment for drug or alcohol abuse.
☐ Sickle cell anemia.

The Investigator, Kim S. Schairer, Ph.D. may use and share my health information with:

- The East Tennessee State University Human Research Protections Program (HRPP) Institutional Review Board Administration when the researcher or the research site is undergoing Quality Improvement Program (QIP) auditing.
- The James H. Quillen Veterans Affairs Medical Center Office of Research & Development when the researcher or the research site is undergoing Quality Improvement Program (QIP) auditing.
- Government representatives, when required by law
- Hospital (VAMC or Mountain States Health Alliance) representatives

Once my health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

The investigator(s) Kim S. Schairer, Ph.D. (researcher) agree to protect my health information by using and disclosing it only as permitted by me in this Authorization and as directed by state and federal law. I do not have to sign this Authorization. If I decide not to sign the Authorization:

- It will not affect my treatment, payment or enrollment in any health plans nor affect my eligibility for benefits.

Subject's Initials

_____

- I may not be allowed to participate in this research study

After signing the Authorization, I can change my mind and:

- Not let the researcher disclose or use my protected health information (revoke the Authorization).
- If I revoke the Authorization, I will send a written letter to: Kim S. Schairer, Audiology (126), James H. Quillen VAMC, P.O. Box 4000, Mountain Home, TN 37684 to inform him/her of my decision.
- If I revoke this Authorization, researchers may only use and disclose the protected health information **already collected** for this research study.
- If I revoke this Authorization my protected health information may still be used and disclosed should I have an adverse event (a bad effect, or experience something unanticipated).
- If I change my mind and withdraw the authorization, I may not be allowed to continue to participate in the study.

This Authorization does not have an expiration date.

If I have not already received a copy of the Privacy Notice, I may request one by contacting the Privacy Officer. If I have any questions or concerns about my privacy rights, I should contact the VAMC Privacy Officer, Ms. Angela Mullins - Allen, at (423) 926-1171, Ext 7620, or the East Tennessee State University, James H. Quillen College of Medicine Privacy Officer, Ms. Paula Wright, at (423) 433-6074.

I am the subject or am authorized to act on behalf of the subject. I have read this information, and I will receive a copy of this form after it is signed.

_____ _____

Signature of research subject or Date **Last 4 of SSN**

_____

Printed name of research subject

Subject's Initials

_____